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Risk of diabetic foot ulcer and its predictors among Bangladeshi subjects: a multi-centric cross-sectional study

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3 1 **Risk of diabetic foot ulcer and its predictors among Bangladeshi subjects: a multi-**
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5 2 **centric cross-sectional study**
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24 **Abstract**

25 **Objective**

26 To assess the risk of diabetic foot ulcer (DFU) and find out its predictors among type 2
27 diabetic (T2D) subjects of Bangladesh.

28 **Design, setting and participants**

29 This cross-sectional study recruited 1200 T2D subjects who visited sixteen centres of Health
30 Care Development Project's owned by Diabetic Association of Bangladesh (DAB).

31 **Primary and secondary outcome measures**

32 Risk of DFU was assessed using modified version of International Working Group on the
33 Diabetic Foot (IWGDF) Risk Classification System. This classification system was based on
34 five parameters namely peripheral neuropathy (PN), peripheral arterial diseases (PAD),
35 deformity, ulcer history and amputation. The risks were categorized as Group 0 (no PN, no
36 PAD), Group 1 (PN, no PAD, and no deformity), Group 2A (PN and deformity, no PAD),
37 Group 2B (PAD), Group 3A (ulcer history) and Group 3B (amputation). The predictors of
38 DFU risk were determined using multinomial logistic regression for each risk category
39 separately.

40 **Interventions:** not applicable for this manuscript.

41 **Results:**

42 Overall 44.5% of the participants were 'at risk' of DFU. The burden was higher among men
43 (45.6%) and those lived in rural areas (45.5%). According to IWGDF categories, the risk
44 was distributed as 55.5%, 4.2%, 11.6%, 0.3%, 20.6% and 7.9% for group 0, group 1, group
45 2A, group 2B, group 3A and group 3B respectively. The predictors of DFU (odd ratio > 1)
46 were age \geq 50 years, rural area, low economy status, insulin use, history of trauma, diabetic
47 retinopathy and diabetic nephropathy.

48 **Conclusion**

1
2
3 49 Significant proportion of T2D subjects of Bangladesh was at risk of DFU that demands
4
5 50 effective screening program to reduce the DFU related morbidity and mortality.
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8

9 51 **Keywords:** diabetes; diabetic foot ulcer; diabetic foot ulcer risk; Bangladesh; International
10
11 52 Working Group on the Diabetic Foot; predictors; risk factors
12
13

14 53 **Article summary**

17 54 **Strengths and limitations of this study**

- 20 55 • First study in Bangladesh that prompted to assess the risk of DFU among Bangladeshi
21
22 56 subjects using a standard tool
- 24 57 • First time, the predictors of DFU was explored to guide the prevention effort
- 27 58 • Area-wise and gender-wise risk difference will help to identify the disparities and
28
29 59 promote decentralization of diabetes foot care for all
- 31 60 • Cross-sectional design did not allow to establish any causal relationship
- 34 61 • The risk may be overestimated or underestimated as all the centers were not provided
35
36 62 same quality diabetes care

39 63 **Introduction**

41
42 64 In recent years, the epidemic of diabetes mellitus (DM) has become a fast-expanding public
43
44 65 health problem affecting both developed and developing countries [1]. The International
45
46 66 Diabetes Federation (IDF) reported that about 415 million people had DM globally and it will
47
48 67 be projected to reach 642 million by 2040 or may be even doubled by the year 2040 [2].
49
50
51 68 Among the clinical classifications of DM, Type 2 diabetes (T2D) is more common and
52
53 69 prevalent in certain ethnic groups, estimates are of up to six times more common in people of
54
55 70 South Asian descent, three times more common in those of African and African-Caribbean
56
57
58 71 descent, and is more common in people of Chinese descent compared with the white
59
60

1
2
3 72 population [3]. Like other developed and developing countries, it is also an epidemic in
4
5 73 Bangladesh. Evidence suggested that 9.7% of Bangladeshi adult population (>35 years) are
6
7 74 diabetic and 22.4% are prediabetic [4]. Trend analysis revealed an increasing prevalence of
8
9 75 DM in Bangladesh as from 4% in 1995 to 2000 and 5% in 2001 to 2005 to 9% in 2006 to
10
11 76 2010 respectively [5]. As the prevalence of diabetes increases, the prevalence of long-term
12
13 77 diabetes-related complications is also likely to increase. Diabetic foot ulcer (DFU) is a
14
15 78 common and important complication of diabetes, representing a major healthcare burden with
16
17 79 significant morbidity [6].
18
19
20

21 80 Diabetic foot is defined as the presence of infection, ulceration and/or destruction of deep
22
23 81 tissues associated with neurologic abnormalities and various degrees of peripheral arterial
24
25 82 disease (PAD) in the lower limb in patients with diabetes [7]. It is a significant cause of
26
27 83 morbidity and can lead to prolonged hospital stays, which is evidenced by the fact that ~20%
28
29 84 of hospitalizations related to diabetes involve DFU [8]. The mortality rate in patients with
30
31 85 DFU is also high and is approximately twice that of patients without ulceration [9]. Other
32
33 86 than the morbidity and mortality, the toll of economic burden in terms of direct and indirect
34
35 87 cost is also high for those having DFU, estimated approximately €11.6 billion per year for
36
37 88 Europe in 2017 and €7.6–11 billion among Medicare beneficiaries of United States from
38
39 89 2007 to 2014. Another issue related to foot ulcers among diabetic patient is health-related
40
41 90 quality of life that cannot be measured in economic terms. It has reported that patients with
42
43 91 foot ulcers or amputation have low health-related quality of life due to substantial burden of
44
45 92 depression and other physical problems like inability to do simple task or recreational
46
47 93 activities [7].
48
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50

51 94 The major risk factors of DFU are a loss of protective sensation due to diabetic peripheral
52
53 95 neuropathy (DPN), peripheral arterial diseases (PAD) and trauma. However, first two are not
54
55 96 independently responsible for DFU; it is the combination of triad of neuropathy and PAD
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1
2
3 97 with trauma that leads to foot problems. It has reported that trauma and PAD are the major
4
5 98 contributors to foot ulceration, and diabetic neuropathy is the common denominator in almost
6
7 99 90% of DFU. Other than these three leading risk factors, male gender, previous foot
8
9
10 100 ulceration or amputation, foot deformities, calluses, Charcot arthropathy and high plantar
11
12 101 pressures have been associated with an increased risk for foot ulceration. There are some
13
14 102 diabetes related risk factors that also associated with risk of foot ulcers including duration of
15
16 103 diabetes, poor glycaemic control, diabetic retinopathy, nephropathy, poor compliance of the
17
18 104 patient with medical instructions and neglectful behavior. Some societal and behavioral risk
19
20 105 factors also showed significant association with DFU including low socioeconomic
21
22 106 condition, poor access to healthcare services, poor educational status, living alone and
23
24 107 cigarette smoking [7, 10]. Previous studies reported that the risk of diabetic foot or
25
26 108 amputation is significantly lower among the Asians compared to Europeans in the United
27
28 109 Kingdom [11-12]. This reduced risk is probably due to low prevalence of DPN and PAD
29
30 110 among Asians, but the exact reason is not fully understood. However, previous study reported
31
32 111 the prevalence of DPN among Bangladeshi subjects was 19.7% and it was significantly as
33
34 112 well as independently associated with age, mode of treatment, income, duration of diabetes
35
36 113 and glycaemic status [13].

37
38 114 The best possible way to prevent DFU is identification of individuals at risk, proper health
39
40 115 education and timely follow-up [14]. It has estimated that the lifetime risk of foot ulcers
41
42 116 among diabetic population is 19% – 34% [7]. To overcome this burden of DFU, clinicians are
43
44 117 recommended to estimate the risk and response to the associated factors that increase risk
45
46 118 [10]. However, published data related to diabetic foot risk assessment and associated factors
47
48 119 among Bangladeshi subjects are absolutely lacking. Hence, we prompted to assess the risk of
49
50 120 foot ulcers and sought to determine the factors that influenced the risk among T2D patients of
51
52 121 Bangladesh.

122 **Methods**

123 **Study design**

124 This cross-sectional study was conducted among 1200 T2D patients visited multiple centres
125 of Health Care Development Project's (HCDP) owned by Diabetic Association of
126 Bangladesh (DAB). Total sixteen centres were selected; seven from Dhaka districts and rest
127 nine from northern part of Bangladesh. We selected the centre purposively and followed
128 convenient sampling technique to collect data from diabetic subjects. Exclusion criteria
129 included presence of DFU during interview, acute illness of the subjects, unwilling to
130 participate or those with mental instability. To meet the eligibility, the subjects were screened
131 as having no DFU based on their self-reported statement, clinical history, foot examination
132 and medical records review.

133 **Data collection and measurement**

134 The data collection procedure was comprised of two phases and conducted from July 2011 to
135 June 2012. At first phase, face-to-face interview was conducted using pre-tested
136 questionnaire adapted from STEP-wise approach to Surveillance (STEPS) of
137 Noncommunicable diseases risk factors of World Health Organization (WHO) with
138 appropriate modifications [15]. The questionnaire collected sociodemographic, behavioral
139 risk factors (tobacco use, physical inactivity), diabetes (duration, medication) and its
140 complications (retinopathy, nephropathy), and foot problem related information (neuropathy,
141 PAD, trauma, Foot hygiene) of the participants. The blood glucose levels (fasting/random)
142 and presence of diabetic nephropathy or retinopathy related information of the participants
143 were extracted from their diabetes record book. The last record within one month was
144 considered to assess glycaemic status. In second phase, physical measurements
145 (anthropometric and blood pressure) and foot examination were carried out by trained
146 physicians. The anthropometric and blood pressure measurement followed the methods

1
2
3 147 described in ‘Noncommunicable disease risk factors survey Bangladesh 2010’ [16]. The
4
5 148 anthropometric measurements included height, weight, waist circumference, hip
6
7 149 circumference, and their derivatives like body mass index (BMI) and waist-hip ratio. The foot
8
9 150 examination was the part of DFU risk assessment that described below briefly.

12 151 **Assessment of DFU**

14 152 Risk of DFU was assessed using modified version International Working Group on the
15
16 153 Diabetic Foot (IWGDF) Risk Classification System proposed by Lavery *et al.* [17]. We
17
18 154 screened each patient to identify lower extremity complications and presence of any risk
19
20 155 factors like ulcerations, amputation, peripheral neuropathy (PN), PAD, foot deformities,
21
22 156 limited joint mobility, and abnormal foot pressures using the methods followed by Lavery *et*
23
24 157 *al.* [17-18]. We used a 10-g Semmes-Weinstein monofilament and vibration perception
25
26 158 threshold tester to assess peripheral neuropathy (PN), Ankle Brachial Index (ABI) to detect
27
28 159 PAD, Goniometer to identify foot deformity and clinical examinations to evaluate joint
29
30 160 mobility. We defined PAD as non-palpable dorsalis pedis or posterior tibial arterial pulse and
31
32 161 ankle brachial index in either foot < 0.80 . The deformity was defined as any contracture that
33
34 162 could not be fully corrected manually, such as hallux valgus, hammer toes or claw toes,
35
36 163 hallux rigidus and ankle equines [17]. Again, infection was defined by criteria consistent with
37
38 164 the International Working Group and Infectious Diseases Society of America guidelines [19].
39
40 165 The risks were categorized according to modified IWGDF risk classification system: Group 0
41
42 166 (no PN, no PAD), Group 1 (PN, no PAD, no deformity), Group 2A (PN and deformity, no
43
44 167 PAD), Group 2B (PAD), Group 3A (ulcer history) and Group 3B (amputation). Here, Group
45
46 168 0 indicated ‘no risk’ and rest of the groups (1, 2A, 2B, 3A, 3B) classified the study
47
48 169 population ‘at risk’ of varying degree.

56 170 **Quality assurance**

1
2
3 171 To ensure standard quality control, a panel of senior researchers and survey investigators
4
5 172 visited the data collection sites to monitor the activities. To prevent bias, anonymity of the
6
7
8 173 monitoring panel was preserved to the data collectors. All team members including
9
10 174 investigators, supervisor and data collectors were participated in an intensive 3-consecutive
11
12 175 training programme in Dhaka before commencement of the survey. First training program
13
14 176 was conducted for the physicians who involved in foot examination. This training program
15
16 177 was focused on “Detection of Diabetic Foot Problem at the Early Stage” through screening
17
18 178 using standard instrument. A highly qualified neurologist from a reputed post-graduate
19
20 179 training institution was appointed as a resource person to conduct the sessions. Second and
21
22 180 third training was conducted for volunteer data collectors who interviewed the respondents to
23
24 181 fill-up the questionnaire. The purpose of these training was to inform the data collectors
25
26 182 about potential difficulties associated with data collection. During this intensive training, data
27
28 183 collectors got practical training about mode of self-administration of the questionnaire, mode
29
30 184 of physical measurement and maintenances of data collection environment. Other than these
31
32 185 initiatives, to assure quality of the study we also followed certain protocol as (1) pre-testing
33
34 186 of the whole procedure (2) used standard method of measurement as per STEPS survey of
35
36 187 Bangladesh 2010 (3) used show cards to better understanding of different forms of tobacco
37
38 188 use and intensity of physical activities (4) maintained adequate privacy during physical
39
40 189 measurements and clinical examinations (5) applied robust equipment for physical
41
42 190 measurement and clinical examination. None of the quality control observer reported any
43
44 191 violation of physical measurement and data collection.
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51 192 **Patient and public involvement**

52 193 We collected data from the patients who visited the selected diabetes care centers of DAB.
53
54 194 However, they were not involved directly in the setting of the research question or the
55
56 195 outcome measures. They did not have any role in designing or implementing this work or
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1
2
3 196 interpretation of the results. We were unable to disseminate results of this study directly to
4
5 197 study participants due to the anonymous nature of the data. We had a plan to disseminate our
6
7
8 198 findings to the general population through the local and national press.
9

10 199 **Ethical consideration**

11
12
13 200 The purpose of the study, rights of the respondents and data safety issues were explained to
14
15 201 the participants. All subjects gave their informed written consent for inclusion before they
16
17 202 participated in the study. The study was conducted in accordance with the Declaration of
18
19 203 Helsinki, and the protocol was approved by the Ethical Review Committee of Bangladesh
20
21 204 Diabetic Association (Identification number: BADAS/BIO/EA/11/033) on 17th January 2011.
22
23

24 205 **Data processing and analysis**

25
26 206 Data were analyzed using the Statistical Package for Social Science (SPSS) version 20.0 for
27
28 207 Windows (SPSS, Inc. Chicago. IL.USA). All estimates of precision were presented at 95%
29
30 208 confidence interval (CI) in the tables. Descriptive analysis included mean, standard deviation
31
32 209 (SD), median and interquartile range (IQR), frequencies and percentages where appropriate.
33
34
35 210 In this study the p-value was considered statistically significant at a threshold of $p < 0.05$. In
36
37 211 our study, we found only three respondents having PAD. Hence, we had to merge group 2B
38
39 212 with group 2A and made a new variable namely group 2-A/B which was implied in
40
41 213 multinomial logistic regression analysis. To find out the predictors, we run chi-square test
42
43 214 and the variables showed significant association ($p < 0.05$) with the modified IWGDF risk
44
45 215 classification were identified. Then those variables were examined as independent variable
46
47 216 against the dependent variable in the multinomial logistic regression analysis. For
48
49 217 multinomial logistic regression analysis, we calculated odds ratios (OR), and 95% CI for each
50
51 218 independent variable. In the regression table, predictors those had $OR > 1$ were presented for
52
53 219 each risk category. We ensured presence of no multicollinearity using Variance Inflation
54
55 220 Factor (VIF) to run the regression analysis.
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60

221 We used the STROBE (Strengthening the Reporting of Observational Studies in
222 Epidemiology) guidelines for reporting the cross-sectional observational study [20].

223 Results

224 Sociodemographic characteristics and diabetes related information

225 The mean age of the participants was 51.6 ± 11.9 years and most of them were 50 - 59 years
226 age group (33.1%). More than half of the participants were women (62.9%) and
227 predominantly urban residents (67.3%). Most of them completed primary level education
228 (36.7%), married (99%), housewives (57.8%) and came from middle-income background
229 (44.5%). However, urban participants were more literate (88.2%) and economically stable
230 ($60.3\% >$ lower-middle-income range) than their rural counterpart. The mean duration of
231 diabetes was 6.9 ± 5.9 years and majority of them had uncontrolled glycaemic status (89.3%).
232 Among the diabetes related complications, the proportion of retinopathy (14.3%) was much
233 higher than the nephropathy (5.6%). No mentionable urban-rural difference was observed for
234 glycaemic status and diabetic nephropathy (Table 1).

235 **Table 1: Sociodemographic and diabetes related information of the study subjects,**
236 **n=1200**

Variables	Urban		Rural		Total	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
Age (years)*	52.3 ± 11.9		50.2 ± 11.8		51.6 ± 11.9	
Age categories (years)						
< 30	52 (4)	2.6 – 5.4	22 (5.6)	3.3 – 7.9	54 (4.5)	3.3 – 5.7
30 - 39	63 (7.8)	5.9 – 9.7	39 (9.9)	14.6 - 18	102 (8.5)	6.9 – 10.1
40 - 49	212 (26.3)	23.3 – 29.3	109 (27.7)	23.3 – 32.1	321 (26.8)	24.3 – 29.3
50 - 59	270 (33.5)	30.2 – 36.8	127 (32.3)	27.7 – 36.9	397 (33.1)	30.4 – 35.8
≥ 60	230 (28.5)	25.4 – 31.6	96 (24.4)	20.2 – 28.6	326 (27.2)	24.7 – 29.7
Gender						
Men	302 (37.4)	34.1 – 40.7	143 (36.4)	31.6 – 41.2	445 (37.1)	34.4 – 39.8
Women	505 (62.6)	59.3 – 65.9	250 (63.6)	58.8 – 68.4	755 (62.9)	60.2 – 65.6
Educational status						
Illiterate	95 (11.8)	9.6 – 14	107 (27.2)	22.8 – 31.6	210 (16.8)	14.7 – 18.9
Primary	288 (35.7)	32.4 – 39	152 (38.7)	33.9 – 43.5	440 (36.7)	34 – 39.4
Secondary	265 (32.8)	29.6 – 36	98 (24.9)	20.6 – 29.2	363 (30.3)	27.7 – 32.9
Higher education	159 (19.7)	17 – 22.4	36 (9.2)	6.3 – 12.1	195 (16.3)	14.2 – 18.4
Marital status						
Married	797 (98.8)	98 – 99.6	391 (99.5)	98.8 – 100.2	1188 (99)	98.4 – 99.6
Others	10 (1.2)	0.4 – 2	2 (0.5)	-0.2 – 1.2	12 (1)	0.4 – 1.6

Occupational status						
Service holder	184 (22.8)	19.9 – 25.7	49 (12.5)	9.2 – 15.8	233 (19.4)	17.2 – 21.6
Business	89 (11)	8.8 – 13.2	38 (9.7)	6.8 – 12.6	127 (10.6)	8.9 – 12.3
Housewife	462 (57.2)	53.8 – 60.6	231 (58.8)	53.9 – 63.7	693 (57.8)	55 – 60.6
Others	72 (8.9)	6.9 – 10.9	75 (15.2)	11.7 – 18.7	147 (12.3)	10.4 – 14.2
Monthly household income (BDT) †	20000 (10000 – 40000)		10000 (6000 – 20000)		20000 (10000 – 30000)	
Monthly household income groups						
<4907 (low)	21 (2.6)	1.5 – 3.7	41 (10.4)	7.4 – 13.4	62 (5.2)	3.9 – 6.5
4907–19,488 (lower-middle)	299 (37.1)	33.8 – 40.4	238 (60.6)	55.8 – 65.4	537 (44.8)	42 – 47.6
19489–60252 (upper-middle)	422 (52.3)	48.9 – 55.7	108 (27.5)	23.1 – 31.9	530 (44.2)	41.4 – 47
>60,252 (high)	65 (8.1)	6.2 – 10	6 (1.5)	0.3 – 2.7	71 (5.9)	4.6 – 7.2
Duration of diabetes (years)*	7.3 ± 6		6.3 ± 5.8		6.9 ± 5.9	
Glycaemic status§						
Controlled	87 (10.8)	8.7 – 12.9	42 (10.7)	7.6–13.8	129 (10.8)	9 – 12.6
Uncontrolled	720 (89.2)	87.1 – 91.3	351 (89.3)	86.2 – 92.4	1071 (89.3)	87.6 – 91
Diabetic retinopathy	134 (16.6)	14 – 19.2	38 (9.7)	6.8 – 12.6	172 (14.3)	12.3 – 16.3
Diabetic nephropathy	46 (5.7)	4.1 – 7.3	21 (5.3)	3.1 – 7.5	67 (5.6)	4.3 – 6.9

*Representing mean and standard deviation,

†Presented as median with interquartile range,

‡ According to the 2006 per-capita gross national income (GNI) and the World Bank calculation,

§Based on plasma glucose level pre-meal (fasting) < 6.1 mmol/l and / two hours post meal < 7.8 mmol/l

Risk of DFU among the study population

Here, Table 2 depicted the gender and area-based distribution of DFU risk according to modified version of IWGDF classification. Overall 44.5% of the study population were diagnosed as ‘at risk’ of DFU and the burden was higher among men (45.6%) and those lived in rural areas (45.5%). The risk of DFU according to modified version of IWGDF was 55.5%, 4.2%, 11.6%, 0.3%, 20.6% and 7.9% for group 0, group 1, group 2A, group 2B, group 3A and group 3B respectively. Among the six groups of risk classification, group 3A (ulcer history) showed maximum burden (20.6%) compared to other groups. Gender and area-wise distribution revealed that 21.8% men and one fourth of the rural residents (25.7%) had the previous history of foot ulceration than their counterpart.

Table 2: Gender and area-based distribution of DFU risk among the study subjects, n = 1200

IWGDF DFU risk classification	Gender		Area of residence		Overall
	Men	Women	Urban	Rural	
	n (%)	n (%)	n (%)	n (%)	
Group 0 (no PN, no PAD)	242 (54.4)	430 (57)	452 (56)	214 (54.5)	666 (55.5)

Group 1 (PN, no PAD, no deformity)	18 (4)	32 (4.2)	32 (4)	18 (4.6)	50 (4.2)
Group 2A (PN and deformity, no PAD)	49 (11)	90 (11.9)	103 (12.8)	36 (9.2)	139 (11.6)
Group 2B (PAD)	1(0.2)	2 (0.3)	3 (0.4)	0	3 (0.3)
Group 3A (ulcer history)	97 (21.8)	150 (19.9)	146 (18.1)	101 (25.7)	247 (20.6)
Group 3B (amputation)	38 (8.5)	57 (7.5)	71 (8.8)	24 (6.1)	95 (7.9)

253 IWGDF, International Working Group on the Diabetic Foot; DFU, diabetic foot ulcer, PN, peripheral
254 neuropathy; PAD, peripheral arterial disease

255 Predictors of DFU risk among the study subjects

256 Here, Table 3 depicted the predictors of DFU risk among the study population. Total six
257 predictors were identified those showed high odds (>1) for different groups of risk as age
258 (group 2, OR 1.212; group 3B, OR 1.173), area of residence (group 1, OR 1.188; group 3A,
259 OR 1.461), monthly income (group 2, OR 1.491; group 3A, OR 1.415; group 3B, OR 1.768),
260 medication (group 2, OR 1.014), history of trauma (group 1, OR 2.015; group 2, OR 1.032;
261 group 3A, OR 2.998; group 3B, OR 3.104), diabetic retinopathy (group 1, OR 1.104; group
262 3B, OR, 1.933) and diabetic nephropathy (group 1, OR 2.174; group 3A, OR 1.260; group
263 3B, OR 2.389). Overall, the odds for risk of DFU was higher among those having age ≥ 50
264 years, living in rural area, monthly income $\leq 19,488$ BDT, with previous history of trauma,
265 insulin user and having diabetic complications as retinopathy or nephropathy.

266 **Table 3: Predictors of diabetic foot ulcer among type 2 diabetic subjects of Bangladesh using multinomial**
267 **logistic regression, n = 1200**

Risk groups	Predictors	B	p-value	OR	95% CI for OR	
					Lower Bound	Upper Bound
Group 1	Area of residence					
	Rural area	0.172	0.573	1.188	0.652	2.165
	Urban area				<i>Ref.</i>	
	History of trauma					
	Present	0.7	0.076	2.015	0.929	4.369
	Absent				<i>Ref.</i>	
	Diabetic retinopathy					
	Present	0.099	0.814	1.104	0.486	2.508
Absent				<i>Ref.</i>		
Diabetic nephropathy	Present	0.526	0.14	2.174	755	6.099
	Absent				<i>Ref.</i>	
Group 2-A/B†	Age					
	≥ 50 years	0.192	0.324	1.212	0.827	1.774

	< 50 years				<i>Ref.</i>		
	Monthly income (BDT)						
	≤ 19,488	0.4	0.039*	1.491		1.020	2.181
	> 19,488				<i>Ref.</i>		
	Medication						
	Insulin user	0.013	0.945	1.014		0.692	1.485
	Insulin non-user				<i>Ref.</i>		
	History of trauma						
	Present	0.032	0.916	1.032		0.570	1.870
	Absent				<i>Ref.</i>		
	Area of residence						
	Rural area	0.379	0.014*	1.461		1.081	1.975
	Urban area				<i>Ref.</i>		
	Monthly income (BDT)						
	≤ 19,488	0.347	0.031*	1.415		1.032	1.940
	> 19,488				<i>Ref.</i>		
Group 3A	History of trauma						
	Present	1.098	< 0.001*	2.998		2.044	4.396
	Absent				<i>Ref.</i>		
	Diabetic Nephropathy						
	Present	0.231	0.504	1.260		0.640	2.482
	Absent				<i>Ref.</i>		
	Age						
	≥ 50 years	0.160	0.494	1.173		0.742	1.854
	< 50 years				<i>Ref.</i>		
	Monthly income (BDT)						
	≤ 19,488	0.570	0.016*	1.768		1.114	2.805
	> 19,488				<i>Ref.</i>		
	History of trauma						
Group 3B	Present	1.133	< 0.001*	3.104		1.810	5.324
	Absent				<i>Ref.</i>		
	Diabetic retinopathy						
	Present	0.659	0.018*	1.933		1.122	3.329
	Absent				<i>Ref.</i>		
	Diabetic nephropathy						
	Present	0.871	0.024*	2.389		1.123	5.083
	Absent				<i>Ref.</i>		

268 OR, odd-ratio; CI, confidence interval; Ref, reference; BDT, Bangladesh taka

269 *indicates significant

270 †Group 2B was merged with 2A as the participants were very few in the group 2B

271 Discussion

272 Our study demonstrated that nearly half (45%) of the T2D subjects of Bangladesh were at
 273 risk of DFU and rural population was mostly affected. This finding was significant as there is
 274 no straight forward evidence on risk of DFU among T2D population of Bangladesh.
 275 Moreover, the contributing factors have not yet been explored from the Bangladesh
 276 perspective to take an effective initiative to reduce the burden of associated morbidity and
 277 mortality.

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3 278 In our modified DFU risk classification as per IWGDF, higher burden was observed in the
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5 279 group of those had previous history of foot ulcer (20.6%). This proportion is much higher
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8 280 than the Iranian study that detected only 7% of the study subjects had previous history of foot
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10 281 ulceration [21]. Our finding was also higher than the European country Portugal that reported
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12 282 previous history of DFU among 16% of study subjects using modified IWGDF risk
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14 283 classification [22]. Although it has estimated that the annual risk of DFU is around 2%, this
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16 284 risk in patients with previous history of foot ulceration is expected to increase to 17–60%
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18 285 over the next three years [23]. Several studies reported the cumulative burden of previous
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20 286 history of foot ulcer and amputation as a part of diabetic foot risk assessment. In our study,
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22 287 the cumulative proportion of previous history of foot ulcer and amputation was 14.3% which
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24 288 was twice of the study conducted in neighboring country India [24,25] and half of the
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26 289 Portugal [22]. A follow-up study of USA detected nearly three-times higher proportion of
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28 290 foot ulcer or amputation compared to current study [26]. In this regard, a systematic review
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30 291 comprised of 41 documents by Hunt et al. found that the person with previous history of DFU
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32 292 have the 66% and 12% five-years cumulative rate of ulcer recurrence and amputation
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34 293 respectively [27].

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39 294 We have mentioned previously that PN is one of the major risk factors of DFU. In our study,
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41 295 4.2% of the T2D subjects had only PN and 11.6% had PN with deformity, represented as
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43 296 group 1 and group 2A respectively. This finding was much lower compared to similar studies
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45 297 conducted among subjects of India [24,28-29] and Iran [21,29]. However, this burden is
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47 298 higher than the European country Portugal [22]. Current study classified very low proportion
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49 299 of T2D subjects as having PAD compared to aforementioned studies [21-22,24,28-30]. The
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51 300 overall burden of ‘at risk’ (other than group 0) T2D subjects of this study were also lower
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53 301 than the findings of India [28-29] and Portugal [22]. However, proportion of ‘at risk’ subjects
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55 302 was more than twice of aforementioned Indian [24] and Iranian study [21]. The reasons of
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3 303 risk difference in different countries are still unclear. The study of Abott et al. tried to explore
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5 304 this risk difference among different ethnic population including South-Asians, African-
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7 305 Caribbean's and Europeans of United Kingdom [11]. They reported the possibilities of such
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9 306 difference might be due to methods applied to detect neuropathy, provision of primary health
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11 307 care services, such as diabetes mini-clinics, podiatric care, and referrals for special footwear
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13 308 for the health care districts and variable quality of health care. Regarding burden of risk
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15 309 factors of DFU, Abott et al. added that the lower level of PN and PAD also contributed for
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17 310 less percentage of South-Asian population 'at risk' compared to Europeans. Another cause of
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19 311 DFU risk difference is application of various risk classification system in different countries.
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21 312 We applied modified IWGDF risk classification similar to the study of Iran [21] and Portugal
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23 313 [11], where one of the two Indian [24] study applied semi-structured pre-tested questionnaire
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25 314 and another [28] applied American Diabetic Association (ADA) task force report for
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27 315 comprehensive foot examination risk classification.
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29 316 Our study demonstrated gender-wise and area-wise difference in risk of DFU among T2D
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31 317 population of Bangladesh. Overall proportion of DFU risk was higher among men than their
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33 318 counterpart women and previous studies [7,21,24,31] also reported similar findings.
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35 319 However, a community-based study of India reported that the DFU risk was high in women
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37 320 [25], contradictory to our finding. Current study demonstrated that the risk of DFU was
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39 321 greater among men with previous history of ulcer or amputation. This higher burden of foot
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41 322 ulcer history or amputation in men was also supported by another study of Iran using IWGDF
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43 323 risk classification system [21]. This men-to-women risk difference might be due to diabetes
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45 324 related healthy behavioral practice, health seeking behavior and self-care. In this regard, a
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47 325 Brazilian study reported that gender was significantly associated with changes of lifestyle
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49 326 behavior that related to control of T2D, foot self-care and prevent ulceration, and women
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51 327 were more adhere to lifestyle changes than men [32]. Same study also reported that men were
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3 328 highly reluctant to check their glycaemic status and lipid profile compared to women [31]. In
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5 329 this case, the fact is that women are more sensitive to their health issues and more frequently
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8 330 seek health services than men [33,34].
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10 331 According to urban-rural difference, we found the risk was higher among those lived in a
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12 332 rural area and this finding was also supported by other studies [24,29,35]. The possible
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14 333 explanation included that the diabetic patients of rural area are not aware about their PN due
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16 334 to illiteracy, especially lack of knowledge about diabetic foot related complications. Hence,
17
18 335 they used to barefoot walking that lead to injury to the foot and subsequent complications.
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20 336 [36] Another explanation included that individuals in rural areas often sleep in huts or
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22 337 farmhouses where rodents are common; rodent bites to the feet of the patients with diabetes
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24 338 can lead to chronic ulcers [35].
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28 339 One of the major objectives of this study was to identify the predictors of DFU risk among
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30 340 Bangladeshi T2D population. Sociodemographic predictors including age ≥ 50 years, living
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32 341 in rural area and monthly income $\leq 19,488$ BDT showed higher odds for the risk of DFU. In
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34 342 diabetic research, age is widely evaluated as a predictor of DFU. Like our study, there are
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36 343 some other studies that found age as a significant predictor [37-39]. In our study, age below
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38 344 50 years was a protective factor and above this cut-off value was associated with
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40 345 development of DFU, also supported by the other studies that reported older age was a
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42 346 significant predictor [38,39]. Globally, findings about the association of economic status and
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44 347 area of residence with the risk of DFU are inconsistent. Current study demonstrated lower
45
46 348 economic status (monthly income $\leq 19,488$ BDT) and living in a rural area were the strong
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48 349 predictors of DFU. This finding was consistent with the results of other studies conducted in
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50 350 India [25,28] and Sri Lanka [40]. It has postulated that financial status is directly related to
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52 351 burden of risk factors leading to complications of chronic diseases. This is because lack of
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54 352 financial resources interferes in the access to healthcare services, options of treatments, and
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3 353 hinders the adoption of preventive measures that are necessary to avoid amputations [32].
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5 354 Regarding place of residence, significant urban-rural risk difference for DFU was explained
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7 355 by the study of Viswanathan et al. and we mentioned it in this section previously [35].
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10 356 However, one study reported no association for the aforementioned predictors that concurred
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12 357 with the current study [41].
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14 358 Our study informed that the odds for risk of DFU were higher among insulin user, having
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16 359 diabetic related complications as nephropathy and retinopathy. Previous studies also reported
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18 360 that use of insulin is a predictor of diabetic foot [30,42]. However, exact mechanism has not
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20 361 yet been explored and hence this finding is inconclusive. The possibility may include the fact
21
22 362 that when patients acquiesce to start insulin, they may already have diabetes for a long time
23
24 363 with greater associated complications [30]. Our findings of retinopathy and nephropathy were
25
26 364 also supported by other studies [21,39,43-44]. Regarding nephropathy, it has suggested that
27
28 365 about 10% of diabetic patient have a history of amputation when they entered into a dialysis
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30 366 program [45]. Several factors responsible for increased risk of DFU among nephropathy
31
32 367 patients. They included co-existence of PN, peripheral vascular diseases, susceptibility to
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34 368 infection, reduce self-care, dialysis therapy and anemia [46]. On the other hand, one study
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36 369 reported that the prevalence of diabetic retinopathy was much higher (90%) among patients
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38 370 with DFU than those had no DFU [43]. Another study [44] applied IWGDF risk classification
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40 371 to predict DFU and they found that around 67.58% of patients had diabetic retinopathy and
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42 372 they were included in the risk group 3, similar to our study. In this regard, a systematic
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44 373 review and meta-analysis explained that both the retinopathy and nephropathy are
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46 374 microvascular complications. The impairment of microcirculation in T2D may lead to
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48 375 secondary complications in lower extremity due to dysfunctional vasodilatation. Moreover,
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50 376 patients of diabetic foot with retinopathy have higher level of diabetic biomarkers like
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52 377 ceruloplasmin. Again, this ceruloplasmin is an independent predictor of progression of
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3 378 diabetic nephropathy in T2D patients. Thus, aforementioned explanation implied the link
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5 379 among DFU, retinopathy and nephropathy [47].
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8 380 Previous history of trauma was identified as a significant predictor of DFU (group 3A, OR
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10 381 2.998, $p < 0.001$; group 3B, $p < 0.001$) in our study. This finding was similar with other
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12 382 studies that reported significant association between previous history of trauma and DFU [48-
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14 383 50]. However, the exact mechanism of previous trauma leading to DFU is not clear that
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16 384 demands further research on this issue.

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19 385 This study has some limitations that should be considered. First, the participating centers
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21 386 were not representative of the Bangladesh diabetes centers as a whole, considering their
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23 387 geographical distribution, as some areas were underrepresented or not represented at all. So,
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25 388 the results of our study cannot be extrapolated to the general diabetic population in
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27 389 Bangladesh. Second, in our study some diabetes related complications were
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29 390 underrepresented, especially for diabetic retinopathy and nephropathy. These co-morbidities
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31 391 were not based on real-time clinical examination of eyes and assessment of kidney functions,
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33 392 rather based on diabetic record books review. In the similar way, glycaemic status was
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35 393 evaluated using the values previously recorded in the diabetic record book instead of
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37 394 biochemical measurement during data collection.

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40 395 Other than these issues, this study was important from the public health and clinical
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42 396 perspective. This was the first study of Bangladesh that predicted DFU risk in a moderately
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44 397 large sample of T2D population. Moreover, it was a multi-centric study that recruited
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46 398 respondents from world renowned DAB affiliated diabetes centers. The other strength of this
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48 399 study was gender-wise and area-wise reporting of DFU risk among the study subjects. This
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50 400 will help to address the gender and urban-rural disparities in diabetes foot care in Bangladesh
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52 401 and remodeling of the chain of diabetes centers where appropriate. Finally, and most
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54 402 importantly, first time we explored the predictors that influence the risk of DFU among
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3 403 Bangladeshi T2D subjects. The clinicians of Bangladesh will concentrate more on these
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5 404 predictors during diabetes patient management as they are associated with significant
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7 405 morbidity and mortality resulting from DFU.
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10 406 **Conclusions**

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12 407 Current study detected a significant proportion of T2D population of Bangladesh were at high
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14 408 risk of DFU. This indicated that each and every diabetic patient must be screened for their
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16 409 foot ulcer risk factors according to IWGDF recommendation. In this regard, diabetic foot
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18 410 screening program can be introduced in primary health care system of Bangladesh. Based on
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20 411 the findings of this study, we also recommend that specialized diabetic foot care center
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22 412 should be established in both urban and rural area to stop the devastating consequences of
23
24 413 DFU.
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33
34 417 Bangladesh.
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38 418 **Conflicts of Interest**

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40 419 All authors have none to declare.
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43 420 **Data statement**

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45 421 Dataset is available in the supplementary file.
46
47

48 422 **Author Contributions**

49
50 423 Conceptualization, Palash Chandra Banik and Liaquat Ali; Data curation, Palash Chandra
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52 424 Banik and Rajib Mondal; Formal analysis, Palash Chandra Banik, Mohammad
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54 425 Moniruzzaman and Lingkan Barua; Methodology, Farhana Zaman, Mohammad
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3 426 Moniruzzaman and Liaquat Ali; Resources, Farhana Zaman and Rajib Mondal; Supervision,
4
5 427 Liaquat Ali; Writing – original draft, Lingkan Barua.
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7

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9
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13
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17 432 chain diabetes care centers.
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457 [and-role-standard-wound-care-and-adva](https://www.o-wm.com/content/diabetic-foot-ulcers—effects-qol-costs-and-mortality-and-role-standard-wound-care-and-adva) (accessed June 11, 2019).

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22	617	1	70	2	1	3	3	1	5000
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34	627	1	55	2	1	2	3	1	8000
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36	629	1	55	1	1	3	1	1	50000
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17	815	2	45	2	1	3	3	1	10000
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20	818	2	50	2	1	4	1	1	10000
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27	825	2	65	2	2	2	3	1	10000
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46	844	2	50	2	2	2	3	1	10000
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2	1000	2	40	2	2	2	3	1	10000
3	1001	2	45	2	2	2	3	1	8000
4	1002	2	62	2	1	4	1	1	10000
5	1003	2	45	2	1	3	3	1	15000
6	1004	2	46	2	1	2	1	1	35000
8	1005	2	55	2	2	1	3	1	10000
9	1006	2	59	2	1	3	3	1	5000
10	1007	2	74	2	1	3	3	1	5000
11	1008	2	60	2	1	3	3	1	10000
12	1009	2	70	2	1	2	3	1	4000
14	1010	2	60	2	2	2	3	1	15000
15	1011	2	63	2	1	3	3	1	7000
16	1012	2	62	2	1	2	3	1	5000
17	1013	2	70	2	1	3	3	1	20000
18	1014	2	43	1	1	3	1	1	22000
20	1015	2	50	1	2	1	2	1	6000
21	1016	2	45	2	2	3	1	1	15000
22	1017	2	63	2	2	3	2	1	15000
23	1018	2	63	1	1	4	1	1	20000
24	1019	2	35	2	2	1	3	1	4000
25	1020	2	60	2	2	2	3	1	15000
27	1021	2	73	2	2	1	3	1	10000
28	1022	2	58	2	2	3	3	1	15000
29	1023	2	40	2	2	3	1	1	15000
30	1024	2	65	2	2	2	3	1	9000
32	1025	2	50	2	2	1	3	1	10000
33	1026	2	45	2	2	2	1	1	15000
34	1027	2	35	2	2	3	1	1	12000
35	1028	2	46	2	2	3	3	1	15000
36	1029	2	63	2	2	1	3	1	12000
38	1030	2	45	2	2	2	1	1	40000
39	1031	2	63	2	2	2	3	1	15000
40	1032	2	45	2	2	1	3	1	9000
41	1033	2	40	2	2	2	3	1	10000
42	1034	2	42	2	2	2	3	1	10000
44	1035	2	61	2	2	2	3	1	18000
45	1036	2	66	2	2	1	3	1	4000
46	1037	2	62	2	2	2	3	1	10000
47	1038	2	60	2	2	2	3	1	10000
49	1039	2	50	2	2	2	3	1	8000
50	1040	2	45	2	2	3	1	1	8000
51	1041	2	45	2	2	2	3	1	5000
52	1042	2	60	2	2	1	3	1	7000
53	1043	2	45	2	1	3	3	1	10000
54	1044	2	60	2	1	3	1	1	5000
56	1045	2	61	2	2	3	3	1	45000
57	1046	2	43	2	1	3	1	1	10000
58	1047	2	69	1	1	4	2	1	10000
59	1048	2	40	2	1	1	3	1	10000
60	1049	2	42	2	1	3	3	1	10000

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2	1050	2	62	2	1	3	3	1	15000
3	1051	2	70	2	1	3	3	1	10000
4	1052	2	49	2	1	1	3	1	10000
5	1053	2	58	2	2	1	3	1	45000
6	1054	2	53	2	2	2	3	1	20000
7	1055	2	44	2	1	3	3	1	15000
8	1056	2	40	2	2	2	3	1	15000
9	1057	2	60	2	2	4	1	1	8000
10	1058	2	48	2	1	2	3	1	20000
11	1059	2	56	2	2	1	3	1	30000
12	1060	2	65	2	1	3	3	1	20000
13	1061	2	57	2	1	3	3	1	7000
14	1062	2	70	2	1	1	3	1	20000
15	1063	2	52	2	1	2	3	1	50000
16	1064	2	49	2	2	2	3	1	8000
17	1065	2	60	2	1	1	3	1	70000
18	1066	2	55	2	1	3	1	1	10000
19	1067	2	55	2	1	2	3	1	10000
20	1068	2	93	2	1	3	3	1	50000
21	1069	2	68	2	1	1	3	1	60000
22	1070	2	70	2	2	1	3	1	5000
23	1071	2	60	1	1	3	1	1	8000
24	1072	2	59	1	1	4	1	1	32000
25	1073	2	75	1	1	2	1	1	25000
26	1074	2	80	1	2	3	2	1	30000
27	1075	2	48	1	1	3	1	1	20000
28	1076	2	30	1	1	1	1	1	15000
29	1077	2	44	1	1	4	1	1	30000
30	1078	2	65	1	2	3	1	1	50000
31	1079	2	52	1	1	3	1	1	20000
32	1080	2	47	1	1	2	2	1	15000
33	1081	2	42	1	2	2	4	1	30000
34	1082	2	75	1	1	3	4	1	20000
35	1083	2	50	1	1	2	2	1	5000
36	1084	2	36	1	1	2	1	1	8000
37	1085	2	24	1	2	3	2	1	7000
38	1086	2	47	1	2	4	1	1	10000
39	1087	2	41	1	1	3	1	1	7000
40	1088	2	49	2	1	2	3	1	20000
41	1089	2	35	2	1	1	3	1	30000
42	1090	2	37	2	1	1	3	1	70000
43	1091	2	50	2	1	2	3	1	6000
44	1092	2	50	1	1	3	1	2	40000
45	1093	2	23	1	1	3	4	1	20000
46	1094	2	52	1	1	3	1	1	10000
47	1095	2	30	1	2	1	4	1	7000
48	1096	2	45	2	1	2	3	1	10000
49	1097	2	60	1	2	1	4	1	8000
50	1098	2	42	2	2	1	3	1	12000
51	1099	2	35	2	1	1	3	1	60000

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2	1100	2	53	1	1	1	4	1	25000
3	1101	2	70	1	1	3	2	1	10000
4	1102	2	46	2	1	2	3	1	15000
5	1103	2	43	2	2	1	3	1	20000
6	1104	2	49	2	1	2	3	1	20000
8	1105	2	70	1	1	4	1	1	7000
9	1106	2	79	2	1	1	3	1	50000
10	1107	2	25	2	1	3	3	1	50000
11	1108	2	40	1	1	1	4	1	10000
12	1109	2	50	2	1	1	3	1	10000
14	1110	2	30	2	1	1	3	1	50000
15	1111	2	46	1	1	3	2	1	3000
16	1112	2	70	1	2	2	4	1	25000
17	1113	2	35	1	1	4	4	1	5000
18	1114	2	45	1	1	4	1	1	30000
20	1115	2	47	1	1	4	4	1	30000
21	1116	2	65	2	1	1	3	1	15000
22	1117	2	20	2	2	1	3	1	10000
23	1118	2	45	2	2	1	3	1	6000
24	1119	2	55	1	1	1	1	1	10000
26	1120	2	65	2	1	2	3	1	30000
27	1121	2	46	1	1	2	1	1	5000
28	1122	2	45	1	1	4	4	1	10000
29	1123	2	41	1	2	2	2	1	30000
30	1124	2	47	2	2	1	3	1	20000
32	1125	2	55	2	1	2	3	1	10000
33	1126	2	70	2	2	1	3	1	20000
34	1127	2	43	2	1	4	4	1	15000
35	1128	2	55	1	1	3	2	1	7000
36	1129	2	55	2	1	2	3	1	40000
38	1130	2	72	2	1	3	3	1	25000
39	1131	2	40	2	2	1	3	1	20000
40	1132	2	39	1	1	3	1	1	10000
41	1133	2	70	2	1	2	3	1	15000
42	1134	2	50	2	2	1	3	1	15000
44	1135	2	35	1	2	1	4	1	3000
45	1136	2	42	2	1	2	3	1	15000
46	1137	2	50	2	1	4	1	1	7000
47	1138	2	42	2	1	2	3	1	7000
48	1139	2	36	2	2	1	3	1	5000
50	1140	2	55	2	1	1	3	1	10000
51	1141	2	50	1	2	4	1	1	5000
52	1142	2	60	2	1	2	3	1	60000
53	1143	2	45	2	2	2	3	1	10000
54	1144	2	60	1	2	1	4	1	3000
56	1145	2	73	2	2	3	3	1	30000
57	1146	2	90	2	2	2	3	1	4000
58	1147	2	40	2	1	2	3	1	5000
59	1148	2	46	2	1	2	3	1	15000
60	1149	2	56	2	1	1	3	1	15000

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2	1150	2	45	2	1	1	3	1	2000
3	1151	2	55	2	1	2	2	1	10000
4	1152	2	42	2	2	2	2	1	10000
5	1153	2	50	2	2	2	3	1	20000
6	1154	2	45	2	2	1	3	1	3000
7	1155	2	42	2	2	2	3	1	30000
8	1156	2	35	2	2	2	3	1	3000
9	1157	2	45	1	2	3	4	1	5000
10	1158	2	42	1	2	4	4	1	10000
11	1159	2	65	2	2	2	3	1	80000
12	1160	2	40	2	2	2	3	1	5000
13	1161	2	55	2	1	1	3	1	10000
14	1162	2	60	1	2	2	2	1	5000
15	1163	2	50	1	2	1	4	1	15000
16	1164	2	47	2	2	1	3	1	15000
17	1165	2	70	1	2	3	4	1	5000
18	1166	2	52	2	1	2	3	1	10000
19	1167	2	40	1	2	3	4	1	20000
20	1168	2	40	2	2	1	3	1	4000
21	1169	2	60	2	2	1	3	1	12000
22	1170	2	46	1	2	4	1	1	15000
23	1171	2	40	1	2	3	4	1	5000
24	1172	2	50	2	1	2	3	1	10000
25	1173	2	50	2	2	1	3	1	8000
26	1174	2	40	2	2	1	3	1	15000
27	1175	2	56	2	1	3	3	1	10000
28	1176	2	60	2	2	2	3	1	3000
29	1177	2	60	1	2	3	2	1	30000
30	1178	2	30	2	2	2	3	1	15000
31	1179	2	40	1	2	3	4	1	3000
32	1180	2	30	2	2	1	3	1	30000
33	1181	2	55	2	2	2	3	1	8000
34	1182	2	60	2	2	1	3	1	20000
35	1183	2	65	2	2	3	3	1	10000
36	1184	2	41	2	2	1	3	1	7000
37	1185	2	60	2	2	2	3	1	6000
38	1186	2	30	2	2	1	3	1	6000
39	1187	2	35	2	2	1	3	1	60000
40	1188	2	56	2	2	1	3	1	30000
41	1189	2	56	2	2	1	3	1	10000
42	1190	2	72	1	2	2	1	1	5000
43	1191	2	65	1	2	3	2	1	20000
44	1192	2	54	1	2	3	1	1	11500
45	1193	2	55	1	2	2	1	1	10000
46	1194	2	45	2	2	2	4	1	10000
47	1195	2	45	1	1	4	1	1	6000
48	1196	2	63	2	2	2	3	1	50000
49	1197	2	70	2	2	1	3	1	40000
50	1198	2	68	2	2	1	3	1	20000
51	1199	2	37	1	1	3	4	1	10000

1									
2	1200	2	59	2	1	2	4	1	2500
3									
4									
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For peer review only

	BMI	18_dur_DN	insulin_user	Q20_FBG	Q21_RBG	_current_sn6	_current_	PA	use_fitting_f
1									
2									
3	22.22222	8	2	8.9	10.9	2	2	2	1
4	26.25499	2	2	7.2	11.5	2	2	1	1
5	25.63117	8	2	6.4	10.5	2	2	2	1
6									
7	23.55556	12	2	9	12	2	2	1	1
8	26.57538	15	1	9.8	13.5	2	1	1	1
9	23.55556	11	1	6.4	9.1	2	2	1	1
10	24.86395	1	2	5.5	8.4	2	2	2	1
11	31.73973	6	1	5.7	7.8	2	2	2	1
12									
13	24	20	2	5.2	6.6	2	1	1	1
14	29.17489	19	1	7.7	12	2	1	2	1
15	22.21368	11	2	6.6	8.9	2	1	2	1
16	22.37034	3	2	6.2	11.2	2	1	2	1
17	23.82813	7	2	5.5	7.8	2	2	1	1
18	23.11111	14	1	6.5	8.4	2	2	2	1
19	36.21228	8	2	7.9	8.9	2	2	2	1
20	23.55556	14	1	6.3	11.5	2	2	2	1
21									
22	26.3656	13	2	6.9	9.5	2	2	2	1
23	21.48438	8	2	3.2	11.5	2	2	2	1
24	25.91068	10	2	5.8	7.2	2	2	1	1
25	24.76757	2	2	5.3	7.6	2	1	2	1
26									
27	25	8	2	7.1	14.7	2	1	1	1
28	23.8048	3	1	9.7	16.9	2	2	1	1
29	25.71166	15	2	5.2	9.9	1	2	1	1
30	23.73996	7	2	9.1	11.3	2	2	2	1
31	20.80856	8	2	8.5	13.6	2	2	2	1
32	22.03857	2	2	4.5	12.5	2	2	2	1
33	24.38653	6	1	5.2	9.7	1	1	1	1
34	26.12861	7	2	6	10.2	2	2	1	1
35	22.30815	15	1	7	12.7	2	2	2	1
36	23.91883	3	2	5.3	6.4	1	1	2	1
37	24.97399	15	1	4.1	7.2	2	2	2	2
38	25.81663	5	2	6.6	8.6	1	2	2	1
39	26.15933	19	1	10	18	2	2	1	2
40	25.03992	13	2	17.9	14.2	2	2	2	1
41	20.17715	15	1	10	15	1	2	2	1
42	24.38237	5	2	6.8	13.2	2	2	2	1
43	19.00391	3	2	6	7.5	2	2	2	1
44	28.99931	12	1	4.1	7.2	2	2	2	1
45	24.14152	7	1	5.9	12.5	1	1	1	1
46	28.57796	12	1	6.6	9.9	2	1	2	1
47	23.11111	11	1	6.9	10.7	2	2	1	1
48	22.10029	12	1	5.8	7.2	2	2	2	1
49	25.71166	10	2	6.2	8.1	2	1	2	1
50	25.91068	5	2	4.2	9.6	1	2	2	2
51	25.63117	2	2	5.9	7.7	1	2	1	1
52	19.95935	17	1	5	8.9	2	1	2	1
53	24.53897	21	1	5.9	11.1	2	2	2	1
54	24.97399	16	1	8.8	16	1	1	2	1
55									
56	28.959	12	2	5.2	6.9	2	1	2	1

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2	25.45236	6	2	6.9	8.6	2	2	1	1
3	28.51563	11	1	6.8	11.2	2	2	1	1
4	32.88919	7	2	7	8.5	2	2	2	1
5	26.57313	6	2	6.8	8.9	2	2	2	1
6	23.55556	14	1	6.7	11.9	2	2	2	1
7	26.3656	7	2	6.911	11.1	2	2	2	1
8	23.4375	15	2	7.2	8.3	2	2	2	2
9	22.03173	26	1	6.2	7.2	2	2	2	1
10	27.11111	23	2	9	13	2	2	2	1
11	21.875	24	2	6.7	13	2	2	2	1
12	29.38476	5	2	6	10.5	2	2	1	1
13	30.07813	3	2	5.9	10.2	2	2	2	1
14	22.03857	9	1	5.1	8.2	2	2	1	1
15	27.91552	10	2	6.4	13.9	1	2	2	1
16	24.21875	20	2	5.7	9.8	2	1	2	1
17	17.99015	25	1	6	11	1	1	1	1
18	27.34375	5	2	5.8	9.9	2	2	1	1
19	32.46618	20	2	9.3	9.9	2	2	2	1
20	24.00549	3	2	6.7	10.3	2	1	2	1
21	24.52435	8	2	8.2	11.5	2	1	1	1
22	26.29758	25	2	6.4	8.4	1	2	1	1
23	24.39482	1	2	6.8	11	2	1	2	1
24	24.79667	1	1	5.2	8	2	2	2	1
25	23.11111	10	1	8.1	12	2	2	2	1
26	37.53049	1	2	4.9	6.2	2	2	2	1
27	22.22222	3	2	5.8	8	2	1	2	1
28	23.11111	1	2	7.2	11.2	2	2	2	1
29	24.64665	12	2	8.8	14.4	2	1	2	1
30	30.29778	10	2	5.3	7.2	2	2	2	1
31	27.8488	10	1	6.5	10.8	2	2	1	1
32	22.82688	10	1	7.4	8.4	2	2	1	2
33	25.5102	12	2	6.4	7.8	2	1	1	1
34	25.78125	1	2	6.2	7.5	2	2	2	1
35	28.06894	5	2	7.4	13.5	2	2	1	1
36	22.0741	15	2	6.7	7.4	2	2	2	2
37	23.42237	3	2	6.9	9.2	2	2	1	2
38	28.93407	6	2	7	10.8	2	2	1	1
39	21.64127	2	2	7.2	10.7	2	2	2	1
40	26.17188	8	2	6.6	8.1	2	1	1	1
41	29.35752	5	2	6.8	12.1	2	2	2	1
42	27.20961	2	2	5.1	6.1	2	2	1	1
43	25.56611	5	2	6.6	7.6	2	2	1	1
44	23.8048	5	2	6.1	11.6	2	2	1	1
45	24.00549	10	1	6	10.4	2	2	2	2
46	23.73996	16	1	8.3	10.8	2	2	1	1
47	29.08613	5	2	6.4	8.8	2	2	2	1
48	25.91068	8	2	7.2	13.7	2	1	1	1
49	17.77778	1	2	7.2	11.9	2	2	2	1
50	24.30462	1	2	7.9	13	2	2	2	1
51	25.5102	1	2	8.1	10.1	2	2	1	2

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2	24.97399	6	2	9.2	11	2	2	1	1
3	28.98114	2	1	11.6	14.2	2	2	2	1
4	28.30385	19	1	6.2	7.9	2	2	2	1
5	27.20961	2	2	4.3	4.9	2	1	2	1
6	27.76621	5	2	6	10	2	2	1	1
7	20.3428	4	2	11	13	2	1	2	1
8	27.99302	7	2	8	9	2	2	1	1
9	23.23346	2	2	7	10	2	2	1	1
10	26.27135	2	2	8	9	2	2	1	1
11	19.43635	5	2	9	14	2	2	1	1
12	28.06894	20	1	5	9	2	2	2	1
13	25.67452	8	2	4	7	2	2	2	1
14	32.89474	14	1	7	9	2	1	1	1
15	29.67495	2	2	6.5	7	2	2	2	1
16	32.51821	7	2	8	10	2	2	2	1
17	26.83518	3	2	7	13	2	1	2	1
18	27.70083	15	2	6	9	2	1	2	1
19	24.83576	3	2	7	14	2	2	1	1
20	24.76757	19	1	7	12	2	2	1	1
21	24.65303	20	1	7	9	2	1	2	1
22	25.20398	12	2	7	10	2	2	1	1
23	29.34129	2	2	6	8	2	1	2	1
24	27.55556	10	1	8	4	2	2	2	1
25	24	5	1	7	6	2	2	1	1
26	23.42209	20	2	8	11	2	2	2	1
27	26.40236	16	1	7	10	2	1	2	1
28	29.43213	2	2	6	8	2	2	2	1
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30	22.93975	14	2	13	17	2	2	2	1
31	29.08613	3	2	11	16	2	1	2	1
32	24.21875	4	2	4	7	2	2	1	1
33	21.36752	15	1	10	17	2	2	1	2
34	29.51594	6	2	8	11	2	1	1	1
35	18.75	1	2	5	7	2	2	1	1
36	22.0741	2	2	6	14	2	2	1	1
37	33.28402	10	2	12	14	2	2	1	1
38	26.83518	17	2	8	11	2	2	1	1
39	21.1109	5	2	9	10	2	2	2	1
40	26.22269	20	1	7	10	2	2	1	1
41	30.49353	9	2	8	11	2	1	2	1
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44	27.00617	5	2	7	9	2	2	2	1
45	26.03749	10	2	4	14	2	2	1	2
46	24	2	2	7	9	2	2	2	2
47	28.76187	16	2	10	11	2	2	1	1
48	23.83301	1	2	6	9	2	2	2	1
49	23.83301	1	2	5	6	2	2	2	1
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2	32	4	2	10	12	2	2	1	1
3	23.87512	1	2	6.4	7.2	2	2	1	1
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13	24.74745	8	2	5	6	2	2	2	1
14	23.8054	5	2	14	19	2	2	1	1
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16	29.86496	1	2	8	11	2	1	2	1
17	23.61275	9	2	13	17	2	1	2	1
18	28.76187	7	1	11	14	2	1	2	1
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21	23.95123	12	2	11	13	2	1	2	1
22	21.20845	9	2	12	13	2	1	2	1
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25	33.32756	16	2	7	12	2	2	1	2
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43	25.5367	6	2	10	11	2	1	2	1
44	26.66667	5	2	6	16	2	2	1	1
45	24.65483	12	2	7	10	2	2	2	1
46	32.87311	9	1	8	12	2	2	2	1
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9	23.8054	3	2	8.7	13.3	2	2	2	2
10	24.03441	8	1	10	15	2	1	2	1
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13	25.14861	3	2	6	8	2	2	2	2
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16	23.87512	15	2	6	10	2	2	1	1
17	23.79536	2	1	4	9	2	2	2	1
18	26.95313	1	2	9.5	17	2	2	2	1
19	32.8125	12	1	7	4	2	2	2	1
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21	26.95313	10	1	14	22	2	2	1	1
22	22.26563	5	1	11	14	2	2	1	1
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36	24.50895	4	2	5	9	2	2	1	1
37	21.875	3	2	7	9	2	2	2	1
38	26.43807	3	2	7	10	2	2	2	1
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41	25.39063	7	2	5	6	2	2	2	1
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44	21.56455	3	2	6	7	2	2	1	1
45	21.19274	8	2	12	18	1	1	2	1
46	29.32099	10	2	7	9	2	2	2	1
47	26.83518	5	2	8	12	2	2	2	1
48	27.00513	8	1	14	21	1	2	2	1
49	25.40282	2	2	13	17	2	1	2	1
50	25.03992	15	2	7	10	2	2	2	1
51	23.8054	3	2	8.7	13.3	2	2	2	2

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2	24.03441	8	1	10	15	2	1	2	1
3	24.03441	5	1	13.3	24	2	2	1	1
4	27.11058	4	1	7.6	9	2	2	1	1
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7	21.56455	1	2	6	8	2	2	2	1
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11	32.8125	12	1	7	9	2	2	2	1
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13	24.03441	5	1	13.3	24	2	2	1	1
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16	28.76397	1	2	5	7	2	2	1	1
17	21.56455	1	2	6	8	2	2	2	1
18	23.87512	15	2	6	10	2	2	1	1
19	23.79536	2	1	4	5	2	2	2	1
20	26.95313	1	2	9.5	17	2	2	2	1
21	32.8125	12	2	7	4	2	2	2	1
22	22.3403	1	2	6	11	2	2	1	1
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24	32.88889	10	1	11	13	2	2	1	1
25	22.15102	3	2	9	13	2	2	1	1
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27	24.59491	10	2	10	11	2	1	1	1
28	30.29778	15	1	9	13	2	1	1	1
29	21.21832	4	1	10	18	2	1	1	1
30	30.22222	4	1	7	13	2	2	2	1
31	22.94213	3	2	9	13	2	2	1	1
32	32.08944	12	1	6	16	2	1	1	1
33	28.99931	10	2	4	10	2	2	2	1
34	27.97068	8	2	9	13	2	1	1	1
35	24.14152	4	1	10	18	2	1	1	1
36	29.33333	7	1	5	7	2	2	1	1
37	24.14152	6	2	7	12	2	2	1	1
38	23.29072	4	2	15	18	2	1	1	1
39	24.59491	10	2	10	11	2	1	1	1
40	25.33333	6	2	17.4	8.4	2	1	2	2
41	26.47918	5	2	11.8	14.5	2	2	2	2
42	30.29778	1	2	5.6	13	2	2	1	2
43	24.55775	5	2	7.9	9.1	2	2	1	1
44	29.27796	20	1	9.4	12.5	2	2	2	1
45	21.63115	3	1	9	11.2	2	2	2	1
46	23.8054	3	2	8.7	13.3	2	2	2	2
47	24.03441	8	1	10	15	2	1	2	1
48	27.82931	7	2	5	9	2	2	1	1
49	27.11058	4	1	7.6	9	2	2	1	1
50	25.14861	3	2	6	8	2	2	2	2
51	28.76397	1	2	5	7	2	2	1	1

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3	27.40766	3	2	7	14	2	1	1	2
4	21.36752	1	2	7	8	1	2	1	1
5	24.60938	2	2	8	10	2	1	1	1
6	27.81588	3	1	8	16	2	1	1	1
7	26.04167	10	1	7	8	2	1	2	1
8	22.64087	4	2	8	16	2	2	2	1
9	25.39022	1	2	8	10	2	2	1	1
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11	24.65483	10	1	9	19	2	2	1	1
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13	24.24392	7	1	7	16	2	1	1	1
14	24.39482	5	2	6	10	2	2	2	1
15	27.23922	4	2	8	13	2	2	2	1
16	28.45293	6	2	6	11	2	2	2	1
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18	19.72387	6	2	14	17	2	2	2	2
19	26.52392	3	2	10	14	2	1	1	1
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28	34.72222	10	2	8	14	2	1	2	1
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30	29.89969	12	1	7	16	2	2	2	1
31	24.67702	11	1	6	12	1	2	2	1
32	29.27796	9	2	7	14	2	1	1	1
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34	25.1559	16	2	7	12	1	1	1	1
35	25.33333	1	2	7	8	2	2	1	1
36	23.82813	2	2	4	10	2	2	1	1
37	29.33333	1	2	12	20	2	2	1	1
38	23.33768	6	1	9	10	2	1	1	1
39	32.71862	5	1	9	11	2	2	1	1
40	22.60026	4	1	5	11	2	2	1	1
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42	24.03441	1	2	6	16	2	1	1	1
43	34.31953	1	1	7	8	2	2	1	1
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45	28.93519	8	1	11	14	2	2	1	1
46	32.31096	15	2	6	8	2	2	1	1
47	23.04688	18	1	9	11	2	2	2	1
48	24.22145	2	2	6	7	1	1	2	1
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50	23.62445	4	1	6	8	1	2	2	1
51	30.38194	10	2	5	9	2	2	2	1

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3	18.36547	5	2	5.5	8	2	2	2	1
4	23.30668	10	1	13.4	20	2	2	2	1
5	23.87543	20	2	8	14	2	2	2	1
6	23.87512	1	1	7	11	2	2	2	1
7	24.91077	9	1	6	8	2	2	2	1
8	21.92613	7	1	7	9	2	2	2	1
9	37.10575	18	1	8	12	2	2	2	1
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11	25.87606	15	2	6	11	2	2	2	1
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13	31.55556	3	2	9	14	2	2	2	1
14	27.63037	20	1	8	11	2	2	2	1
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16	29.08163	1	2	7	8	2	1	2	1
17	32.46618	3	1	8	3	2	2	2	2
18	30.13148	10	2	11	18	2	1	2	2
19	34.24499	8	1	15	20	2	1	2	1
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21	27.88762	8	2	5	7	2	1	2	1
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25	27.88762	8	2	5	7	2	1	2	1
26	43.67106	13	1	7	9	2	2	2	1
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29	24.14152	13	2	5	8	2	2	2	1
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32	29.13632	25	1	9	12	2	2	2	1
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34	34.24499	8	1	15	20	2	1	2	1
35	30.08006	1	1	8	10	2	2	2	1
36	21.09619	2	2	6	8	2	2	2	1
37	23.8054	2	1	8	11	2	2	2	1
38	28.04038	30	1	11	20	2	2	1	1
39	25.22409	1	1	9	11	2	2	1	1
40	29.59184	10	1	8	10	2	1	2	1
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42	24.9135	22	1	14	15	2	2	2	1
43	26.12245	12	1	11	12	2	1	1	1
44	28.69898	8	2	6	8	1	2	1	1
45	22.03857	14	1	5	9	2	2	1	1
46	28.30385	7	2	6	7	2	2	1	1
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50	23.4375	21	1	9	13	2	2	2	1
51	22.26563	18	2	6	7	2	2	2	1

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2	20.0796	10	1	6	8	2	2	2	1
3	24.34176	4	2	6.7	18	1	2	2	1
4	23.30668	3	1	6.1	4.7	2	1	2	1
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6	24.00549	1	2	5.7	7.3	2	2	2	1
7	22.51631	8	1	7.4	12.1	2	2	2	1
8	23.33768	4	2	6.1	4.7	1	2	1	1
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16	27.27633	4	2	4	7	2	2	2	1
17	27.05515	4	2	7	8	2	2	2	1
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19	23.8048	4	2	7	6	2	2	1	1
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25	26.40236	3	1	6	11.5	1	2	2	1
26	25.65437	15	1	11	7.3	2	2	2	1
27	21.21832	2	2	11	12	2	2	2	1
28	28.90625	19	2	5	8	2	2	2	1
29	33.59375	1	2	8	11.4	2	2	2	1
30	25.86451	15	2	8	12	2	2	1	1
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34	22.47659	13	2	5	7	2	1	2	1
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36	20.86112	20	1	7	18	1	2	2	1
37	22.83737	5	2	6	10	2	2	2	1
38	21.51386	6	2	7	10	2	2	2	1
39	25.63692	2	2	9	11	2	2	2	1
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42	25.52965	12	2	7	12	1	2	2	1
43	30.42185	5	2	6	12	2	2	2	1
44	25	1	2	7	9	2	2	2	1
45	20.95717	11	1	12	11	1	2	2	1
46	27.6398	14	2	12	15	2	2	2	1
47	24.97399	13	2	9	20	2	2	2	1
48	29.40227	2	2	6	9	1	1	2	1
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50	20.79673	10	2	10	14	2	2	2	1
51	24.65483	5	1	9	10	2	2	2	1

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3	22.37034	4	2	6	7	2	1	2	1
4	22.0741	20	1	13	15	2	1	2	1
5	32	1	2	5	7	2	2	2	1
6	27.70526	2	2	5	9	2	1	2	1
7	25.07619	11	2	8	12	2	2	2	1
8	21.50447	2	1	5	7	2	1	2	1
9	23.45656	6	1	11	14	2	1	2	1
10	27.20961	11	2	7	9	2	2	2	1
11	29.51594	14	1	13	15	2	2	2	1
12	33.7477	3	1	13	14	2	2	2	1
13	32.7316	1	2	7	8	2	2	2	1
14	27.67874	9	1	7	8	2	2	2	1
15	23.06805	6	1	6	7	2	2	2	1
16	27.19179	10	1	12	11	2	1	2	1
17	26.77593	3	2	7	9	2	2	2	1
18	27.67874	3	2	11	12	2	2	2	1
19	20.8292	7	1	15	18	2	1	2	1
20	26.02264	9	1	8	11	2	1	2	1
21	27.11111	3	2	6	8	2	2	2	1
22	24.67105	6	2	9	11	2	2	2	1
23	24.19649	13	1	8	10	2	2	2	1
24	30.74787	3	2	9	11	2	2	2	1
25	30.63043	4	1	9	11	2	1	2	1
26	18.98659	10	1	12	16	2	1	2	1
27	24.14152	4	1	6	8	2	2	2	1
28	26.93572	15	1	18	20	2	2	2	1
29	33.22753	1	1	7	9	2	2	2	1
30	24.52682	9	1	8	14	2	2	2	1
31	45.88009	2	1	10	20	2	2	2	1
32	28.25097	12	1	5	8	2	2	2	1
33	33.69494	2	1	13	18	2	1	2	1
34	23.61275	6	1	6	12	2	2	2	1
35	17.25838	5	1	6	8	2	2	2	1
36	17.30104	1	2	11	18	2	2	2	1
37	32.83918	6	1	7	9	2	1	2	1
38	25.29938	9	1	8	14	2	2	2	1
39	32.31096	2	2	4	8	2	2	2	2
40	21.64127	2	2	7	9	2	2	2	1
41	21.58003	6	1	6	7	2	2	2	1
42	28.93519	4	1	7	8	2	2	2	1
43	27.27633	5	1	5	9	2	1	2	1
44	27.97068	5	1	7	9	2	1	2	1
45	26.91273	8	1	7	9	2	2	2	1
46	34.43526	2	1	7	9	2	2	2	1
47	28.13366	4	1	7	9	2	1	2	1
48	23.1911	1	1	7	8	2	2	2	1
49	26.27135	10	1	11	14	2	1	2	1
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51	29.26997	12	1	7	8	2	1	2	1

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2	32.45472	1	1	7	9	2	2	2	1
3	30.80125	9	2	8	11.1	2	1	2	1
4	27.55556	1	2	6.3	9.8	2	2	2	1
5	31.29737	16	1	11.8	13.1	2	1	2	1
6	25.45236	12	1	9.1	11.8	2	1	2	1
7	26.3779	4	2	5.2	8.1	2	1	2	1
8	35.7072	1	2	8.5	9	2	1	2	1
9	23.47303	5	1	9.2	10	2	2	2	1
10	30.73061	2	2	5.2	7.8	2	2	2	1
11	28.30385	1	1	6	7.2	2	2	2	1
12	26.22269	1	2	4.7	5.9	2	2	2	1
13	34.69686	1	2	4.7	6.8	2	1	2	1
14	29.03179	9	1	6.8	9.8	2	2	2	1
15	23.6304	8	2	6.5	12.1	2	2	2	1
16	29.43213	6	2	12.7	17.7	2	2	2	1
17	20.2395	1	1	6.4	11.4	2	2	2	1
18	23.49524	9	1	6.8	9.1	2	2	2	1
19	27.39226	1	2	3.1	8.8	2	2	2	1
20	27.76621	2	1	11.6	19	2	2	2	1
21	16.97601	1	2	4.2	6.3	2	2	2	1
22	24	5	2	6.8	9.3	2	2	2	1
23	22.89282	1	1	7.9	16.3	2	2	2	1
24	21.77778	10	1	15.2	22.4	2	2	2	2
25	22.0741	5	1	10.4	18.1	2	1	2	1
26	29.90303	5	2	6.1	7.9	2	1	2	1
27	26.75321	18	1	6.8	10.3	2	2	2	1
28	23.8048	2	1	6.8	7.9	2	2	2	1
29	28.53746	10	2	6.3	8.3	2	2	2	1
30	19.97622	6	2	12.2	14.2	2	1	2	1
31	33.70052	11	2	5.4	7	2	2	2	1
32	23.42237	13	2	6.4	7.7	2	2	2	1
33	25.65263	5	2	7.5	8.5	2	2	2	1
34	34.70776	1	2	10.8	16.1	2	2	2	1
35	23.2446	4	1	5	7.3	2	1	2	1
36	17.85714	6	1	16.6	18.2	2	2	2	1
37	27.58621	18	2	6	12.9	2	1	2	1
38	21.58003	3	1	6.2	16.2	2	2	2	2
39	27.11058	9	2	10.7	13.2	2	2	2	1
40	17.30104	11	1	6.7	9.3	2	1	2	1
41	27.47138	3	2	11	14	2	2	2	1
42	29.96878	4	1	7.2	11.2	2	2	2	2
43	26.84067	6	2	5	9.2	2	2	2	1
44	22.22222	5	2	6.4	9	2	2	2	1
45	27.05515	6	1	5.3	8	2	2	1	1
46	27.76621	1	1	5.7	8.9	2	2	1	1
47	21.70139	15	2	1.2	3.6	2	2	2	1
48	23.18339	6	2	9.5	11.3	2	2	2	2
49	26.67276	8	1	6	8.5	2	2	2	1
50	25.10957	5	1	9.8	12.1	2	2	2	1
51	22.49135	5	1	13.2	17.3	2	2	2	1

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2	24.12175	12	2	9.6	16.8	1	2	2	1
3	22.52151	1	2	5.6	8.5	2	2	1	1
4	31.99217	6	1	5	10	2	1	2	1
5	32.83918	3	2	4	8	2	2	2	1
6	22.82688	2	2	14	18	2	1	1	1
7	24.44444	6	2	6	8	2	2	1	2
8	23.45656	3	2	5	8	2	2	2	2
9	25.33333	3	2	10	22	2	1	2	1
10	24.44444	1	2	6.5	9	2	1	1	1
11	20.76125	10	1	11	13	1	1	1	1
12	23.14815	3	1	11	14	2	2	1	1
13	24.34176	2.5	2	6.6	7.4	2	2	2	1
14	22.22222	12	2	8.5	11.3	2	2	1	1
15	24.45107	10	2	7	10	2	1	1	1
16	22.82688	3	2	6	7	2	2	2	1
17	21.45727	5	1	6	5	2	2	2	1
18	26.89618	3	2	8	9	2	2	2	1
19	27.05515	10	2	4.5	8	2	2	2	1
20	23.49524	2	2	14	17	2	2	1	1
21	27.02581	4	2	8	14	2	2	2	1
22	25.5102	4	2	7	11	2	2	2	1
23	28.80441	3	1	10.11	18.1	2	2	2	1
24	31.95763	3	1	4	8	2	2	2	2
25	24.79667	6	2	8	12	2	2	1	1
26	20.81165	5	2	9	13	2	2	2	1
27	22.21368	5	2	4	6	2	2	2	1
28	19.29012	2	2	8	11	2	1	1	1
29	26.31464	2	1	12.6	15	2	2	2	2
30	18.76525	1	2	7.5	7.6	2	2	2	1
31	30.70041	6	2	5	10	2	2	1	1
32	25.33333	7	2	3.5	5.1	2	2	2	1
33	23.22543	8	1	4.8	16.8	2	2	2	1
34	22.22222	1	2	6.5	8.4	2	2	2	1
35	25.91068	3	2	5.4	8.9	2	2	2	1
36	24.80159	2	2	6	8.4	2	2	2	1
37	19.81768	2	2	8	13	2	2	2	1
38	19.39619	12	2	5.7	15	2	2	2	1
39	23.72529	4	2	5.1	7.4	2	2	2	1
40	25.39063	2	1	8	10	2	2	2	2
41	20.81165	3	1	9	11	2	1	2	1
42	18.64534	6	1	8	11	2	2	2	1
43	23.4375	2	2	6	8	2	2	2	1
44	25.88757	4	2	9	10	2	2	1	1
45	25.96953	5	1	10	13	2	2	2	1
46	21.22789	5	2	9	11	1	2	1	2
47	38.04994	4	2	11	14	2	2	2	2
48	27.68166	8	2	10	13	2	1	1	2
49	23.4375	1	2	8	11	2	2	1	1
50	28	8	2	5	8	2	2	2	1
51	19.05197	10	1	9	11	2	2	2	1

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2	27.34375	2	1	9	11	1	2	2	1
3	21.95248	5	1	6	11	2	2	2	1
4	20.81165	3	1	5	9	2	2	2	1
5	24.22145	1	2	6	8	2	2	2	1
6									
7	19.53125	10	1	10	14	2	1	2	1
8	24.21875	3	2	10	14	2	2	2	1
9	22.89282	1	2	5	6	2	2	2	1
10	21.56455	8	2	8	12	2	2	2	1
11	35.20955	1	2	9	10	2	2	2	1
12									
13	31.11111	12	2	12	16	2	2	2	1
14	22.86237	1	1	11	14	2	2	2	1
15	30.22222	6	2	4	7	2	2	2	1
16	31.21748	4	2	6	9	2	1	2	1
17	21.7502	8	2	10	13	2	2	2	1
18	22.86237	6	2	5	7	2	2	2	1
19									
20	23.58833	10	2	12	14	2	1	2	1
21	32.79321	7	2	7	10	2	2	2	2
22	20	10	2	6.3	9	2	2	2	2
23									
24	28.14787	4	2	11	15.8	2	2	2	2
25	31.11111	20	2	6	7	2	2	2	1
26	22.22222	7	2	10	9	2	2	2	1
27	31.46837	1	2	5	9	2	2	2	1
28	30.61225	14	2	8	10	2	2	1	1
29	25.56611	8	2	6	8	2	2	2	2
30	33.21799	8	1	18	21	2	2	2	2
31	24.12175	7	1	5	7	2	2	1	1
32	24.97704	5	1	25	27	2	2	1	1
33	28.88889	10	1	8	9	2	2	2	1
34	21.30395	8	2	7	9	2	2	1	1
35	21.22281	20	2	9	7	2	2	2	1
36	30.10212	16	1	7	12	2	2	2	1
37	29.29688	1	2	6	8	2	2	1	1
38	23.38869	3	2	10	13	2	2	2	1
39	29.26007	1	1	5	7	2	2	1	1
40	27.84585	20	2	9	11	2	2	1	1
41	25.10957	5	2	3	13	2	2	2	1
42	26.7094	10	1	6	9	2	2	2	1
43	23.18339	7	1	8	17	2	2	2	2
44	28.57796	2	1	13	16	2	2	1	1
45	27.11111	15	1	7	9	2	1	1	1
46	28.76397	8	2	6	9	2	2	2	1
47	27.26801	3	2	15.6	17.83	2	2	2	1
48	22.34778	8	1	15.1	17.66	2	1	2	1
49	31.16344	4	1	6.3	9.6	2	2	1	1
50	22.47659	3	1	11.9	13.4	1	2	2	1
51	18.66667	10	1	18.74	21.94	2	2	1	2
52	21.64127	1	1	6.9	9.3	2	1	2	1
53	21.33333	1	2	6	7.8	2	2	1	1
54	20.45184	1	1	5.05	9.55	2	2	1	2
55	24.88889	3	1	13.6	25.66	2	1	1	2

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2	20.77562	3	1	6.3	7.6	1	1	2	1
3	19.47715	4	2	11.6	22.2	2	2	2	1
4	22.89282	1	2	8.22	15	2	2	1	1
5	22.26563	7	1	8.9	11.27	2	1	1	1
6	26.93572	5	1	8.9	10.1	2	2	2	1
7	20.19509	1	1	5.3	7	2	2	2	1
8	21.09619	9	1	11	19	2	2	2	1
9	20.50493	12	1	9	14	2	1	2	1
10	27.81588	2	1	6	17	2	2	2	1
11	19.90997	15	1	14	18	2	1	1	1
12	24.52682	5	1	6	9	2	2	2	1
13	24.38653	7	2	15	22	2	2	2	1
14	19.29012	7	2	8	16	2	2	2	1
15	22.22222	12	1	13	21	2	2	2	2
16	22.82996	3	2	11	17	2	1	2	1
17	23.55556	6	2	5	7	2	2	2	1
18	22.64087	10	2	6	9	2	1	2	1
19	22.58271	3	1	17	21	2	1	1	1
20	14.0625	20	1	9	14	2	2	2	1
21	18.5178	7	2	11	22	1	2	2	1
22	26.29172	3	1	6	10	2	2	2	1
23	21.30395	4	2	14	21	2	2	1	1
24	15.05514	12	2	6	8	2	2	1	1
25	21.77384	14	1	8	15	2	2	1	1
26	43.80165	8	1	7	9	1	2	1	1
27	25.5102	15	1	13	16	1	1	2	1
28	21.64127	10	1	9	14	1	2	2	1
29	17.00882	1	2	6	10	2	2	2	1
30	24.76757	2	2	8	9	1	1	2	1
31	22.86237	13	2	16	24	2	2	2	1
32	19.84127	1	1	8	13	2	2	2	1
33	19.22769	9	1	8	15	1	1	2	1
34	22.26563	2	1	6	7	2	1	2	1
35	20.50493	11	2	9	15	1	2	2	2
36	23.1911	3	1	6	7	1	1	2	1
37	23.4375	1	2	6	7	2	1	2	1
38	20.93664	2	2	6	8	2	2	2	1
39	16.44737	8	1	18	20	2	2	2	1
40	21.50189	1	1	19	28	2	2	1	1
41	20.0796	1	1	17	26	1	2	2	1
42	22.31328	5	2	6	8	2	2	1	1
43	20.28123	18	1	14	22	2	2	2	1
44	21.23057	19	1	6	13	2	2	1	1
45	20.95717	24	2	12	17	2	1	1	1
46	24.34176	15	1	5	8	2	2	1	1
47	21.33821	30	1	6	9	2	2	2	1
48	22.37568	3	2	9	14	2	2	2	1
49	22.18935	12	1	7	9	2	2	2	1
50	21.71925	18	1	6	10	2	2	1	2
51	20.54569	10	1	5	8	2	1	2	1

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2	24.38653	16	1	9	13	2	1	2	1
3	29.06977	12	1	16	19	2	2	2	1
4	29.06977	12	1	16	19	2	2	2	1
5	21.875	8	2	12	20	2	2	2	2
6	30.86304	9	1	6	8	2	1	1	1
7	26.02758	2	2	5.4	8.1	2	1	2	1
8	21.22789	36	2	5.8	7.9	1	2	2	1
9	20.95717	24	2	12	17	2	1	1	1
10	21.00767	3	1	6.4	8	1	2	2	1
11	24.09297	5	2	7	22	1	1	1	1
12	27.47624	10	1	9	12	2	2	2	1
13	23.73866	8	1	7	10	1	2	1	2
14	28.959	4	1	7	13	2	2	2	1
15	25.96454	9	1	10	17	2	1	2	1
16	22.26563	2	2	6	7	1	1	1	1
17	24.30462	10	1	7.9	19	2	2	2	1
18	18.55956	12	1	7	10	2	2	2	1
19	24.67702	15	1	7	9	2	1	2	1
20	15.94388	12	1	9	22	2	1	2	1
21	22.83737	5	1	7	9	2	1	2	2
22	19.69267	12	1	9	14	2	2	2	2
23	23.33768	10	1	11	14	2	1	2	1
24	22.49135	10	2	8.4	9	2	1	2	1
25	19.53125	5	2	9	12	1	2	2	1
26	21.93635	12	1	11	12	2	2	2	1
27	18.30577	16	1	8	12	2	1	2	1
28	29.72108	15	1	8	10	2	1	1	1
29	25.34435	8	2	24	11	2	1	2	1
30	17.71542	1	1	7	28	2	1	2	2
31	21.19274	2	1	12	17	1	1	2	1
32	26.17188	2	2	8	9	2	1	2	1
33	20.54569	20	1	8	10	2	2	1	2
34	21.33333	7	1	15	24	2	1	2	1
35	23.45856	10	1	15	30	2	2	2	1
36	19.39619	9	1	24	28	2	1	2	2
37	17.1875	20	2	6	8	2	2	2	1
38	29.7442	1	2	7	8	2	1	2	1
39	21.67126	22	1	10	16	2	2	2	1
40	29.05475	15	2	13	21	2	1	2	1
41	21.38394	15	1	8	10	2	2	2	1
42	23.56663	3	1	10	14	2	2	2	1
43	22.60026	17	1	12	14	2	2	2	1
44	24.38272	10	1	6	13	2	1	2	2
45	25.07619	12	1	10	19	2	1	2	1
46	25.95156	3	1	7.3	8.14	2	2	2	2
47	26.23356	7	1	11	12	2	2	2	1
48	19.05197	6	2	7	9	2	1	2	1
49	22.47659	10	2	7	11	2	1	2	1
50	22.67995	3	1	8	9	2	2	2	1
51	22.86237	7	1	9	11	2	2	2	1

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2	20.77562	2	2	10	17	2	1	2	1
3	23.78121	4	2	6	8	2	2	1	2
4	22.5183	20	2	7	10	2	2	2	1
5	22.98401	3	1	6	8	2	2	2	1
6	18.59104	5	1	9	17	2	2	2	1
7	24.7768	10	2	6	24	2	1	2	1
8	26.47918	9	1	6.7	8.3	2	1	2	2
9	25.14861	6	2	7.9	10.8	2	2	1	2
10	25.96953	5	1	9.8	17	2	2	2	2
11	46.23725	12	1	9.7	11.5	2	2	2	1
12	27.40766	3	2	6	8.5	2	2	2	1
13	23.8054	4	1	8.9	14.9	2	2	2	1
14	18.08021	7	1	6.4	7.5	2	2	2	1
15	32.14286	2	1	11.6	14.6	2	1	2	1
16	23.33768	6	2	13.7	14.4	2	2	2	1
17	24.21875	3	2	6.6	24	2	2	2	1
18	26.14269	14	2	9.3	12.6	2	1	2	1
19	33.77045	1	2	13.7	24	2	1	2	1
20	25.78125	15	1	14.8	17.9	2	2	2	1
21	21.70139	1	1	3.6	8.8	2	2	2	2
22	26.67276	8	2	10.6	12.6	2	2	2	1
23	27.67874	1	2	5.2	9.2	2	2	2	1
24	18.51081	1	1	9.1	20.4	2	2	2	1
25	21.35992	12	2	5	7.1	2	1	2	1
26	25.23634	1	2	10.6	13.6	2	2	2	1
27	24.52435	1	1	5.4	6.4	2	1	2	1
28	18.85882	2	1	19	23	2	1	1	1
29	29.51594	1	2	6.4	7.8	2	2	2	1
30	26.75321	8	2	6.8	7.5	2	2	2	1
31	24.32323	1	2	8.3	12.4	2	1	1	2
32	21.00073	7	1	8.3	10.4	2	1	2	1
33	24.03461	5	2	5.8	8.7	2	1	2	1
34	21.04805	8	2	5.4	6	2	1	2	1
35	18.66667	16	1	5.7	12.2	2	1	1	1
36	23.11111	5	2	9.5	11.5	2	1	2	1
37	24.24392	3	2	4.8	6.9	2	1	2	1
38	23.37258	5	2	8.5	10.4	2	1	2	1
39	22.93975	4	1	6.7	8.8	2	2	2	1
40	23.45656	4	2	5.8	15.8	2	2	2	1
41	28.76397	1	2	6.1	8.2	2	2	2	1
42	22.82688	13	1	5.4	7.4	2	1	2	1
43	21.50189	4	2	7.9	9.9	2	1	2	1
44	23.96205	4	1	9.8	11.3	2	2	2	1
45	20.50493	8	1	11.2	13.2	2	2	2	1
46	24.34176	2	2	6.4	9.4	2	1	2	1
47	25	6	2	9.8	12.8	2	1	2	1
48	20.3428	1	2	6.1	7.4	2	2	2	1
49	18.369	4	2	7.9	17.2	2	2	2	1
50	21.875	2	1	9.8	16.8	2	2	2	1
51	22.83288	1	2	6.9	10	2	1	2	2

1									
2	18.32562	5	2	5.9	6	2	1	2	1
3	24.34961	15	1	9.8	14.5	2	1	2	1
4	25.15315	13	2	6.9	8.4	2	2	2	2
5	18.42025	2	1	8.7	12	2	2	2	1
6	22.4323	18	1	10	14.2	2	2	1	1
7	25.96953	4	2	10	12	2	1	2	1
8	15.78878	2	1	10.8	13.7	2	2	2	1
9	24.19649	15	2	7.2	9.7	2	2	1	2
10	23.04688	8	1	16.6	20	2	2	1	1
11	24.12175	5	2	6.9	8.7	2	2	2	1
12	17.85714	10	2	10.1	17.8	2	1	2	1
13	31.95763	3	2	8.8	10.5	2	2	2	1
14	26.66667	3	2	6.7	8.1	2	1	1	1
15	20.54419	8	1	10.6	11.1	2	2	2	1
16	24.65303	12	1	7.3	10.2	2	2	2	2
17	24.14152	2	1	8.7	10.1	2	2	2	1
18	21.73801	2	2	6.9	9.9	2	1	1	1
19	21.32513	4	2	6.3	7.3	2	1	1	1
20	22.82688	11	1	6.6	19.5	2	1	1	1
21	24.24392	14	1	9.1	13.3	2	2	2	1
22	24.34961	1	2	6.9	9.7	2	1	2	1
23	21.33333	8	2	6.7	9.8	2	1	2	1
24	19.22338	30	2	5.8	10.6	2	2	2	1
25	21.90758	8	1	7.2	15.2	2	1	1	1
26	23.49524	6	2	13	18	2	1	2	1
27	24.53897	3	2	6.9	8.9	2	1	2	1
28	25.06575	21	1	5	10.3	2	2	2	1
29	22.86237	5	1	8.4	10.7	2	2	1	1
30	20.57613	15	1	9.8	12.6	2	1	2	2
31	22.22222	3	2	9.6	15.1	2	2	2	2
32	26.83865	1	2	6.9	7.8	2	2	2	1
33	23.37258	6	2	9.6	15	2	2	1	1
34	24.34961	20	2	10.6	16.9	2	1	2	1
35	37.16563	6	2	5	6.9	2	1	2	2
36	31.11111	4	2	9.6	11.5	2	2	2	1
37	25.47666	1	1	6.7	9	2	1	2	2
38	28.617	4	1	8	10	2	1	2	1
39	17.60477	1	1	6	8.9	2	2	1	1
40	20.2395	4	2	9	10	2	2	2	1
41	23.37258	4	2	5.2	6	2	1	1	1
42	28.125	1	2	6.9	11.6	2	1	2	1
43	28.44444	12	2	5.2	6.4	2	2	2	1
44	23.82813	6	1	8.2	11.5	2	1	2	2
45	26.83865	2	2	6.7	9.8	1	1	2	1
46	21.45727	4	2	6.3	9.3	2	1	2	1
47	28.19692	2	2	5.3	11.6	2	1	2	1
48	22.31328	2	1	11.5	13.5	2	1	2	1
49	17.62538	2	1	18.4	28.6	2	2	2	1
50	18.25632	5	2	9.5	10.9	1	1	1	2
51	20.2848	4	2	6.5	9.5	2	2	2	1

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2	20.57613	5	2	6.7	9.8	2	1	2	1
3	26.47918	5	2	9.8	12.3	2	1	2	1
4	32.45568	3	2	8.7	10.3	2	2	2	1
5	33.62209	22	1	7.8	11.9	2	1	2	2
6	23.66864	3	1	6.5	9.8	2	2	2	1
7	21.33333	18	1	5.5	9.8	1	1	2	1
8	26.89232	5	2	6.8	12.2	2	2	2	2
9	22.50693	2	2	8.3	10.3	2	2	2	1
10	27.14158	1	2	7.6	8.7	2	1	1	1
11	24.14152	7	1	16.9	19.3	2	1	2	1
12	27.11111	1	2	4.9	9.8	2	1	2	1
13	22.23099	5	2	5.8	8	2	1	1	1
14	23.14815	20	2	6.8	9.7	2	2	1	2
15	33.12131	1	2	8.7	10.6	2	2	1	1
16	26.67276	1	2	7.1	8.3	2	1	2	1
17	24.76757	1	2	5.2	6.3	2	2	1	1
18	26.67276	3	2	5.8	6.8	1	2	1	1
19	20.28123	1	2	6.3	8.6	2	2	1	1
20	20.77562	1	2	10.5	21.6	1	1	1	1
21	21.09619	4	2	6.2	8.5	2	2	1	1
22	19.05197	2	2	11.5	15	2	1	1	1
23	29.33333	12	2	5.6	7.9	2	1	2	1
24	21.09619	5	1	12.2	27.3	1	1	2	1
25	28.40816	15	2	8.8	14.1	2	2	1	1
26	33.28402	5	2	10.6	16	2	2	2	1
27	26.02618	1	2	6.9	9	2	1	2	2
28	25.34435	2	2	5.2	8.6	2	2	2	2
29	26.89767	10	2	6.2	9.4	2	2	2	1
30	21.21914	5	2	6.9	8.3	2	1	1	1
31	24	5	2	8.8	12.6	2	2	2	2
32	30.25193	4	2	6.3	9.2	2	1	2	1
33	23.82813	1	2	6.6	9.7	2	1	2	1
34	24.88889	1	2	8.4	11.6	2	2	2	2
35	29.6875	3	2	5.8	7.4	2	1	2	1
36	31.20256	2	2	6.1	7.3	2	1	1	1
37	24.88889	2	1	8.5	10.5	2	1	2	2
38	20.40816	2	2	6.8	10	2	2	2	1
39	26.52392	3	2	5.8	7	2	2	1	1
40	23.8054	1	2	7.1	9.8	2	1	1	1
41	18.90204	17	1	14.8	24.8	2	2	2	1
42	17.77778	7	2	10.2	14.8	2	1	2	1
43	21.82107	1	2	12.6	18.6	2	2	2	1
44	22.22222	2	2	6.9	9.3	2	1	1	1
45	21.64127	10	2	6.9	9.8	2	1	2	1
46	23.30905	12	1	8.8	11.6	2	1	2	1
47	20.26936	6	2	8.3	10.8	2	2	1	1
48	26.03749	3	2	8.9	11.9	2	1	2	1
49	16.87886	2	1	9.8	15.5	2	1	2	1
50	29.27796	1	2	6.2	10.2	2	2	2	1
51	23.4375	2	2	14	16	2	2	1	1

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2	23.14815	1	2	9	16	2	2	1	1
3	25.96953	2	2	5.2	7.8	2	1	2	1
4	19.39619	15	2	5.4	8.4	2	1	2	2
5	27.70083	1	2	5.2	7.8	2	1	2	1
6									
7	24.23823	1	1	5.8	9.2	2	2	2	1
8	24.88889	1	2	6.7	16.2	2	2	2	2
9	24	3	2	8.7	8.2	2	1	2	1
10	28.56648	2	2	9.1	8.4	2	1	2	2
11	35.69304	4	1	7.8	16.1	2	2	2	1
12									
13	25.31545	1	2	9.2	15.6	2	1	2	1
14	29.37758	5	2	6.5	9.4	2	1	1	1
15	23.1911	4	2	6.4	12.3	2	2	1	1
16	25.77778	1	2	5.6	7.3	2	2	2	1
17	22.22222	1	1	4.6	7.2	2	2	2	1
18									
19	17.48179	20	2	5.8	7.9	2	2	2	1
20	25.43748	2	2	6.4	12.3	2	1	2	1
21	22.34778	3	2	5.8	9.4	2	2	2	2
22	24.86395	1	2	15.2	21.1	2	2	1	1
23									
24	28.72008	18	2	6.8	10.3	2	1	2	1
25	23.83301	3	2	5.8	9.7	2	2	1	1
26	25.77778	10	2	5.3	5.5	2	1	2	1
27	25.5367	2	2	9.8	10.2	2	2	2	1
28	22.07108	2	2	7	9	2	2	2	2
29									
30	22.22222	30	2	10	20.6	2	2	1	2
31	24.55775	12	2	6.9	15.6	2	2	1	1
32	12.98477	4	2	5.5	9.9	2	2	2	2
33	22.81293	2	2	5.5	10.4	2	2	2	2
34	24.83576	12	1	5.5	9.9	2	2	1	1
35									
36	20.54569	10	2	2.6	4.5	2	2	2	1
37	27.09925	1	2	5.9	10.5	2	1	2	1
38	24.83576	2	2	5.5	9.9	2	2	2	1
39	29.77778	1	2	2.6	4.5	2	2	2	1
40	25.06575	3	2	5.9	4.3	2	2	2	1
41									
42	19.90997	10	2	5.5	4.2	2	1	2	1
43	22.18935	17	2	2.6	18.1	2	2	2	1
44	23.45656	3	2	5.9	6.1	2	1	2	1
45	26.74048	5	2	6.6	8.7	2	1	2	1
46	24.52682	18	2	6.8	12.3	2	1	2	1
47									
48	24	2	2	6.2	8	2	1	2	2
49	20.88889	1	2	6.2	9.9	2	2	1	1
50	27.55556	3	2	15	20	2	1	2	1
51	15.55556	4	1	5.8	9.2	2	1	2	1
52	26.66667	20	2	6.2	9.4	2	1	2	1
53									
54	18.73049	1	1	6.2	9.6	2	2	1	1
55	19.47715	16	1	16.2	21.6	2	2	2	1
56	25.63692	2	2	5.8	7.2	2	2	2	1
57	26.56435	1	2	6.2	8.5	2	1	2	2
58	22.22222	6	2	7	11	2	2	2	2
59	25.06575	21	2	7	10	2	2	2	1
60	22.18364	1	2	6	7	2	2	2	1

1									
2	20.25463	1	2	6	15	2	2	2	1
3	24.65303	6	2	6	9	2	2	2	1
4	21.45727	1	2	6	8	2	2	2	1
5	22.04917	1	2	9	15	2	2	2	1
6	27.00617	3	1	6	18	2	2	2	1
7	19.29012	1	2	12	19	2	2	1	1
8	31.63265	3	2	7	12	2	2	1	2
9	25.10388	10	1	7	4	2	2	2	1
10	18.73049	2	2	6	7	2	1	2	1
11	27.30519	1	2	9	11	2	2	2	1
12	22.95918	4	2	6	5	2	2	2	1
13	24.59491	6	1	5.7	13	2	2	2	1
14	22.98743	13	2	11.1	21	2	2	2	1
15	22.07108	16	2	8.5	12	2	2	2	2
16	21.91381	8	2	8	13	2	2	2	1
17	37.06136	2	2	7	10	2	2	2	2
18	26.52392	5	2	6	7	2	2	2	1
19	36.88889	1	2	6	10	2	2	2	2
20	29.51594	1	2	5	7	2	2	2	1
21	24.4646	8	1	9	11	2	2	2	1
22	20.95717	8	1	3	6	2	2	2	1
23	21.20845	15	1	10	13	2	1	2	1
24	22.27531	24	1	7	12	2	2	2	1
25	16.86625	3	2	15	19	1	2	2	2
26	21.40309	2	2	6	21	2	2	2	2
27	33.76039	4	2	7	13	2	2	1	1
28	29.24211	8	1	7	15	1	2	2	1
29	24.38653	10	2	9	12	2	2	2	2
30	22.50693	1	2	12	15	2	2	2	1
31	20.95717	3	1	7	9	2	2	2	1
32	24.60938	14	1	7	17	2	2	2	2
33	23.55556	4	2	10	13	2	2	2	2
34	22.34778	9	2	4.5	6	2	2	2	2
35	20.79673	5	2	12	15	1	1	2	1
36	38.77551	2	2	8	10	2	2	2	2
37	27.02581	5	1	8.8	9	2	2	2	1
38	21.91381	5	1	7	23	2	2	2	1
39	25.55941	5	2	5.8	7.2	2	2	2	1
40	24.11265	1	2	5.5	8	2	2	2	2
41	27.39226	2	2	5.4	8	2	1	2	1
42	30.38194	1	2	5	9	2	2	2	1
43	26.66667	1	2	6	8	2	1	2	1
44	20.17264	7	2	11	16	2	2	2	2
45	23.78121	3	1	9	12.5	2	2	2	2
46	35.0032	12	2	9	12	2	1	2	2
47	24.69136	5	1	14	20	2	2	2	2
48	18.87755	5	2	6.5	7	2	2	2	2
49	29.96433	1	2	7	7	2	2	2	1
50	27.77227	6	2	7	9	2	2	2	2
51	29.96433	7	1	16	26	2	1	2	1

1									
2	28.76397	1	2	4	6	2	2	2	1
3	24.73246	1	2	8	12	2	2	2	2
4	25.39063	2	2	5.1	13	2	2	2	1
5	25	12	2	6	10	2	1	2	1
6	20.68515	7	1	13	17	2	2	1	1
7	20.88889	12	2	3	6	2	1	2	1
8	23.92569	12	2	9	16	2	2	1	1
9	23.01118	15	1	8	10	2	1	2	1
10	22.76944	3	2	6	7	2	2	1	1
11	24.88889	3	2	12.1	16.2	2	2	2	2
12	25.56611	5	2	12	16	2	2	2	1
13	25.29938	10	2	7	10	2	2	2	1
14	15.78878	2	2	15	25	2	2	2	1
15	23.37258	2	2	6	6	2	2	2	1
16	26.50212	12	2	10	10	2	2	2	1
17	26.43807	1	2	8	10	2	2	2	1
18	28.84153	2	1	12	17	2	1	2	1
19	27.11111	1	2	8.4	11.6	2	2	2	1
20	25.39063	5	2	8	10.8	2	2	2	1
21	16.88889	1	2	18.3	24	2	2	2	1
22	16.44444	2	1	4.8	6.6	2	2	2	1
23	18.97453	1	2	5.6	7	2	2	2	1
24	24.19649	1.5	2	7	9	2	2	2	1
25	27.70083	3	2	12	15	2	2	2	1
26	25.55941	3	2	16	18	2	2	2	1
27	31.11111	5	2	5	7	2	2	2	1
28	20.45184	3	2	10	13	2	2	2	1
29	28.53746	6	2	8	10	2	2	2	2
30	27.23922	4	1	7	9	2	2	2	1
31	28.88889	2	2	20	22.6	2	2	2	1
32	19.3414	9	2	16	18	2	2	2	1
33	23.11111	3	2	3	7	2	1	2	1
34	20.77562	17	1	12	15	2	2	2	1
35	24.9401	2	2	20	24	2	2	2	1
36	19.5006	10	2	8	11	2	2	2	2
37	20.66116	4	2	8	10	2	2	2	1
38	28.30533	4	2	5	7.2	2	2	2	1
39	27.30344	2	2	3	7.5	2	2	2	1
40	25.33308	2	2	8	11	2	2	2	1
41	20.44444	5	2	24	28.52	2	2	2	1
42	25.33308	8	2	3.1	8.6	2	2	2	1
43	29.16667	2	2	9	11	2	2	2	2
44	19.29012	2	2	9	11	2	2	2	1
45	24.7768	2	2	3.1	4.6	2	2	2	1
46	40.97222	2	2	10	11	2	2	2	1
47	26.74048	6	2	3.1	8.5	2	2	2	1
48	23.87512	6	2	5	6.4	2	2	2	2
49	24.38653	13	2	15	17	1	2	2	1
50	18.26151	1	2	9	12	2	2	2	1
51	40.97222	9	2	10	11	2	2	2	2

1									
2	23.30887	8	2	8	10	2	1	2	1
3	21.08281	3	1	10	11	2	2	2	1
4	21.82107	5	2	9	11	2	2	2	1
5	18.71804	8	1	4	8	2	2	2	1
6	16.87886	2	2	10	17	2	2	2	1
7	23.55556	20	1	11	14	2	2	2	1
8	24.87772	10	2	12	15	2	2	2	1
9	20.02884	2	2	5	6.4	2	2	2	1
10	17.14678	3	2	10	12	2	2	2	2
11	19.17458	3	2	4	6	2	2	2	1
12	24.88889	13	1	18	22	2	2	2	1
13	32.02909	4	1	10	12	2	2	2	1
14	24.32323	5	1	8	11	2	2	2	1
15	17.62538	12	1	8	12	2	2	2	1
16	19.14063	12	1	7	9	2	2	2	1
17	23.73996	25	2	18	20	2	2	2	1
18	22.83288	23	1	15	17	2	2	2	1
19	23.49524	8	2	5	7	2	2	2	1
20	26.53061	6	2	6	9	2	2	2	2
21	21.20845	10	1	9.8	14	2	2	2	1
22	25.78853	9	2	9	11	2	2	2	1
23	42.80618	1	2	5	7	2	2	2	1
24	24.97399	1	2	14	15	1	2	2	1
25	23.1405	2	1	17	21	1	1	2	1
26	25.91068	5	1	8	11	2	2	2	1
27	24.33748	1	2	6	7	2	2	2	1
28	22.10029	15	2	5	7	1	2	2	1
29	33.16327	13	2	5	8	2	2	2	1
30	17.26355	3	2	8	10	1	2	2	1
31	23.82813	5	2	11	15	2	2	2	2
32	24.55775	2	1	8	10	2	2	2	1
33	22.22222	12	1	6	9	2	2	2	2
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35	31.25	3	2	7	9	2	2	2	1
36	14.09846	2	1	11	15	2	2	2	1
37	27.0538	28	1	17	19	2	2	2	2
38	23.1405	1	2	12	15	2	2	2	1
39	21.91381	1	1	4	6	2	2	2	1
40	23.37258	3	2	6.2	8.3	2	2	2	1
41	23.14815	5	2	4.2	6.4	2	1	2	1
42	20.17264	2	2	7.8	9.7	2	2	2	2
43	24.45606	12	1	6.5	8.2	2	1	2	2
44	15.75575	5	1	6.7	9.1	2	2	2	1
45	24.74745	22	1	6.1	12.4	2	2	2	1
46	25.20479	6	2	10.5	15.3	2	2	1	1
47	23.73866	2	1	10.8	14.6	2	2	2	1
48	25.5367	3	2	6.2	8.1	2	2	2	1
49	24.44444	2	2	6.8	8.1	1	2	2	1
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5	25.63692	3	2	18.1	24.1	2	2	2	1
6	26.22222	14	1	9.8	15.9	2	2	2	1
7	26.40236	3	2	5.2	6.3	2	2	2	1
8	29.04866	3	1	8.8	15.5	2	2	2	1
9	29.09428	8	2	8.2	11	2	2	2	1
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13	22.77319	1	2	6.2	8.5	2	2	2	1
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21	22.86253	25	1	14.2	18.2	1	1	1	1
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24	30.7574	15	1	6.1	8.4	2	2	2	1
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27	26.40236	7	2	5.8	7.7	2	2	1	1
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For peer review only

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For peer review only

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For peer review only

1				
2	SEX	1=men	2=women	
3	AREA	1=urban	2=rural	
4	Education	1=illiterate	2=primary	3=secondary
5	Occupation	1=service	2=business	3=housewife
6	Marrital status	1=married	2=others	
8	Insulin use	1=user	2=non-user	
9	Current smoking	1=smoking	2=other form	
10	Current smokeless tobacco use	1=yes	2=non-user	
11	Physical activity	1=sufficient	2=insufficient	
12	Use fitting foot wear	1=yes	2=non-user	
14	History of trauma	1=yes	2=no	
15	Regular foot care	1=yes	2=no	
16	Self foot examination	1=yes	2=no	
17	Hypertension (HTN)	1=yes	2=no	
18	Diabetic retinopathy	1=yes	2=no	
19	Diabetic nephropathy	1=yes	2=no	
20	Peripheral neuropathy	1=yes	2=no	
21	Peripheral arterial disease	1=yes	2=no	
22	Foot deformity	1=yes	2=no	
23	H/O amputation	1=yes	2=no	
24	H/O foot ulcer	1=yes	2=no	
27	IWGDF risk six categories	0=group 1 (0)	1=group 1 (1)	21=group 2A
28	IWGDF risk five categories	0=group 1 (0)	1=group 1 (1)	2=group 2A+2B
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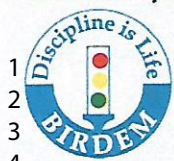
4=higher education
4=others

22=group 2B

31=group 3A
31=group 3A

32=group 3B
32=group 3B

For peer review only



BIRDEM

An Enterprise of the
Diabetic Association of
Bangladesh

Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders



WHO Collaborating Centre
for Prevention and Control
of Diabetes

Memo No: BADAS/BIO/EA/11/033

Date: 17.01.2011

To

Palash Chandra Banik

Student, MPhil in Noncommunicable Diseases (NCD)

Department of Community Medicine (CM)

Bangladesh Institute of Health Sciences (BIHS)

Subject: Ethical Clearance

The Ethical Review Committee (ERC) of the Bangladesh Diabetic Association (BADAS) has the pleasure to accord ethical clearance to your Protocol "**Risk of foot ulcer and its determinants among type 2 diabetic subjects in Bangladesh**" subject to the condition that the guidelines must be followed carefully.

- The Ethical Review Committee approves this study from an ethical point of view upon the addressing by the researchers of the concerns as raised by the ERC affiliates.
- Approval is given for three years. Projects, which have not commenced within two years of original approval, must be re-submitted to ERC. You must inform ERC when the research has been completed.
- Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical considerations must be reported immediately to the ERC.
- Approval is given on the understanding that the 'Guidelines for Ethical Review' are adhered to.

(Prof. Tofail Ahmed, PhD)

Chairman

Ethical Review Committee

Consent Form

1 **Dear Participant,**
2

3 **Purposive Selection**

4 You have been purposively selected to be part of this thesis and this is why we would like to interview
5 you. This thesis is being conducted by **Palash Chandra Banik**, a student of M.Phil in Non-
6 communicable Diseases at Bangladesh Institute of Health Sciences (BIHS) under Bangabandhu Sheikh
7 Mujib Medical University (BSMMU). This type of study is currently taking place in several countries
8 around the world.
9

10 **Title of Thesis**

11 The title of this thesis is **“Risk of foot ulcer and its determinants among Type 2 diabetic subjects”**.
12

13 **Aim of the Thesis**

14 To determine diabetic patients at risk for foot ulceration through a multi-center hospital based study in
15 Bangladesh
16

17 **Data Collection Methods**

18 **Step 1-** Interview questions

19 **Step 2-** Physical examination & screening test (foot)
20

21 **Timeframe**

22 It is estimated that step 1 & 2 of this study will take approximately 30-40 minutes.
23

24 **Confidentiality**

25 The information you provide is totally confidential and will not be disclosed to anyone. It will only be
26 used for research purposes. Your name, address, and other personal information will be removed from
27 the instrument, and only a code will be used to connect your name and your answers without
28 identifying you.
29

30 **Results**

31 The results of this thesis will be used to help plan strategies in reducing the risk factor that contribute to
32 diabetic foot ulcer among the diabetic patients as well as chronic non-communicable diseases in
33 Bangladesh.
34

35 The results will be published in research publications, media briefings and reports and can be made
36 available to you by local health workers.
37

38 **Voluntary Participation**

39 Your participation is voluntary and you can withdraw from the study after having agreed to participate.
40 You are free to refuse to answer any question that is asked in the questionnaire. If you have any
41 questions about this study you may ask me or contact to the researcher [Palash Chandra Banik, cell:
42 +8801710972498].
43

44 **Consent to Participate**

45 Signing this consent indicates that you understand what will be expected of you and are willing to
46 participate in this survey.

Read by Participant		Interviewer	
Agreed		Refused	

50 **Signatures**

51 I hereby provide INFORMED CONSENT to take part in Steps 1 and 2 of this Risk Factor Study.
52
53

54 **Name of the participant:**

Witness:

56 **Sign or fingerprint**

Sign or fingerprint

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

Reporting Item

Page Number

Title and abstract

Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	Page-1, Line Number-1
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1	Abstract	#1b	Provide in the abstract an informative and	Page-2,3, Line Number-
2				24-52
3				
4			balanced summary of what was done and what	
5				
6			was found	
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9	Introduction			
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12	Background /	#2	Explain the scientific background and rationale for	Page-3-5, Line Number-
13				63-121
14	rationale		the investigation being reported	
15				
16				
17	Objectives	#3	State specific objectives, including any prespecified	Page-5, Line Number-
18				119-121
19			hypotheses	
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23	Methods			
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26	Study design	#4	Present key elements of study design early in the	Page-6, Line Number-124
27				
28			paper	
29				
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31	Setting	#5	Describe the setting, locations, and relevant dates,	Page-6, Line Number-
32				124-127
33			including periods of recruitment, exposure, follow-	
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35			up, and data collection	
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39	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and	Page-6, Line Number-
40				127-132
41			methods of selection of participants.	
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44		#7	Clearly define all outcomes, exposures, predictors,	Page-6, 7, Line Number-
45				133-169
46			potential confounders, and effect modifiers. Give	
47				
48			diagnostic criteria, if applicable	
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52	Data sources /	#8	For each variable of interest give sources of data	Page-7, Line Number-
53				151-169
54	measurement		and details of methods of assessment	
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56			(measurement). Describe comparability of	
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assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.

8	Bias	#9	Describe any efforts to address potential sources of bias	Page-8, Line Number-172-173
13	Study size	#10	Explain how the study size was arrived at	Page-6, Line Number-134-135
18	Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Page-9, Line Number-205-220
25	Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	Page-9, Line Number-205-220
31	Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
36	Statistical methods	#12c	Explain how missing data were addressed	n/a
41	Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
47	Statistical methods	#12e	Describe any sensitivity analyses	n/a

Results

55	Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined	n/a
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for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.

Participants	#13b	Give reasons for non-participation at each stage	Some of the participants were not participate as they had limited time.
Participants	#13c	Consider use of a flow diagram	n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	Page-10, Line Number-224-234
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	n/a
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which	Page-10, Line Number-235-Page-13, Line Number-270.

1		confounders were adjusted for and why they were	
2			
3		included	
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5			
6	Main results	#16b Report category boundaries when continuous	Page-10, Line
7			
8		variables were categorized	Number-225-234
9			
10			
11	Main results	#16c If relevant, consider translating estimates of	n/a
12			
13		relative risk into absolute risk for a meaningful time	
14			
15		period	
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18	Other analyses	#17 Report other analyses done—e.g., analyses of	n/a
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20		subgroups and interactions, and sensitivity	
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22		analyses	
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24			
25			
26	Discussion		
27			
28			
29	Key results	#18 Summarise key results with reference to study	Page-13, Line
30			
31		objectives	Number- 272 to
32			
33			
34			Page-19, Line
35			
36			number-405
37			
38			
39	Limitations	#19 Discuss limitations of the study, taking into account	Page-18, Line
40			
41		sources of potential bias or imprecision. Discuss	Number-385-394
42			
43		both direction and magnitude of any potential bias.	
44			
45			
46			
47	Interpretation	#20 Give a cautious overall interpretation considering	Page-18, Line
48			
49		objectives, limitations, multiplicity of analyses,	Number-401 to
50			
51		results from similar studies, and other relevant	Page19, Line
52			
53		evidence.	Number-405
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1 Generalisability [#21](#) Discuss the generalisability (external validity) of the Page-18, Line
2
3 study results Number-395-401
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5

6 Other

7 Information

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11
12 Funding [#22](#) Give the source of funding and the role of the Page-19, Line
13 funders for the present study and, if applicable, for Number-415-417
14 the original study on which the present article is
15 based
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BMJ Open

Risk of diabetic foot ulcer and its predictors among Bangladeshi subjects: a multi-centric cross-sectional study

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3 1 **Risk of diabetic foot ulcer and its predictors among Bangladeshi subjects: a**
4 **multi-centric cross-sectional study**
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9
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25 **Abstract**

26 **Objective**

27 To assess the risk of diabetic foot ulcer (DFU) and find out its predictors among type
28 2 diabetic (T2D) subjects of Bangladesh.

29 **Design, setting and participants**

30 This cross-sectional study recruited 1200 T2D subjects who visited sixteen centres of
31 Health Care Development Project run by Diabetic Association of Bangladesh (DAB).

32 **Primary and secondary outcome measures**

33 Risk of DFU was assessed using a modified version of International Working Group
34 on the Diabetic Foot (IWGDF) Risk Classification System. The modified system was
35 based on five parameters, namely peripheral neuropathy (PN), peripheral arterial
36 diseases (PAD), deformity, ulcer history and amputation. The risks were categorised
37 as Group 0 (no PN, no PAD), Group 1 (PN, no PAD, and no deformity), Group 2A (PN
38 and deformity, no PAD), Group 2B (PAD), Group 3A (ulcer history) and Group 3B
39 (amputation). The predictors of DFU risk were determined using multinomial logistic
40 regression for each risk category separately.

41 **Results**

42 Overall, 44.5% of the subjects were found 'at risk' of DFU. This risk was higher among
43 men (45.6%) than women and among those who lived in rural areas (45.5%) as
44 compared to the urban population. According to IWGDF categories, the risk was
45 distributed as 55.5%, 4.2%, 11.6%, 0.3%, 20.6% and 7.9% for group 0, group 1, group
46 2A, group 2B, group 3A and group 3B respectively. The predictors of DFU (odd ratio
47 >1) were age ≥ 50 years, rural area, low economic status, insulin use, history of trauma,
48 diabetic retinopathy and diabetic nephropathy.

49 **Conclusion**

50 A significant number of the T2D subjects under study were at risk of DFU, which

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4 51 demands an effective screening programme to reduce DFU related morbidity and
5
6 52 mortality.

7
8 53 **Keywords:** diabetes; diabetic foot ulcer; diabetic foot ulcer risk; Bangladesh;
9
10 54 International Working Group on the Diabetic Foot; predictors; risk factors

11 12 55 **Article summary**

13 14 15 56 **Strengths and limitations of this study**

- 16
17
18 57 • This is the first study in Bangladesh that assesses the risk of DFU using a standard
19
20 58 tool
- 21
22 59 • For the first time, the predictors of DFU were explored to guide the prevention
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24 60 effort
- 25
26 61 • Sex- and area-specific difference in the risk of DFU will help to identify the
27
28 62 disparities and promote decentralisation of diabetes care for all
- 29
30 63 • Because of the cross-sectional design, we could not establish any causal
31
32 64 relationship between the predictors and risk of DFU
- 33
34 65 • The risk of DFU may be overestimated or underestimated as all centres did not
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36 66 provide the same quality diabetes care

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75 **Introduction**

76 In recent years, diabetes mellitus (DM) has become a fast-growing public health
77 problem that affects both developed and developing countries [1]. The International
78 Diabetes Federation (IDF) reports that about 415 million people globally had DM in
79 2015 and it is projected to affect 642 million by 2040. It was deemed possible that by
80 the year 2040 it might even double the number [2]. Among the clinical classifications
81 of DM, Type 2 diabetes (T2D) is more common and prevalent in certain ethnic groups,
82 with estimates up to six times more common in the people of South Asian descent,
83 three times more common in those of African and African-Caribbean descent and is
84 more common in people of Chinese descent compared with the white population [3].

85 Like in other developed and developing countries affected by it, it is also highly
86 prevalent in Bangladesh. Evidence suggests that 9.7% of Bangladeshi adult population
87 (>35 years) are diabetic and 22.4% are prediabetic [4]. A trend analysis revealed an
88 increasing prevalence of DM in Bangladesh, from 4% in 1995 to 2000 and 5% in 2001
89 to 2005 to 9% in 2006 to 2010 respectively [5]. As the prevalence of diabetes increases,
90 the prevalence of long-term diabetes-related complications is also likely to increase.
91 Diabetic foot ulcer (DFU) is a common and major complication of diabetes,
92 representing a major healthcare burden with significant morbidity [6].

93 Diabetic foot is defined as the presence of infection, ulceration and/or destruction of
94 deep tissues associated with neurologic abnormalities and various degrees of
95 peripheral arterial disease (PAD) in the lower limb in patients with diabetes [7]. It is a
96 significant cause of morbidity and can lead to prolonged hospital stays, which is
97 evidenced by the fact that ~20% of diabetes related hospitalisations are related to DFU
98 [8]. The mortality rate in patients with DFU is also high and is approximately twice that
99 of the patients without ulceration [9]. Other than morbidity and mortality, the toll of
100 economic burden in terms of direct and indirect costs is also high for those having
101 DFU, estimated approximately €11.6 billion per year for Europe in 2017 and €7.6–11
102 billion among Medicare beneficiaries of the United States from 2007 to 2014 [7].

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3 103 Another issue related to foot ulcers among diabetic patient is the health-related quality
4
5 104 of life that cannot be measured in economic terms. It has been reported that patients
6
7 105 with foot ulcers or amputation have low health-related quality of life because of
8
9 106 substantial depression and other physical problems like inability to do simple tasks or
10
11 107 recreational activities [7].
12

13
14 108 The major risk factors of DFU are a loss of protective sensation due to diabetic
15
16 109 peripheral neuropathy (DPN), peripheral arterial diseases (PAD) and trauma. However,
17
18 110 the first two are not independently responsible for DFU; it is the combination
19
20 111 neuropathy and PAD with trauma that leads to foot problems. It has been reported
21
22 112 that trauma and PAD are major contributors to foot ulceration and diabetic neuropathy
23
24 113 is the common denominator in almost 90% of DFU cases. There are some other risk
25
26 114 factors namely male gender, previous foot ulceration or amputation, foot deformities,
27
28 115 calluses, Charcot arthropathy and high plantar pressures have been associated with an
29
30 116 increased risk for foot ulceration. There are some diabetes-related risk factors also that
31
32 117 influence the risk of foot ulcers such as the duration of diabetes, poor glycaemic
33
34 118 control, diabetic retinopathy or nephropathy, poor compliance with medical
35
36 119 instructions and neglectful behaviour. Some societal and behavioural risk factors also
37
38 120 show significant association with DFU including low socioeconomic condition, poor
39
40 121 access to healthcare services, poor educational status, living alone and smoking [7, 10].
41
42 122 Previous studies have reported that the risk of diabetic foot or amputation is
43
44 123 significantly lower among the Asians compared to the Europeans in the United
45
46 124 Kingdom [11–12]. This reduced risk is probably due to a low prevalence of DPN and
47
48 125 PAD among Asians, but the exact reason is not fully understood. However, a previous
49
50 126 study has reported prevalence of DPN among Bangladeshi subjects at 19.7% and
51
52 127 found it significantly as well as independently associated with age, mode of treatment,
53
54 128 income, duration of diabetes and glycaemic status [13].
55

56 129 The best possible way to prevent DFU is the identification of individuals at risk, proper
57
58 130 health education and timely follow-up [14]. It is estimated that the lifetime risk of foot
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3 131 ulcers among diabetic population is 19%–34% [7]. To overcome this burden of DFU, it
4
5 132 is recommended that clinicians estimate the risk of and the response to associated
6
7 133 factors that increase the risk [10]. However, studies related to diabetic foot risk
8
9 134 assessment and associated factors among Bangladeshi subjects are absolutely lacking.
10
11 135 Hence, we were prompted to assess the risk of foot ulcers and sought to determine
12
13 136 the factors that influence the risk among T2D patients of Bangladesh.

16 137 **Methods**

18 138 **Study design**

21 139 This cross-sectional study was conducted among 1200 T2D subjects who visited
22
23 140 several centres of Health Care Development Project (HCDP) run by the Diabetic
24
25 141 Association of Bangladesh (DAB). A total of sixteen centres were selected: seven from
26
27 142 Dhaka and nine from the northern part of Bangladesh. We purposefully selected the
28
29 143 centres and followed convenient sampling technique to collect data from diabetic
30
31 144 subjects. Our exclusion criteria included presence of DFU during the interview (active
32
33 145 ulcer), acute illness of the subject, unwillingness to participate and mental instability.
34
35 146 To meet the eligibility criteria, all subjects were screened for DFU, based on their self-
36
37 147 reported statement, their clinical history, foot examination and medical records review.

39 148 **Data collection and measurement**

42 149 The data collection comprised of two phases and was conducted from July 2011 to
43
44 150 June 2012. In the first phase, a face-to-face interview was conducted using a pre-tested
45
46 151 questionnaire adapted from the STEP-wise approach to Surveillance (STEPS) of
47
48 152 noncommunicable diseases risk factors of World Health Organization (WHO) [15]. The
49
50 153 questionnaire collected sociodemographic and behavioural risk factors (tobacco use,
51
52 154 physical inactivity), status of diabetes (duration, medication) and its complications
53
54 155 (retinopathy, nephropathy) and foot problem-related information (neuropathy, PAD,
55
56 156 trauma, foot hygiene) of the participants. The blood glucose levels (fasting/2-hours
57
58 157 post meal) and information about diabetic nephropathy or retinopathy in the
59
60 158 participants was extracted from their diabetes records book. The last record within one

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2
3 159 month was used to assess their glycaemic status. In the second phase, physical
4
5 160 measurements (anthropometric and blood pressure) and foot examination were
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7 161 carried out by trained physicians. The anthropometric and blood pressure
8
9 162 measurement followed the methods described in 'Noncommunicable disease risk
10
11 163 factors survey Bangladesh 2010' [16]. The anthropometric measurements included
12
13 164 height, weight, waist circumference, hip circumference and derivatives like body mass
14
15 165 index (BMI) and waist-hip ratio.

166 **Assessment of DFU**

167 The risk of DFU was assessed using a modified version of International Working Group
168 on the Diabetic Foot (IWGDF) Risk Classification System proposed by Lavery *et al.* [17].
169 We screened each patient to identify lower extremity complications and presence of
170 any risk factors, like ulcerations, amputation, peripheral neuropathy (PN), PAD, foot
171 deformities and limited joint mobility using the methods followed by Lavery *et al.* [17–
172 18]. We used a 10 g Semmes-Weinstein monofilament and vibration perception
173 threshold tester to assess PN, Ankle Brachial Index (ABI) to detect PAD, goniometer to
174 identify foot deformity and clinical examinations to evaluate joint mobility. The risks
175 were categorised according to the modified IWGDF risk classification system: Group 0
176 (no PN, no PAD), Group 1 (PN, no PAD, no deformity), Group 2A (PN and deformity,
177 no PAD), Group 2B (PAD), Group 3A (ulcer history) and Group 3B (amputation). Here,
178 Group 0 indicated 'no risk' and rest of the groups (1, 2A, 2B, 3A, 3B) classified the study
179 population 'at risk' of in varying degrees

180 **Ascertainment of key variables**

181 *Peripheral neuropathy*

182 PN was defined as lack of feeling/protective sensation (at four or more of 10 sites) [19]
183 and vibration perception threshold value in either foot >25 volts using an
184 electromechanical instrument [18].

185 *Peripheral arterial disease*

186 We defined PAD as non-palpable dorsalis pedis or posterior tibial arterial pulse and
187 ABI in either foot as <0.80 [17].

188 *Limited joint mobility*

189 Limited joint mobility was defined based on three averaged measurements of the first
190 metatarsophalangeal joint, the subtalar joint and ankle joint range of motion of the
191 forefoot, rear foot and ankle. From these measurements, we determined the presence
192 of ankle joint equinus ($<0^\circ$ dorsiflexion), limited subtalar joint motion ($<20^\circ$ total joint
193 motion), and hallux rigidus ($<50^\circ$ hallux dorsiflexion) [18]. It was measured using
194 goniometer and details technique was described elsewhere (see online supplementary
195 file 1)

196 *Foot deformity*

197 Deformity was defined as any contracture that could not be fully corrected manually,
198 such as hallux valgus, hammer toes or claw toes, hallux rigidus and ankle equines [17].
199 It was measured using goniometer and details technique was described elsewhere (see
200 online supplementary file 1).

201 *Foot ulcer*

202 Foot ulcers were defined as full thickness wounds involving the foot or the ankle [20].

203 **Quality assurance**

204 To ensure standard quality control, a panel of senior researchers and survey
205 investigators visited the data collection sites to monitor the research activities. To
206 prevent bias, monitoring panel was anonymised for the data collectors. All team
207 members including investigators, supervisor and data collectors participated in
208 intensive three consecutive training programmes (lasting two and a half days) in Dhaka
209 before the survey. The first training program was conducted for the physicians who
210 were involved in foot examination. This training program focused on 'Detection of
211 Diabetic Foot Problem at the Early Stage' through screening using a standard
212 instrument. A certified neurologist from a reputed post-graduate training institution

1
2
3 213 was appointed as a resource person to conduct the sessions. Second and third training
4
5 214 programmes were conducted for the volunteering data collectors selected from
6
7 215 undergraduate physiotherapy students, who interviewed the respondents to fill-up the
8
9 216 questionnaire. The purpose of this training was to inform the data collectors about
10
11 217 potential difficulties associated with data collection. During this intensive training, data
12
13 218 collectors got practical training about self-administration of a questionnaire, physical
14
15 219 measurement and maintenances of data collection environment. Other than these, we
16
17 220 also followed specific protocols to assure quality of the study that included: (1) pre-
18
19 221 testing of the questionnaire and data collection procedure (2) standard method of
20
21 222 measurement as per STEPS survey 2010 of Bangladesh (3) used show cards for a better
22
23 223 understanding of different forms of tobacco use and intensity of physical activities (4)
24
25 224 adequate privacy during physical measurements and clinical examinations (5) robust
26
27 225 equipment for physical measurement and clinical examination. None of the quality
28
29 226 control observer reported any violation of physical measurement and data collection.

31 227 **Patient and public involvement**

32
33
34 228 We collected data from the patients who visited the selected diabetes care centres of
35
36 229 DAB. However, they were not involved directly in the setting of the research question
37
38 230 or outcome measures. They did not have any role in designing or implementing this
39
40 231 work or interpretation of the results.

41 232 **Ethical consideration**

42
43
44
45 233 The purpose of the study, rights of the respondents and data safety issues were
46
47 234 explained to each participant. All subjects gave their informed written consent for
48
49 235 inclusion before they participated in the study (see online supplementary file 2). The
50
51 236 study was conducted in accordance with the Declaration of Helsinki, and the protocol
52
53 237 was approved by the Ethical Review Committee of Bangladesh Diabetic Association
54
55 238 (Identification number: BADAS/BIO/EA/11/033) on January 17, 2011 (see online
56
57 239 supplementary file 3).

58 59 60 240 **Data processing and analysis**

1
2
3 241 Data were analysed using the Statistical Package for Social Science (SPSS) version 20.0
4
5 242 for Windows (SPSS, Inc. Chicago. IL. USA). All estimates of precision were presented at
6
7 243 95% confidence interval (CI) in the tables. Descriptive analysis included mean, standard
8
9 244 deviation (SD), median and interquartile range (IQR), frequencies and percentages
10
11 245 where appropriate. In this study, the p -value (two-sided) was considered statistically
12
13 246 significant at the threshold of $p < 0.05$. In our study, there were only three respondents
14
15 247 with PAD. Hence, we had to merge group 2B with group 2A and make a new group 2-
16
17 248 A/B that was used in multinomial logistic regression analysis.

19
20 249 To find the predictors of DFU, first we run chi-square test considering modified IWGDF
21
22 250 risk classification as a dependent variable. Variables that showed significant association
23
24 251 ($p < 0.05$) with the dependent variable in the chi-square test were identified. Then
25
26 252 statistically significant variables were examined as independent variable against the
27
28 253 dependent variable in the multinomial logistic regression analysis. For multinomial
29
30 254 logistic regression analysis, we calculated odds ratios (OR), and 95% CI for each
31
32 255 independent variable. In the regression table, predictors that had OR > 1 were
33
34 256 presented for each risk category. We ensured presence of no multicollinearity using
35
36 257 variance inflation factor (VIF) to run the regression analysis. We used the STROBE
37
38 258 (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for
39
40 259 reporting the results of cross-sectional observational study (see online supplementary
41
42 260 file 4).

261 **Results**

262 **Sociodemographic characteristics and diabetes-related information**

263 The mean age of the participants was 51.6 ± 11.9 years and most of them (33.1%) were
264 in the 50–59 year age group. More than half of the participants were women (62.9%)
265 and predominantly urban residents (67.3%). Most of them had completed primary level
266 education (36.7%), 99% were married, 57.8% were housewives and 44.5% came from
267 middle-income background. However, urban participants were more literate (88.2%)
268 and economically stable (60.3% $>$ lower-middle-income range) than their rural

269 counterparts. The mean duration of diabetes was 6.9 ± 5.9 years and a majority of them
 270 had uncontrolled glycaemic status (89.3%). Among the diabetes-related complications,
 271 retinopathy (14.3%) was much higher than nephropathy (5.6%). No mentionable
 272 urban-rural difference was observed for the glycaemic status and diabetic
 273 nephropathy (Table 1).

274 **Table 1: Sociodemographic and diabetes-related information of the study**
 275 **subjects, $n=1200$**

Variables	Urban		Rural		Total	
	<i>n</i> (%)	95% CI	<i>n</i> (%)	95% CI	<i>n</i> (%)	95% CI
Age (years)*	52.3 \pm 11.9		50.2 \pm 11.8		51.6 \pm 11.9	
Age categories (years)						
<30	52 (4)	2.6–5.4	22 (5.6)	3.3–7.9	54 (4.5)	3.3–5.7
30–39	63 (7.8)	5.9–9.7	39 (9.9)	14.6–18	102 (8.5)	6.9–10.1
40–49	212 (26.3)	23.3–29.3	109 (27.7)	23.3–32.1	321 (26.8)	24.3–29.3
50–59	270 (33.5)	30.2–36.8	127 (32.3)	27.7–36.9	397 (33.1)	30.4–35.8
≥ 60	230 (28.5)	25.4–31.6	96 (24.4)	20.2–28.6	326 (27.2)	24.7–29.7
Sex						
Men	302 (37.4)	34.1–40.7	143 (36.4)	31.6–41.2	445 (37.1)	34.4–39.8
Women	505 (62.6)	59.3–65.9	250 (63.6)	58.8–68.4	755 (62.9)	60.2–65.6
Educational status						
Illiterate	95 (11.8)	9.6–14	107 (27.2)	22.8–31.6	202 (16.8)	14.7–18.9
Primary	288 (35.7)	32.4–39	152 (38.7)	33.9–43.5	440 (36.7)	34–39.4
Secondary	265 (32.8)	29.6–36	98 (24.9)	20.6–29.2	363 (30.3)	27.7–32.9
Higher education	159	17–22.4	36 (9.2)	6.3–12.1	195	14.2–18.4

1							
2							
3		(19.7)	—		—	(16.3)	
4							
5	Marital status						
6							
7	Married	797 (98.8)	98–99.6	391 (99.5)	98.8–100.2	1188 (99)	98.4–99.6
8							
9	Others	10 (1.2)	0.4–2	2 (0.5)	-0.2–1.2	12 (1)	0.4–1.6
10							
11	Occupational status						
12							
13	Service	184 (22.8)	19.9–25.7	49 (12.5)	9.2–15.8	233 (19.4)	17.2–21.6
14							
15	Business	89 (11)	8.8–13.2	38 (9.7)	6.8–12.6	127 (10.6)	8.9–12.3
16							
17	Housewife	462 (57.2)	53.8–60.6	231 (58.8)	53.9–63.7	693 (57.8)	55–60.6
18							
19	Others	72 (8.9)	6.9–10.9	75 (15.2)	11.7–18.7	147 (12.3)	10.4–14.2
20							
21	Monthly household income (BDT)†	20000 (10000–40000)		10000 (6000–20000)		20000 (10000–30000)	
22							
23	Monthly household income groups						
24							
25	<4907 (low)	21 (2.6)	1.5–3.7	41 (10.4)	7.4–13.4	62 (5.2)	3.9–6.5
26							
27	4907–19,488 (lower-middle)	299 (37.1)	33.8–40.4	238 (60.6)	55.8–65.4	537 (44.8)	42–47.6
28							
29	19489–60252 (upper-middle)	422 (52.3)	48.9–55.7	108 (27.5)	23.1–31.9	530 (44.2)	41.4–47
30							
31	>60,252 (high)	65 (8.1)	6.2–10	6 (1.5)	0.3–2.7	71 (5.9)	4.6–7.2
32							
33	Duration of diabetes (years)*	7.3 ±6		6.3 ±5.8		6.9 ±5.9	
34							
35	Glycaemic status‡						
36							
37	Controlled	87 (10.8)	8.7–12.9	42 (10.7)	7.6–13.8	129 (10.8)	9–12.6
38							
39	Uncontrolled	720 (89.2)	87.1–91.3	351 (89.3)	86.2–92.4	1071 (89.3)	87.6–91
40							
41	Diabetic retinopathy	134 (16.6)	14–19.2	38 (9.7)	6.8–12.6	172 (14.3)	12.3–16.3
42							
43	Diabetic nephropathy	46 (5.7)	4.1–7.3	21 (5.3)	3.1–7.5	67 (5.6)	4.3–6.9
44							
45							
46							
47							
48							
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52							
53							
54							
55							
56	276	*Representing mean and standard deviation,					
57							
58	277	†Presented as median with interquartile range,					
59							
60	278	‡According to the 2006 per-capita gross national income (GNI) and the World Bank calculation					

279 §Based on plasma glucose level pre-meal (fasting) <6.1 mmol/l and/or two hours post meal <7.8
280 mmol/l

281 **Risk of DFU among the study population**

282 Table 2 shows the sex and area-specific distribution of the DFU risk according to the
283 modified version of IWGDF classification. Overall, 44.5% of the study population was
284 diagnosed as 'at risk' of DFU and the burden was higher among men (45.6%) and those
285 who lived in rural areas (45.5%). The risk of DFU according to the modified version of
286 IWGDF was 55.5%, 4.2%, 11.6%, 0.3%, 20.6% and 7.9% for group 0, group 1, group 2A,
287 group 2B, group 3A and group 3B respectively. Among the six groups of risk
288 classification, group 3A (ulcer history) showed maximum risk (20.6%) compared to
289 other groups. For sex and area variables, 21.8% of men and one-fourth of the rural
290 residents (25.7%) had a previous history of foot ulceration.

291 **Table 2: Sex and area-specific distribution of DFU risk among the study subjects, n = 1200**

IWGDF DFU risk classification	Sex		Area of residence		Overall n (%)
	Men	Women	Urban	Rural	
	n (%)	n (%)	n (%)	n (%)	
Group 0 (no PN, no PAD)	242 (54.4)	430 (57)	452 (56)	214 (54.5)	666 (55.5)
Group 1 (PN, no PAD, no deformity)	18 (4)	32 (4.2)	32 (4)	18 (4.6)	50 (4.2)
Group 2A (PN and deformity, no PAD)	49 (11)	90 (11.9)	103 (12.8)	36 (9.2)	139 (11.6)
Group 2B (PAD)	1(0.2)	2 (0.3)	3 (0.4)	0	3 (0.3)
Group 3A (ulcer history)	97 (21.8)	150 (19.9)	146 (18.1)	101 (25.7)	247 (20.6)
Group 3B (amputation)	38 (8.5)	57 (7.5)	71 (8.8)	24 (6.1)	95 (7.9)

292 IWGDF, International Working Group on the Diabetic Foot; DFU, diabetic foot ulcer, PN, peripheral
293 neuropathy; PAD, peripheral arterial disease

294 **Predictors of DFU risk among the study subjects**

295 Table 3 shows the predictors of DFU risk among the study population. Total six
296 predictors were identified which showed high odds (>1) for different groups at risk:

297 age (group 2-A/B, OR 1.212; group 3B, OR 1.173), area of residence (group 1, OR 1.188;
 298 group 3A, OR 1.461), monthly income (group 2-A/B, OR 1.491; group 3A, OR 1.415;
 299 group 3B, OR 1.768), medication (group 2-A/B, OR 1.014), history of trauma (group 1,
 300 OR 2.015; group 2-A/B, OR 1.032; group 3A, OR 2.998; group 3B, OR 3.104), diabetic
 301 retinopathy (group 1, OR 1.104; group 3B, OR, 1.933) and diabetic nephropathy (group
 302 1, OR 2.174; group 3A, OR 1.260; group 3B, OR 2.389).

303 Overall, the odds for risk of DFU was higher among those who were ≥ 50 years old,
 304 lived in rural areas, had a monthly income $\leq 19,488$ BDT, had a previous history of foot
 305 ulcer, were insulin user and had diabetic complications as retinopathy or nephropathy.

306 **Table 3: Predictors of diabetic foot ulcer among type 2 diabetic subjects of Bangladesh using**
 307 **multinomial logistic regression, $n = 1200$**

Risk groups	Predictors	B	p-value	OR	95% CI for OR	
					Lower Bound	Upper Bound
Group 1	Area of residence					
	Rural area	0.172	0.573	1.188	0.652	2.165
	Urban area			<i>Ref.</i>		
	History of trauma					
	Present	0.7	0.076	2.015	0.929	4.369
	Absent			<i>Ref.</i>		
	Diabetic retinopathy					
	Present	0.099	0.814	1.104	0.486	2.508
	Absent			<i>Ref.</i>		
	Diabetic nephropathy					
	Present	0.526	0.14	2.174	755	6.099
	Absent			<i>Ref.</i>		

Group 2-A/B† Age

	≥50 years	0.192	0.324	1.212	0.827	1.774
	<50 years				<i>Ref.</i>	
	Monthly income (BDT)					
	≤19,488	0.4	0.039*	1.491	1.020	2.181
	>19,488				<i>Ref.</i>	
	Medication					
	Insulin user	0.013	0.945	1.014	0.692	1.485
	Insulin non-user				<i>Ref.</i>	
	History of trauma					
	Present	0.032	0.916	1.032	0.570	1.870
	Absent				<i>Ref.</i>	
<hr/>						
	Area of residence					
	Rural area	0.379	0.014*	1.461	1.081	1.975
	Urban area				<i>Ref.</i>	
	Monthly income (BDT)					
	≤19,488	0.347	0.031*	1.415	1.032	1.940
	>19,488				<i>Ref.</i>	
Group 3A	History of trauma					
	Present	1.098	<0.001*	2.998	2.044	4.396
	Absent				<i>Ref.</i>	
	Diabetic Nephropathy					
	Present	0.231	0.504	1.260	0.640	2.482
	Absent				<i>Ref.</i>	
<hr/>						
	Age					
Group 3B	≥50 years	0.160	0.494	1.173	0.742	1.854
	<50 years				<i>Ref.</i>	

Monthly income (BDT)						
≤19,488	0.570	0.016*	1.768	1.114	2.805	
>19,488				<i>Ref.</i>		
History of trauma						
Present	1.133	<0.001*	3.104	1.810	5.324	
Absent				<i>Ref.</i>		
Diabetic retinopathy						
Present	0.659	0.018*	1.933	1.122	3.329	
Absent				<i>Ref.</i>		
Diabetic nephropathy						
Present	0.871	0.024*	2.389	1.123	5.083	
Absent				<i>Ref.</i>		

308 OR, odd-ratio; CI, confidence interval; Ref, reference; BDT, Bangladesh taka

309 *indicates significant

310 †Group 2B was merged with 2A as the participants were very few in the group 2B

311 Discussion

312 The results show that nearly half (45%) of the T2D subjects were at the risk of DFU and
 313 rural population was mostly affected. This is significant as there is no straightforward
 314 evidence on the risk of DFU among T2D population of Bangladesh. Moreover, the
 315 contributing factors are not yet explored in Bangladesh to take an effective initiative
 316 to reduce the burden of associated morbidity and mortality.

317 In our modified DFU risk classification as per IWGDF, the higher burden was observed
 318 in those who had a previous history of foot ulcer (20.6%). This proportion is much
 319 higher than an Iranian study that reported only 7% of the study subjects to have a
 320 previous history of foot ulceration [21]. The percentage of our finding is also higher
 321 than Portugal, where a study reported a previous history of DFU among 16% of study
 322 subjects using modified IWGDF risk classification [22]. Although it has been estimated
 323 that the annual risk of DFU is approximately 2%, this risk in patients with a previous

1
2
3 324 history of foot ulcer is expected to increase to 17%–60% over the next three years [23].
4

5
6 325 Several studies have reported the cumulative burden of a previous history of foot ulcer
7
8 326 and amputation as a part of their diabetic foot risk assessment. In our study, the
9
10 327 cumulative proportion of a previous history of foot ulcer and amputation was 14.3%,
11
12 328 which is twice that of studies conducted in India [24,25] and in a half of Portugal [22].
13
14 329 A follow-up study from the USA reported nearly three times higher proportion of foot
15
16 330 ulcer or amputation compared to our study [26]. In this regard, a systematic review
17
18 331 comprised of 41 documents by Hunt et al. [27] found that a person with a previous
19
20 332 history of DFU has a 66% chance of ulcer recurrence and 12% chance of amputation
21
22 333 over five years.

23
24 334 We have mentioned earlier that PN is one of the major risk factors for DFU. In our
25
26 335 study, 4.2% of the T2D subjects had only PN and 11.6% had PN with deformity,
27
28 336 represented as group 1 and group 2A respectively. This finding has much lower
29
30 337 percentages compared to similar studies conducted among subjects of India [24,28–
31
32 338 29] and Iran [21,29]. However, this burden is still higher than Portugal [22]. Our study
33
34 339 classified very low proportion of T2D subjects as having PAD compared to
35
36 340 aforementioned studies [21–24,28–30]. This might be due to the cut-off value applied
37
38 341 to define PAD. The compared studies used ABI 0.9 or less as the cut-off, which included
39
40 342 more participants as PAD. The overall burden of 'at risk' (other than group 0) T2D
41
42 343 subjects of this study was also lower than the findings from India [28–29] and Portugal
43
44 344 [22]. However, the proportion of 'at risk' subjects is more than twice that of
45
46 345 aforementioned Indian [24] and Iranian [21] studies. The reasons for the risk difference
47
48 346 in different countries are still unclear.

49
50
51 347 A study by Abott et al. explored this risk difference among different ethnic population
52
53 348 including South-Asians, African-Caribbeans and Europeans of the United Kingdom
54
55 349 [11]. They reported that such difference might be due to the methods applied to detect
56
57 350 neuropathy, provisions of primary health care services, such as diabetes mini-clinics,
58
59 351 podiatric care and referrals for special footwear for the health care districts and a
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3 352 variable quality of health care. Regarding the burden of risk factors of DFU, Abott et
4
5 353 al. added that lower level of PN and PAD also contribute to the less percentage of
6
7 354 South-Asian population 'at risk' compared to Europeans. Another reason behind this
8
9 355 difference is the application of various risk classification system in different countries.
10
11 356 We used modified IWGDF risk classification, similar to the studies from Iran [21] and
12
13 357 Portugal [22], whereas one of the two Indian [24] studies used semi-structured pre-
14
15 358 tested questionnaire and another [28] applied American Diabetic Association (ADA)
16
17 359 task force report for comprehensive foot examination risk classification.

18
19
20 360 Our study reports a sex-specific and area-specific difference in risk of DFU among T2D
21
22 361 population of Bangladesh. The overall proportion of DFU risk was higher among men
23
24 362 than women. Previous studies [7,21,24,31] have also reported similar findings.
25
26 363 However, a community-based study from India reported that DFU risk was high in
27
28 364 women [25], which is contradictory to our finding.

29
30 365 Our study shows that the risk of DFU is greater among men with a previous history of
31
32 366 ulcer or amputation. This higher risk of foot ulcer history or amputation in men was
33
34 367 also supported by a study from Iran, which used IWGDF risk classification system [21].
35
36 368 This men-to-women risk difference might be due to diabetes-related healthy
37
38 369 behavioural practice, health-seeking behaviour and self-care. In this regard, a Brazilian
39
40 370 study reported that sex is significantly associated with changes of lifestyle behaviour
41
42 371 related to control of T2D, foot self-care and prevention of ulceration, and women were
43
44 372 found to adhere more to lifestyle changes than men [32]. The same study also reported
45
46 373 that men were highly reluctant to check their glycaemic status and lipid profile
47
48 374 compared to women [32]. In this case, the fact is that women are more sensitive to
49
50 375 health issues and more frequently seek health services than men do [33,34].

51
52
53 376 For the urban–rural difference, we found that the risk was higher among those who
54
55 377 lived in a rural area. This finding is also supported by other studies [24,29,35]. A
56
57 378 possible explanation is that diabetic patients of rural area are not aware of their PN
58
59 379 due to illiteracy, especially their lack of knowledge about diabetic foot-related
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3 380 complications. They walk barefoot and this leads to an injury to the foot and
4
5 381 subsequent complications [36]. Another explanation could be that people in rural areas
6
7 382 often sleep in huts or farmhouses where rodents are common; rodents bite their feet
8
9 383 and in case of patients with diabetes, this can lead to chronic ulcers [35].
10

11
12 384 One of the major objectives of this study was to identify the predictors of DFU risk
13
14 385 among Bangladeshi T2D population. Sociodemographic predictors age ≥ 50 years,
15
16 386 living in a rural area and monthly income $\leq 19,488$ BDT predicted higher odds for the
17
18 387 risk of DFU. In diabetic research, age is widely evaluated as a predictor of DFU. Some
19
20 388 other studies also found age as a significant predictor [37–39] of DFU. In our study, it
21
22 389 was found that age below 50 years was a protective factor and age above this was
23
24 390 associated with development of DFU. This has also been supported by the other
25
26 391 studies that reported older age was a significant predictor [38,39].
27

28
29 392 Globally, the findings of the association of economic status and area of residence with
30
31 393 the risk of DFU are inconsistent. Our results show that lower economic status (monthly
32
33 394 income $\leq 19,488$ BDT) and living in a rural area are the strong predictors of DFU. These
34
35 395 findings were consistent with the results of other studies conducted in India [25,28]
36
37 396 and Sri Lanka [40]. It was postulated that financial status is directly related to burden
38
39 397 of risk factors, which leads to complications of chronic diseases. This is because a lack
40
41 398 of financial resources interferes with the access to healthcare services, options of
42
43 399 treatments and hinders the adoption of preventive measures that are necessary to
44
45 400 avoid amputations [32]. Regarding place of residence, significant urban–rural risk
46
47 401 difference for DFU was explained by the study of Viswanathan et al. [35] and we
48
49 402 mentioned it in this section previously. However, one study has reported no
50
51 403 association for the aforementioned predictors [41].
52

53 404 Our study found that the odds for risk of DFU were higher among insulin users, having
54
55 405 diabetic-related complications as nephropathy and retinopathy. Previous studies also
56
57 406 reported that use of insulin is a predictor of diabetic foot [30,42]. However, the exact
58
59 407 mechanism behind this has not yet been explored and this finding is thus inconclusive.
60

1
2
3 408 It might be possible that when patients acquiesce to start insulin, they may already
4
5 409 have diabetes for a long time with greater associated complications [30].
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7
8 410 Our findings of retinopathy and nephropathy are also supported by other studies
9
10 411 [21,39,43,44]. Regarding nephropathy, we found that about 10% of diabetic patients
11
12 412 had a history of amputation when they entered a dialysis program [45]. Several factors
13
14 413 might be responsible for an increased risk of DFU among nephropathy patients.
15
16 414 Coexistence of PN, peripheral vascular diseases, susceptibility to infection, minimal
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18 415 self-care, dialysis therapy and anaemia [46]. On the other hand, one study has reported
19
20 416 that the prevalence of diabetic retinopathy is much higher (90%) among patients with
21
22 417 DFU than those who had no DFU [43]. Another study [44] used IWGDF risk classification
23
24 418 to predict DFU and they found that around 67.58% of patients had diabetic retinopathy
25
26 419 and they were included in the risk group 3, which was similar to our study. In this
27
28 420 regard, a systematic review and a meta-analysis show that both retinopathy and
29
30 421 nephropathy are microvascular complications. The impairment of microcirculation in
31
32 422 T2D may lead to secondary complications in lower extremity due to dysfunctional
33
34 423 vasodilatation. Moreover, patients of diabetic foot with retinopathy have higher level
35
36 424 of diabetic biomarkers like ceruloplasmin. Again, this ceruloplasmin is an independent
37
38 425 predictor of progression of diabetic nephropathy in T2D patients. Thus
39
40 426 aforementioned explanation implies a link between DFU, and retinopathy and
41
42 427 nephropathy [47].
43

44 428 Previous history of trauma was identified as a significant predictor of DFU (group 3A,
45
46 429 OR 2.998, $p < 0.001$; group 3B, $p < 0.001$) in our study. This finding was similar to other
47
48 430 studies that reported a significant association between a previous history of trauma
49
50 431 and DFU [48–50]. However, the exact mechanism of a previous trauma leading to DFU
51
52 432 is not clear. As such, further research on this issue is required.
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54 433 **Limitations**

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56
57 434 Our study has some limitations that should be mentioned. First, the participating
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59 435 centres were not representative of the Bangladesh diabetes centres as a whole
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3 436 considering their geographical distribution as some areas were underrepresented or
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5 437 not represented at all. Therefore, the results of our study cannot be extrapolated to
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7 438 the general diabetic population in Bangladesh. Second, in our study some diabetes-
8
9 439 related complications were underrepresented, especially for diabetic retinopathy and
10
11 440 nephropathy. These co-morbidities were not based on real-time clinical examination
12
13 441 of eyes and assessment of kidney functions, rather based on diabetic record books
14
15 442 review. In a similar way, glycaemic status was evaluated using the values previously
16
17 443 recorded in the diabetic records of the subject instead of using a biochemical
18
19 444 measurement during data collection.

21 445 **Strengths**

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23
24 446 Our study is important from the public health and clinical perspective. It is the first
25
26 447 study in Bangladesh that predicts DFU risk in a moderately large sample of T2D
27
28 448 population. Moreover, a multi-centric study recruited participants from world-
29
30 449 renowned DAB affiliated diabetes centres. The other strength of this study is sex- and
31
32 450 area-specific reporting of DFU risk among the study subjects. This difference will help
33
34 451 to address the men–women and urban–rural disparities in diabetes foot care in
35
36 452 Bangladesh and in remodelling the chain of diabetes centres where appropriate. The
37
38 453 clinicians of Bangladesh should concentrate more on these predictors in the
39
40 454 management of diabetic patients as these are associated with morbidity and mortality
41
42 455 resulting from DFU.

44 456 **Conclusion**

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46
47 457 We found that a significant proportion of T2D population of Bangladesh is at a high
48
49 458 risk of DFU. The findings indicate that each diabetic patient must be screened for his
50
51 459 or her foot ulcer risk factors according to IWGDF recommendation. In this regard,
52
53 460 diabetic foot screening program can be introduced in the primary health care system
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55 461 of Bangladesh. Based on the findings of this study, we also recommend that specialized
56
57 462 diabetic foot care centres should be established in both urban and rural areas to stop
58
59 463 the debilitating consequences of DFU.

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469 All authors have none to declare.

470 **Data statement**

471 Data are available as a supplementary file (see online supplementary file 5). All data
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473 **Author statement**

474 Conceptualization, Palash Chandra Banik and Liaquat Ali; Data curation, Palash
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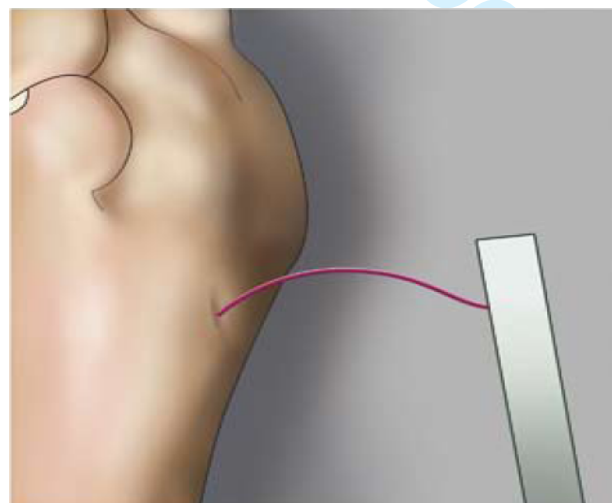


BANGLADESH UNIVERSITY OF HEALTH SCIENCES

Faculty of Public Health

Department of Noncommunicable Diseases (NCD)

TRAINING MODULE ON DETECTION OF DIABETIC FOOT PROBLEM AT THE EARLY STAGE



By

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www.buhs.ac.bd

Collaboration with



Health Care Development Project (HCDP) of BADAS



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Introduction

Why foot care is important for patients with Type 2 Diabetes?

Foot problems from diabetes represent a significant burden of care for primary care physicians. Most of the adverse outcomes of a diabetic foot are preventable with resources currently available in primary care settings where most patients with diabetes get their care.

The Center for Disease Control estimates that in 2010:

- 1 in 12 adults Americans, and 1 in 4 adult American Indians, has diabetes.
- Approximately 90% of these patients are managed by primary care providers.
- Of the diabetes patients seen, 20% will present with an acute foot problem.
- Over the course of their care, 15% will experience a foot ulcer.
- 5 – 10% will need lower limb amputation.
- 50% of those who get an amputation die within 5 years.

How is this training set up?

This Training can be used in a variety of different ways:

- Read the Essential Elements that offer a detailed explanation.
- Just want the key points? Then browse through the Quick Facts.
- Use these printable notes if you want to be able to write alongside the information offered.

Feel free to use any of these avenues to better enhance your learning needs.

Objectives:

At the end of this training, you will be able to:

1. List four risk factors for diabetic foot complications.
2. Be able to conduct a complete diabetic foot exam.

Screening for High Risk Patients: Overview

Foot ulceration and amputation are preventable with resources currently available in primary care settings where most patients with diabetes get their care. There are several principle risk factors for ulceration and lower extremity amputation (LEA) among patients with diabetes:

- Neuropathy
- Deformity
- Limited joint mobility
- Prior ulcer/ LEA
- PVD
- Onychomycosis

It is also important to assess non-foot related risk factors; some of them are potentially modifiable:

- Male sex
- Duration of diabetes
- Age
- Hyperglycemia
- Hypertension
- Dyslipidemia
- Smoking
- Poor vision
- Other complications such as renal disease

Patients at high risk for foot ulcer and amputation can be identified with simple criteria that involve several testing and inspection measures. Patients with all normal criteria are at low-risk, while those with insensitivity, deformity, absent pulses, or prior foot ulcers or amputations are at high-risk. These simple criteria have been validated in Indian Health Services (IHS) and adopted by most professional and public health organizations including the American Diabetes Association (ADA) and World Health Organization (WHO).

- Sensory testing with a 10 gram monofilament
- Foot inspection for deformity
- Reports of prior ulcer or amputation
- Checking for pedal pulses and taking measurements for an ABI pressure
- Checking joint mobility with goniometer

Screening for High Risk Patients: Sensation

A test using a 10 g monofilament is the recommended method for assessing for neuropathy of the foot. Loss of protective sensation at any site on the foot indicates evidence of neuropathy, increasing the risk of ulceration and other complications.

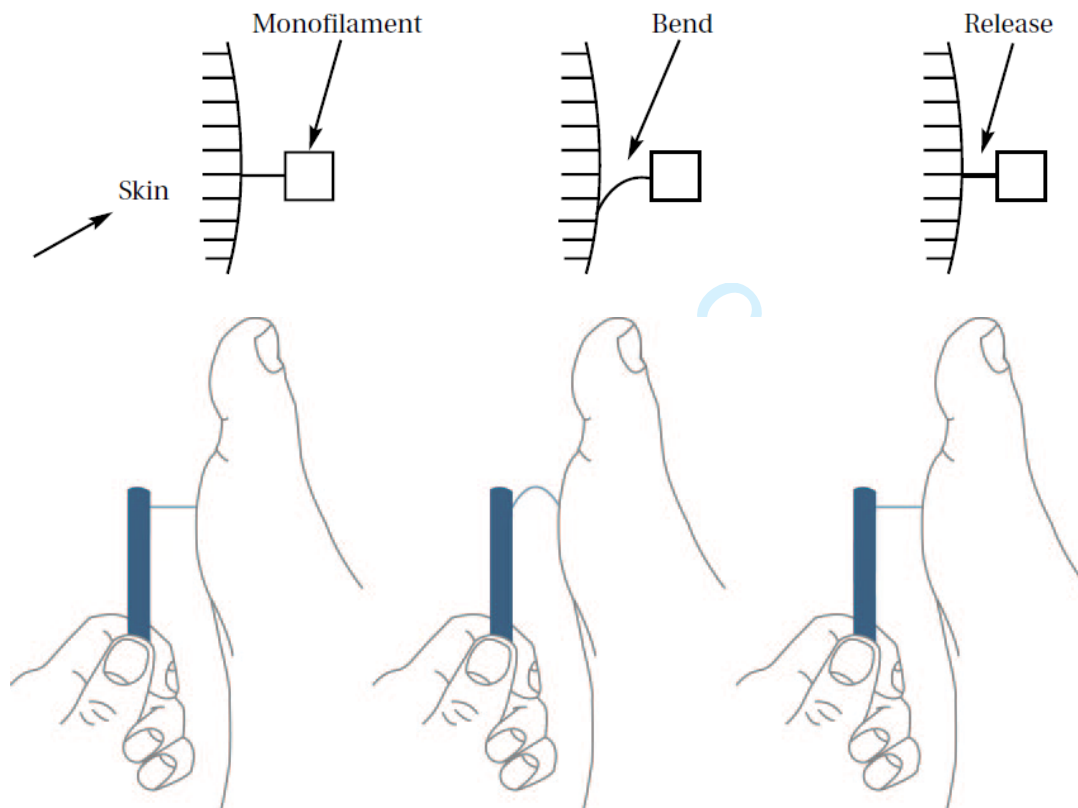
Equipment: 10 g monofilament

Monofilament is the test used to help identify high risk feet in people with diabetes. The monofilament exam involves using a 10 gram monofilament to test sensation on the tip of the great toe, little figure and 1st, 3rd and 5th metatarsal heads & heel of each foot.

The technique for monofilament testing is as follows:

Directions for use of Semmes- Weinstein Monofilament

1. Assess integrity of monofilament (no bends/breaks).
2. Show the monofilament to the patient. Place the end of the monofilament on his/her hand or arm to show that the testing procedure will not hurt.
3. Ask the patient to turn his/her head and close his/her eyes or look at the ceiling.
4. Hold the monofilament perpendicular to the skin.



5. Place the end of the monofilament on the sole of the foot. Ask the patient to say 'yes' when he/she feels you touching his/her foot with the monofilament. **DO NOT ASK THE PATIENT "did you feel that?"** If the patient does not say "yes" when you touch a given

testing site, continue on to another site. When you have completed the sequence RETEST the area(s) where the patient did not feel monofilament.

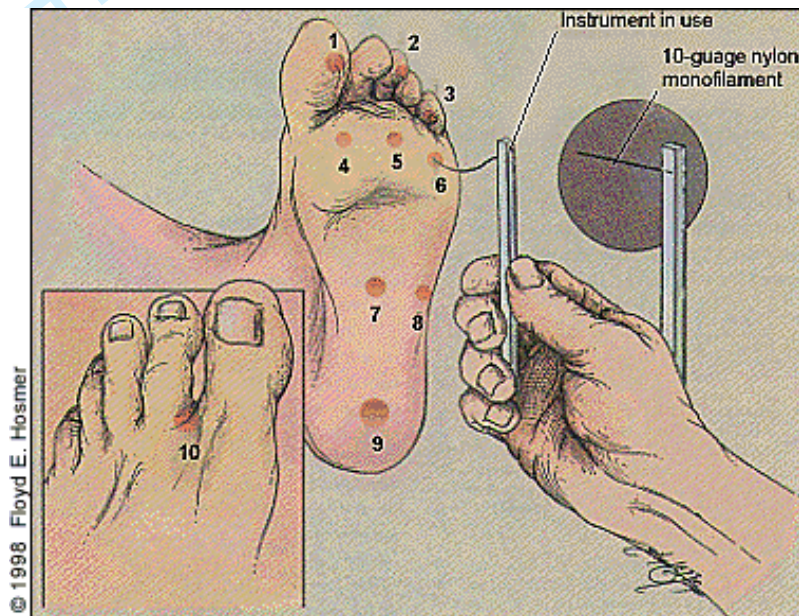
6. Push the monofilament until it bends, then hold for 1-3 seconds.

7. Lift the monofilament from the skin. Do not brush or slide along the skin.

8. Repeat the sequence randomly at each testing site on the foot (see pictures below).

Sites on the sole of the foot for monofilament testing

Loss of protective sensation = absent sensation at one or more sites



Using the monofilament, test the sites listed. Do not test over heavy callus.

- digits: 1st, 3rd, 5th
- MTH: 1st, 3rd, 5th
- midfoot: Medial, Lateral
- heel
- top (*dorsum*) of foot

N. B.:

Apply only to intact skin. Avoid calluses, ulcerated or scarred areas. DO NOT use a rapid or tapping movement.

- If the monofilament accidentally slides along the skin, re-test that area later in the testing sequence.
- Store the monofilament according to the manufacturer's instructions.
- Clean the monofilament according to agency infection control protocols.
- The filament should be cleaned after use with an alcohol swab or dilute bleach solution and returned to its case.
- Do not apply the filament directly on an ulcer, callous, scar or necrotic tissue. Apply the filament on near-by normal tissue.

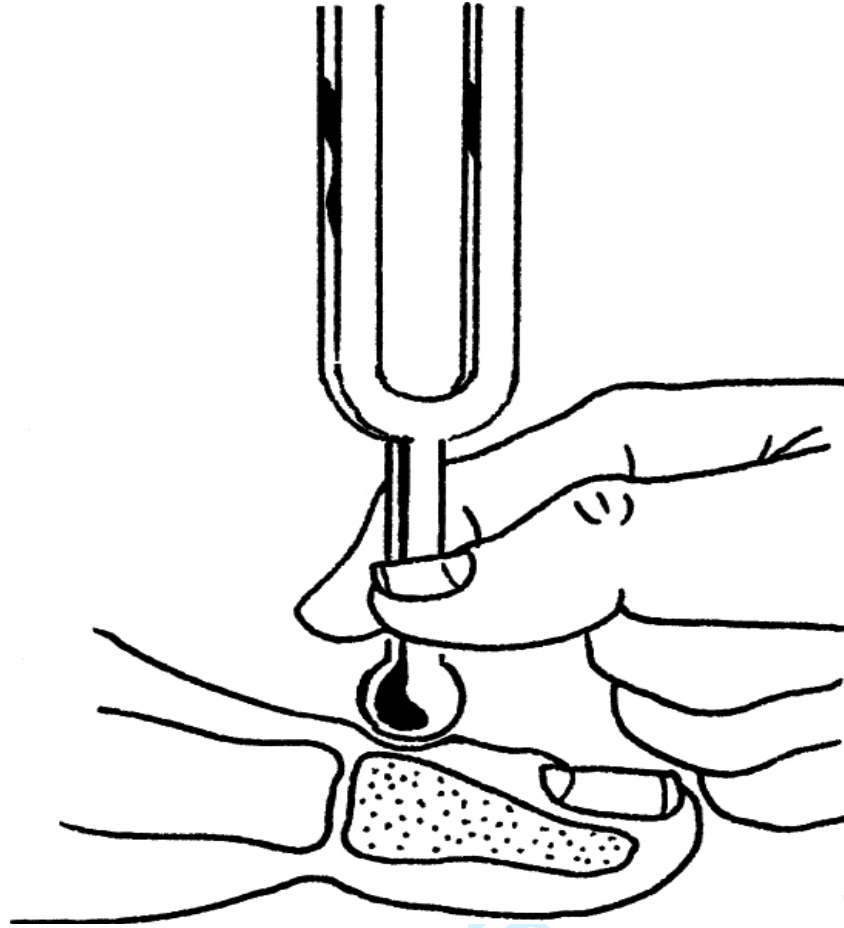


Figure: How to use a tuning fork

Tuning fork

- The sensory examination should be carried out in a quiet and relaxed setting. First, apply the tuning fork on the patient's wrists (or elbow or clavicle) so that he/she knows what to expect.
- The patient must not be able to see whether or where the examiner applies the tuning fork. The tuning fork is applied on a bony part on the dorsal side of the distal phalanx of the first toe.
- The tuning fork should be applied perpendicularly with constant pressure.
- Repeat this application twice, but alternate this with at least one 'mock' application in which the tuning fork is not vibrating.
- ***The test is positive if the patient incorrectly answers at least two out of three applications, ('at risk for ulceration') and negative with two out of three correct answers. (A test is positive if it identifies the risk).***
- If the patient is unable to sense the vibrations on the big toe, the test is repeated more proximally (malleolus, tibial tuberosity).
- Encourage the patient during testing by giving a positive feedback.

Screening for High Risk Patients: Foot Deformities

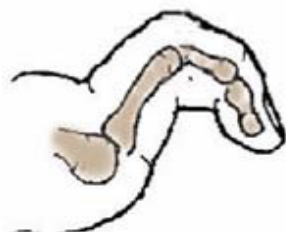
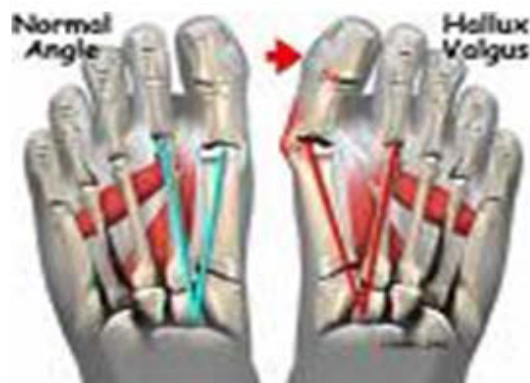
To understand foot deformities, it is important to recognize that foot structure and function is incredibly complex and can easily go awry. Normal foot architecture is maintained through a balance of forces applied by muscles and tendons on bones. Atrophy of a muscle group through nerve damage can lead to deformity. It is important to watch areas that can be open to friction and repetitive micro-trauma as those sites can lead to callus and ulceration.

Types of foot deformities include:

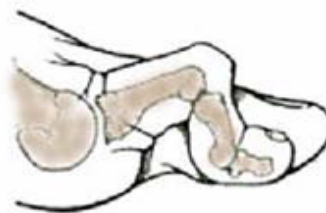
- The **bunion**, or **hallux valgus**, increases the risk for ulceration through a mechanism of increased pressures and friction and repetitive micro-trauma that out paces the healing capacity at the bunion site.
- **Hammer** and **claw toe** deformities develop from atrophy of the small muscles between the toes. Both the dorsal and plantar aspects of the involved toes are at risk for friction and pressure related trauma with subsequent ulceration.
- **Charcot foot** is one of the most severe diabetic foot deformity in which the entire mid-section of the foot collapses and forms a classic “rocker bottom” sole. It is caused by a combination of sensory and autonomic nerve dysfunction in which microscopic fractures to the tarsal bones trigger an inflammatory response and subsequent dissolution of the tarsal and metatarsal bones of the foot. The arch becomes inverted, which causes high plantar pressures, and is at extreme risk for ulceration.

Bunion

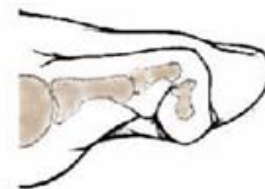
Charcot Foot



Claw toe



Hammer toe



Mallet toe

Hammer toe and other toe deformities

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Hammer toe – bent middle joint



Claw Toe – joint at base of toe is bent up and middle joint is bent down

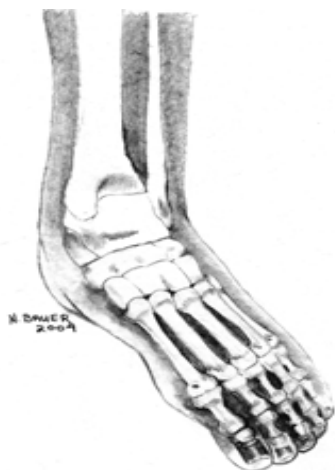


Halgus Valgus or Small Bunion (Mild/Moderate)
– joint at the base of big toe is pushed to the side

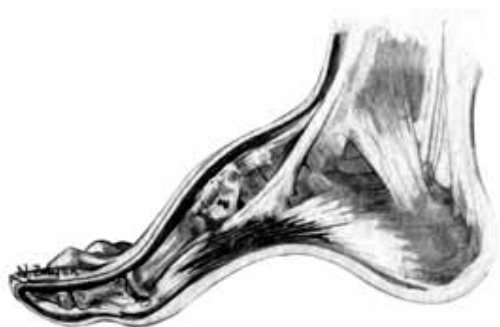


Hallus Valgus or Large Bunion (Severe)
– big toe may move under second toe

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Pes Planus



Pes Cavus



Charcot Arthropathy

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3 Pes planus produces flattening of the foot. Pes planus feet have increased lateral
4 talometatarsal angle and increased second metatarsal length (Ledoux, Shofer, Ahroni,
5 Smith, Sangeorzan & Boyko, 2003). There are many reasons for this condition, the first
6 of which is heredity. Many have this condition and never have any problems of any kind.
7

8 However, others will have this condition created through years in soft, unsupportive
9 shoes on hard surfaces, injury, pregnancy, or other factors. This often leads to other
10 problems.
11

12 The arch in the foot is caused by a broad band of fibrous connective tissue, called the
13 longitudinal ligament. A ligament is nothing more than connective tissue that connects
14 bone to bone. The longitudinal ligament connects the metatarsal phalangeal joints to the
15 os calcis or heel bone. Like a string on a bow, they hold the two ends together and create
16 an arch. This arch is a shock absorption structure and it also helps to maintain all the
17 tarsals in proper erect anatomic position. As this arch decreases, impact from the
18 concrete becomes worse.
19
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21 When the arch ligament stretches or tears, the arch falls. If it falls far enough, the tarsals
22 may begin to shift to the inside or create pronation or a valgus (greater than 90 degree
23 erect) position at the ankle. This can cause problems in the origin area, (the metatarsals)
24 or in the heel. It also may cause pressure on the medial (inner) knee and perhaps the hip
25 and back. It is like pulling the string on a marionette too tight, the result is a kinked mass
26 on one side. The human body is much the same, put too much tension on major muscle
27 groups and the joints kink and yell back.
28
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30 In pes cavus, the arch is abnormally high on weight bearing. The heel is often tilted
31 inwards at the ankle (but not always). In many, the toes will appear clawed. When not
32 standing the front half of the foot (forefoot) will appear to be dropped below the level of
33 the rear foot. Ledoux et al. (2003) identified biomechanical differences among pes planus
34 and pes cavus feet in persons with diabetes. They found pes cavus feet had more
35 prominent metatarsal heads, bony prominences, hammer/claw toes, increased hallux
36 dorsiflexion and Pes Cavus decreased hallux plantarflexion.
37
38

39 Charcot joint is a form of neuroarthropathy that occurs most often in the foot. **Nerve**
40 **damage from diabetes causes decreased sensation, muscle and ligamental atrophy**
41 **and subsequent joint instability.** Walking on this insensitive and weakened joint can
42 cause even more damage to the foot structure. In the acute stage there is inflammation
43 and bone reabsorption which destroys the bone. In later stages, the arch falls and the foot
44 may develop a rocker bottom appearance. Weight distribution of the sole is altered
45 causing deformities leading to pressure points that enhance ulcer development. Signs to
46 assess for are: hot on the onset, pain, discomfort, erythema, swelling, rigid deformities,
47 limited joint mobility, callus formation (ADA, 2001; Bowker & Pfeifer, 2001). One in
48 680 people with diabetes develop Charcot joint with an incidence of 9-12% individuals
49 with documented diabetic peripheral neuropathy (Royal Melbourne Hospital, 2002). It is
50 important that the Charcot foot is recognized early so that appropriate treatment of the
51 foot can be provided to prevent further injury and promote a stable foot (Lavery et al.,
52 1998).
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Screening for high risk patient: Vascular

There are three non-invasive assessments for detecting peripheral vascular disease:

- **The palpitation of pedal pulses is most simple and fastest.** The dorsalis pedis and posterior tibial are the two main arteries in the foot.

- o The dorsalis pedis is on the dorsum or top of the foot.

- o The posterior tibial is palpitated behind the medial malleolus, or inside the ankle bone.

Pedal Pulse Assessment:

Locating a pedal pulse is part of the trauma patient assessment and performed before and after lower extremity splint application as well as long backboard immobilization. Locating a pedal pulse can be difficult even in healthy patients. Use these tips to find a patient's pedal pulse:

- 1) First assess the patient's radial pulse rate and rhythm so you know what you are seeking.

- 2) Move shoes, socks, tights, and anklets out of the way to expose the patient's skin.

- 3) Move, if not compromised by injury, the patient's foot towards the normal anatomical position.

- 4) Check for either the dorsalis pedis pulse (on the top of the foot) or the posterior tibial pulse (located behind the medial malleolus — the ankle bone).

- 5) For dorsalis pedis, first visualize because you might see the skin pulsating above the artery. If you are unable to see anything, hold two or more fingers lightly against the skin. Move up from the toes towards the leg until you locate the pulse.

- 6) For posterior tibial — on the medial side of the ankle — use two or more fingers. If find more pressure is needed to find this pulse.

If you are unable to find the pedal pulse on one leg, switch to the patient's other leg. Knowing the location of one pulse might help you find the other.

Once you have found a pedal pulse, consider using a ballpoint or felt pen to make a light mark at the pulse location to make reassessment easier. Finally, if the patient's foot is warm with normal color, it is adequately perfused.



Dorsalis Pedis: To palpate pulse, place fingers just lateral to the extensor tendon of the great toe. If you cannot feel a pulse, move fingers more laterally.



Posterior Tibial: To palpate pulse, place fingers behind and slightly below the medial malleolus of the ankle. In an obese or edematous ankle, the pulse may be more difficult to feel.

While the dorsalis pedis is easier to palpitate, it is congenitally absent in approximately 8-15% of individuals.

Ankle Brachial Index (ABI):

• An Ankle Brachial Index (ABI) can be performed with a handheld Doppler and a blood pressure cuff.

To obtain an ABI:

1. First measure brachial pressures in each arm.

- Apply the cuff to the upper arm
- Locate the brachial pulse with the Doppler and mark with a pen
- Inflate the cuff, apply Doppler, deflate the cuff and record the pressure at which flow is heard.

2. Next measure pressure in each ankle.

- Apply cuff to the calf
- Locate the posterior tibial pulse with the Doppler and mark with a pen.
- Inflate the cuff, apply Doppler, deflate the cuff and record the pressure at which the flow is heard.

3. **To calculate ABI**, divide the ankle pressure by the greater of the toe brachial pressures. While there is no clear threshold for increased risk, most accept a value of below 0.9 or 0.8 as conferring moderately high risk.

Example: Calculate ankle brachial index by dividing systolic ankle pressure by systolic brachial pressure e.g. ankle pressure is 120 mmHg and brachial pressure is 132 mmHg, ankle brachial index is $120/132 = 0.9$

Some data suggests the Toe BI measurement is more accurate than the ABI, but it requires specialized equipment and is not routine in primary care.

Normal	0.9 - 1.2	Risk of vascular foot ulcer is small
Definite vascular disease	0.6 - 0.9	Risk of vascular ulcer moderate, depending on other risk factors
Severe vascular disease	Less than 0.6	Risk of vascular foot ulcer very high

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3 **N.B.:** Ankle brachial index may not be able to be reliably calculated in some people with
4 diabetes as the arteries in the ankles may be calcified.
5

6 **Assess peripheral circulation** with thorough palpation of **pedal pulses** (dorsalis pedis
7 and posterior tibial). If there are no palpable pulses, and calculate ankle brachial index or
8 consider referral to a vascular specialist. **Absent pulses, calf claudication, absence of**
9 **hair on the feet, altered temperature** (a cold foot) and **thin, bluish skin** are suggestive
10 of **peripheral arterial disease**. A bounding, easily detected pulse in a **warm, dry foot** is
11 suggestive of **autonomic neuropathy**, which causes abnormal arterio-venous shunting.
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Screening for high risk patient: Foot mobility

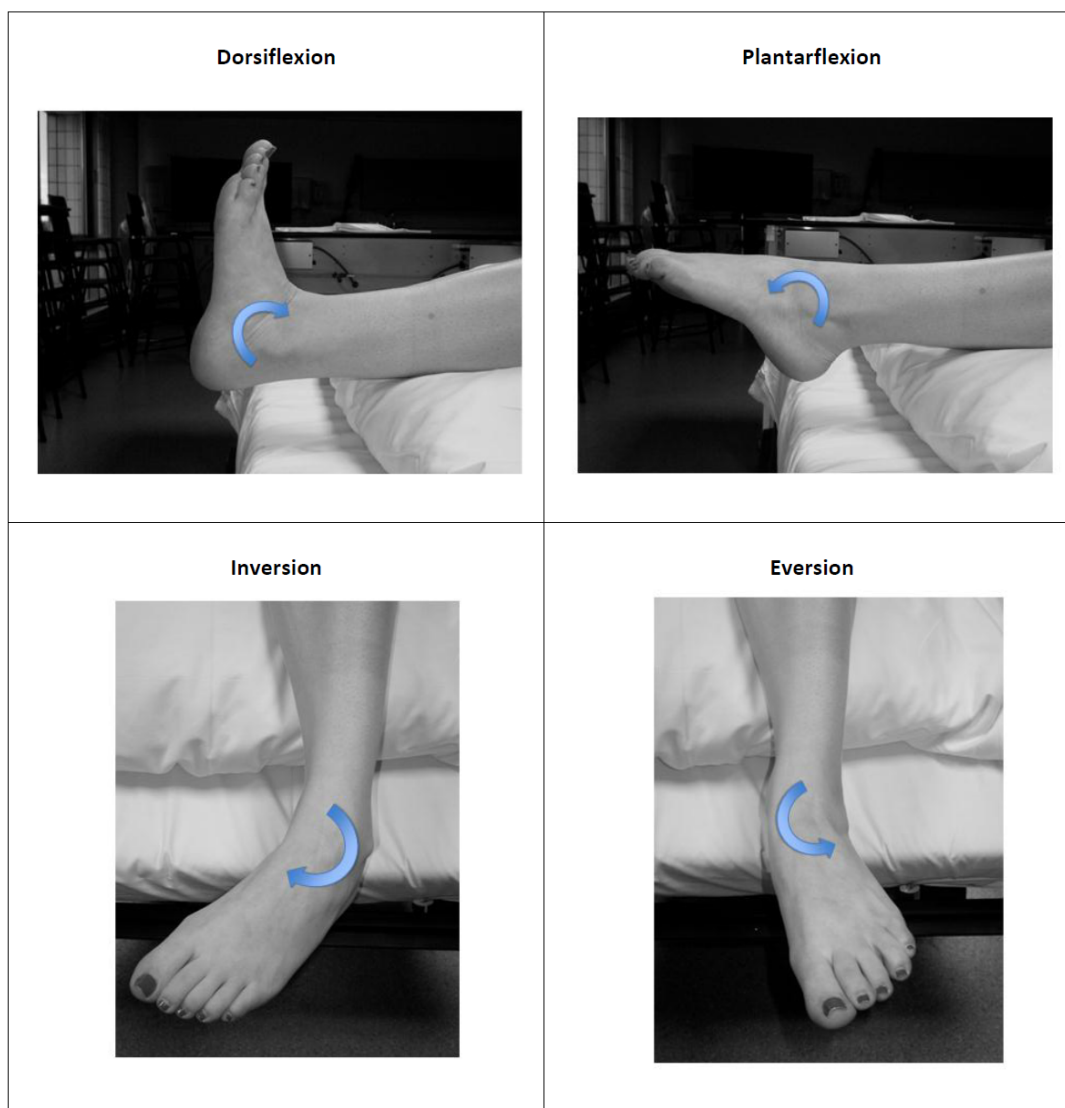
Limited Joint Mobility:

Progressive stiffening of collagen-containing tissues leads to thickening of the skin, loss of joint mobility, and potential fixed flexor deformity. Up to 30% of patients with diabetes may have limited joint mobility. Reduction in mobility of the ankle joint may cause increased plantar pressure when walking and be a major risk factor in the pathogenesis of diabetic foot ulcers (Fernando, Masson, Veves & Boulton, 1991; Zimny, Schatz & Pfohl, 2004). Achilles tendon contracture is a common cause of limited joint mobility causing increased pressure on the forefoot during ambulation (Armstrong, Lavery & Bushman, 1998; Mueller, Sinacore, Hastings, Strube & Johnson, 2004).

Starting position:

For all of the measurements, the same starting position is used. Position the participant on the bed / plinth in long sitting, reclined to about 45 degrees. Place a pillow under upper part of the lower legs to flex the knee to 20-30° and lifting the heels off the surface of the bed / plinth. Ensure the patient is comfortable during the measurements. If it is not possible for the patient to get into the starting position then the measurements could be taken sitting, as long as the knee remains more than 20 degrees flexed and the heel is not directly resting on a support.





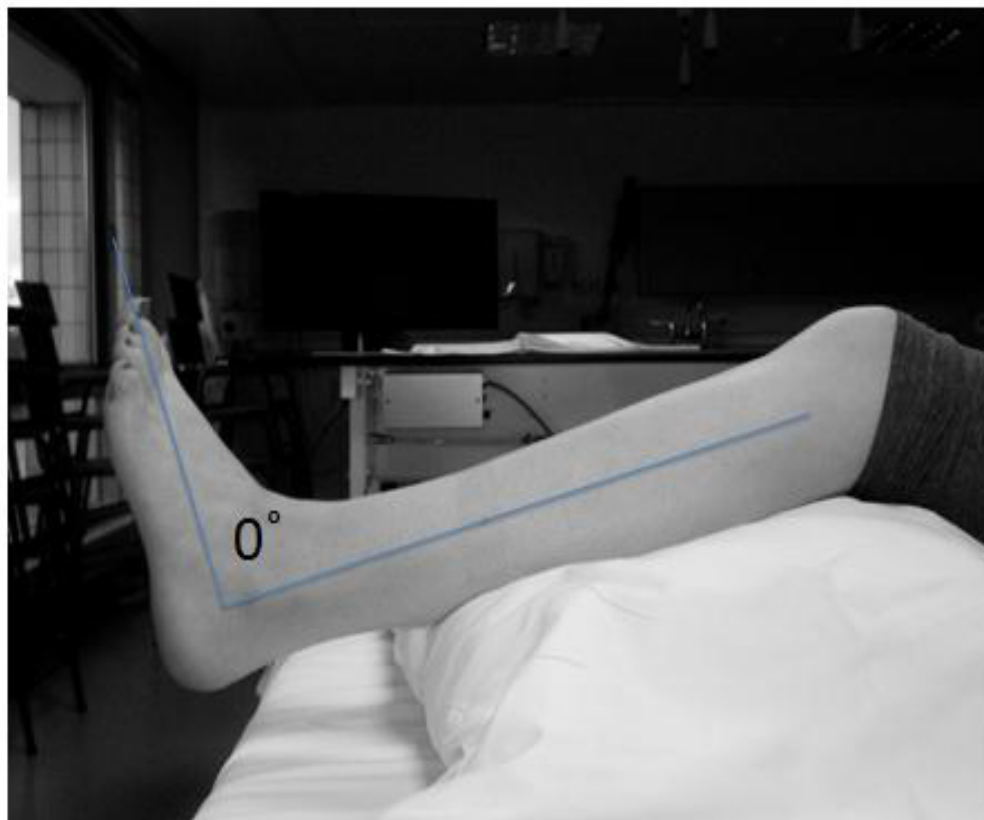
Measuring the range of motion

For the purposes of the trial, measure the uninjured ankle (if appropriate) and then the injured ankle.

Ask the patient to move as far as comfortable, not into pain. Measure how far the patient can move the foot / ankle themselves, do not assist the movement.

Ankle dorsiflexion and plantar flexion

Angles are measured from neutral (plantar grade), which is measured as 0°.

**Goniometer axis:**

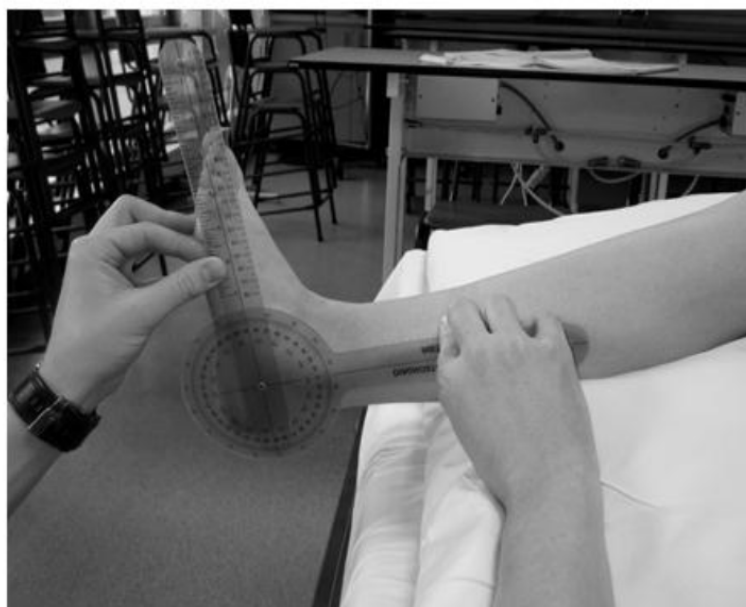
The axis of the goniometer is placed approximately 1.5cm inferior to the lateral malleolus.

Stationary arm:

Parallel to the longitudinal axis of the fibula, lining up with the fibula head.

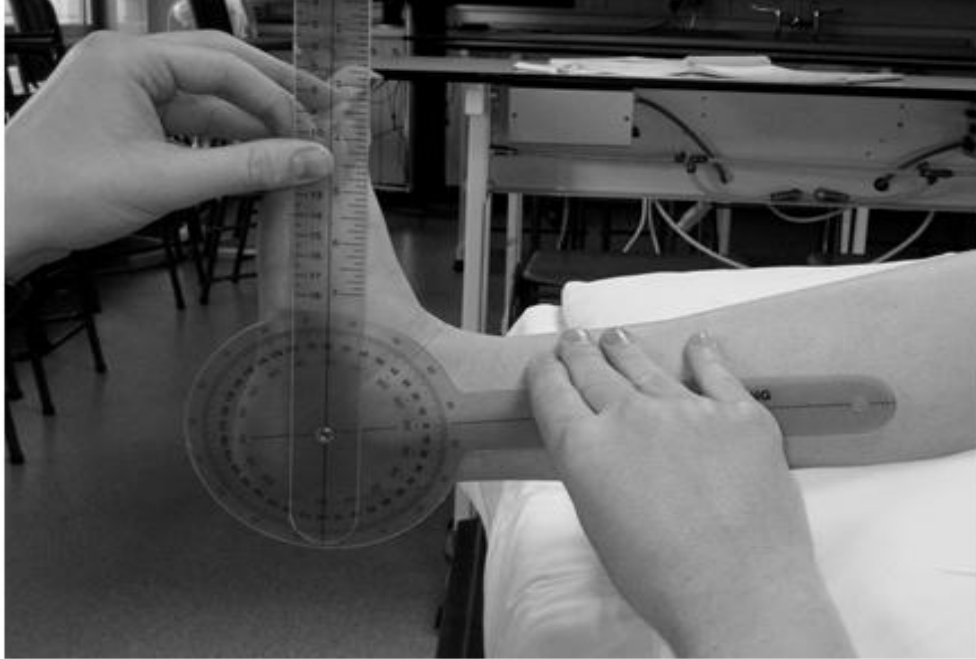
Moveable arm:

Parallel to the longitudinal axis of the 5th metatarsal

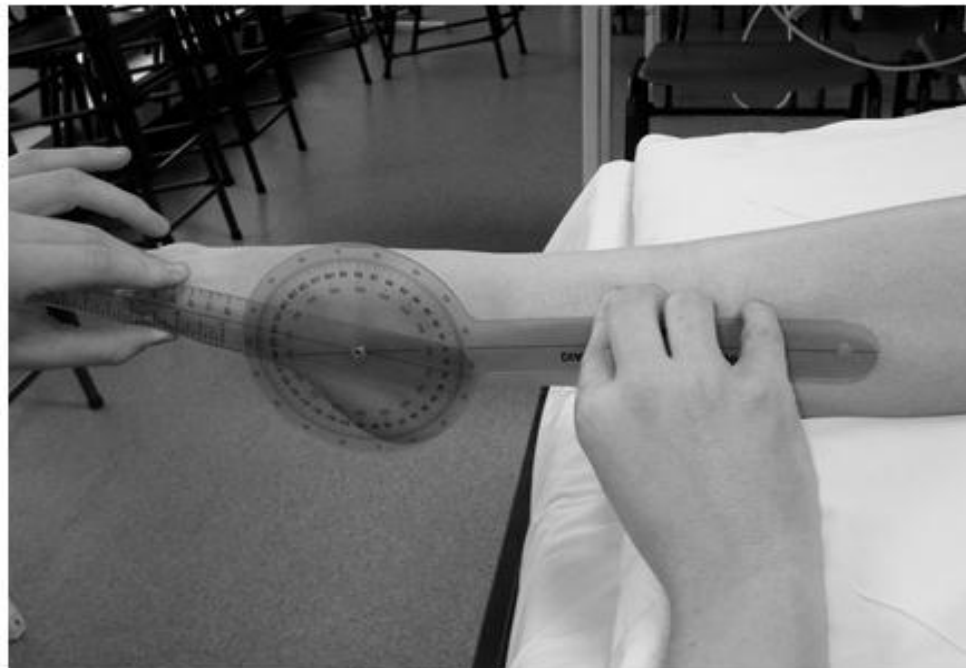


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3 **Instructions:**

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5 **Dorsiflexion:** Ask the patient to pull their foot towards them
6 (Normal range is typically 0-20°)
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32 **Plantarflexion:** Ask the patient to point their foot away
33 (normal range is typically 0-50°)
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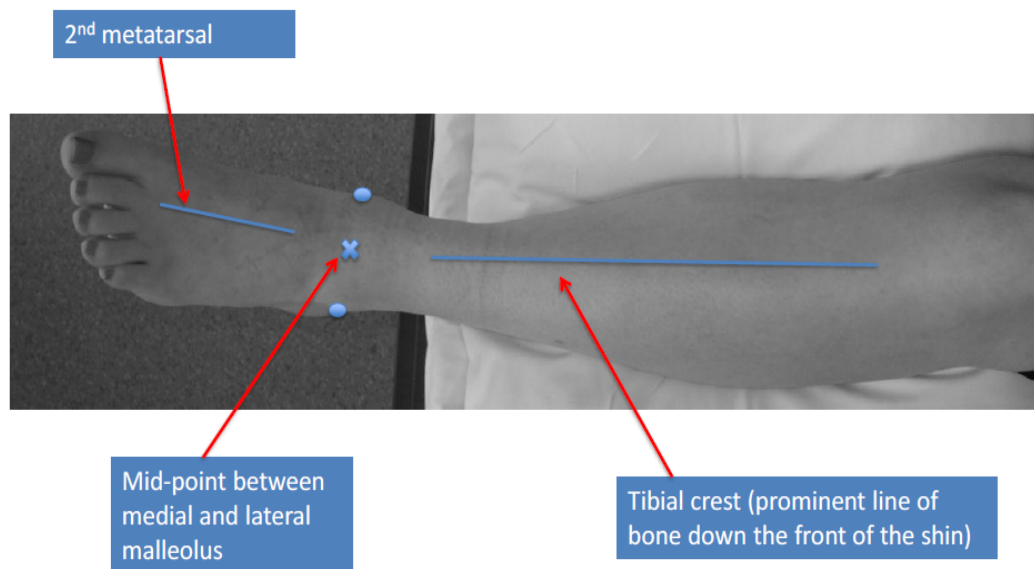


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3 **Measure and record the angle between the movable and stationary arms in degrees.**

4
5 **Ankle inversion and eversion**

6
7 Angles are measured from neutral, which is measured as 0°.

8 Key bony landmarks that help to orientate the goniometer



31 **Positioning and alignment of the goniometer:**

32 **Goniometer axis:**

33 The axis of the
34 goniometer is placed on
35 the front of the ankle at
36 the mid-point between
37 the medial and lateral
38 malleoli.

39
40
41 **Stationary arm:**

42 Along the tibial crest
43 (prominent line of bone
44 down the front of the shin)

45
46
47 **Moveable arm:**

48 In line with the 2nd
49 metatarsal (lining up
50 with the base of the
51 second toe).



Consent Form

1 **Dear Participant,**

2 **Purposive Selection**

3
4 You have been purposively selected to be part of this thesis and this is why we would like to interview
5 you. This thesis is being conducted by **Palash Chandra Banik**, a student of M.Phil in Non-
6 communicable Diseases at Bangladesh Institute of Health Sciences (BIHS) under Bangabandhu Sheikh
7 Mujib Medical University (BSMMU). This type of study is currently taking place in several countries
8 around the world.

9
10 **Title of Thesis**

11 The title of this thesis is **“Risk of foot ulcer and its determinants among Type 2 diabetic subjects”**.

12
13 **Aim of the Thesis**

14 To determine diabetic patients at risk for foot ulceration through a multi-center hospital based study in
15 Bangladesh

16
17 **Data Collection Methods**

18 **Step 1-** Interview questions

19 **Step 2-** Physical examination & screening test (foot)

20 **Timeframe**

21 It is estimated that step 1 & 2 of this study will take approximately 30-40 minutes.

22
23 **Confidentiality**

24 The information you provide is totally confidential and will not be disclosed to anyone. It will only be
25 used for research purposes. Your name, address, and other personal information will be removed from
26 the instrument, and only a code will be used to connect your name and your answers without
27 identifying you.

28
29 **Results**

30 The results of this thesis will be used to help plan strategies in reducing the risk factor that contribute to
31 diabetic foot ulcer among the diabetic patients as well as chronic non-communicable diseases in
32 Bangladesh.

33
34 The results will be published in research publications, media briefings and reports and can be made
35 available to you by local health workers.

36
37 **Voluntary Participation**

38 Your participation is voluntary and you can withdraw from the study after having agreed to participate.
39 You are free to refuse to answer any question that is asked in the questionnaire. If you have any
40 questions about this study you may ask me or contact to the researcher [Palash Chandra Banik, cell:
41 +8801710972498].

42
43 **Consent to Participate**

44 Signing this consent indicates that you understand what will be expected of you and are willing to
45 participate in this survey.

46 Read by Participant		47 Interviewer	
48 Agreed		49 Refused	

50 **Signatures**

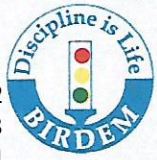
51 I hereby provide INFORMED CONSENT to take part in Steps 1 and 2 of this Risk Factor Study.

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54 **Name of the participant:**

Witness:

55
56 **Sign or fingerprint**

Sign or fingerprint



BIRDEM

An Enterprise of the
Diabetic Association of
Bangladesh

Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders



WHO Collaborating Centre
for Prevention and Control
of Diabetes

Memo No: BADAS/BIO/EA/11/033

Date: 17.01.2011

To

Palash Chandra Banik
Student, MPhil in Noncommunicable Diseases (NCD)
Department of Community Medicine (CM)
Bangladesh Institute of Health Sciences (BIHS)

Subject: Ethical Clearance

The Ethical Review Committee (ERC) of the Bangladesh Diabetic Association (BADAS) has the pleasure to accord ethical clearance to your Protocol "**Risk of foot ulcer and its determinants among type 2 diabetic subjects in Bangladesh**" subject to the condition that the guidelines must be followed carefully.

- The Ethical Review Committee approves this study from an ethical point of view upon the addressing by the researchers of the concerns as raised by the ERC affiliates.
- Approval is given for three years. Projects, which have not commenced within two years of original approval, must be re-submitted to ERC. You must inform ERC when the research has been completed.
- Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical considerations must be reported immediately to the ERC.
- Approval is given on the understanding that the 'Guidelines for Ethical Review' are adhered to.

(Prof. Tofail Ahmed, PhD)

Chairman
Ethical Review Committee

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

	Reporting Item	Page Number
Title and abstract		
Title	#1a Indicate the study's design with a commonly used term in the title or the abstract	Page-1, Line Number-1
Abstract	#1b Provide in the abstract an informative and balanced summary of what was done and what was found	Page-2,3, Line Number-25-54
Introduction		
Background / rationale	#2 Explain the scientific background and rationale for the investigation being reported	Page-4-6, Line Number-75-136
Objectives	#3 State specific objectives, including any prespecified hypotheses	Page-6, Line Number-135-136
Methods		

1	Study design	#4	Present key elements of study design early in the paper	Page-6, Line Number-139
2				
3				
4	Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page-6, Line Number-139-142
5				
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10	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	Page-6, Line Number-143-147
11				
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14		#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page-6-8, Line Number-148-202
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19	Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	Page-7, Line Number-180-202
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29	Bias	#9	Describe any efforts to address potential sources of bias	Page-8, Line Number-203-226
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33	Study size	#10	Explain how the study size was arrived at	Page-6, Line Number-139-140
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36	Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Page-9, Line Number-239-258
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41	Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	Page-9, Line Number-239-258
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45	Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
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49	Statistical methods	#12c	Explain how missing data were addressed	n/a
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52				
53	Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
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57	Statistical methods	#12e	Describe any sensitivity analyses	n/a
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Results

Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	n/a
Participants	#13b	Give reasons for non-participation at each stage	Some of the participants were not participate as they had limited time.
Participants	#13c	Consider use of a flow diagram	n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	Page-10, Line Number-242-244
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	n/a
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page-13-16, Line Number- 292-308
Main results	#16b	Report category boundaries when continuous variables were categorized	Page-10-16, Line Number- 259-308
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a

1	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	n/a
2				
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6	Discussion			
7				
8				
9	Key results	#18	Summarise key results with reference to study objectives	Page-16-20, Line Number- 309-430
10				
11				
12	Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	Page-20-21, Line Number-431-442
13				
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18	Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	Page-21, Line Number-443 to 461
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24	Generalisability	#21	Discuss the generalisability (external validity) of the study results	Page-20, Line Number-432-442
25				
26				
27				
28	Other			
29	Information			
30				
31				
32	Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page-21, Line Number-462-465
33				
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42	340	1	45	2	2	1	3	1	10000
43	341	1	70	2	1	3	3	1	30000
44	342	1	60	2	1	4	1	1	10000
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46	344	1	61	2	2	3	3	1	10000
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9	357	1	50	2	1	4	1	1	40000
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56	445	1	50	1	2	3	4	1	5000
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14	510	1	48	2	1	4	3	1	20000
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16	512	1	56	2	1	1	3	1	30000
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20	515	1	60	2	1	3	3	1	50000
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24	519	1	63	2	1	2	3	1	20000
26	520	1	42	2	1	1	3	1	60000
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35	528	1	50	2	1	1	3	1	10000
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22	567	1	40	2	1	2	3	1	13000
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29	573	1	30	2	1	2	3	1	6000
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17	613	1	51	2	1	2	3	1	15000
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24	619	1	40	1	1	1	1	1	10000
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16	662	2	55	2	2	2	3	1	2000
17	663	2	39	2	2	2	3	1	3000
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20	665	2	50	2	2	2	3	1	90000
21	666	2	54	2	2	3	3	1	10000
22	667	2	53	1	2	4	1	1	10000
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26	670	2	38	1	1	1	2	1	50000
27	671	2	61	1	1	2	1	1	20000
28	672	2	52	1	2	3	4	1	2000
29	673	2	30	1	2	3	1	1	6000
31	674	2	45	1	2	3	4	1	10000
32	675	2	38	1	2	3	2	1	2000
33	676	2	50	1	2	1	2	1	10000
34	677	2	50	1	1	4	2	1	50000
35	678	2	55	1	1	2	2	1	10000
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38	680	2	42	1	1	2	2	1	35000
39	681	2	45	1	2	1	4	1	5000
40	682	2	30	1	2	1	2	1	3000
41	683	2	45	1	2	3	4	1	20000
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45	686	2	70	1	1	3	1	1	10000
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58	698	2	35	1	1	1	4	1	10000
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60	700	2	40	1	1	4	4	1	6000

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6	704	2	50	1	2	4	4	1	10000
8	705	2	35	1	2	4	4	1	8000
9	706	2	55	1	2	2	2	1	10000
10	707	2	46	1	2	3	4	1	5000
11	708	2	50	1	2	4	4	1	10000
12	709	2	35	1	2	2	2	1	20000
14	710	2	52	1	2	2	3	1	16000
15	711	2	24	1	2	4	2	1	3000
16	712	2	65	1	2	3	4	1	5000
17	713	2	40	1	2	3	2	1	10000
18	714	2	55	1	1	4	1	1	40000
20	715	2	40	1	2	3	4	1	2000
21	716	2	45	1	2	4	4	1	10000
22	717	2	51	1	2	4	4	1	5000
23	718	2	52	1	2	2	4	1	10000
24	719	2	40	1	1	4	1	1	20000
26	720	2	35	1	1	2	4	1	100000
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31	724	2	43	1	2	4	1	1	10000
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35	728	2	60	1	1	3	2	1	5000
36	729	2	60	1	1	2	1	1	30000
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39	731	2	50	1	1	3	2	1	25000
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43	734	2	80	2	1	2	3	1	10000
44	735	2	45	1	2	4	1	1	2000
45	736	2	32	1	2	2	1	1	15000
46	737	2	62	1	2	2	4	1	100000
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52	742	2	35	1	2	2	4	1	22000
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56	745	2	32	1	2	4	1	1	30000
57	746	2	49	1	2	3	4	1	2000
58	747	2	65	2	1	3	3	1	9000
59	748	2	52	2	2	4	3	1	30000
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52	792	2	60	2	2	1	3	1	6000
53	793	2	71	2	2	1	3	1	3000
54	794	2	44	2	1	2	3	1	5000
56	795	2	45	2	1	1	3	1	45000
57	796	2	56	2	1	3	1	1	2000
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9	807	2	60	2	2	2	3	1	20000
10	808	2	60	2	1	2	3	1	10000
11	809	2	27	2	1	3	3	1	2000
12	810	2	61	2	2	2	3	1	25000
13	811	2	55	2	2	3	3	1	20000
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15	813	2	35	2	1	3	3	1	6000
16	814	2	60	2	2	3	3	1	3000
17	815	2	45	2	1	3	3	1	10000
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23	821	2	62	2	2	2	3	1	10000
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27	825	2	65	2	2	2	3	1	10000
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32	830	2	56	1	2	3	2	1	100000
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34	832	2	42	1	2	3	1	1	5000
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41	839	2	50	2	2	2	3	1	6000
42	840	2	45	1	2	2	4	1	10000
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45	843	2	55	1	1	2	2	1	8000
46	844	2	50	2	2	2	3	1	10000
47	845	2	22	1	2	4	2	1	8000
48	846	2	45	1	2	2	2	1	4000
49	847	2	35	1	2	2	4	2	20000
50	848	2	45	1	2	1	4	1	10000
51	849	2	48	1	2	4	1	1	20000

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5	853	2	59	1	2	3	2	1	20000
6	854	2	92	2	2	2	3	1	1500
7	855	2	50	1	2	3	1	1	30000
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9	857	2	27	1	1	1	3	1	10000
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14	862	2	52	1	1	4	4	1	10000
15	863	2	35	1	1	3	2	1	10000
16	864	2	20	1	1	4	1	1	6000
17	865	2	35	1	2	4	1	1	5000
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26	874	2	60	1	1	3	4	1	10000
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28	876	2	55	1	2	1	4	1	20000
29	877	2	35	1	2	3	1	1	5000
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31	879	2	56	2	2	1	3	1	10000
32	880	2	46	2	2	1	4	1	40000
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34	882	2	45	2	1	2	3	1	40000
35	883	2	58	2	2	2	3	1	3000
36	884	2	73	2	2	2	3	1	10000
37	885	2	48	2	2	1	3	1	15000
38	886	2	43	2	2	2	3	1	4000
39	887	2	45	2	2	2	3	1	12000
40	888	2	39	2	2	2	3	1	10000
41	889	2	55	2	2	2	3	1	15000
42	890	2	55	2	2	2	3	1	14000
43	891	2	35	2	2	1	3	1	4000
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46	894	2	44	2	2	2	3	1	3000
47	895	2	66	2	2	3	3	1	2000
48	896	2	59	2	1	2	3	1	30000
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50	898	2	33	2	2	2	3	1	10000
51	899	2	34	2	2	3	3	1	10000

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7	905	2	25	2	2	2	3	1	25000
8	906	2	47	2	2	1	3	1	10000
9	907	2	55	2	2	2	3	1	40000
10	908	2	60	2	1	1	3	1	10000
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14	912	2	54	2	1	4	1	1	40000
15	913	2	36	2	2	2	4	1	15000
16	914	2	40	2	2	2	2	1	10000
17	915	2	68	2	1	1	3	1	3000
18	916	2	58	2	1	1	3	1	50000
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21	919	2	40	2	2	2	2	1	9000
22	920	2	57	2	1	2	3	1	50000
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13	961	2	55	2	2	1	3	1	6000
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22	970	2	56	1	2	4	1	1	20000
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27	975	2	78	1	2	3	2	1	1000
28	976	2	52	1	1	3	1	1	20000
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8	1005	2	55	2	2	1	3	1	10000
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10	1007	2	74	2	1	3	3	1	5000
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12	1009	2	70	2	1	2	3	1	4000
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60	1049	2	42	2	1	3	3	1	10000

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9	1057	2	60	2	2	4	1	1	8000
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11	1059	2	56	2	2	1	3	1	30000
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16	1064	2	49	2	2	2	3	1	8000
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19	1067	2	55	2	1	2	3	1	10000
20	1068	2	93	2	1	3	3	1	50000
21	1069	2	68	2	1	1	3	1	60000
22	1070	2	70	2	2	1	3	1	5000
23	1071	2	60	1	1	3	1	1	8000
24	1072	2	59	1	1	4	1	1	32000
25	1073	2	75	1	1	2	1	1	25000
26	1074	2	80	1	2	3	2	1	30000
27	1075	2	48	1	1	3	1	1	20000
28	1076	2	30	1	1	1	1	1	15000
29	1077	2	44	1	1	4	1	1	30000
30	1078	2	65	1	2	3	1	1	50000
31	1079	2	52	1	1	3	1	1	20000
32	1080	2	47	1	1	2	2	1	15000
33	1081	2	42	1	2	2	4	1	30000
34	1082	2	75	1	1	3	4	1	20000
35	1083	2	50	1	1	2	2	1	5000
36	1084	2	36	1	1	2	1	1	8000
37	1085	2	24	1	2	3	2	1	7000
38	1086	2	47	1	2	4	1	1	10000
39	1087	2	41	1	1	3	1	1	7000
40	1088	2	49	2	1	2	3	1	20000
41	1089	2	35	2	1	1	3	1	30000
42	1090	2	37	2	1	1	3	1	70000
43	1091	2	50	2	1	2	3	1	6000
44	1092	2	50	1	1	3	1	2	40000
45	1093	2	23	1	1	3	4	1	20000
46	1094	2	52	1	1	3	1	1	10000
47	1095	2	30	1	2	1	4	1	7000
48	1096	2	45	2	1	2	3	1	10000
49	1097	2	60	1	2	1	4	1	8000
50	1098	2	42	2	2	1	3	1	12000
51	1099	2	35	2	1	1	3	1	60000

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2	1100	2	53	1	1	1	4	1	25000
3	1101	2	70	1	1	3	2	1	10000
4	1102	2	46	2	1	2	3	1	15000
5	1103	2	43	2	2	1	3	1	20000
6	1104	2	49	2	1	2	3	1	20000
8	1105	2	70	1	1	4	1	1	7000
9	1106	2	79	2	1	1	3	1	50000
10	1107	2	25	2	1	3	3	1	50000
11	1108	2	40	1	1	1	4	1	10000
12	1109	2	50	2	1	1	3	1	10000
13	1110	2	30	2	1	1	3	1	50000
14	1111	2	46	1	1	3	2	1	3000
15	1112	2	70	1	2	2	4	1	25000
16	1113	2	35	1	1	4	4	1	5000
17	1114	2	45	1	1	4	1	1	30000
18	1115	2	47	1	1	4	4	1	30000
19	1116	2	65	2	1	1	3	1	15000
20	1117	2	20	2	2	1	3	1	10000
21	1118	2	45	2	2	1	3	1	6000
22	1119	2	55	1	1	1	1	1	10000
23	1120	2	65	2	1	2	3	1	30000
24	1121	2	46	1	1	2	1	1	5000
25	1122	2	45	1	1	4	4	1	10000
26	1123	2	41	1	2	2	2	1	30000
27	1124	2	47	2	2	1	3	1	20000
28	1125	2	55	2	1	2	3	1	10000
29	1126	2	70	2	2	1	3	1	20000
30	1127	2	43	2	1	4	4	1	15000
31	1128	2	55	1	1	3	2	1	7000
32	1129	2	55	2	1	2	3	1	40000
33	1130	2	72	2	1	3	3	1	25000
34	1131	2	40	2	2	1	3	1	20000
35	1132	2	39	1	1	3	1	1	10000
36	1133	2	70	2	1	2	3	1	15000
37	1134	2	50	2	2	1	3	1	15000
38	1135	2	35	1	2	1	4	1	3000
39	1136	2	42	2	1	2	3	1	15000
40	1137	2	50	2	1	4	1	1	7000
41	1138	2	42	2	1	2	3	1	7000
42	1139	2	36	2	2	1	3	1	5000
43	1140	2	55	2	1	1	3	1	10000
44	1141	2	50	1	2	4	1	1	5000
45	1142	2	60	2	1	2	3	1	60000
46	1143	2	45	2	2	2	3	1	10000
47	1144	2	60	1	2	1	4	1	3000
48	1145	2	73	2	2	3	3	1	30000
49	1146	2	90	2	2	2	3	1	4000
50	1147	2	40	2	1	2	3	1	5000
51	1148	2	46	2	1	2	3	1	15000
52	1149	2	56	2	1	1	3	1	15000

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2	1150	2	45	2	1	1	3	1	2000
3	1151	2	55	2	1	2	2	1	10000
4	1152	2	42	2	2	2	2	1	10000
5	1153	2	50	2	2	2	3	1	20000
6	1154	2	45	2	2	1	3	1	3000
7	1155	2	42	2	2	2	3	1	30000
8	1156	2	35	2	2	2	3	1	3000
9	1157	2	45	1	2	3	4	1	5000
10	1158	2	42	1	2	4	4	1	10000
11	1159	2	65	2	2	2	3	1	80000
12	1160	2	40	2	2	2	3	1	5000
13	1161	2	55	2	1	1	3	1	10000
14	1162	2	60	1	2	2	2	1	5000
15	1163	2	50	1	2	1	4	1	15000
16	1164	2	47	2	2	1	3	1	15000
17	1165	2	70	1	2	3	4	1	5000
18	1166	2	52	2	1	2	3	1	10000
19	1167	2	40	1	2	3	4	1	20000
20	1168	2	40	2	2	1	3	1	4000
21	1169	2	60	2	2	1	3	1	12000
22	1170	2	46	1	2	4	1	1	15000
23	1171	2	40	1	2	3	4	1	5000
24	1172	2	50	2	1	2	3	1	10000
25	1173	2	50	2	2	1	3	1	8000
26	1174	2	40	2	2	1	3	1	15000
27	1175	2	56	2	1	3	3	1	10000
28	1176	2	60	2	2	2	3	1	3000
29	1177	2	60	1	2	3	2	1	30000
30	1178	2	30	2	2	2	3	1	15000
31	1179	2	40	1	2	3	4	1	3000
32	1180	2	30	2	2	1	3	1	30000
33	1181	2	55	2	2	2	3	1	8000
34	1182	2	60	2	2	1	3	1	20000
35	1183	2	65	2	2	3	3	1	10000
36	1184	2	41	2	2	1	3	1	7000
37	1185	2	60	2	2	2	3	1	6000
38	1186	2	30	2	2	1	3	1	6000
39	1187	2	35	2	2	1	3	1	60000
40	1188	2	56	2	2	1	3	1	30000
41	1189	2	56	2	2	1	3	1	10000
42	1190	2	72	1	2	2	1	1	5000
43	1191	2	65	1	2	3	2	1	20000
44	1192	2	54	1	2	3	1	1	11500
45	1193	2	55	1	2	2	1	1	10000
46	1194	2	45	2	2	2	4	1	10000
47	1195	2	45	1	1	4	1	1	6000
48	1196	2	63	2	2	2	3	1	50000
49	1197	2	70	2	2	1	3	1	40000
50	1198	2	68	2	2	1	3	1	20000
51	1199	2	37	1	1	3	4	1	10000

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2	1200	2	59	2	1	2	4	1	2500
3									
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For peer review only

	BMI	Q18_dur_DN	insulin_user	Q20_FBG	Q21_RBG	_current_sn6	_current_	PA	use_fitting_f
1									
2									
3	22.22222	8	2	8.9	10.9	2	2	2	1
4	26.25499	2	2	7.2	11.5	2	2	1	1
5	25.63117	8	2	6.4	10.5	2	2	2	1
6									
7	23.55556	12	2	9	12	2	2	1	1
8	26.57538	15	1	9.8	13.5	2	1	1	1
9	23.55556	11	1	6.4	9.1	2	2	1	1
10	24.86395	1	2	5.5	8.4	2	2	2	1
11	31.73973	6	1	5.7	7.8	2	2	2	1
12									
13	24	20	2	5.2	6.6	2	1	1	1
14	29.17489	19	1	7.7	12	2	1	2	1
15	22.21368	11	2	6.6	8.9	2	1	2	1
16	22.37034	3	2	6.2	11.2	2	1	2	1
17	23.82813	7	2	5.5	7.8	2	2	1	1
18	23.11111	14	1	6.5	8.4	2	2	2	1
19									
20	36.21228	8	2	7.9	8.9	2	2	2	1
21	23.55556	14	1	6.3	11.5	2	2	2	1
22	26.3656	13	2	6.9	9.5	2	2	2	1
23	21.48438	8	2	3.2	11.5	2	2	2	1
24	25.91068	10	2	5.8	7.2	2	2	1	1
25	24.76757	2	2	5.3	7.6	2	1	2	1
26									
27	25	8	2	7.1	14.7	2	1	1	1
28	23.8048	3	1	9.7	16.9	2	2	1	1
29	25.71166	15	2	5.2	9.9	1	2	1	1
30	23.73996	7	2	9.1	11.3	2	2	2	1
31	20.80856	8	2	8.5	13.6	2	2	2	1
32	22.03857	2	2	4.5	12.5	2	2	2	1
33	24.38653	6	1	5.2	9.7	1	1	1	1
34	26.12861	7	2	6	10.2	2	2	1	1
35	22.30815	15	1	7	12.7	2	2	2	1
36	23.91883	3	2	5.3	6.4	1	1	2	1
37	24.97399	15	1	4.1	7.2	2	2	2	2
38	25.81663	5	2	6.6	8.6	1	2	2	1
39	26.15933	19	1	10	18	2	2	1	2
40	25.03992	13	2	17.9	14.2	2	2	2	1
41	20.17715	15	1	10	15	1	2	2	1
42	24.38237	5	2	6.8	13.2	2	2	2	1
43	19.00391	3	2	6	7.5	2	2	2	1
44	28.99931	12	1	4.1	7.2	2	2	2	1
45	24.14152	7	1	5.9	12.5	1	1	1	1
46	28.57796	12	1	6.6	9.9	2	1	2	1
47	23.11111	11	1	6.9	10.7	2	2	1	1
48	22.10029	12	1	5.8	7.2	2	2	2	1
49	25.71166	10	2	6.2	8.1	2	1	2	1
50	25.91068	5	2	4.2	9.6	1	2	2	2
51	25.63117	2	2	5.9	7.7	1	2	1	1
52	19.95935	17	1	5	8.9	2	1	2	1
53	24.53897	21	1	5.9	11.1	2	2	2	1
54	24.97399	16	1	8.8	16	1	1	2	1
55	28.959	12	2	5.2	6.9	2	1	2	1

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2	25.45236	6	2	6.9	8.6	2	2	1	1
3	28.51563	11	1	6.8	11.2	2	2	1	1
4	32.88919	7	2	7	8.5	2	2	2	1
5	26.57313	6	2	6.8	8.9	2	2	2	1
6	23.55556	14	1	6.7	11.9	2	2	2	1
7	26.3656	7	2	6.911	11.1	2	2	2	1
8	23.4375	15	2	7.2	8.3	2	2	2	2
9	22.03173	26	1	6.2	7.2	2	2	2	1
10	27.11111	23	2	9	13	2	2	2	1
11	21.875	24	2	6.7	13	2	2	2	1
12	29.38476	5	2	6	10.5	2	2	1	1
13	30.07813	3	2	5.9	10.2	2	2	2	1
14	22.03857	9	1	5.1	8.2	2	2	1	1
15	27.91552	10	2	6.4	13.9	1	2	2	1
16	24.21875	20	2	5.7	9.8	2	1	2	1
17	17.99015	25	1	6	11	1	1	1	1
18	27.34375	5	2	5.8	9.9	2	2	1	1
19	32.46618	20	2	9.3	9.9	2	2	2	1
20	24.00549	3	2	6.7	10.3	2	1	2	1
21	24.52435	8	2	8.2	11.5	2	1	1	1
22	26.29758	25	2	6.4	8.4	1	2	1	1
23	24.39482	1	2	6.8	11	2	1	2	1
24	24.79667	1	1	5.2	8	2	2	2	1
25	23.11111	10	1	8.1	12	2	2	2	1
26	37.53049	1	2	4.9	6.2	2	2	2	1
27	22.22222	3	2	5.8	8	2	1	2	1
28	23.11111	1	2	7.2	11.2	2	2	2	1
29	24.64665	12	2	8.8	14.4	2	1	2	1
30	30.29778	10	2	5.3	7.2	2	2	2	1
31	27.8488	10	1	6.5	10.8	2	2	1	1
32	22.82688	10	1	7.4	8.4	2	2	1	2
33	25.5102	12	2	6.4	7.8	2	1	1	1
34	25.78125	1	2	6.2	7.5	2	2	2	1
35	28.06894	5	2	7.4	13.5	2	2	1	1
36	22.0741	15	2	6.7	7.4	2	2	2	2
37	23.42237	3	2	6.9	9.2	2	2	1	2
38	28.93407	6	2	7	10.8	2	2	1	1
39	21.64127	2	2	7.2	10.7	2	2	2	1
40	26.17188	8	2	6.6	8.1	2	1	1	1
41	29.35752	5	2	6.8	12.1	2	2	2	1
42	27.20961	2	2	5.1	6.1	2	2	1	1
43	25.56611	5	2	6.6	7.6	2	2	1	1
44	23.8048	5	2	6.1	11.6	2	2	1	1
45	24.00549	10	1	6	10.4	2	2	2	2
46	23.73996	16	1	8.3	10.8	2	2	1	1
47	29.08613	5	2	6.4	8.8	2	2	2	1
48	25.91068	8	2	7.2	13.7	2	1	1	1
49	17.77778	1	2	7.2	11.9	2	2	2	1
50	24.30462	1	2	7.9	13	2	2	2	1
51	25.5102	1	2	8.1	10.1	2	2	1	2

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2	24.97399	6	2	9.2	11	2	2	1	1
3	28.98114	2	1	11.6	14.2	2	2	2	1
4	28.30385	19	1	6.2	7.9	2	2	2	1
5	27.20961	2	2	4.3	4.9	2	1	2	1
6	27.76621	5	2	6	10	2	2	1	1
7	20.3428	4	2	11	13	2	1	2	1
8	27.99302	7	2	8	9	2	2	1	1
9	23.23346	2	2	7	10	2	2	1	1
10	26.27135	2	2	8	9	2	2	1	1
11	19.43635	5	2	9	14	2	2	1	1
12	28.06894	20	1	5	9	2	2	2	1
13	25.67452	8	2	4	7	2	2	2	1
14	32.89474	14	1	7	9	2	1	1	1
15	29.67495	2	2	6.5	7	2	2	2	1
16	32.51821	7	2	8	10	2	2	2	1
17	26.83518	3	2	7	13	2	1	2	1
18	27.70083	15	2	6	9	2	1	2	1
19	24.83576	3	2	7	14	2	2	1	1
20	24.76757	19	1	7	12	2	2	1	1
21	24.65303	20	1	7	9	2	1	2	1
22	25.20398	12	2	7	10	2	2	1	1
23	29.34129	2	2	6	8	2	1	2	1
24	27.55556	10	1	8	4	2	2	2	1
25	24	5	1	7	6	2	2	1	1
26	23.42209	20	2	8	11	2	2	2	1
27	26.40236	16	1	7	10	2	1	2	1
28	29.43213	2	2	6	8	2	2	2	1
29	25.55885	8	2	6	14	2	2	2	1
30	22.93975	14	2	13	17	2	2	2	1
31	29.08613	3	2	11	16	2	1	2	1
32	24.21875	4	2	4	7	2	2	1	1
33	21.36752	15	1	10	17	2	2	1	2
34	29.51594	6	2	8	11	2	1	1	1
35	18.75	1	2	5	7	2	2	1	1
36	22.0741	2	2	6	14	2	2	1	1
37	33.28402	10	2	12	14	2	2	1	1
38	26.83518	17	2	8	11	2	2	1	1
39	21.1109	5	2	9	10	2	2	2	1
40	26.22269	20	1	7	10	2	2	1	1
41	30.49353	9	2	8	11	2	1	2	1
42	27.55556	17	2	9	12	2	2	2	1
43	27.18163	6	2	13	18	2	2	2	1
44	27.00617	5	2	7	9	2	2	2	1
45	26.03749	10	2	4	14	2	2	1	2
46	24	2	2	7	9	2	2	2	2
47	28.76187	16	2	10	11	2	2	1	1
48	23.83301	1	2	6	9	2	2	2	1
49	23.83301	1	2	5	6	2	2	2	1
50	23.8054	15	2	9	10	2	2	2	1
51	22.89282	5	1	9	11	2	2	2	1

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2	32	4	2	10	12	2	2	1	1
3	23.87512	1	2	6.4	7.2	2	2	1	1
4	29.09428	5	2	6	10	2	2	2	1
5	26.29849	18	2	9	10	2	2	2	1
6	29.41744	17	2	11	12	2	2	2	2
7	22.50693	6	2	9	16	2	2	1	1
8	24.31412	5	2	7	11	2	2	2	1
9	28.13366	17	2	14	24	2	2	2	1
10	33.77778	1	2	6	8	2	1	2	2
11	30.13148	5	2	7	13	2	1	2	1
12	31.07968	1	2	7	11	2	2	1	1
13	24.74745	8	2	5	6	2	2	2	1
14	23.8054	5	2	14	19	2	2	1	1
15	20.44444	1	2	5	9	2	2	1	1
16	29.86496	1	2	8	11	2	1	2	1
17	23.61275	9	2	13	17	2	1	2	1
18	28.76187	7	1	11	14	2	1	2	1
19	33.7325	4	2	6	8	2	1	2	1
20	31.90092	9	1	6	10	2	2	2	1
21	23.95123	12	2	11	13	2	1	2	1
22	21.20845	9	2	12	13	2	1	2	1
23	28.88889	1	2	6	11	2	2	1	2
24	29.26007	25	2	14	22	2	2	2	2
25	33.32756	16	2	7	12	2	2	1	2
26	31.5011	7	2	3	12	2	2	1	1
27	21.33821	3	2	7	8	2	2	2	1
28	25.10957	8	2	6	7	2	2	1	1
29	22.18364	16	2	9	16	2	2	1	1
30	28.88889	10	2	8	12	2	2	2	1
31	20.70082	11	2	5	6	2	2	1	1
32	22.67995	12	2	9	14	2	2	2	1
33	25.5367	30	2	14	16	2	1	2	1
34	27.29322	8	2	8	9	2	2	1	1
35	26.95313	2	2	6	7	2	2	1	2
36	27.55556	7	2	7	9	2	2	2	2
37	23.92242	22	2	8	18	2	2	1	2
38	21.21914	1	2	8	10	2	2	2	1
39	28	8	2	9	11	2	2	2	1
40	25.5367	25	2	6	8	2	2	1	2
41	25.80221	17	2	20	22	2	2	2	1
42	34.29355	2	1	10	12	2	2	1	2
43	25.5367	6	2	10	11	2	1	2	1
44	26.66667	5	2	6	16	2	2	1	1
45	24.65483	12	2	7	10	2	2	2	1
46	32.87311	9	1	8	12	2	2	2	1
47	29.77778	4	2	6	11	2	2	2	2
48	32.46614	7	2	5	9	2	2	1	1
49	32.29787	5	2	8	10	2	1	2	1
50	24.38653	4	2	7	8	2	2	1	2
51	33.32756	1	2	5	8	2	2	2	1

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2	21.64127	8	1	9	12	2	2	2	1
3	25.33333	6	2	17.4	8.4	2	1	2	2
4	26.47918	5	2	11.8	14.5	2	2	2	2
5	30.29778	1	2	5.6	13	2	2	1	2
6	24.55775	5	2	7.9	9.1	2	2	1	1
7	29.27796	20	2	9.4	12.5	2	2	2	1
8	21.63115	3	1	9	11.2	2	2	2	1
9	23.8054	3	2	8.7	13.3	2	2	2	2
10	24.03441	8	1	10	15	2	1	2	1
11	24.03441	5	1	13.3	24	2	2	1	1
12	27.11058	4	1	7.6	9	2	2	1	1
13	25.14861	3	2	6	8	2	2	2	2
14	28.76397	1	2	5	7	2	2	1	1
15	21.56455	1	2	6	8	2	2	2	1
16	23.87512	15	2	6	10	2	2	1	1
17	23.79536	2	1	4	9	2	2	2	1
18	26.95313	1	2	9.5	17	2	2	2	1
19	32.8125	12	1	7	4	2	2	2	1
20	22.3403	1	2	6	11	2	2	1	1
21	26.95313	10	1	14	22	2	2	1	1
22	22.26563	5	1	11	14	2	2	1	1
23	20.68515	11	2	6	7	2	2	1	2
24	28.04967	1	2	6	8	2	2	1	1
25	25.5367	15	1	17	30	2	2	1	1
26	26.7094	16	1	6	17	2	2	1	1
27	26.66667	20	1	8	16	2	2	1	1
28	23.22543	1	2	8	14	2	2	1	1
29	26.57313	1	2	7	16	2	2	1	1
30	22.03173	1	2	6	19.9	1	2	1	1
31	26.67276	3	2	8	14	2	2	2	1
32	30.07813	1	2	6	10	1	2	2	1
33	26.17188	4	2	5	9	2	2	1	1
34	25.68956	12	2	9	14	1	2	1	1
35	22.30815	3	2	12	19	1	2	2	1
36	24.50895	4	2	5	9	2	2	1	1
37	21.875	3	2	7	9	2	2	2	1
38	26.43807	3	2	7	10	2	2	2	1
39	26.17188	10	2	8	8	2	2	1	1
40	18.55288	22	2	9	12	2	2	1	2
41	25.39063	7	2	5	6	2	2	2	1
42	25.63117	14	2	6	13	1	1	1	1
43	25.03992	4	2	9	14	2	2	2	1
44	21.56455	3	2	6	7	2	2	1	1
45	21.19274	8	2	12	18	1	1	2	1
46	29.32099	10	2	7	9	2	2	2	1
47	26.83518	5	2	8	12	2	2	2	1
48	27.00513	8	1	14	21	1	2	2	1
49	25.40282	2	2	13	17	2	1	2	1
50	25.03992	15	2	7	10	2	2	2	1
51	23.8054	3	2	8.7	13.3	2	2	2	2

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2	24.03441	8	1	10	15	2	1	2	1
3	24.03441	5	1	13.3	24	2	2	1	1
4	27.11058	4	1	7.6	9	2	2	1	1
5	25.14861	3	2	6	8	2	2	2	2
6	28.76397	1	2	5	7	2	2	1	1
7	21.56455	1	2	6	8	2	2	2	1
8	23.87512	15	2	6	10	2	2	1	1
9	23.79536	2	1	4	8	2	2	2	1
10	26.95313	1	2	9.5	17	2	2	2	1
11	32.8125	12	1	7	9	2	2	2	1
12	24.03441	8	1	10	15	2	1	2	1
13	24.03441	5	1	13.3	24	2	2	1	1
14	27.11058	4	1	7.6	9	2	2	1	1
15	25.14861	3	2	6	8	2	2	2	2
16	28.76397	1	2	5	7	2	2	1	1
17	21.56455	1	2	6	8	2	2	2	1
18	23.87512	15	2	6	10	2	2	1	1
19	23.79536	2	1	4	5	2	2	2	1
20	26.95313	1	2	9.5	17	2	2	2	1
21	32.8125	12	2	7	4	2	2	2	1
22	22.3403	1	2	6	11	2	2	1	1
23	26.63892	4	1	10	18	2	1	1	1
24	32.88889	10	1	11	13	2	2	1	1
25	22.15102	3	2	9	13	2	2	1	1
26	23.29072	4	2	15	18	2	1	1	1
27	24.59491	10	2	10	11	2	1	1	1
28	30.29778	15	1	9	13	2	1	1	1
29	21.21832	4	1	10	18	2	1	1	1
30	30.22222	4	1	7	13	2	2	2	1
31	22.94213	3	2	9	13	2	2	1	1
32	32.08944	12	1	6	16	2	1	1	1
33	28.99931	10	2	4	10	2	2	2	1
34	27.97068	8	2	9	13	2	1	1	1
35	24.14152	4	1	10	18	2	1	1	1
36	29.33333	7	1	5	7	2	2	1	1
37	24.14152	6	2	7	12	2	2	1	1
38	23.29072	4	2	15	18	2	1	1	1
39	24.59491	10	2	10	11	2	1	1	1
40	25.33333	6	2	17.4	8.4	2	1	2	2
41	26.47918	5	2	11.8	14.5	2	2	2	2
42	30.29778	1	2	5.6	13	2	2	1	2
43	24.55775	5	2	7.9	9.1	2	2	1	1
44	29.27796	20	1	9.4	12.5	2	2	2	1
45	21.63115	3	1	9	11.2	2	2	2	1
46	23.8054	3	2	8.7	13.3	2	2	2	2
47	24.03441	8	1	10	15	2	1	2	1
48	27.82931	7	2	5	9	2	2	1	1
49	27.11058	4	1	7.6	9	2	2	1	1
50	25.14861	3	2	6	8	2	2	2	2
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2	18.96193	15	1	6	8	2	2	2	1
3	27.40766	3	2	7	14	2	1	1	2
4	21.36752	1	2	7	8	1	2	1	1
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6	27.81588	3	1	8	16	2	1	1	1
7	26.04167	10	1	7	8	2	1	2	1
8	22.64087	4	2	8	16	2	2	2	1
9	25.39022	1	2	8	10	2	2	1	1
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11	24.65483	10	1	9	19	2	2	1	1
12	24.11265	2	2	7	8	2	2	2	1
13	24.24392	7	1	7	16	2	1	1	1
14	24.39482	5	2	6	10	2	2	2	1
15	27.23922	4	2	8	13	2	2	2	1
16	28.45293	6	2	6	11	2	2	2	1
17	26.04005	1	2	7	11	2	2	1	1
18	19.72387	6	2	14	17	2	2	2	2
19	26.52392	3	2	10	14	2	1	1	1
20	21.91381	6	1	11	16	2	2	2	1
21	24.24392	3	2	9	11	2	2	2	1
22	28.45293	14	1	6	9	2	1	2	1
23	28.3771	24	2	9	11	2	2	1	1
24	28.617	2	2	11	17	2	2	1	1
25	27.19179	6	2	7	11	2	2	2	2
26	25.87858	1	2	5	9	2	2	2	1
27	31.34645	1	2	13	23	2	2	2	1
28	34.72222	10	2	8	14	2	1	2	1
29	23.83301	14	2	7	11	2	2	1	1
30	29.89969	12	1	7	16	2	2	2	1
31	24.67702	11	1	6	12	1	2	2	1
32	29.27796	9	2	7	14	2	1	1	1
33	18.02596	1	2	7	8	1	2	1	1
34	25.1559	16	2	7	12	1	1	1	1
35	25.33333	1	2	7	8	2	2	1	1
36	23.82813	2	2	4	10	2	2	1	1
37	29.33333	1	2	12	20	2	2	1	1
38	23.33768	6	1	9	10	2	1	1	1
39	32.71862	5	1	9	11	2	2	1	1
40	22.60026	4	1	5	11	2	2	1	1
41	24.03461	2	2	5	10	2	2	1	1
42	24.03441	1	2	6	16	2	1	1	1
43	34.31953	1	1	7	8	2	2	1	1
44	28.67263	16	1	13	15	2	2	1	1
45	28.93519	8	1	11	14	2	2	1	1
46	32.31096	15	2	6	8	2	2	1	1
47	23.04688	18	1	9	11	2	2	2	1
48	24.22145	2	2	6	7	1	1	2	1
49	20.95717	1	2	7	8	2	2	2	1
50	23.62445	4	1	6	8	1	2	2	1
51	30.38194	10	2	5	9	2	2	2	1

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2	32.46753	2	2	5	9	2	2	2	1
3	18.36547	5	2	5.5	8	2	2	2	1
4	23.30668	10	1	13.4	20	2	2	2	1
5	23.87543	20	2	8	14	2	2	2	1
6	23.87512	1	1	7	11	2	2	2	1
7	24.91077	9	1	6	8	2	2	2	1
8	21.92613	7	1	7	9	2	2	2	1
9	37.10575	18	1	8	12	2	2	2	1
10	30.48338	5	2	5	7	2	2	2	1
11	25.87606	15	2	6	11	2	2	2	1
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13	31.55556	3	2	9	14	2	2	2	1
14	27.63037	20	1	8	11	2	2	2	1
15	24.14152	13	2	5	8	2	2	2	1
16	29.08163	1	2	7	8	2	1	2	1
17	32.46618	3	1	8	3	2	2	2	2
18	30.13148	10	2	11	18	2	1	2	2
19	34.24499	8	1	15	20	2	1	2	1
20	32.04995	3	2	6	8	2	2	2	1
21	27.88762	8	2	5	7	2	1	2	1
22	27.76621	8	1	14	17	2	2	1	1
23	22.22222	1	2	5	7.2	2	2	2	1
24	22.65625	3	2	8.1	11.3	2	2	2	1
25	27.88762	8	2	5	7	2	1	2	1
26	43.67106	13	1	7	9	2	2	2	1
27	30.29778	11	2	7	9	2	2	2	1
28	28.13366	8	2	5	10	2	2	2	2
29	24.14152	13	2	5	8	2	2	2	1
30	28.93519	20	1	6	13	2	2	2	1
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32	29.13632	25	1	9	12	2	2	2	1
33	23.8054	9	2	8	10	2	1	2	1
34	34.24499	8	1	15	20	2	1	2	1
35	30.08006	1	1	8	10	2	2	2	1
36	21.09619	2	2	6	8	2	2	2	1
37	23.8054	2	1	8	11	2	2	2	1
38	28.04038	30	1	11	20	2	2	1	1
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40	29.59184	10	1	8	10	2	1	2	1
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42	24.9135	22	1	14	15	2	2	2	1
43	26.12245	12	1	11	12	2	1	1	1
44	28.69898	8	2	6	8	1	2	1	1
45	22.03857	14	1	5	9	2	2	1	1
46	28.30385	7	2	6	7	2	2	1	1
47	24.60973	3	2	6	10	2	2	1	1
48	26.39798	1	2	4	8	1	2	2	1
49	24.9135	34	2	7	10	1	1	1	1
50	23.4375	21	1	9	13	2	2	2	1
51	22.26563	18	2	6	7	2	2	2	1

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2	20.0796	10	1	6	8	2	2	2	1
3	24.34176	4	2	6.7	18	1	2	2	1
4	23.30668	3	1	6.1	4.7	2	1	2	1
5	27.23922	5	1	5.5	9.8	2	2	2	1
6	24.00549	1	2	5.7	7.3	2	2	2	1
7	22.51631	8	1	7.4	12.1	2	2	2	1
8	23.33768	4	2	6.1	4.7	1	2	1	1
9	27.91552	5	1	9.7	15.5	2	2	2	1
10	19.83471	8	2	6.7	4.7	2	2	1	1
11	27.25089	8	1	5.6	9	2	2	2	1
12	24.30462	3	1	8	6	2	2	2	1
13	26.31464	1	1	8	12.3	2	2	2	1
14	23.30905	12	2	8	14	2	2	2	1
15	27.30344	1	2	8.2	7	2	2	2	1
16	27.27633	4	2	4	7	2	2	2	1
17	27.05515	4	2	7	8	2	2	2	1
18	30.58802	1	2	12	10	2	2	2	1
19	23.8048	4	2	7	6	2	2	1	1
20	27.11111	3	2	7	9	2	2	2	1
21	24.23823	4	1	11	13	2	2	2	1
22	21.58003	4	2	8	11	2	2	2	1
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25	26.40236	3	1	6	11.5	1	2	2	1
26	25.65437	15	1	11	7.3	2	2	2	1
27	21.21832	2	2	11	12	2	2	2	1
28	28.90625	19	2	5	8	2	2	2	1
29	33.59375	1	2	8	11.4	2	2	2	1
30	25.86451	15	2	8	12	2	2	1	1
31	25.78125	8	2	9	15	2	2	2	1
32	23.12467	8	2	5	18	2	2	1	1
33	22.21297	7	2	10	13	2	2	2	1
34	22.47659	13	2	5	7	2	1	2	1
35	25.71166	0	2	10	12	2	2	2	1
36	20.86112	20	1	7	18	1	2	2	1
37	22.83737	5	2	6	10	2	2	2	1
38	21.51386	6	2	7	10	2	2	2	1
39	25.63692	2	2	9	11	2	2	2	1
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41	23.73866	7	2	8	11	2	1	2	1
42	25.52965	12	2	7	12	1	2	2	1
43	30.42185	5	2	6	12	2	2	2	1
44	25	1	2	7	9	2	2	2	1
45	20.95717	11	1	12	11	1	2	2	1
46	27.6398	14	2	12	15	2	2	2	1
47	24.97399	13	2	9	20	2	2	2	1
48	29.40227	2	2	6	9	1	1	2	1
49	23.87512	11	1	6	9	2	2	2	1
50	20.79673	10	2	10	14	2	2	2	1
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4	22.0741	20	1	13	15	2	1	2	1
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10	27.20961	11	2	7	9	2	2	2	1
11	29.51594	14	1	13	15	2	2	2	1
12	33.7477	3	1	13	14	2	2	2	1
13	32.7316	1	2	7	8	2	2	2	1
14	27.67874	9	1	7	8	2	2	2	1
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16	27.19179	10	1	12	11	2	1	2	1
17	26.77593	3	2	7	9	2	2	2	1
18	27.67874	3	2	11	12	2	2	2	1
19	20.8292	7	1	15	18	2	1	2	1
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21	27.11111	3	2	6	8	2	2	2	1
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24	30.74787	3	2	9	11	2	2	2	1
25	30.63043	4	1	9	11	2	1	2	1
26	18.98659	10	1	12	16	2	1	2	1
27	24.14152	4	1	6	8	2	2	2	1
28	26.93572	15	1	18	20	2	2	2	1
29	33.22753	1	1	7	9	2	2	2	1
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31	45.88009	2	1	10	20	2	2	2	1
32	28.25097	12	1	5	8	2	2	2	1
33	33.69494	2	1	13	18	2	1	2	1
34	23.61275	6	1	6	12	2	2	2	1
35	17.25838	5	1	6	8	2	2	2	1
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37	32.83918	6	1	7	9	2	1	2	1
38	25.29938	9	1	8	14	2	2	2	1
39	32.31096	2	2	4	8	2	2	2	2
40	21.64127	2	2	7	9	2	2	2	1
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43	27.27633	5	1	5	9	2	1	2	1
44	27.97068	5	1	7	9	2	1	2	1
45	26.91273	8	1	7	9	2	2	2	1
46	34.43526	2	1	7	9	2	2	2	1
47	28.13366	4	1	7	9	2	1	2	1
48	23.1911	1	1	7	8	2	2	2	1
49	26.27135	10	1	11	14	2	1	2	1
50	30.11028	14	2	7	6.5	2	2	2	1
51	29.26997	12	1	7	8	2	1	2	1

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2	32.45472	1	1	7	9	2	2	2	1
3	30.80125	9	2	8	11.1	2	1	2	1
4	27.55556	1	2	6.3	9.8	2	2	2	1
5	31.29737	16	1	11.8	13.1	2	1	2	1
6	25.45236	12	1	9.1	11.8	2	1	2	1
7	26.3779	4	2	5.2	8.1	2	1	2	1
8	35.7072	1	2	8.5	9	2	1	2	1
9	23.47303	5	1	9.2	10	2	2	2	1
10	30.73061	2	2	5.2	7.8	2	2	2	1
11	28.30385	1	1	6	7.2	2	2	2	1
12	26.22269	1	2	4.7	5.9	2	2	2	1
13	34.69686	1	2	4.7	6.8	2	1	2	1
14	29.03179	9	1	6.8	9.8	2	2	2	1
15	23.6304	8	2	6.5	12.1	2	2	2	1
16	29.43213	6	2	12.7	17.7	2	2	2	1
17	20.2395	1	1	6.4	11.4	2	2	2	1
18	23.49524	9	1	6.8	9.1	2	2	2	1
19	27.39226	1	2	3.1	8.8	2	2	2	1
20	27.76621	2	1	11.6	19	2	2	2	1
21	16.97601	1	2	4.2	6.3	2	2	2	1
22	24	5	2	6.8	9.3	2	2	2	1
23	22.89282	1	1	7.9	16.3	2	2	2	1
24	21.77778	10	1	15.2	22.4	2	2	2	2
25	22.0741	5	1	10.4	18.1	2	1	2	1
26	29.90303	5	2	6.1	7.9	2	1	2	1
27	26.75321	18	1	6.8	10.3	2	2	2	1
28	23.8048	2	1	6.8	7.9	2	2	2	1
29	28.53746	10	2	6.3	8.3	2	2	2	1
30	19.97622	6	2	12.2	14.2	2	1	2	1
31	33.70052	11	2	5.4	7	2	2	2	1
32	23.42237	13	2	6.4	7.7	2	2	2	1
33	25.65263	5	2	7.5	8.5	2	2	2	1
34	34.70776	1	2	10.8	16.1	2	2	2	1
35	23.2446	4	1	5	7.3	2	1	2	1
36	17.85714	6	1	16.6	18.2	2	2	2	1
37	27.58621	18	2	6	12.9	2	1	2	1
38	21.58003	3	1	6.2	16.2	2	2	2	2
39	27.11058	9	2	10.7	13.2	2	2	2	1
40	17.30104	11	1	6.7	9.3	2	1	2	1
41	27.47138	3	2	11	14	2	2	2	1
42	29.96878	4	1	7.2	11.2	2	2	2	2
43	26.84067	6	2	5	9.2	2	2	2	1
44	22.22222	5	2	6.4	9	2	2	2	1
45	27.05515	6	1	5.3	8	2	2	1	1
46	27.76621	1	1	5.7	8.9	2	2	1	1
47	21.70139	15	2	1.2	3.6	2	2	2	1
48	23.18339	6	2	9.5	11.3	2	2	2	2
49	26.67276	8	1	6	8.5	2	2	2	1
50	25.10957	5	1	9.8	12.1	2	2	2	1
51	22.49135	5	1	13.2	17.3	2	2	2	1

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2	24.12175	12	2	9.6	16.8	1	2	2	1
3	22.52151	1	2	5.6	8.5	2	2	1	1
4	31.99217	6	1	5	10	2	1	2	1
5	32.83918	3	2	4	8	2	2	2	1
6	22.82688	2	2	14	18	2	1	1	1
7	24.44444	6	2	6	8	2	2	1	2
8	23.45656	3	2	5	8	2	2	2	2
9	25.33333	3	2	10	22	2	1	2	1
10	24.44444	1	2	6.5	9	2	1	1	1
11	20.76125	10	1	11	13	1	1	1	1
12	23.14815	3	1	11	14	2	2	1	1
13	24.34176	2.5	2	6.6	7.4	2	2	2	1
14	22.22222	12	2	8.5	11.3	2	2	1	1
15	24.45107	10	2	7	10	2	1	1	1
16	22.82688	3	2	6	7	2	2	2	1
17	21.45727	5	1	6	5	2	2	2	1
18	26.89618	3	2	8	9	2	2	2	1
19	27.05515	10	2	4.5	8	2	2	2	1
20	23.49524	2	2	14	17	2	2	1	1
21	27.02581	4	2	8	14	2	2	2	1
22	25.5102	4	2	7	11	2	2	2	1
23	28.80441	3	1	10.11	18.1	2	2	2	1
24	31.95763	3	1	4	8	2	2	2	2
25	24.79667	6	2	8	12	2	2	1	1
26	20.81165	5	2	9	13	2	2	2	1
27	22.21368	5	2	4	6	2	2	2	1
28	19.29012	2	2	8	11	2	1	1	1
29	26.31464	2	1	12.6	15	2	2	2	2
30	18.76525	1	2	7.5	7.6	2	2	2	1
31	30.70041	6	2	5	10	2	2	1	1
32	25.33333	7	2	3.5	5.1	2	2	2	1
33	23.22543	8	1	4.8	16.8	2	2	2	1
34	22.22222	1	2	6.5	8.4	2	2	2	1
35	25.91068	3	2	5.4	8.9	2	2	2	1
36	24.80159	2	2	6	8.4	2	2	2	1
37	19.81768	2	2	8	13	2	2	2	1
38	19.39619	12	2	5.7	15	2	2	2	1
39	23.72529	4	2	5.1	7.4	2	2	2	1
40	25.39063	2	1	8	10	2	2	2	2
41	20.81165	3	1	9	11	2	1	2	1
42	18.64534	6	1	8	11	2	2	2	1
43	23.4375	2	2	6	8	2	2	2	1
44	25.88757	4	2	9	10	2	2	1	1
45	25.96953	5	1	10	13	2	2	2	1
46	21.22789	5	2	9	11	1	2	1	2
47	38.04994	4	2	11	14	2	2	2	2
48	27.68166	8	2	10	13	2	1	1	2
49	23.4375	1	2	8	11	2	2	1	1
50	28	8	2	5	8	2	2	2	1
51	19.05197	10	1	9	11	2	2	2	1

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2	27.34375	2	1	9	11	1	2	2	1
3	21.95248	5	1	6	11	2	2	2	1
4	20.81165	3	1	5	9	2	2	2	1
5	24.22145	1	2	6	8	2	2	2	1
6									
7	19.53125	10	1	10	14	2	1	2	1
8	24.21875	3	2	10	14	2	2	2	1
9	22.89282	1	2	5	6	2	2	2	1
10	21.56455	8	2	8	12	2	2	2	1
11	35.20955	1	2	9	10	2	2	2	1
12									
13	31.11111	12	2	12	16	2	2	2	1
14	22.86237	1	1	11	14	2	2	2	1
15	30.22222	6	2	4	7	2	2	2	1
16	31.21748	4	2	6	9	2	1	2	1
17	21.7502	8	2	10	13	2	2	2	1
18									
19	22.86237	6	2	5	7	2	2	2	1
20	23.58833	10	2	12	14	2	1	2	1
21	32.79321	7	2	7	10	2	2	2	2
22	20	10	2	6.3	9	2	2	2	2
23									
24	28.14787	4	2	11	15.8	2	2	2	2
25	31.11111	20	2	6	7	2	2	2	1
26	22.22222	7	2	10	9	2	2	2	1
27	31.46837	1	2	5	9	2	2	2	1
28	30.61225	14	2	8	10	2	2	1	1
29	25.56611	8	2	6	8	2	2	2	2
30									
31	33.21799	8	1	18	21	2	2	2	2
32	24.12175	7	1	5	7	2	2	1	1
33	24.97704	5	1	25	27	2	2	1	1
34	28.88889	10	1	8	9	2	2	2	1
35	21.30395	8	2	7	9	2	2	1	1
36									
37	21.22281	20	2	9	7	2	2	2	1
38	30.10212	16	1	7	12	2	2	2	1
39	29.29688	1	2	6	8	2	2	1	1
40	23.38869	3	2	10	13	2	2	2	1
41									
42	29.26007	1	1	5	7	2	2	1	1
43	27.84585	20	2	9	11	2	2	1	1
44	25.10957	5	2	3	13	2	2	2	1
45	26.7094	10	1	6	9	2	2	2	1
46	23.18339	7	1	8	17	2	2	2	2
47									
48	28.57796	2	1	13	16	2	2	1	1
49	27.11111	15	1	7	9	2	1	1	1
50	28.76397	8	2	6	9	2	2	2	1
51	27.26801	3	2	15.6	17.83	2	2	2	1
52	22.34778	8	1	15.1	17.66	2	1	2	1
53									
54	31.16344	4	1	6.3	9.6	2	2	1	1
55	22.47659	3	1	11.9	13.4	1	2	2	1
56	18.66667	10	1	18.74	21.94	2	2	1	2
57	21.64127	1	1	6.9	9.3	2	1	2	1
58	21.33333	1	2	6	7.8	2	2	1	1
59	20.45184	1	1	5.05	9.55	2	2	1	2
60	24.88889	3	1	13.6	25.66	2	1	1	2

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2	20.77562	3	1	6.3	7.6	1	1	2	1
3	19.47715	4	2	11.6	22.2	2	2	2	1
4	22.89282	1	2	8.22	15	2	2	1	1
5	22.26563	7	1	8.9	11.27	2	1	1	1
6	26.93572	5	1	8.9	10.1	2	2	2	1
7	20.19509	1	1	5.3	7	2	2	2	1
8	21.09619	9	1	11	19	2	2	2	1
9	20.50493	12	1	9	14	2	1	2	1
10	27.81588	2	1	6	17	2	2	2	1
11	19.90997	15	1	14	18	2	1	1	1
12	24.52682	5	1	6	9	2	2	2	1
13	24.38653	7	2	15	22	2	2	2	1
14	19.29012	7	2	8	16	2	2	2	1
15	22.22222	12	1	13	21	2	2	2	2
16	22.82996	3	2	11	17	2	1	2	1
17	23.55556	6	2	5	7	2	2	2	1
18	22.64087	10	2	6	9	2	1	2	1
19	22.58271	3	1	17	21	2	1	1	1
20	14.0625	20	1	9	14	2	2	2	1
21	18.5178	7	2	11	22	1	2	2	1
22	26.29172	3	1	6	10	2	2	2	1
23	21.30395	4	2	14	21	2	2	1	1
24	15.05514	12	2	6	8	2	2	1	1
25	21.77384	14	1	8	15	2	2	1	1
26	43.80165	8	1	7	9	1	2	1	1
27	25.5102	15	1	13	16	1	1	2	1
28	21.64127	10	1	9	14	1	2	2	1
29	17.00882	1	2	6	10	2	2	2	1
30	24.76757	2	2	8	9	1	1	2	1
31	22.86237	13	2	16	24	2	2	2	1
32	19.84127	1	1	8	13	2	2	2	1
33	19.22769	9	1	8	15	1	1	2	1
34	22.26563	2	1	6	7	2	1	2	1
35	20.50493	11	2	9	15	1	2	2	2
36	23.1911	3	1	6	7	1	1	2	1
37	23.4375	1	2	6	7	2	1	2	1
38	20.93664	2	2	6	8	2	2	2	1
39	16.44737	8	1	18	20	2	2	2	1
40	21.50189	1	1	19	28	2	2	1	1
41	20.0796	1	1	17	26	1	2	2	1
42	22.31328	5	2	6	8	2	2	1	1
43	20.28123	18	1	14	22	2	2	2	1
44	21.23057	19	1	6	13	2	2	1	1
45	20.95717	24	2	12	17	2	1	1	1
46	24.34176	15	1	5	8	2	2	1	1
47	21.33821	30	1	6	9	2	2	2	1
48	22.37568	3	2	9	14	2	2	2	1
49	22.18935	12	1	7	9	2	2	2	1
50	21.71925	18	1	6	10	2	2	1	2
51	20.54569	10	1	5	8	2	1	2	1

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2	24.38653	16	1	9	13	2	1	2	1
3	29.06977	12	1	16	19	2	2	2	1
4	29.06977	12	1	16	19	2	2	2	1
5	21.875	8	2	12	20	2	2	2	2
6									
7	30.86304	9	1	6	8	2	1	1	1
8	26.02758	2	2	5.4	8.1	2	1	2	1
9	21.22789	36	2	5.8	7.9	1	2	2	1
10	20.95717	24	2	12	17	2	1	1	1
11	21.00767	3	1	6.4	8	1	2	2	1
12									
13	24.09297	5	2	7	22	1	1	1	1
14	27.47624	10	1	9	12	2	2	2	1
15	23.73866	8	1	7	10	1	2	1	2
16	28.959	4	1	7	13	2	2	2	1
17	25.96454	9	1	10	17	2	1	2	1
18									
19	22.26563	2	2	6	7	1	1	1	1
20	24.30462	10	1	7.9	19	2	2	2	1
21	18.55956	12	1	7	10	2	2	2	1
22	24.67702	15	1	7	9	2	1	2	1
23									
24	15.94388	12	1	9	22	2	1	2	1
25	22.83737	5	1	7	9	2	1	2	2
26	19.69267	12	1	9	14	2	2	2	2
27	23.33768	10	1	11	14	2	1	2	1
28	22.49135	10	2	8.4	9	2	1	2	1
29	19.53125	5	2	9	12	1	2	2	1
30									
31	21.93635	12	1	11	12	2	2	2	1
32	18.30577	16	1	8	12	2	1	2	1
33	29.72108	15	1	8	10	2	1	1	1
34	25.34435	8	2	24	11	2	1	2	1
35	17.71542	1	1	7	28	2	1	2	2
36									
37	21.19274	2	1	12	17	1	1	2	1
38	26.17188	2	2	8	9	2	1	2	1
39	20.54569	20	1	8	10	2	2	1	2
40	21.33333	7	1	15	24	2	1	2	1
41									
42	23.45856	10	1	15	30	2	2	2	1
43	19.39619	9	1	24	28	2	1	2	2
44	17.1875	20	2	6	8	2	2	2	1
45	29.7442	1	2	7	8	2	1	2	1
46	21.67126	22	1	10	16	2	2	2	1
47									
48	29.05475	15	2	13	21	2	1	2	1
49	21.38394	15	1	8	10	2	2	2	1
50	23.56663	3	1	10	14	2	2	2	1
51	22.60026	17	1	12	14	2	2	2	1
52	24.38272	10	1	6	13	2	1	2	2
53									
54	25.07619	12	1	10	19	2	1	2	1
55	25.95156	3	1	7.3	8.14	2	2	2	2
56	26.23356	7	1	11	12	2	2	2	1
57	19.05197	6	2	7	9	2	1	2	1
58	22.47659	10	2	7	11	2	1	2	1
59	22.67995	3	1	8	9	2	2	2	1
60	22.86237	7	1	9	11	2	2	2	1

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2	20.77562	2	2	10	17	2	1	2	1
3	23.78121	4	2	6	8	2	2	1	2
4	22.5183	20	2	7	10	2	2	2	1
5	22.98401	3	1	6	8	2	2	2	1
6	18.59104	5	1	9	17	2	2	2	1
7	24.7768	10	2	6	24	2	1	2	1
8	26.47918	9	1	6.7	8.3	2	1	2	2
9	25.14861	6	2	7.9	10.8	2	2	1	2
10	25.96953	5	1	9.8	17	2	2	2	2
11	46.23725	12	1	9.7	11.5	2	2	2	1
12	27.40766	3	2	6	8.5	2	2	2	1
13	23.8054	4	1	8.9	14.9	2	2	2	1
14	18.08021	7	1	6.4	7.5	2	2	2	1
15	32.14286	2	1	11.6	14.6	2	1	2	1
16	23.33768	6	2	13.7	14.4	2	2	2	1
17	24.21875	3	2	6.6	24	2	2	2	1
18	26.14269	14	2	9.3	12.6	2	1	2	1
19	33.77045	1	2	13.7	24	2	1	2	1
20	25.78125	15	1	14.8	17.9	2	2	2	1
21	21.70139	1	1	3.6	8.8	2	2	2	2
22	26.67276	8	2	10.6	12.6	2	2	2	1
23	27.67874	1	2	5.2	9.2	2	2	2	1
24	18.51081	1	1	9.1	20.4	2	2	2	1
25	21.35992	12	2	5	7.1	2	1	2	1
26	25.23634	1	2	10.6	13.6	2	2	2	1
27	24.52435	1	1	5.4	6.4	2	1	2	1
28	18.85882	2	1	19	23	2	1	1	1
29	29.51594	1	2	6.4	7.8	2	2	2	1
30	26.75321	8	2	6.8	7.5	2	2	2	1
31	24.32323	1	2	8.3	12.4	2	1	1	2
32	21.00073	7	1	8.3	10.4	2	1	2	1
33	24.03461	5	2	5.8	8.7	2	1	2	1
34	21.04805	8	2	5.4	6	2	1	2	1
35	18.66667	16	1	5.7	12.2	2	1	1	1
36	23.11111	5	2	9.5	11.5	2	1	2	1
37	24.24392	3	2	4.8	6.9	2	1	2	1
38	23.37258	5	2	8.5	10.4	2	1	2	1
39	22.93975	4	1	6.7	8.8	2	2	2	1
40	23.45656	4	2	5.8	15.8	2	2	2	1
41	28.76397	1	2	6.1	8.2	2	2	2	1
42	22.82688	13	1	5.4	7.4	2	1	2	1
43	21.50189	4	2	7.9	9.9	2	1	2	1
44	23.96205	4	1	9.8	11.3	2	2	2	1
45	20.50493	8	1	11.2	13.2	2	2	2	1
46	24.34176	2	2	6.4	9.4	2	1	2	1
47	25	6	2	9.8	12.8	2	1	2	1
48	20.3428	1	2	6.1	7.4	2	2	2	1
49	18.369	4	2	7.9	17.2	2	2	2	1
50	21.875	2	1	9.8	16.8	2	2	2	1
51	22.83288	1	2	6.9	10	2	1	2	2

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2	18.32562	5	2	5.9	6	2	1	2	1
3	24.34961	15	1	9.8	14.5	2	1	2	1
4	25.15315	13	2	6.9	8.4	2	2	2	2
5	18.42025	2	1	8.7	12	2	2	2	1
6	22.4323	18	1	10	14.2	2	2	1	1
7	25.96953	4	2	10	12	2	1	2	1
8	15.78878	2	1	10.8	13.7	2	2	2	1
9	24.19649	15	2	7.2	9.7	2	2	1	2
10	23.04688	8	1	16.6	20	2	2	1	1
11	24.12175	5	2	6.9	8.7	2	2	2	1
12	17.85714	10	2	10.1	17.8	2	1	2	1
13	31.95763	3	2	8.8	10.5	2	2	2	1
14	26.66667	3	2	6.7	8.1	2	1	1	1
15	20.54419	8	1	10.6	11.1	2	2	2	1
16	24.65303	12	1	7.3	10.2	2	2	2	2
17	24.14152	2	1	8.7	10.1	2	2	2	1
18	21.73801	2	2	6.9	9.9	2	1	1	1
19	21.32513	4	2	6.3	7.3	2	1	1	1
20	22.82688	11	1	6.6	19.5	2	1	1	1
21	24.24392	14	1	9.1	13.3	2	2	2	1
22	24.34961	1	2	6.9	9.7	2	1	2	1
23	21.33333	8	2	6.7	9.8	2	1	2	1
24	19.22338	30	2	5.8	10.6	2	2	2	1
25	21.90758	8	1	7.2	15.2	2	1	1	1
26	23.49524	6	2	13	18	2	1	2	1
27	24.53897	3	2	6.9	8.9	2	1	2	1
28	25.06575	21	1	5	10.3	2	2	2	1
29	22.86237	5	1	8.4	10.7	2	2	1	1
30	20.57613	15	1	9.8	12.6	2	1	2	2
31	22.22222	3	2	9.6	15.1	2	2	2	2
32	26.83865	1	2	6.9	7.8	2	2	2	1
33	23.37258	6	2	9.6	15	2	2	1	1
34	24.34961	20	2	10.6	16.9	2	1	2	1
35	37.16563	6	2	5	6.9	2	1	2	2
36	31.11111	4	2	9.6	11.5	2	2	2	1
37	25.47666	1	1	6.7	9	2	1	2	2
38	28.617	4	1	8	10	2	1	2	1
39	17.60477	1	1	6	8.9	2	2	1	1
40	20.2395	4	2	9	10	2	2	2	1
41	23.37258	4	2	5.2	6	2	1	1	1
42	28.125	1	2	6.9	11.6	2	1	2	1
43	28.44444	12	2	5.2	6.4	2	2	2	1
44	23.82813	6	1	8.2	11.5	2	1	2	2
45	26.83865	2	2	6.7	9.8	1	1	2	1
46	21.45727	4	2	6.3	9.3	2	1	2	1
47	28.19692	2	2	5.3	11.6	2	1	2	1
48	22.31328	2	1	11.5	13.5	2	1	2	1
49	17.62538	2	1	18.4	28.6	2	2	2	1
50	18.25632	5	2	9.5	10.9	1	1	1	2
51	20.2848	4	2	6.5	9.5	2	2	2	1

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2	20.57613	5	2	6.7	9.8	2	1	2	1
3	26.47918	5	2	9.8	12.3	2	1	2	1
4	32.45568	3	2	8.7	10.3	2	2	2	1
5	33.62209	22	1	7.8	11.9	2	1	2	2
6	23.66864	3	1	6.5	9.8	2	2	2	1
7	21.33333	18	1	5.5	9.8	1	1	2	1
8	26.89232	5	2	6.8	12.2	2	2	2	2
9	22.50693	2	2	8.3	10.3	2	2	2	1
10	27.14158	1	2	7.6	8.7	2	1	1	1
11	24.14152	7	1	16.9	19.3	2	1	2	1
12	27.11111	1	2	4.9	9.8	2	1	2	1
13	22.23099	5	2	5.8	8	2	1	1	1
14	23.14815	20	2	6.8	9.7	2	2	1	2
15	33.12131	1	2	8.7	10.6	2	2	1	1
16	26.67276	1	2	7.1	8.3	2	1	2	1
17	24.76757	1	2	5.2	6.3	2	2	1	1
18	26.67276	3	2	5.8	6.8	1	2	1	1
19	20.28123	1	2	6.3	8.6	2	2	1	1
20	20.77562	1	2	10.5	21.6	1	1	1	1
21	21.09619	4	2	6.2	8.5	2	2	1	1
22	19.05197	2	2	11.5	15	2	1	1	1
23	29.33333	12	2	5.6	7.9	2	1	2	1
24	21.09619	5	1	12.2	27.3	1	1	2	1
25	28.40816	15	2	8.8	14.1	2	2	1	1
26	33.28402	5	2	10.6	16	2	2	2	1
27	26.02618	1	2	6.9	9	2	1	2	2
28	25.34435	2	2	5.2	8.6	2	2	2	2
29	26.89767	10	2	6.2	9.4	2	2	2	1
30	21.21914	5	2	6.9	8.3	2	1	1	1
31	24	5	2	8.8	12.6	2	2	2	2
32	30.25193	4	2	6.3	9.2	2	1	2	1
33	23.82813	1	2	6.6	9.7	2	1	2	1
34	24.88889	1	2	8.4	11.6	2	2	2	2
35	29.6875	3	2	5.8	7.4	2	1	2	1
36	31.20256	2	2	6.1	7.3	2	1	1	1
37	24.88889	2	1	8.5	10.5	2	1	2	2
38	20.40816	2	2	6.8	10	2	2	2	1
39	26.52392	3	2	5.8	7	2	2	1	1
40	23.8054	1	2	7.1	9.8	2	1	1	1
41	18.90204	17	1	14.8	24.8	2	2	2	1
42	17.77778	7	2	10.2	14.8	2	1	2	1
43	21.82107	1	2	12.6	18.6	2	2	2	1
44	22.22222	2	2	6.9	9.3	2	1	1	1
45	21.64127	10	2	6.9	9.8	2	1	2	1
46	23.30905	12	1	8.8	11.6	2	1	2	1
47	20.26936	6	2	8.3	10.8	2	2	1	1
48	26.03749	3	2	8.9	11.9	2	1	2	1
49	16.87886	2	1	9.8	15.5	2	1	2	1
50	29.27796	1	2	6.2	10.2	2	2	2	1
51	23.4375	2	2	14	16	2	2	1	1

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2	23.14815	1	2	9	16	2	2	1	1
3	25.96953	2	2	5.2	7.8	2	1	2	1
4	19.39619	15	2	5.4	8.4	2	1	2	2
5	27.70083	1	2	5.2	7.8	2	1	2	1
6									
7	24.23823	1	1	5.8	9.2	2	2	2	1
8	24.88889	1	2	6.7	16.2	2	2	2	2
9	24	3	2	8.7	8.2	2	1	2	1
10	28.56648	2	2	9.1	8.4	2	1	2	2
11	35.69304	4	1	7.8	16.1	2	2	2	1
12									
13	25.31545	1	2	9.2	15.6	2	1	2	1
14	29.37758	5	2	6.5	9.4	2	1	1	1
15	23.1911	4	2	6.4	12.3	2	2	1	1
16	25.77778	1	2	5.6	7.3	2	2	2	1
17	22.22222	1	1	4.6	7.2	2	2	2	1
18									
19	17.48179	20	2	5.8	7.9	2	2	2	1
20	25.43748	2	2	6.4	12.3	2	1	2	1
21	22.34778	3	2	5.8	9.4	2	2	2	2
22	24.86395	1	2	15.2	21.1	2	2	1	1
23									
24	28.72008	18	2	6.8	10.3	2	1	2	1
25	23.83301	3	2	5.8	9.7	2	2	1	1
26	25.77778	10	2	5.3	5.5	2	1	2	1
27	25.5367	2	2	9.8	10.2	2	2	2	1
28	22.07108	2	2	7	9	2	2	2	2
29	22.22222	30	2	10	20.6	2	2	1	2
30									
31	24.55775	12	2	6.9	15.6	2	2	1	1
32	12.98477	4	2	5.5	9.9	2	2	2	2
33	22.81293	2	2	5.5	10.4	2	2	2	2
34	24.83576	12	1	5.5	9.9	2	2	1	1
35	20.54569	10	2	2.6	4.5	2	2	2	1
36									
37	27.09925	1	2	5.9	10.5	2	1	2	1
38	24.83576	2	2	5.5	9.9	2	2	2	1
39	29.77778	1	2	2.6	4.5	2	2	2	1
40	25.06575	3	2	5.9	4.3	2	2	2	1
41									
42	19.90997	10	2	5.5	4.2	2	1	2	1
43	22.18935	17	2	2.6	18.1	2	2	2	1
44	23.45656	3	2	5.9	6.1	2	1	2	1
45	26.74048	5	2	6.6	8.7	2	1	2	1
46	24.52682	18	2	6.8	12.3	2	1	2	1
47									
48	24	2	2	6.2	8	2	1	2	2
49	20.88889	1	2	6.2	9.9	2	2	1	1
50	27.55556	3	2	15	20	2	1	2	1
51	15.55556	4	1	5.8	9.2	2	1	2	1
52	26.66667	20	2	6.2	9.4	2	1	2	1
53									
54	18.73049	1	1	6.2	9.6	2	2	1	1
55	19.47715	16	1	16.2	21.6	2	2	2	1
56	25.63692	2	2	5.8	7.2	2	2	2	1
57	26.56435	1	2	6.2	8.5	2	1	2	2
58	22.22222	6	2	7	11	2	2	2	2
59	25.06575	21	2	7	10	2	2	2	1
60	22.18364	1	2	6	7	2	2	2	1

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2	20.25463	1	2	6	15	2	2	2	1
3	24.65303	6	2	6	9	2	2	2	1
4	21.45727	1	2	6	8	2	2	2	1
5	22.04917	1	2	9	15	2	2	2	1
6	27.00617	3	1	6	18	2	2	2	1
7	19.29012	1	2	12	19	2	2	1	1
8	31.63265	3	2	7	12	2	2	1	2
9	25.10388	10	1	7	4	2	2	2	1
10	18.73049	2	2	6	7	2	1	2	1
11	27.30519	1	2	9	11	2	2	2	1
12	22.95918	4	2	6	5	2	2	2	1
13	24.59491	6	1	5.7	13	2	2	2	1
14	22.98743	13	2	11.1	21	2	2	2	1
15	22.07108	16	2	8.5	12	2	2	2	2
16	21.91381	8	2	8	13	2	2	2	1
17	37.06136	2	2	7	10	2	2	2	2
18	26.52392	5	2	6	7	2	2	2	1
19	36.88889	1	2	6	10	2	2	2	2
20	29.51594	1	2	5	7	2	2	2	1
21	24.4646	8	1	9	11	2	2	2	1
22	20.95717	8	1	3	6	2	2	2	1
23	21.20845	15	1	10	13	2	1	2	1
24	22.27531	24	1	7	12	2	2	2	1
25	16.86625	3	2	15	19	1	2	2	2
26	21.40309	2	2	6	21	2	2	2	2
27	33.76039	4	2	7	13	2	2	1	1
28	29.24211	8	1	7	15	1	2	2	1
29	24.38653	10	2	9	12	2	2	2	2
30	22.50693	1	2	12	15	2	2	2	1
31	20.95717	3	1	7	9	2	2	2	1
32	24.60938	14	1	7	17	2	2	2	2
33	23.55556	4	2	10	13	2	2	2	2
34	22.34778	9	2	4.5	6	2	2	2	2
35	20.79673	5	2	12	15	1	1	2	1
36	38.77551	2	2	8	10	2	2	2	2
37	27.02581	5	1	8.8	9	2	2	2	1
38	21.91381	5	1	7	23	2	2	2	1
39	25.55941	5	2	5.8	7.2	2	2	2	1
40	24.11265	1	2	5.5	8	2	2	2	2
41	27.39226	2	2	5.4	8	2	1	2	1
42	30.38194	1	2	5	9	2	2	2	1
43	26.66667	1	2	6	8	2	1	2	1
44	20.17264	7	2	11	16	2	2	2	2
45	23.78121	3	1	9	12.5	2	2	2	2
46	35.0032	12	2	9	12	2	1	2	2
47	24.69136	5	1	14	20	2	2	2	2
48	18.87755	5	2	6.5	7	2	2	2	2
49	29.96433	1	2	7	7	2	2	2	1
50	27.77227	6	2	7	9	2	2	2	2
51	29.96433	7	1	16	26	2	1	2	1

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2	28.76397	1	2	4	6	2	2	2	1
3	24.73246	1	2	8	12	2	2	2	2
4	25.39063	2	2	5.1	13	2	2	2	1
5	25	12	2	6	10	2	1	2	1
6	20.68515	7	1	13	17	2	2	1	1
7	20.88889	12	2	3	6	2	1	2	1
8	23.92569	12	2	9	16	2	2	1	1
9	23.01118	15	1	8	10	2	1	2	1
10	22.76944	3	2	6	7	2	2	1	1
11	24.88889	3	2	12.1	16.2	2	2	2	2
12	25.56611	5	2	12	16	2	2	2	1
13	25.29938	10	2	7	10	2	2	2	1
14	15.78878	2	2	15	25	2	2	2	1
15	23.37258	2	2	6	6	2	2	2	1
16	26.50212	12	2	10	10	2	2	2	1
17	26.43807	1	2	8	10	2	2	2	1
18	28.84153	2	1	12	17	2	1	2	1
19	27.11111	1	2	8.4	11.6	2	2	2	1
20	25.39063	5	2	8	10.8	2	2	2	1
21	16.88889	1	2	18.3	24	2	2	2	1
22	16.44444	2	1	4.8	6.6	2	2	2	1
23	18.97453	1	2	5.6	7	2	2	2	1
24	24.19649	1.5	2	7	9	2	2	2	1
25	27.70083	3	2	12	15	2	2	2	1
26	25.55941	3	2	16	18	2	2	2	1
27	31.11111	5	2	5	7	2	2	2	1
28	20.45184	3	2	10	13	2	2	2	1
29	28.53746	6	2	8	10	2	2	2	2
30	27.23922	4	1	7	9	2	2	2	1
31	28.88889	2	2	20	22.6	2	2	2	1
32	19.3414	9	2	16	18	2	2	2	1
33	23.11111	3	2	3	7	2	1	2	1
34	20.77562	17	1	12	15	2	2	2	1
35	24.9401	2	2	20	24	2	2	2	1
36	19.5006	10	2	8	11	2	2	2	2
37	20.66116	4	2	8	10	2	2	2	1
38	28.30533	4	2	5	7.2	2	2	2	1
39	27.30344	2	2	3	7.5	2	2	2	1
40	25.33308	2	2	8	11	2	2	2	1
41	20.44444	5	2	24	28.52	2	2	2	1
42	25.33308	8	2	3.1	8.6	2	2	2	1
43	29.16667	2	2	9	11	2	2	2	2
44	19.29012	2	2	9	11	2	2	2	1
45	24.7768	2	2	3.1	4.6	2	2	2	1
46	40.97222	2	2	10	11	2	2	2	1
47	26.74048	6	2	3.1	8.5	2	2	2	1
48	23.87512	6	2	5	6.4	2	2	2	2
49	24.38653	13	2	15	17	1	2	2	1
50	18.26151	1	2	9	12	2	2	2	1
51	40.97222	9	2	10	11	2	2	2	2

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2	23.30887	8	2	8	10	2	1	2	1
3	21.08281	3	1	10	11	2	2	2	1
4	21.82107	5	2	9	11	2	2	2	1
5	18.71804	8	1	4	8	2	2	2	1
6	16.87886	2	2	10	17	2	2	2	1
7	23.55556	20	1	11	14	2	2	2	1
8	24.87772	10	2	12	15	2	2	2	1
9	20.02884	2	2	5	6.4	2	2	2	1
10	17.14678	3	2	10	12	2	2	2	2
11	19.17458	3	2	4	6	2	2	2	1
12	24.88889	13	1	18	22	2	2	2	1
13	32.02909	4	1	10	12	2	2	2	1
14	24.32323	5	1	8	11	2	2	2	1
15	17.62538	12	1	8	12	2	2	2	1
16	19.14063	12	1	7	9	2	2	2	1
17	23.73996	25	2	18	20	2	2	2	1
18	22.83288	23	1	15	17	2	2	2	1
19	23.49524	8	2	5	7	2	2	2	1
20	26.53061	6	2	6	9	2	2	2	2
21	21.20845	10	1	9.8	14	2	2	2	1
22	25.78853	9	2	9	11	2	2	2	1
23	42.80618	1	2	5	7	2	2	2	1
24	24.97399	1	2	14	15	1	2	2	1
25	23.1405	2	1	17	21	1	1	2	1
26	25.91068	5	1	8	11	2	2	2	1
27	24.33748	1	2	6	7	2	2	2	1
28	22.10029	15	2	5	7	1	2	2	1
29	33.16327	13	2	5	8	2	2	2	1
30	17.26355	3	2	8	10	1	2	2	1
31	23.82813	5	2	11	15	2	2	2	2
32	24.55775	2	1	8	10	2	2	2	1
33	22.22222	12	1	6	9	2	2	2	2
34	20	1	2	8	12	1	2	1	1
35	31.25	3	2	7	9	2	2	2	1
36	14.09846	2	1	11	15	2	2	2	1
37	27.0538	28	1	17	19	2	2	2	2
38	23.1405	1	2	12	15	2	2	2	1
39	21.91381	1	1	4	6	2	2	2	1
40	23.37258	3	2	6.2	8.3	2	2	2	1
41	23.14815	5	2	4.2	6.4	2	1	2	1
42	20.17264	2	2	7.8	9.7	2	2	2	2
43	24.45606	12	1	6.5	8.2	2	1	2	2
44	15.75575	5	1	6.7	9.1	2	2	2	1
45	24.74745	22	1	6.1	12.4	2	2	2	1
46	25.20479	6	2	10.5	15.3	2	2	1	1
47	23.73866	2	1	10.8	14.6	2	2	2	1
48	25.5367	3	2	6.2	8.1	2	2	2	1
49	24.44444	2	2	6.8	8.1	1	2	2	1
50	23.8054	1	1	6.2	9.7	2	1	2	1
51	21.40309	3	2	5.8	9.7	2	2	2	1

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2	25.5367	4	2	10.8	18.7	2	1	1	1
3	28.99931	5	2	5.3	8.5	1	2	2	1
4	23.23346	15	2	6.3	7.6	2	2	2	1
5	25.63692	3	2	18.1	24.1	2	2	2	1
6	26.22222	14	1	9.8	15.9	2	2	2	1
7	26.40236	3	2	5.2	6.3	2	2	2	1
8	29.04866	3	1	8.8	15.5	2	2	2	1
9	29.09428	8	2	8.2	11	2	2	2	1
10	19.81405	1	2	6.2	9.9	1	1	2	1
11	25.07716	3	2	6.2	9.4	2	1	1	1
12	24.03441	9	2	6.8	10	2	2	2	1
13	22.77319	1	2	6.2	8.5	2	2	2	1
14	24.91077	11	2	17	22.7	2	2	2	1
15	25.63692	4	2	8.9	10.6	2	2	2	1
16	27.77671	1	2	6.2	8.8	2	2	2	1
17	20.41523	20	1	6.1	7.8	2	1	1	1
18	26.7094	6	2	9.8	11.5	2	2	1	1
19	18.13122	4	1	9.1	12.6	2	2	1	1
20	21.77844	2	1	17.6	26.4	2	2	1	1
21	22.86253	25	1	14.2	18.2	1	1	1	1
22	22.81293	12	1	6.3	9.5	2	1	2	1
23	23.4375	11	2	9.8	13.7	2	1	1	1
24	30.7574	15	1	6.1	8.4	2	2	2	1
25	24.6755	7	2	6.7	11	2	2	1	1
26	18.09034	5	2	6.2	10	2	2	2	1
27	26.40236	7	2	5.8	7.7	2	2	1	1
28	20.3428	3	2	10	12.8	2	2	2	1
29	32.45472	1	2	5	6	2	2	2	1
30	28.76397	8	2	12	19	2	2	2	2
31	25.33333	6	1	8	17	2	2	1	1
32	28	5	1	8.7	6	2	2	1	2
33	48.65917	9	2	7	14	2	2	1	1
34	24.57787	3	2	7	9	1	2	2	1
35	22.6659	11	2	7	11	2	2	2	1
36	26.66667	6	2	5	8	2	1	2	1
37	22.07108	10	2	5	11	2	2	2	1
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39	28.13366	1	2	8.6	7	2	2	2	1
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44	23.78121	4	2	6	8	2	2	1	2
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47	22.60026	17	1	12	14	2	2	2	1
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5	18.25632	1	2	7.4	10.9	2	1	2	1
6	17.84336	7	2	11.8	20.2	2	1	2	1
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9	26.95313	1	1	8.7	11.5	2	2	2	1
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For peer review only

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For peer review only

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45	2	2	21	2
46	2	2	21	2
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28	2	2	0	0
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For peer review only

1				
2	SEX	1=men	2=women	
3	AREA	1=urban	2=rural	
4	Education	1=illiterate	2=primary	3=secondary
5	Occupation	1=service	2=business	3=housewife
6	Marrital status	1=married	2=others	
8	Insulin use	1=user	2=non-user	
9	Current smoking	1=smoking	2=other form	
10	Current smokeless tobacco use	1=yes	2=non-user	
11	Physical activity	1=sufficient	2=insufficient	
12	Use fitting foot wear	1=yes	2=non-user	
14	History of trauma	1=yes	2=no	
15	Regular foot care	1=yes	2=no	
16	Self foot examination	1=yes	2=no	
17	Hypertension (HTN)	1=yes	2=no	
18	Diabetic retinopathy	1=yes	2=no	
19	Diabetic nephropathy	1=yes	2=no	
20	Diabetic neuropathy	1=yes	2=no	
21	Peripheral neuropathy	1=yes	2=no	
22	Peripheral arterial disease	1=yes	2=no	
23	Foot deformity	1=yes	2=no	
24	H/O amputation	1=yes	2=no	
25	H/O foot ulcer	1=yes	2=no	
27	IWGDF risk six categories	0=group 1 (0)	1=group 1 (1)	2=group 2A
28	IWGDF risk five categories	0=group 1 (0)	1=group 1 (1)	2=group 2A+2B
29				
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4=higher education
4=others

22=group 2B

31=group 3A
31=group 3A

32=group 3B
32=group 3B

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BMJ Open

Risk of diabetic foot ulcer and its associated factors among Bangladeshi subjects: a multi-centric cross-sectional study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-034058.R2
Article Type:	Original research
Date Submitted by the Author:	14-Dec-2019
Complete List of Authors:	<p>Banik, Palash; Bangladesh Institute of Health Sciences, Community Medicine; Bangladesh University of Health Sciences, Noncommunicable Diseases</p> <p>Barua, Lingkan; Bangladesh University of Health Sciences, Noncommunicable Diseases</p> <p>Moniruzzaman, Mohammad; Bangladesh Institute of Health Sciences, Community Medicine</p> <p>Mondal, Rajib; Bangladesh University of Health Sciences, Noncommunicable Diseases</p> <p>Zaman, Farhana; Bangladesh Institute of Health Sciences, Community Medicine</p> <p>Ali, Liaquat; Bangladesh University of Health Sciences, Biochemistry and Cell Biology</p>
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Diabetes and endocrinology, Epidemiology, Public health, Neurology
Keywords:	Diabetic foot < DIABETES & ENDOCRINOLOGY, DIABETES & ENDOCRINOLOGY, Bangladesh, diabetic foot ulcer risk, International Working Group on the Diabetic Foot, diabetic foot ulcer

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3 **1 Risk of diabetic foot ulcer and its associated factors among Bangladeshi subjects:**
4 **2 a multi-centric cross-sectional study**

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25 **Abstract**

26 **Objective**

27 To assess the risk of diabetic foot ulcer (DFU) and find out its associated factors
28 among type 2 diabetic (T2D) subjects of Bangladesh.

29 **Design, setting and participants**

30 This cross-sectional study recruited 1200 T2D subjects who visited sixteen centres of
31 Health Care Development Project run by Diabetic Association of Bangladesh (DAB).

32 **Primary and secondary outcome measures**

33 Risk of DFU was assessed using a modified version of International Working Group
34 on the Diabetic Foot (IWGDF) Risk Classification System. The modified system was
35 based on five parameters, namely peripheral neuropathy (PN), peripheral arterial
36 diseases (PAD), deformity, ulcer history and amputation. The risks were categorised
37 as Group 0 (no PN, no PAD), Group 1 (PN, no PAD, and no deformity), Group 2A (PN
38 and deformity, no PAD), Group 2B (PAD), Group 3A (ulcer history) and Group 3B
39 (amputation). The associated factors of DFU risk were determined using multinomial
40 logistic regression for each risk category separately.

41 **Results**

42 Overall, 44.5% of the subjects were found 'at risk' of DFU. This risk was higher among
43 men (45.6%) than women and among those who lived in rural areas (45.5%) as
44 compared to the urban population. According to IWGDF categories, the risk was
45 distributed as 55.5%, 4.2%, 11.6%, 0.3%, 20.6% and 7.9% for group 0, group 1, group
46 2A, group 2B, group 3A and group 3B respectively. The associated factors of DFU
47 (odd ratio >1) were age ≥ 50 years, rural area, low economic status, insulin use, history
48 of trauma, diabetic retinopathy and diabetic nephropathy.

49 **Conclusion**

50 A significant number of the T2D subjects under study were at risk of DFU, which

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4 51 demands an effective screening programme to reduce DFU related morbidity and
5
6 52 mortality.

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8 53 **Keywords:** diabetes; diabetic foot ulcer; diabetic foot ulcer risk; Bangladesh;
9
10 54 International Working Group on the Diabetic Foot; associated factors; risk factors

11 12 55 **Article summary**

13 14 15 56 **Strengths and limitations of this study**

- 16
17 57 • This is the first study in Bangladesh that assesses the risk of DFU using a standard
18
19 58 tool
- 20
21 59 • For the first time, the associated factors of DFU were explored to guide the
22
23 60 prevention effort
- 24
25 61 • Sex- and area-specific difference in the risk of DFU will help to identify the
26
27 62 disparities and promote decentralisation of diabetes care for all
- 28
29 63 • Because of the cross-sectional design, we could not establish any causal
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31 64 relationship between the contributing factors and risk of DFU
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33 65 • The risk of DFU may be overestimated or underestimated as all centres did not
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35 66 provide the same quality diabetes care

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75 Introduction

76 In recent years, diabetes mellitus (DM) has become a fast-growing public health
77 problem that affects both developed and developing countries [1]. The International
78 Diabetes Federation (IDF) reports that about 415 million people globally had DM in
79 2015 and it is projected to affect 642 million by 2040. It was deemed possible that by
80 the year 2040 it might even double the number [2]. Among the clinical classifications
81 of DM, Type 2 diabetes (T2D) is more common and prevalent in certain ethnic groups,
82 with estimates up to six times more common in the people of South Asian descent,
83 three times more common in those of African and African-Caribbean descent and is
84 more common in people of Chinese descent compared with the white population [3].

85 Like in other developed and developing countries affected by it, it is also highly
86 prevalent in Bangladesh. Evidence suggests that 9.7% of Bangladeshi adult population
87 (>35 years) are diabetic and 22.4% are prediabetic [4]. A trend analysis revealed an
88 increasing prevalence of DM in Bangladesh, from 4% in 1995 to 2000 and 5% in 2001
89 to 2005 to 9% in 2006 to 2010 respectively [5]. As the prevalence of diabetes increases,
90 the prevalence of long-term diabetes-related complications is also likely to increase.
91 Diabetic foot ulcer (DFU) is a common and major complication of diabetes,
92 representing a major healthcare burden with significant morbidity [6].

93 Diabetic foot is defined as the presence of infection, ulceration and/or destruction of
94 deep tissues associated with neurologic abnormalities and various degrees of
95 peripheral arterial disease (PAD) in the lower limb in patients with diabetes [7]. It is a
96 significant cause of morbidity and can lead to prolonged hospital stays, which is
97 evidenced by the fact that ~20% of diabetes related hospitalisations are related to DFU
98 [8]. The mortality rate in patients with DFU is also high and is approximately twice that
99 of the patients without ulceration [9]. Other than morbidity and mortality, the toll of
100 economic burden in terms of direct and indirect costs is also high for those having
101 DFU, estimated approximately €11.6 billion per year for Europe in 2017 and €7.6–11
102 billion among Medicare beneficiaries of the United States from 2007 to 2014 [7].

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3 103 Another issue related to foot ulcers among diabetic patient is the health-related quality
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5 104 of life that cannot be measured in economic terms. It has been reported that patients
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7 105 with foot ulcers or amputation have low health-related quality of life because of
8
9 106 substantial depression and other physical problems like inability to do simple tasks or
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11 107 recreational activities [7].
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14 108 The major risk factors of DFU are a loss of protective sensation due to diabetic
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16 109 peripheral neuropathy (DPN), peripheral arterial diseases (PAD) and trauma. However,
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18 110 the first two are not independently responsible for DFU; it is the combination
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20 111 neuropathy and PAD with trauma that leads to foot problems. It has been reported
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22 112 that trauma and PAD are major contributors to foot ulceration and diabetic neuropathy
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24 113 is the common denominator in almost 90% of DFU cases. There are some other risk
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26 114 factors namely male gender, previous foot ulceration or amputation, foot deformities,
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28 115 calluses, Charcot arthropathy and high plantar pressures have been associated with an
29
30 116 increased risk for foot ulceration. There are some diabetes-related risk factors also that
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32 117 influence the risk of foot ulcers such as the duration of diabetes, poor glycaemic
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34 118 control, diabetic retinopathy or nephropathy, poor compliance with medical
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36 119 instructions and neglectful behaviour. Some societal and behavioural risk factors also
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38 120 show significant association with DFU including low socioeconomic condition, poor
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40 121 access to healthcare services, poor educational status, living alone and smoking [7, 10].
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42 122 Previous studies have reported that the risk of diabetic foot or amputation is
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44 123 significantly lower among the Asians compared to the Europeans in the United
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46 124 Kingdom [11–12]. This reduced risk is probably due to a low prevalence of DPN and
47
48 125 PAD among Asians, but the exact reason is not fully understood. However, a previous
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50 126 study has reported prevalence of DPN among Bangladeshi subjects at 19.7% and
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52 127 found it significantly as well as independently associated with age, mode of treatment,
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54 128 income, duration of diabetes and glycaemic status [13].
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56 129 It is estimated that the lifetime risk of foot ulcers among diabetic population is 19%–
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58 130 34% [7]. To overcome this burden of DFU, it is recommended that clinicians estimate
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3 131 the risk of and the response to associated factors that increase the risk [10]. However,
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5 132 studies related to diabetic foot risk assessment and associated factors among
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7 133 Bangladeshi subjects are absolutely lacking. Hence, we were prompted to assess the
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9 134 risk of foot ulcers and sought to determine the factors that influence the risk among
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11 135 T2D patients of Bangladesh.
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136 **Methods**

137 **Study design**

138 This cross-sectional study was conducted among 1200 T2D subjects who visited
139 several centres of Health Care Development Project (HCDP) run by the Diabetic
140 Association of Bangladesh (DAB). A total of sixteen centres were selected: seven from
141 Dhaka and nine from the northern part of Bangladesh. We purposefully selected the
142 centres and followed convenient sampling technique to collect data from diabetic
143 subjects. Our exclusion criteria included presence of DFU during the interview (active
144 ulcer), acute illness of the subject, unwillingness to participate and mental instability.
145 To meet the eligibility criteria, all subjects were screened for DFU, based on their self-
146 reported statement, their clinical history, foot examination and medical records review.
147

147 **Data collection and measurement**

148 The data collection comprised of two phases and was conducted from July 2011 to
149 June 2012. In the first phase, a face-to-face interview was conducted using a pre-tested
150 questionnaire adapted from the STEP-wise approach to Surveillance (STEPS) of
151 noncommunicable diseases risk factors of World Health Organization (WHO) [14]. The
152 questionnaire collected sociodemographic and behavioural risk factors (tobacco use,
153 physical inactivity), status of diabetes (duration, medication) and its complications
154 (retinopathy, nephropathy) and foot problem-related information (neuropathy, PAD,
155 trauma, foot hygiene) of the participants. The blood glucose levels (fasting/2-hours
156 post meal) and information about diabetic nephropathy or retinopathy in the
157 participants was extracted from their diabetes records book. The last record within one
158 month was used to assess their glycaemic status. In the second phase, physical

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3 159 measurements (anthropometric and blood pressure) and foot examination were
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5 160 carried out by trained physicians. The anthropometric and blood pressure
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7 161 measurement followed the methods described in 'Noncommunicable disease risk
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9 162 factors survey Bangladesh 2010' [15]. The anthropometric measurements included
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11 163 height, weight, waist circumference, hip circumference and derivatives like body mass
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13 164 index (BMI) and waist-hip ratio.

165 **Assessment of DFU**

166 The risk of DFU was assessed using a modified version of International Working Group
167 on the Diabetic Foot (IWGDF) Risk Classification System proposed by Lavery *et al.* [16].
168 We screened each patient to identify lower extremity complications and presence of
169 any risk factors, like ulcerations, amputation, peripheral neuropathy (PN), PAD, foot
170 deformities and limited joint mobility using the methods followed by Lavery *et al.* [16–
171 17]. We used a 10 g Semmes-Weinstein monofilament and vibration perception
172 threshold tester to assess PN, palpation of the pulses and Ankle Brachial Index (ABI) to
173 detect PAD, goniometer to identify foot deformity and clinical examinations to
174 evaluate joint mobility. The risks were categorised according to the modified IWGDF
175 risk classification system: Group 0 (no PN, no PAD), Group 1 (PN, no PAD, no
176 deformity), Group 2A (PN and deformity, no PAD), Group 2B (PAD), Group 3A (ulcer
177 history) and Group 3B (amputation). Here, Group 0 indicated 'no risk' and rest of the
178 groups (1, 2A, 2B, 3A, 3B) classified the study population 'at risk' of in varying degrees

179 **Ascertainment of key variables**

180 *Peripheral neuropathy*

181 PN was defined as lack of feeling/protective sensation (at four or more of 10 sites) [18]
182 and vibration perception threshold value in either foot >25 volts using an
183 electromechanical instrument [17].

184 *Peripheral arterial disease*

185 We defined PAD as non-palpable dorsalis pedis or posterior tibial arterial pulse and

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3 186 ABI in either foot as <0.80 [16].
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6 187 *Limited joint mobility*
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8 188 Limited joint mobility was defined based on three averaged measurements of the first
9
10 189 metatarsophalangeal joint, the subtalar joint and ankle joint range of motion of the
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12 190 forefoot, rear foot and ankle. From these measurements, we determined the presence
13
14 191 of ankle joint equinus ($<0^\circ$ dorsiflexion), limited subtalar joint motion ($<20^\circ$ total joint
15
16 192 motion), and hallux rigidus ($<50^\circ$ hallux dorsiflexion) [18]. It was measured using
17
18 193 goniometer and details technique was described elsewhere (see online supplementary
19
20 194 file 1)
21

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23 195 *Foot deformity*
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25 196 Deformity was defined as any contracture that could not be fully corrected manually,
26
27 197 such as hallux valgus, hammer toes or claw toes, hallux rigidus and ankle equines [16].
28
29 198 It was measured using goniometer and details technique was described elsewhere (see
30
31 199 online supplementary file 1).
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34 200 *Foot ulcer*
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36 201 Foot ulcers were defined as full thickness wounds involving the foot or the ankle [19].
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39 202 **Quality assurance**
40

41 203 To ensure standard quality control, a panel of senior researchers and survey
42
43 204 investigators visited the data collection sites to monitor the research activities. To
44
45 205 prevent bias, monitoring panel was anonymised for the data collectors. All team
46
47 206 members including investigators, supervisor and data collectors participated in
48
49 207 intensive three consecutive training programmes (lasting two and a half days) in Dhaka
50
51 208 before the survey. The first training program was conducted for the physicians
52
53 209 (doctors) who were involved in foot examination. This training program focused on
54
55 210 'Detection of Diabetic Foot Problem at the Early Stage' through screening using a
56
57 211 standard instrument. A certified neurologist from a reputed post-graduate training
58
59 212 institution was appointed as a resource person to conduct the sessions. Second and
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1
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3 213 third training programmes were conducted for the volunteering data collectors
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5 214 selected from undergraduate physiotherapy students, who interviewed the
6
7 215 respondents to fill-up the questionnaire. The purpose of this training was to inform
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9 216 the data collectors about potential difficulties associated with data collection. During
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11 217 this intensive training, data collectors got practical training about self-administration
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13 218 of a questionnaire, physical measurement and maintenances of data collection
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15 219 environment. Other than these, we also followed specific protocols to assure quality of
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17 220 the study that included: (1) pre-testing of the questionnaire and data collection
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19 221 procedure (2) standard method of measurement as per STEPS survey 2010 of
20
21 222 Bangladesh (3) used show cards for a better understanding of different forms of
22
23 223 tobacco use and intensity of physical activities (4) adequate privacy during physical
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25 224 measurements and clinical examinations (5) robust equipment for physical
26
27 225 measurement and clinical examination. None of the quality control observer reported
28
29 226 any violation of physical measurement and data collection.

227 **Patient and public involvement**

228 We collected data from the patients who visited the selected diabetes care centres of
229 DAB. However, they were not involved directly in the setting of the research question
230 or outcome measures. They did not have any role in designing or implementing this
231 work or interpretation of the results.

232 **Ethical consideration**

233 The purpose of the study, rights of the respondents and data safety issues were
234 explained to each participant. All subjects gave their informed written consent for
235 inclusion before they participated in the study (see online supplementary file 2). The
236 study was conducted in accordance with the Declaration of Helsinki, and the protocol
237 was approved by the Ethical Review Committee of Bangladesh Diabetic Association
238 (Identification number: BADAS/BIO/EA/11/033) on January 17, 2011 (see online
239 supplementary file 3).

240 **Data processing and analysis**

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3 241 Data (see online supplementary file 4) were analysed using the Statistical Package for
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5 242 Social Science (SPSS) version 20.0 for Windows (SPSS, Inc. Chicago. IL. USA). All
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7 243 estimates of precision were presented at 95% confidence interval (CI) in the tables.
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9 244 Descriptive analysis included mean, standard deviation (SD), median and interquartile
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11 245 range (IQR), frequencies and percentages where appropriate. In this study, the p -value
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13 246 (two-sided) was considered statistically significant at the threshold of $p < 0.05$. In our
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15 247 study, there were only three respondents with PAD. Hence, we had to merge group 2B
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17 248 with group 2A and make a new group 2-A/B that was used in multinomial logistic
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19 249 regression analysis.

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22 250 To find the factors that influenced the risk of DFU, first we run chi-square test
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24 251 considering modified IWGDF risk classification as a dependent variable. Variables that
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26 252 showed significant association ($p < 0.05$) with the dependent variable in the chi-square
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28 253 test were identified. Then statistically significant variables were examined as
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30 254 independent variable against the dependent variable in the multinomial logistic
31
32 255 regression analysis. For multinomial logistic regression analysis, we calculated odds
33
34 256 ratios (OR), and 95% CI for each independent variable. In the regression table,
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36 257 predictors that had OR > 1 were presented for each risk category. We ensured presence
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38 258 of no multicollinearity using variance inflation factor (VIF) to run the regression
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40 259 analysis. We used the STROBE (Strengthening the Reporting of Observational Studies
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42 260 in Epidemiology) guidelines for reporting the results of cross-sectional observational
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44 261 study (see online supplementary file 5).

262 **Results**

263 **Sociodemographic characteristics and diabetes-related information**

51 264 The mean age of the participants was 51.6 ± 11.9 years and most of them (33.1%) were
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53 265 in the 50–59 year age group. More than half of the participants were women (62.9%)
54
55 266 and predominantly urban residents (67.3%). Most of them had completed primary level
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57 267 education (36.7%), 99% were married, 57.8% were housewives and 44.5% came from
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59 268 middle-income background. However, urban participants were more literate (88.2%)
60

and economically stable (60.3% >lower-middle-income range) than their rural counterparts. The mean duration of diabetes was 6.9 ± 5.9 years and a majority of them had uncontrolled glycaemic status (89.3%). Among the diabetes-related complications, retinopathy (14.3%) was much higher than nephropathy (5.6%). No mentionable urban-rural difference was observed for the glycaemic status and diabetic nephropathy (Table 1).

Table 1: Sociodemographic and diabetes-related information of the study subjects, $n=1200$

Variables	Urban		Rural		Total	
	<i>n</i> (%)	95% CI	<i>n</i> (%)	95% CI	<i>n</i> (%)	95% CI
Age (years)*	52.3 \pm 11.9		50.2 \pm 11.8		51.6 \pm 11.9	
Age categories (years)						
<30	52 (4)	2.6–5.4	22 (5.6)	3.3–7.9	54 (4.5)	3.3–5.7
30–39	63 (7.8)	5.9–9.7	39 (9.9)	14.6–18	102 (8.5)	6.9–10.1
40–49	212 (26.3)	23.3–29.3	109 (27.7)	23.3–32.1	321 (26.8)	24.3–29.3
50–59	270 (33.5)	30.2–36.8	127 (32.3)	27.7–36.9	397 (33.1)	30.4–35.8
≥ 60	230 (28.5)	25.4–31.6	96 (24.4)	20.2–28.6	326 (27.2)	24.7–29.7
Sex						
Men	302 (37.4)	34.1–40.7	143 (36.4)	31.6–41.2	445 (37.1)	34.4–39.8
Women	505 (62.6)	59.3–65.9	250 (63.6)	58.8–68.4	755 (62.9)	60.2–65.6
Educational status						
Illiterate	95 (11.8)	9.6–14	107 (27.2)	22.8–31.6	202 (16.8)	14.7–18.9
Primary	288 (35.7)	32.4–39	152 (38.7)	33.9–43.5	440 (36.7)	34–39.4
Secondary	265 (32.8)	29.6–36	98 (24.9)	20.6–29.2	363 (30.3)	27.7–32.9

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Higher education	159 (19.7)	17–22.4	36 (9.2)	6.3–12.1	195 (16.3)	14.2–18.4
Marital status						
Married	797 (98.8)	98–99.6	391 (99.5)	98.8–100.2	1188 (99)	98.4–99.6
Others	10 (1.2)	0.4–2	2 (0.5)	-0.2–1.2	12 (1)	0.4–1.6
Occupational status						
Service	184 (22.8)	19.9–25.7	49 (12.5)	9.2–15.8	233 (19.4)	17.2–21.6
Business	89 (11)	8.8–13.2	38 (9.7)	6.8–12.6	127 (10.6)	8.9–12.3
Housewife	462 (57.2)	53.8–60.6	231 (58.8)	53.9–63.7	693 (57.8)	55–60.6
Others	72 (8.9)	6.9–10.9	75 (15.2)	11.7–18.7	147 (12.3)	10.4–14.2
Monthly household income (BDT)†	20000 (10000–40000)		10000 (6000–20000)		20000 (10000–30000)	
Monthly household income groups						
<4907 (low)	21 (2.6)	1.5–3.7	41 (10.4)	7.4–13.4	62 (5.2)	3.9–6.5
4907–19,488 (lower-middle)	299 (37.1)	33.8–40.4	238 (60.6)	55.8–65.4	537 (44.8)	42–47.6
19489–60252 (upper-middle)	422 (52.3)	48.9–55.7	108 (27.5)	23.1–31.9	530 (44.2)	41.4–47
>60,252 (high)	65 (8.1)	6.2–10	6 (1.5)	0.3–2.7	71 (5.9)	4.6–7.2
Duration of diabetes (years)*	7.3 ±6		6.3 ±5.8		6.9 ±5.9	
Glycaemic status§						
Controlled	87 (10.8)	8.7–12.9	42 (10.7)	7.6 -13.8	129 (10.8)	9–12.6
Uncontrolled	720 (89.2)	87.1–91.3	351 (89.3)	86.2–92.4	1071 (89.3)	87.6–91
Diabetic retinopathy	134 (16.6)	14–19.2	38 (9.7)	6.8–12.6	172 (14.3)	12.3–16.3
Diabetic nephropathy	46 (5.7)	4.1–7.3	21 (5.3)	3.1–7.5	67 (5.6)	4.3–6.9

277 *Representing mean and standard deviation,

278 †Presented as median with interquartile range,

279 ‡According to the 2006 per-capita gross national income (GNI) and the World Bank calculation

280 §Based on plasma glucose level pre-meal (fasting) <6.1 mmol/l and/or two hours post meal <7.8
281 mmol/l

282 Risk of DFU among the study population

283 Table 2 shows the sex and area-specific distribution of the DFU risk according to the
284 modified version of IWGDF classification. Overall, 44.5% of the study population was
285 diagnosed as 'at risk' of DFU and the burden was higher among men (45.6%) and those
286 who lived in rural areas (45.5%). The risk of DFU according to the modified version of
287 IWGDF was 55.5%, 4.2%, 11.6%, 0.3%, 20.6% and 7.9% for group 0, group 1, group 2A,
288 group 2B, group 3A and group 3B respectively. Among the six groups of risk
289 classification, group 3A (ulcer history) showed maximum risk (20.6%) compared to
290 other groups. For sex and area variables, 21.8% of men and one-fourth of the rural
291 residents (25.7%) had a previous history of foot ulceration.

292 **Table 2: Sex and area-specific distribution of DFU risk among the study subjects, n = 1200**

IWGDF DFU risk classification	Sex		Area of residence		Overall
	Men	Women	Urban	Rural	
	n (%)	n (%)	n (%)	n (%)	
Group 0 (no PN, no PAD)	242 (54.4)	430 (57)	452 (56)	214 (54.5)	666 (55.5)
Group 1 (PN, no PAD, no deformity)	18 (4)	32 (4.2)	32 (4)	18 (4.6)	50 (4.2)
Group 2A (PN and deformity, no PAD)	49 (11)	90 (11.9)	103 (12.8)	36 (9.2)	139 (11.6)
Group 2B (PAD)	1(0.2)	2 (0.3)	3 (0.4)	0	3 (0.3)
Group 3A (ulcer history)	97 (21.8)	150 (19.9)	146 (18.1)	101 (25.7)	247 (20.6)
Group 3B (amputation)	38 (8.5)	57 (7.5)	71 (8.8)	24 (6.1)	95 (7.9)

293 IWGDF, International Working Group on the Diabetic Foot; DFU, diabetic foot ulcer, PN, peripheral
294 neuropathy; PAD, peripheral arterial disease

295 Factors associated with the risk of DFU among the study subjects

296 Table 3 shows the associated factors of DFU risk among the study population. Total six

297 factors were identified which showed high odds (>1) for different groups at risk: age
 298 (group 2-A/B, OR 1.212; group 3B, OR 1.173), area of residence (group 1, OR 1.188;
 299 group 3A, OR 1.461), monthly income (group 2-A/B, OR 1.491; group 3A, OR 1.415;
 300 group 3B, OR 1.768), medication (group 2-A/B, OR 1.014), history of trauma (group 1,
 301 OR 2.015; group 2-A/B, OR 1.032; group 3A, OR 2.998; group 3B, OR 3.104), diabetic
 302 retinopathy (group 1, OR 1.104; group 3B, OR, 1.933) and diabetic nephropathy (group
 303 1, OR 2.174; group 3A, OR 1.260; group 3B, OR 2.389).

304 Overall, the odds for risk of DFU was higher among those who were ≥ 50 years old,
 305 lived in rural areas, had a monthly income $\leq 19,488$ BDT, had a previous history of foot
 306 ulcer, were insulin user and had diabetic complications as retinopathy or nephropathy.

307 **Table 3: Associated factors of diabetic foot ulcer among type 2 diabetic subjects of Bangladesh**
 308 **using multinomial logistic regression, $n = 1200$**

Risk groups	Predictors	B	p-value	OR	95% CI for OR	
					Lower Bound	Upper Bound
Group 1	Area of residence					
	Rural area	0.172	0.573	1.188	0.652	2.165
	Urban area			<i>Ref.</i>		
	History of trauma					
	Present	0.7	0.076	2.015	0.929	4.369
	Absent			<i>Ref.</i>		
	Diabetic retinopathy					
	Present	0.099	0.814	1.104	0.486	2.508
	Absent			<i>Ref.</i>		
	Diabetic nephropathy					
	Present	0.526	0.14	2.174	755	6.099
	Absent			<i>Ref.</i>		

1						
2						
3		Age				
4						
5		≥50 years	0.192	0.324	1.212	0.827
6						1.774
7		<50 years			<i>Ref.</i>	
8						
9		Monthly income (BDT)				
10						
11		≤19,488	0.4	0.039*	1.491	1.020
12						2.181
13		>19,488			<i>Ref.</i>	
14	Group 2-A/B†					
15		Medication				
16						
17		Insulin user	0.013	0.945	1.014	0.692
18						1.485
19		Insulin non-user			<i>Ref.</i>	
20						
21		History of trauma				
22						
23		Present	0.032	0.916	1.032	0.570
24						1.870
25		Absent			<i>Ref.</i>	
26						
27						
28						
29		Area of residence				
30						
31		Rural area	0.379	0.014*	1.461	1.081
32						1.975
33		Urban area			<i>Ref.</i>	
34						
35		Monthly income (BDT)				
36						
37		≤19,488	0.347	0.031*	1.415	1.032
38						1.940
39		>19,488			<i>Ref.</i>	
40	Group 3A					
41		History of trauma				
42						
43		Present	1.098	<0.001*	2.998	2.044
44						4.396
45		Absent			<i>Ref.</i>	
46						
47		Diabetic Nephropathy				
48						
49		Present	0.231	0.504	1.260	0.640
50						2.482
51		Absent			<i>Ref.</i>	
52						
53						
54						
55						
56	Group 3B	Age				
57						
58		≥50 years	0.160	0.494	1.173	0.742
59						1.854
60						

<50 years					<i>Ref.</i>	
Monthly income (BDT)						
≤19,488	0.570	0.016*	1.768	1.114		2.805
>19,488					<i>Ref.</i>	
History of trauma						
Present	1.133	<0.001*	3.104	1.810		5.324
Absent					<i>Ref.</i>	
Diabetic retinopathy						
Present	0.659	0.018*	1.933	1.122		3.329
Absent					<i>Ref.</i>	
Diabetic nephropathy						
Present	0.871	0.024*	2.389	1.123		5.083
Absent					<i>Ref.</i>	

OR, odd-ratio; CI, confidence interval; Ref, reference; BDT, Bangladesh taka

*indicates significant

†Group 2B was merged with 2A as the participants were very few in the group 2B

Discussion

The results show that nearly half (45%) of the T2D subjects were at the risk of DFU and rural population was mostly affected. This is significant as there is no straightforward evidence on the risk of DFU among T2D population of Bangladesh. Moreover, the contributing factors are not yet explored in Bangladesh to take an effective initiative to reduce the burden of associated morbidity and mortality.

In our modified DFU risk classification as per IWGDF, the higher burden was observed in those who had a previous history of foot ulcer (20.6%). This proportion is much higher than an Iranian study that reported only 7% of the study subjects to have a previous history of foot ulceration [20]. The percentage of our finding is also higher than Portugal, where a study reported a previous history of DFU among 16% of study subjects using modified IWGDF risk classification [21]. Although it has been estimated

1
2
3 324 that the annual risk of DFU is approximately 2%, this risk in patients with a previous
4
5 325 history of foot ulcer is expected to increase to 17%–60% over the next three years [22].
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7
8 326 Several studies have reported the cumulative burden of a previous history of foot ulcer
9
10 327 and amputation as a part of their diabetic foot risk assessment. In our study, the
11
12 328 cumulative proportion of a previous history of foot ulcer and amputation was 14.3%,
13
14 329 which is twice that of studies conducted in India [23,24] and in a half of Portugal [21].
15
16 330 A follow-up study from the USA reported nearly three times higher proportion of foot
17
18 331 ulcer or amputation compared to our study [25]. In this regard, a systematic review
19
20 332 comprised of 41 documents by Hunt et al. [26] found that a person with a previous
21
22 333 history of DFU has a 66% chance of ulcer recurrence and 12% chance of amputation
23
24 334 over five years.

25
26 335 We have mentioned earlier that PN is one of the major risk factors for DFU. In our
27
28 336 study, 4.2% of the T2D subjects had only PN and 11.6% had PN with deformity,
29
30 337 represented as group 1 and group 2A respectively. This finding has much lower
31
32 338 percentages compared to similar studies conducted among subjects of India [23,27–
33
34 339 28] and Iran [20,28]. However, this burden is still higher than Portugal [21]. Our study
35
36 340 classified very low proportion of T2D subjects as having PAD compared to
37
38 341 aforementioned studies [20–23,27–29]. A possible reason for the ABI being above 0.80
39
40 342 in the majority of patients is the presence of medial arterial calcification artefactually
41
42 343 raising the ankle pressure. Another reason might be due to the cut-off value applied
43
44 344 to define PAD. The compared studies used ABI 0.9 or less as the cut-off, which included
45
46 345 more participants as PAD compared to current study. The overall burden of ‘at risk’
47
48 346 (other than group 0) T2D subjects of this study was also lower than the findings from
49
50 347 India [27–28] and Portugal [21]. However, the proportion of ‘at risk’ subjects is more
51
52 348 than twice that of aforementioned Indian [23] and Iranian [20] studies. The reasons for
53
54 349 the risk difference in different countries are still unclear.

55
56
57 350 A study by Abott et al. explored this risk difference among different ethnic population
58
59 351 including South-Asians, African-Caribbeans and Europeans of the United Kingdom
60

1
2
3 352 [11]. They reported that such difference might be due to the methods applied to detect
4
5 353 neuropathy, provisions of primary health care services, such as diabetes mini-clinics,
6
7 354 podiatric care and referrals for special footwear for the health care districts and a
8
9 355 variable quality of health care. Regarding the burden of risk factors of DFU, Abbott et
10
11 356 al. added that lower level of PN and PAD also contribute to the less percentage of
12
13 357 South-Asian population 'at risk' compared to Europeans. Another reason behind this
14
15 358 difference is the application of various risk classification system in different countries.
16
17 359 We used modified IWGDF risk classification, similar to the studies from Iran [20] and
18
19 360 Portugal [21], whereas one of the two Indian [23] studies used semi-structured pre-
20
21 361 tested questionnaire and another [27] applied American Diabetic Association (ADA)
22
23 362 task force report for comprehensive foot examination risk classification.

24
25
26 363 Our study reports a sex-specific and area-specific difference in risk of DFU among T2D
27
28 364 population of Bangladesh. The overall proportion of DFU risk was higher among men
29
30 365 than women. Previous studies [7,20,23,30] have also reported similar findings.
31
32 366 However, a community-based study from India reported that DFU risk was high in
33
34 367 women [24], which is contradictory to our finding.

35
36 368 Our study shows that the risk of DFU is greater among men with a previous history of
37
38 369 ulcer or amputation. This higher risk of foot ulcer history or amputation in men was
39
40 370 also supported by a study from Iran, which used IWGDF risk classification system [20].
41
42 371 This men-to-women risk difference might be due to diabetes-related healthy
43
44 372 behavioural practice, health-seeking behaviour and self-care. In this regard, a Brazilian
45
46 373 study reported that sex is significantly associated with changes of lifestyle behaviour
47
48 374 related to control of T2D, foot self-care and prevention of ulceration, and women were
49
50 375 found to adhere more to lifestyle changes than men [31]. The same study also reported
51
52 376 that men were highly reluctant to check their glycaemic status and lipid profile
53
54 377 compared to women [31]. In this case, the fact is that women are more sensitive to
55
56 378 health issues and more frequently seek health services than men do [32,33].

57
58
59 379 For the urban–rural difference, we found that the risk was higher among those who
60

1
2
3 380 lived in a rural area. This finding is also supported by other studies [23,28,34]. A
4
5 381 possible explanation is that diabetic patients of rural area are not aware of their PN
6
7 382 due to illiteracy, especially their lack of knowledge about diabetic foot-related
8
9 383 complications. They walk barefoot and this leads to an injury to the foot and
10
11 384 subsequent complications [35]. Another explanation could be that people in rural areas
12
13 385 often sleep in huts or farmhouses where rodents are common; rodents bite their feet
14
15 386 and in case of patients with diabetes, this can lead to chronic ulcers [34].

17
18 387 One of the major objectives of this study was to identify the factors that influenced the
19
20 388 risk of DFU among Bangladeshi T2D population. Sociodemographic factors age ≥ 50
21
22 389 years, living in a rural area and monthly income $\leq 19,488$ BDT showed higher odds for
23
24 390 the risk of DFU. In diabetic research, age is widely evaluated as an associated factors
25
26 391 of DFU. Some other studies also found age as a significant risk factors [36–38] of DFU.
27
28 392 In our study, it was found that age below 50 years was a protective factor and age
29
30 393 above this was associated with development of DFU. This has also been supported by
31
32 394 the other studies that reported older age was a significant factor [37,38].

33
34 395 Globally, the findings of the association of economic status and area of residence with
35
36 396 the risk of DFU are inconsistent. Our results show that lower economic status (monthly
37
38 397 income $\leq 19,488$ BDT) and living in a rural area are strongly associated with the risk of
39
40 398 DFU. These findings were consistent with the results of other studies conducted in
41
42 399 India [24,27] and Sri Lanka [39]. It was postulated that financial status is directly related
43
44 400 to burden of risk factors, which leads to complications of chronic diseases. This is
45
46 401 because a lack of financial resources interferes with the access to healthcare services,
47
48 402 options of treatments and hinders the adoption of preventive measures that are
49
50 403 necessary to avoid amputations [31]. Regarding place of residence, significant urban–
51
52 404 rural risk difference for DFU was explained by the study of Viswanathan et al. [34] and
53
54 405 we mentioned it in this section previously. However, one study has reported no
55
56 406 association for the aforementioned factors [40].

57
58
59 407 Our study found that the odds for risk of DFU were higher among insulin users, having
60

1
2
3 408 diabetic-related complications as nephropathy and retinopathy. Previous studies also
4
5 409 reported that use of insulin is a contribution factor of diabetic foot [29,41]. However,
6
7 410 the exact mechanism behind this has not yet been explored and this finding is thus
8
9 411 inconclusive. It might be possible that when patients acquiesce to start insulin, they
10
11 412 may already have diabetes for a long time with greater associated complications [29].
12
13
14 413 Our findings of retinopathy and nephropathy are also supported by other studies
15
16 414 [20,38,42,43]. Regarding nephropathy, we found that about 10% of diabetic patients
17
18 415 had a history of amputation when they entered a dialysis program [44]. Several factors
19
20 416 might be responsible for an increased risk of DFU among nephropathy patients.
21
22 417 Coexistence of PN, peripheral vascular diseases, susceptibility to infection, minimal
23
24 418 self-care, dialysis therapy and anaemia [45]. On the other hand, one study has reported
25
26 419 that the prevalence of diabetic retinopathy is much higher (90%) among patients with
27
28 420 DFU than those who had no DFU [42]. Another study [43] used IWGDF risk classification
29
30 421 to predict DFU and they found that around 67.58% of patients had diabetic retinopathy
31
32 422 and they were included in the risk group 3, which was similar to our study. In this
33
34 423 regard, a systematic review and a meta-analysis show that both retinopathy and
35
36 424 nephropathy are microvascular complications. The impairment of microcirculation in
37
38 425 T2D may lead to secondary complications in lower extremity due to dysfunctional
39
40 426 vasodilatation. Moreover, patients of diabetic foot with retinopathy have higher level
41
42 427 of diabetic biomarkers like ceruloplasmin. Again, this ceruloplasmin is an independent
43
44 428 predictor of progression of diabetic nephropathy in T2D patients. Thus
45
46 429 aforementioned explanation implies a link between DFU, and retinopathy and
47
48 430 nephropathy [46].

49
50 431 Previous history of trauma was identified as a significant contributing factor of DFU
51
52 432 (group 3A, OR 2.998, $p < 0.001$; group 3B, $p < 0.001$) in our study. This finding was
53
54 433 similar to other studies that reported a significant association between a previous
55
56 434 history of trauma and DFU [47–49]. However, the exact mechanism of a previous
57
58 435 trauma leading to DFU is not clear. As such, further research on this issue is required.
59
60

436 **Limitations**

437 Our study has some limitations that should be mentioned. First, the participating
438 centres were not representative of the Bangladesh diabetes centres as a whole
439 considering their geographical distribution as some areas were underrepresented or
440 not represented at all. Therefore, the results of our study cannot be extrapolated to
441 the general diabetic population in Bangladesh. Second, in our study some diabetes-
442 related complications were underrepresented, especially for diabetic retinopathy and
443 nephropathy. These co-morbidities were not based on real-time clinical examination
444 of eyes and assessment of kidney functions, rather based on diabetic record books
445 review. As a result, the exact cut-off value used to define both of these co-morbidities
446 were uncertain. In a similar way, glycaemic status was evaluated using the values
447 previously recorded in the diabetic records of the subject instead of using a
448 biochemical measurement during data collection.

449 **Strengths**

450 Our study is important from the public health and clinical perspective. It is the first
451 study in Bangladesh that assessed DFU risk in a moderately large sample of T2D
452 population. Moreover, a multi-centric study recruited participants from world-
453 renowned DAB affiliated diabetes centres. The other strength of this study is sex- and
454 area-specific reporting of DFU risk among the study subjects. This difference will help
455 to address the men–women and urban–rural disparities in diabetes foot care in
456 Bangladesh and in remodelling the chain of diabetes centres where appropriate. The
457 clinicians of Bangladesh should concentrate more on the contributing factors of DFU
458 in the management of diabetic patients as these are associated with morbidity and
459 mortality resulting from DFU.

460 **Conclusion**

461 We found that a significant proportion of T2D population of Bangladesh is at a high
462 risk of DFU. The findings indicate that each diabetic patient must be screened for his
463 or her foot ulcer risk factors according to IWGDF recommendation. In this regard,

1
2
3 464 diabetic foot screening program can be introduced in the primary health care system
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5 465 of Bangladesh. Based on the findings of this study, we also recommend that specialized
6
7 466 diabetic foot care centres should be established in both urban and rural areas to stop
8
9 467 the debilitating consequences of DFU.
10

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12
13
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17
18 471 Bangladesh.
19

20 472 **Conflicts of Interest**

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22
23
24 473 All authors have none to declare.
25

26 474 **Data statement**

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29 475 Data are available as a supplementary file. All data relevant to the study are included
30
31 476 in the article.
32

33 477 **Author statement**

34
35
36 478 Conceptualization, PCB, FZ, MM and LA; Data curation, PCB, FZ and RM; Data analysis,
37
38 479 PCB, LB, MM and RM; Interpretation; LB, FZ, MM, RM and LA; Writing – original draft,
39
40 480 LB; Writing—review and editing, PCB, LB, MM and LA; All authors read and approved
41
42 481 the final manuscript.
43

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47
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55

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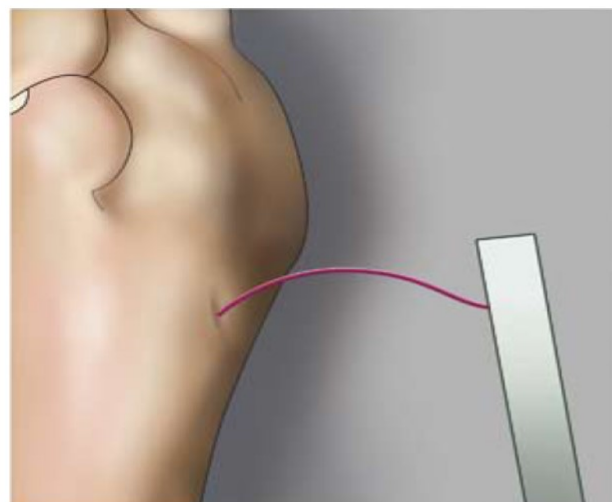
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BANGLADESH UNIVERSITY OF HEALTH SCIENCES

Faculty of Public Health
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TRAINING MODULE ON DETECTION OF DIABETIC FOOT PROBLEM AT THE EARLY STAGE



By

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Collaboration with



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Introduction

Why foot care is important for patients with Type 2 Diabetes?

Foot problems from diabetes represent a significant burden of care for primary care physicians. Most of the adverse outcomes of a diabetic foot are preventable with resources currently available in primary care settings where most patients with diabetes get their care.

The Center for Disease Control estimates that in 2010:

- 1 in 12 adults Americans, and 1 in 4 adult American Indians, has diabetes.
- Approximately 90% of these patients are managed by primary care providers.
- Of the diabetes patients seen, 20% will present with an acute foot problem.
- Over the course of their care, 15% will experience a foot ulcer.
- 5 – 10% will need lower limb amputation.
- 50% of those who get an amputation die within 5 years.

How is this training set up?

This Training can be used in a variety of different ways:

- Read the Essential Elements that offer a detailed explanation.
- Just want the key points? Then browse through the Quick Facts.
- Use these printable notes if you want to be able to write alongside the information offered.

Feel free to use any of these avenues to better enhance your learning needs.

Objectives:

At the end of this training, you will be able to:

1. List four risk factors for diabetic foot complications.
2. Be able to conduct a complete diabetic foot exam.

Screening for High Risk Patients: Overview

Foot ulceration and amputation are preventable with resources currently available in primary care settings where most patients with diabetes get their care. There are several principle risk factors for ulceration and lower extremity amputation (LEA) among patients with diabetes:

- Neuropathy
- Deformity
- Limited joint mobility
- Prior ulcer/ LEA
- PVD
- Onychomycosis

It is also important to assess non-foot related risk factors; some of them are potentially modifiable:

- Male sex
- Duration of diabetes
- Age
- Hyperglycemia
- Hypertension
- Dyslipidemia
- Smoking
- Poor vision
- Other complications such as renal disease

Patients at high risk for foot ulcer and amputation can be identified with simple criteria that involve several testing and inspection measures. Patients with all normal criteria are at low-risk, while those with insensitivity, deformity, absent pulses, or prior foot ulcers or amputations are at high-risk. These simple criteria have been validated in Indian Health Services (IHS) and adopted by most professional and public health organizations including the American Diabetes Association (ADA) and World Health Organization (WHO).

- Sensory testing with a 10 gram monofilament
- Foot inspection for deformity
- Reports of prior ulcer or amputation
- Checking for pedal pulses and taking measurements for an ABI pressure
- Checking joint mobility with goniometer

Screening for High Risk Patients: Sensation

A test using a 10 g monofilament is the recommended method for assessing for neuropathy of the foot. Loss of protective sensation at any site on the foot indicates evidence of neuropathy, increasing the risk of ulceration and other complications.

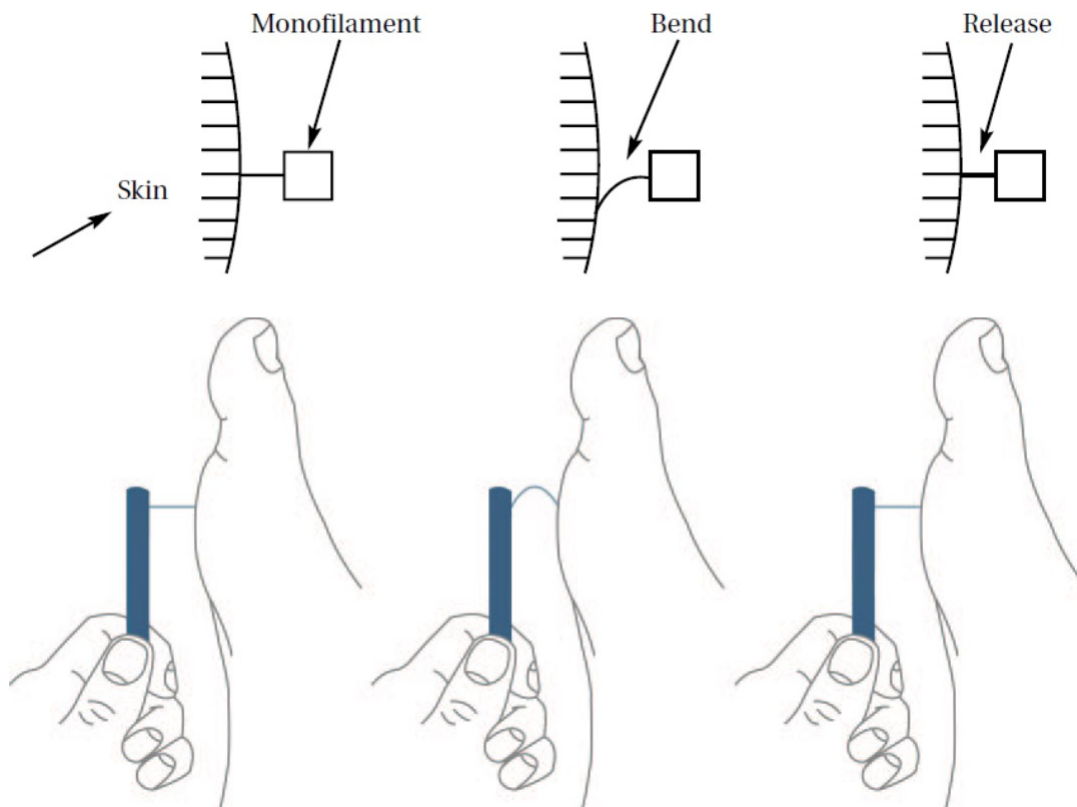
Equipment: 10 g monofilament

Monofilament is the test used to help identify high risk feet in people with diabetes. The monofilament exam involves using a 10 gram monofilament to test sensation on the tip of the great toe, little figure and 1st, 3rd and 5th metatarsal heads & heel of each foot.

The technique for monofilament testing is as follows:

Directions for use of Semmes- Weinstein Monofilament

1. Assess integrity of monofilament (no bends/breaks).
2. Show the monofilament to the patient. Place the end of the monofilament on his/her hand or arm to show that the testing procedure will not hurt.
3. Ask the patient to turn his/her head and close his/her eyes or look at the ceiling.
4. Hold the monofilament perpendicular to the skin.



5. Place the end of the monofilament on the sole of the foot. Ask the patient to say 'yes' when he/she feels you touching his/her foot with the monofilament. DO NOT ASK THE PATIENT "did you feel that?" If the patient does not say "yes" when you touch a given testing site, continue on to another site. When you have completed the sequence RETEST the area(s) where the patient did not feel monofilament.

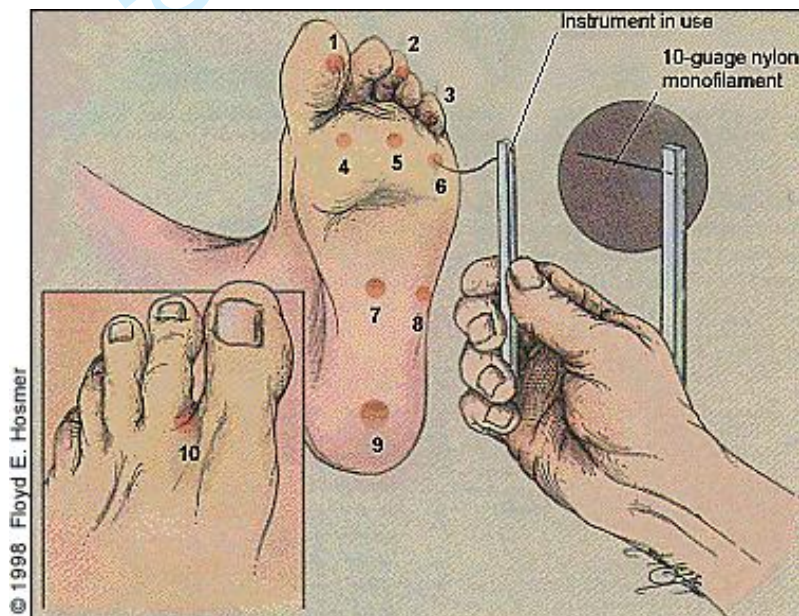
6. Push the monofilament until it bends, then hold for 1-3 seconds.

7. Lift the monofilament from the skin. Do not brush or slide along the skin.

8. Repeat the sequence randomly at each testing site on the foot (see pictures below).

Sites on the sole of the foot for monofilament testing

Loss of protective sensation = absent sensation at one or more sites



Using the monofilament, test the sites listed. Do not test over heavy callus.

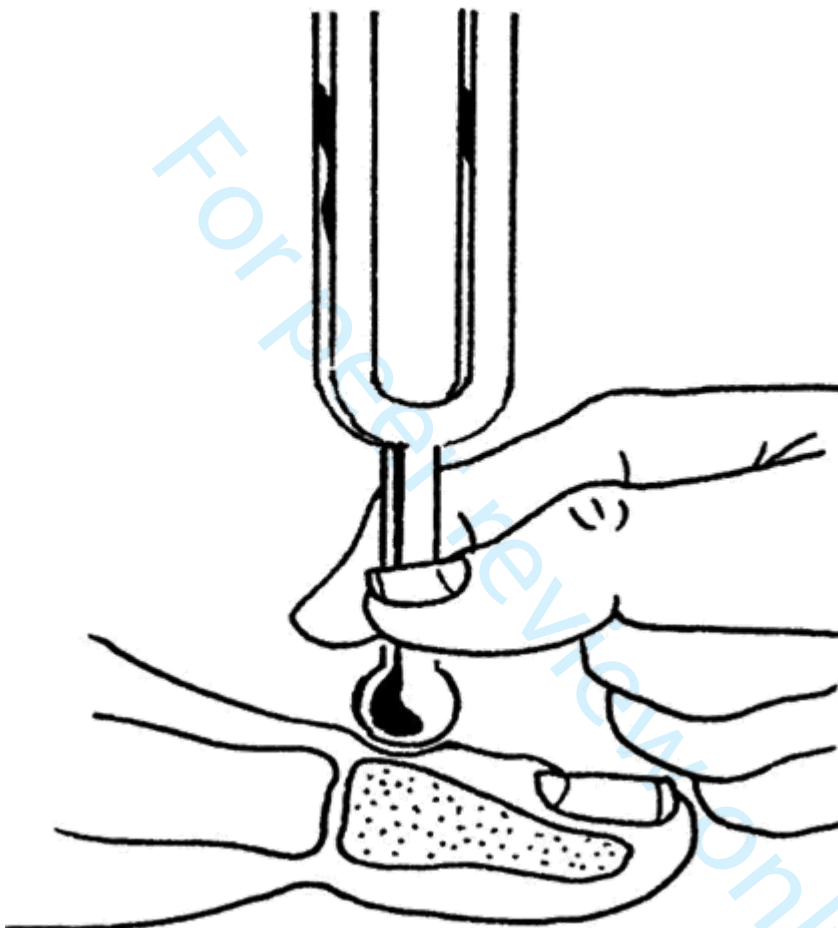
- digits: 1st, 3rd, 5th
- MTH: 1st, 3rd, 5th
- midfoot: Medial, Lateral
- heel
- top (dorsum) of foot

N. B.:

Apply only to intact skin. Avoid calluses, ulcerated or scarred areas. DO NOT use a rapid or tapping movement.

- If the monofilament accidentally slides along the skin, re-test that area later in the testing sequence.

- 1
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- 3 ■ Store the monofilament according to the manufacturer's instructions.
- 4 ■ Clean the monofilament according to agency infection control protocols.
- 5 ■ The filament should be cleaned after use with an alcohol swab or dilute bleach
- 6 solution and returned to its case.
- 7
- 8 ■ Do not apply the filament directly on an ulcer, callous, scar or necrotic tissue.
- 9 Apply the filament on near-by normal tissue.
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42 **Tuning fork**

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- 44 • The sensory examination should be carried out in a quiet and relaxed setting.
- 45 First, apply the tuning fork on the patient's wrists (or elbow or clavicle) so that
- 46 he/she knows what to expect.
- 47
- 48 • The patient must not be able to see whether or where the examiner applies the
- 49 tuning fork. The tuning fork is applied on a bony part on the dorsal side of the distal
- 50 phalanx of the first toe.
- 51 • The tuning fork should be applied perpendicularly with constant pressure.
- 52 • Repeat this application twice, but alternate this with at least one 'mock'
- 53 application in which the tuning fork is not vibrating.
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3 • *The test is positive if the patient incorrectly answers at least two out of three*
4 *applications, ('at risk for ulceration') and negative with two out of three correct*
5 *answers. (A test is positive if it identifies the risk).*
6 • If the patient is unable to sense the vibrations on the big toe, the test is repeated
7 more proximally (malleolus, tibial tuberosity).
8 • Encourage the patient during testing by giving a positive feedback.
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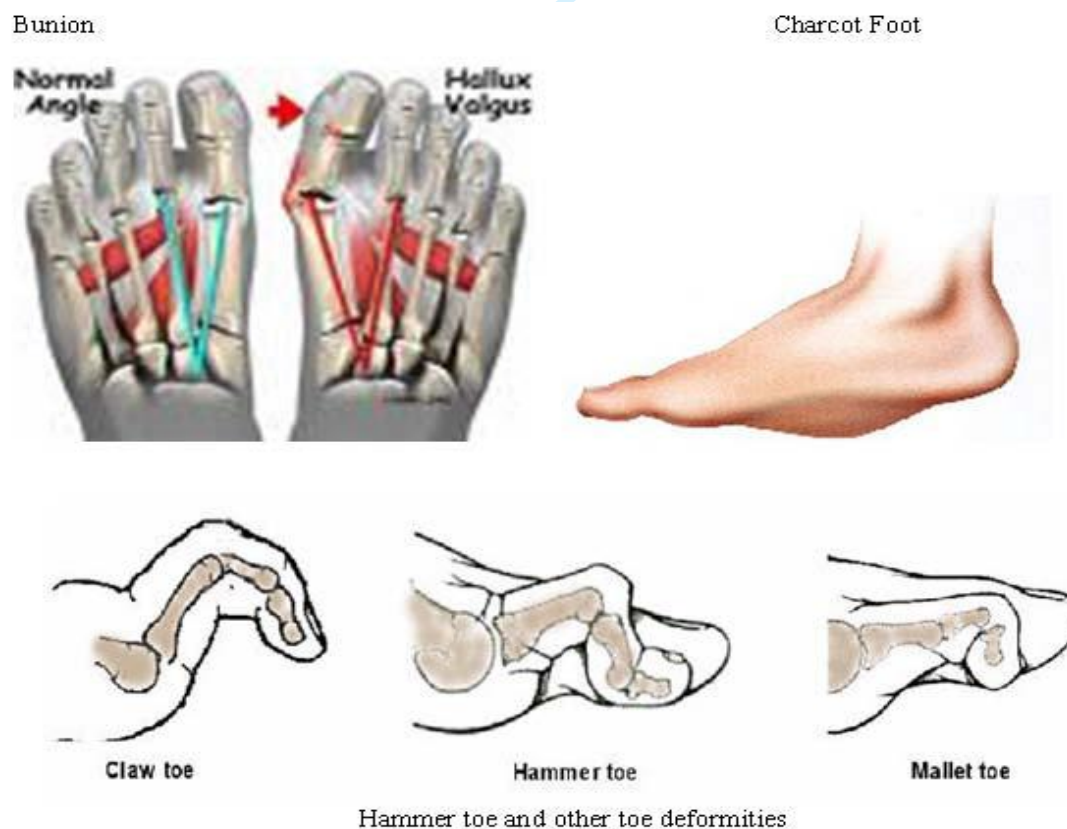
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Screening for High Risk Patients: Foot Deformities

To understand foot deformities, it is important to recognize that foot structure and function is incredibly complex and can easily go awry. Normal foot architecture is maintained through a balance of forces applied by muscles and tendons on bones. Atrophy of a muscle group through nerve damage can lead to deformity. It is important to watch areas that can be open to friction and repetitive micro-trauma as those sites can lead to callus and ulceration.

Types of foot deformities include:

- The **bunion**, or **hallux valgus**, increases the risk for ulceration through a mechanism of increased pressures and friction and repetitive micro-trauma that outpaces the healing capacity at the bunion site.
- **Hammer** and **claw toe** deformities develop from atrophy of the small muscles between the toes. Both the dorsal and plantar aspects of the involved toes are at risk for friction and pressure related trauma with subsequent ulceration.
- **Charcot foot** is one of the most severe diabetic foot deformity in which the entire mid-section of the foot collapses and forms a classic “rocker bottom” sole. It is caused by a combination of sensory and autonomic nerve dysfunction in which microscopic fractures to the tarsal bones trigger an inflammatory response and subsequent dissolution of the tarsal and metatarsal bones of the foot. The arch becomes inverted, which causes high plantar pressures, and is at extreme risk for ulceration.





Hammer toe – bent middle joint



Claw Toe – joint at base of toe is bent up and middle joint is bent down



Halgus Valgus or Small Bunion (Mild/Moderate)

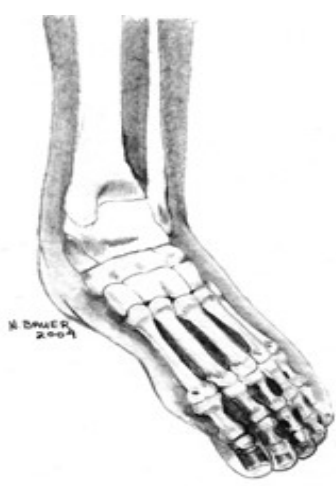
– Joint at the base of big toe is pushed to the side



Hallus Valgus or Large Bunion (Severe)

– Big toe may move under second toe

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Pes Planus



Pes Cavus



Charcot Arthropathy

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3 Pes planus produces flattening of the foot. Pes planus feet have increased lateral
4 talometatarsal angle and increased second metatarsal length (Ledoux, Shofer,
5 Ahroni, Smith, Sangeorzan & Boyko, 2003). There are many reasons for this
6 condition, the first of which is heredity. Many have this condition and never have
7 any problems of any kind.
8

9
10 However, others will have this condition created through years in soft, unsupportive
11 shoes on hard surfaces, injury, pregnancy, or other factors. This often leads to other
12 problems.
13

14 The arch in the foot is caused by a broad band of fibrous connective tissue, called
15 the longitudinal ligament. A ligament is nothing more than connective tissue that
16 connects bone to bone. The longitudinal ligament connects the metatarsal
17 phalangeal joints to the os calcis or heel bone. Like a string on a bow, they hold the
18 two ends together and create an arch. This arch is a shock absorption structure and
19 it also helps to maintain all the tarsals in proper erect anatomic position. As this
20 arch decreases, impact from the concrete becomes worse.
21
22

23 When the arch ligament stretches or tears, the arch falls. If it falls far enough, the
24 tarsals may begin to shift to the inside or create pronation or a valgus (greater than
25 90 degree erect) position at the ankle. This can cause problems in the origin area,
26 (the metatarsals) or in the heel. It also may cause pressure on the medial (inner)
27 knee and perhaps the hip and back. It is like pulling the string on a marionette too
28 tight, the result is a kinked mass on one side. The human body is much the same,
29 put too much tension on major muscle groups and the joints kink and yell back.
30
31

32 In pes cavus, the arch is abnormally high on weight bearing. The heel is often tilted
33 inwards at the ankle (but not always). In many, the toes will appear clawed. When
34 not standing the front half of the foot (forefoot) will appear to be dropped below the
35 level of the rear foot. Ledoux et al. (2003) identified biomechanical differences
36 among pes planus and pes cavus feet in persons with diabetes. They found pes
37 cavus feet had more prominent metatarsal heads, bony prominences, hammer/claw
38 toes, increased hallux dorsiflexion and Pes Cavus decreased hallux plantarflexion.
39
40

41 Charcot joint is a form of neuroarthropathy that occurs most often in the foot.
42 **Nerve damage from diabetes causes decreased sensation, muscle and**
43 **ligament atrophy and subsequent joint instability.** Walking on this insensitive
44 and weakened joint can cause even more damage to the foot structure. In the acute
45 stage there is inflammation and bone reabsorption which destroys the bone. In later
46 stages, the arch falls and the foot may develop a rocker bottom appearance. Weight
47 distribution of the sole is altered causing deformities leading to pressure points that
48 enhance ulcer development. Signs to assess for are: hot on the onset, pain,
49 discomfort, erythema, swelling, rigid deformities, limited joint mobility, callus
50 formation (ADA, 2001; Bowker & Pfeifer, 2001). One in 680 people with diabetes
51 develop Charcot joint with an incidence of 9-12% individuals with documented
52 diabetic peripheral neuropathy (Royal Melbourne Hospital, 2002). It is important
53 that the Charcot foot is recognized early so that appropriate treatment of the foot
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can be provided to prevent further injury and promote a stable foot (Lavery et al., 1998).

Screening for high risk patient: Vascular

There are three non-invasive assessments for detecting peripheral vascular disease:

The palpitation of pedal pulses is most simple and fastest. The dorsalis pedis and posterior tibial are the two main arteries in the foot.

- The dorsalis pedis is on the dorsum or top of the foot.
- The posterior tibial is palpitated behind the medial malleolus, or inside the ankle bone.

Pedal Pulse Assessment:

Locating a pedal pulse is part of the trauma patient assessment and performed before and after lower extremity splint application as well as long backboard immobilization. Locating a pedal pulse can be difficult even in healthy patients. Use these tips to find a patient's pedal pulse:

- 1) First assess the patient's radial pulse rate and rhythm so you know what you are seeking.
- 2) Move shoes, socks, tights, and anklets out of the way to expose the patient's skin.
- 3) Move, if not compromised by injury, the patient's foot towards the normal anatomical position.
- 4) Check for either the dorsalis pedis pulse (on the top of the foot) or the posterior tibial pulse (located behind the medial malleolus — the ankle bone).
- 5) For dorsalis pedis, first visualize because you might see the skin pulsating above the artery. If you are unable to see anything, hold two or more fingers lightly against the skin. Move up from the toes towards the leg until you locate the pulse.
- 6) For posterior tibial — on the medial side of the ankle — use two or more fingers. Sometimes you may need more pressure to find this pulse.

If you are unable to find the pedal pulse on one leg, switch to the patient's other leg. Knowing the location of one pulse might help you find the other.

Once you have found a pedal pulse, consider using a ballpoint or felt pen to make a light mark at the pulse location to make reassessment easier. Finally, if the patient's foot is warm with normal color, it is adequately perfused.

-----**Picture of clinical examination (removed due to ethical issue)**-----

Ankle Brachial Index (ABI):

- An Ankle Brachial Index (ABI) can be performed with a handheld Doppler and a blood pressure cuff.

To obtain an ABI:

1. First measure brachial pressures in each arm.

- Apply the cuff to the upper arm
- Locate the brachial pulse with the Doppler and mark with a pen
- Inflate the cuff, apply Doppler, deflate the cuff and record the pressure at which flow is heard.

2. Next measure pressure in each ankle.

- Apply cuff to the calf
- Locate the posterior tibial pulse with the Doppler and mark with a pen.
- Inflate the cuff, apply Doppler, deflate the cuff and record the pressure at which the flow is heard.

3. ***To calculate ABI***, divide the ankle pressure by the greater of the toe brachial pressures. While there is no clear threshold for increased risk, most accept a value of below 0.9 or 0.8 as conferring moderately high risk.

Example: Calculate ankle brachial index by dividing systolic ankle pressure by systolic brachial pressure e.g. ankle pressure is 120 mmHg and brachial pressure is 132 mmHg, ankle brachial index is $120/132 = 0.9$

Some data suggests the Toe BI measurement is more accurate than the ABI, but it requires specialized equipment and is not routine in primary care.

Normal	0.9 - 1.2	Risk of vascular foot ulcer is small
Definite vascular disease	0.6 - 0.9	Risk of vascular ulcer moderate, depending on other risk factors
Severe vascular disease	Less than 0.6	Risk of vascular foot ulcer very high

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3 **N.B.:** Ankle brachial index may not be able to be reliably calculated in some people
4 with diabetes as the arteries in the ankles may be calcified.
5

6 **Assess peripheral circulation** with thorough palpation of **pedal pulses** (dorsalis
7 pedis and posterior tibial). If there are no palpable pulses, and calculate ankle
8 brachial index or consider referral to a vascular specialist. **Absent pulses, calf**
9 **claudication, absence of hair on the feet, altered temperature** (a cold foot) and
10 **thin, bluish skin** are suggestive of **peripheral arterial disease**. A bounding, easily
11 detected pulse in a **warm, dry foot** is suggestive of **autonomic neuropathy**, which
12 causes abnormal arterio-venous shunting.
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Screening for high risk patient: Foot mobility

Limited Joint Mobility:

Progressive stiffening of collagen-containing tissues leads to thickening of the skin, loss of joint mobility, and potential fixed flexor deformity. Up to 30% of patients with diabetes may have limited joint mobility. Reduction in mobility of the ankle joint may cause increased plantar pressure when walking and be a major risk factor in the pathogenesis of diabetic foot ulcers (Fernando, Masson, Veves & Boulton, 1991; Zimny, Schatz & Pfohl, 2004). Achilles tendon contracture is a common cause of limited joint mobility causing increased pressure on the forefoot during ambulation (Armstrong, Lavery & Bushman, 1998; Mueller, Sinacore, Hastings, Strube & Johnson, 2004).

Starting position:

For all of the measurements, the same starting position is used. Position the participant on the bed / plinth in long sitting, reclined to about 45 degrees. Place a pillow under upper part of the lower legs to flex the knee to 20-30° and lifting the heels off the surface of the bed / plinth. Ensure the patient is comfortable during the measurements. If it is not possible for the patient to get into the starting position then the measurements could be taken sitting, as long as the knee remains more than 20 degrees flexed and the heel is not directly resting on a support.

-----Picture of clinical examination (removed due to ethical issue) -----

Measuring the range of motion

For the purposes of the trial, measure the uninjured ankle (if appropriate) and then the injured ankle.

Ask the patient to move as far as comfortable, not into pain. Measure how far the patient can move the foot / ankle themselves, do not assist the movement.

Ankle dorsiflexion and plantar flexion

Angles are measured from neutral (plantar grade), which is measured as 0°.

-----Picture of clinical examination (removed due to ethical issue) -----

Positioning and alignment of the goniometer:

-----Picture of clinical examination (removed due to ethical issue) -----

Goniometer axis

1
2
3 The axis of the goniometer placed approximately 1.5 cm inferior to the lateral
4 malleolus.

5
6 **Stationary arm**

7
8 Parallel to the longitudinal axis of the fibula, lining up with the fibula head.

9
10
11 **Moveable arm**

12 Parallel to the longitudinal axis of the 5th metatarsal.

13
14
15 **Instructions:**

16
17
18 **Dorsiflexion:** Ask the patient to pull their foot towards
19 them (Normal range is typically 0-20°)

20
21 -----Picture of clinical examination (removed due to ethical issue) -----
22

23
24 **Plantar flexion:** Ask the patient to point their foot
25 away (normal range is typically 0-50°)

26
27 -----Picture of clinical examination (removed due to ethical issue) -----
28

29
30
31 **Measure and record the angle between the movable and stationary arms in degrees.**

32
33 **Ankle inversion and eversion**

34
35 Angles are measured from neutral, which is measured as 0°.
36 Key bony landmarks that help to orientate the goniometer

37
38
39 **Positioning and alignment of the goniometer:**

40
41 -----Picture of clinical examination (removed due to ethical issue) -----
42

43 **Goniometer axis**

44 The axis of the goniometer is placed on the front of the ankle at the mid-point between the
45 medial and lateral malleoli.

46
47
48 **Stationary arm**

49 Along the tibial crest (prominent line of bone down the front of the shin)

50
51 **Moveable arm**

52 In line with the 2nd metatarsal (lining up with the base of the second toe)

Consent Form

Annex 1

1 **Dear Participant,**

2 **Purposive Selection**

3
4 You have been purposively selected to be part of this thesis and this is why we would like to interview
5 you. This thesis is being conducted by **Palash Chandra Banik**, a student of M.Phil in Non-
6 communicable Diseases at Bangladesh Institute of Health Sciences (BIHS) under Bangabandhu Sheikh
7 Mujib Medical University (BSMMU). This type of study is currently taking place in several countries
8 around the world.

9
10 **Title of Thesis**

11 The title of this thesis is **“Risk of foot ulcer and its determinants among Type 2 diabetic subjects”**.

12
13 **Aim of the Thesis**

14 To determine diabetic patients at risk for foot ulceration through a multi-center hospital based study in
15 Bangladesh

16
17 **Data Collection Methods**

18 **Step 1-** Interview questions

19 **Step 2-** Physical examination & screening test (foot)

20 **Timeframe**

21 It is estimated that step 1 & 2 of this study will take approximately 30-40 minutes.

22
23 **Confidentiality**

24 The information you provide is totally confidential and will not be disclosed to anyone. It will only be
25 used for research purposes. Your name, address, and other personal information will be removed from
26 the instrument, and only a code will be used to connect your name and your answers without
27 identifying you.

28
29 **Results**

30 The results of this thesis will be used to help plan strategies in reducing the risk factor that contribute to
31 diabetic foot ulcer among the diabetic patients as well as chronic non-communicable diseases in
32 Bangladesh.

33
34 The results will be published in research publications, media briefings and reports and can be made
35 available to you by local health workers.

36
37 **Voluntary Participation**

38 Your participation is voluntary and you can withdraw from the study after having agreed to participate.
39 You are free to refuse to answer any question that is asked in the questionnaire. If you have any
40 questions about this study you may ask me or contact to the researcher [Palash Chandra Banik, cell:
41 +8801710972498].

42
43 **Consent to Participate**

44 Signing this consent indicates that you understand what will be expected of you and are willing to
45 participate in this survey.

46 Read by Participant		Interviewer	
47 Agreed		Refused	

48
49
50 **Signatures**

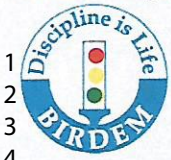
51 I hereby provide INFORMED CONSENT to take part in Steps 1 and 2 of this Risk Factor Study.

52
53
54 **Name of the participant:**

Witness:

55
56 **Sign or fingerprint**

Sign or fingerprint



BIRDEM

An Enterprise of the
Diabetic Association of
Bangladesh

**Bangladesh Institute of Research
and Rehabilitation in Diabetes,
Endocrine and Metabolic Disorders**



WHO Collaborating Centre
for Prevention and Control
of Diabetes

Memo No: BADAS/BIO/EA/11/033

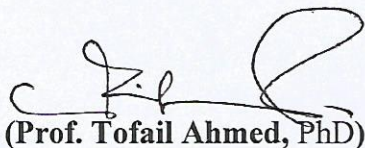
Date: 17.01.2011

To
Palash Chandra Banik
Student, MPhil in Noncommunicable Diseases (NCD)
Department of Community Medicine (CM)
Bangladesh Institute of Health Sciences (BIHS)

Subject: Ethical Clearance

The Ethical Review Committee (ERC) of the Bangladesh Diabetic Association (BADAS) has the pleasure to accord ethical clearance to your Protocol "**Risk of foot ulcer and its determinants among type 2 diabetic subjects in Bangladesh**" subject to the condition that the guidelines must be followed carefully.

- The Ethical Review Committee approves this study from an ethical point of view upon the addressing by the researchers of the concerns as raised by the ERC affiliates.
- Approval is given for three years. Projects, which have not commenced within two years of original approval, must be re-submitted to ERC. You must inform ERC when the research has been completed.
- Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical considerations must be reported immediately to the ERC.
- Approval is given on the understanding that the 'Guidelines for Ethical Review' are adhered to.



(Prof. Tofail Ahmed, PhD)

Chairman
Ethical Review Committee

	id	Center	Q1_age	Q1a_sex	rec_area	rec_edu	rec_occ	rec_marr
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2								
3								
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For peer review only

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For peer review only

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For peer review only

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For peer review only

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For peer review only

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For peer review only

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Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

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Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

	Reporting Item	Page Number
Title and abstract		
Title	#1a Indicate the study's design with a commonly used term in the title or the abstract	Page-1, Line Number-1
Abstract	#1b Provide in the abstract an informative and balanced summary of what was done and what was found	Page-2,3, Line Number-25-54
Introduction		
Background / rationale	#2 Explain the scientific background and rationale for the investigation being reported	Page-4-6, Line Number-75-135
Objectives	#3 State specific objectives, including any prespecified hypotheses	Page-6, Line Number-133-135
Methods		

1	Study design	#4	Present key elements of study design early in the paper	Page-6, Line Number-138
2				
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4	Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page-6, Line Number-140-143
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10	Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	Page-6, Line Number-144-148
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14		#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page-6-8, Line Number-147-201
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19	Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	Page-7, Line Number-179-201
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29	Bias	#9	Describe any efforts to address potential sources of bias	Page-8, Line Number-203-226
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33	Study size	#10	Explain how the study size was arrived at	Page-6, Line Number-139-140
34				
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36	Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Page-9, Line Number-239-258
37				
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41	Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	Page-9 & 10, Line Number-240-260
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45	Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a
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49	Statistical methods	#12c	Explain how missing data were addressed	n/a
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53	Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a
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57	Statistical methods	#12e	Describe any sensitivity analyses	n/a
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Results

Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	n/a
Participants	#13b	Give reasons for non-participation at each stage	Some of the participants were not participate as they had limited time.
Participants	#13c	Consider use of a flow diagram	n/a
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	Page-10, Line Number-242-244
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	n/a
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page-13-16, Line Number- 292-308
Main results	#16b	Report category boundaries when continuous variables were categorized	Page-10-16, Line Number- 259-308
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a

1	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	n/a
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6	Discussion			
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9	Key results	#18	Summarise key results with reference to study objectives	Page-16-20, Line Number- 311-434
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12	Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	Page-20-21, Line Number-436-447
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18	Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	Page-16-20, Line Number- 311-434
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24	Generalisability	#21	Discuss the generalisability (external validity) of the study results	Page-20-21, Line Number-436-447
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28	Other			
29	Information			
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32	Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page-22, Line Number-467-470
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