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Title:

Incidence and risk factors for falls among community dwelling elderly subjects - A prospective cohort study from Ernakulam, Kerala, India

Abstract

Background & Objectives:

Purpose: There is limited knowledge regarding epidemiology and risk of falls in elderly Living in low and middle income countries. The primary objective was to report the incidence of falls in community dwelling elderly population aged 65 years and above from Ernakulam, Kerala, India.

Methods: The study was a prospective cohort with stratified random cluster sampling. We collected information via house visits using a questionnaire. The subjects were followed up prospectively for 12 months by phone at 90 day intervals and missing subjects by house visits.

Participants: Community dwelling elderly above 65years of age.

Findings: We recruited a total of 1000 participants. A total of 201(20.1%) subjects reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 follow-up years. Female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), movement disorders including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05, 2.09, p=0.026), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13, p=0.012), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, p=0.001) and a history of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, p<0.001) predicted a fall in the following year.

Interpretation & Conclusions: One in five community dwelling elderly fall annually and one in four who fall are prone to fall again in the next year. Interventions targeting falls among elderly need to focus on modifiable risk factors like living alone during daytime, movement disorders, arthritis and dependence on basic activities of daily living.

Keywords: **Falls, Elderly, Community based study, Cohort Study, Kerala**

Strengths and limitations of this study

The strengths of the current study include a prospective cohort study design, large sample size (n=1000), representative urban and rural population components, inclusion of participants from different SES levels, no participants lost to follow up and use of a fall diary to avoid recall bias. The limitations include data from a single study site and a short period of follow up (one year).

Introduction

Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent of the total population.[1]This geriatric population is expected to double by 2050 to 2.1 billion.[1] Unintentional injuries are reported to be the fifth leading cause of death globally in this population and falls constitute two out of every three deaths in this category.[2] The Kellogg International Working Group that was constituted to focus on the prevention of elderly falls defined a fall as 'unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure'.[3]

Many prospective population-based studies have examined the epidemiology of falls in the community dwelling elderly across different settings. The reported incidence rates show wide variability from as low as 29% to as high as 40% in this population.[4-9]Various studies done in India have reported the prevalence of falls in community dwelling elderly ranging from 13-53%.[10-13] The incidence of recurrent falls (more than two episodes per calendar year) was reported to be 11 to 21% by Lord et al.[4]

The risk factors for falls in the elderly as reported by Lord et al can be grouped into seven major categories.[4]These include socio-demographic factors, balance and mobility factors, sensory and neuromuscular factors, psychological factors, medical factors, medication use, and environmental factors.[4] A recent meta-analysis by Deandrea et al pooled data from 74 prospective cohort studies that reported risk factors for prospective falls among community dwelling elders.[14] A prior history of falls, gait problems, walking aid use, vertigo, Parkinson

disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age group.[14]

The primary objective of our study was to report the incidence of falls in community dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective follow up schedule. The secondary objective was to identify factors that can predict a risk for future fall in community dwelling elders.

Methods:

Selection and Description of participants:

Design & Setting: The current study is a community based prospective cohort study that was conducted in an area within10 km radius from the study centre (Amrita Institute of Medical Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of 3 years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, 4 municipalities and 1 corporation. The study area comes under Ernakulam district of Kerala, South India.

We calculated the sample size using a previously published study by Mitchell-Fearson et al which reported a 21.7% prevalence for falls in the elderly.[15] We selected an alpha of 0.05 and an allowable error of 20% giving us a minimum sample size of 347 subjects. The design effect for the sampling method (multistage stratified random cluster sampling) was calculated using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC) of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We enrolled a total of 1000 participants anticipating significant sub group differences within the study sample.

Participants: We used stratified random cluster sampling method to select the participants. The sample was stratified at two levels, rural urban (level 1) and at the level of individual local self-governing units (LSGs, level 2). A total of 40 clusters using Probability proportional to size technique were selected randomly from the list of all available clusters within the defined geographical area. Each cluster was from an individual electoral ward within the LSGs. We selected 25 participants from each cluster. In each cluster, a random

starting point was selected and households were visited in a sequential manner by the principal investigator and staff till 25 subjects were recruited. A flowchart on the study design used in the present study is shown in figure.1. The inclusion criteria included (i) minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the study area of a minimum of 12 months after assessment and (iv) comprehensive skills in English/Malayalam language. The exclusion criteria included complete dependence for day to day activities.

Patient and public involvement: Patients and the public were not specifically involved in the planning and execution of this study. However, they were informed of the need of the study and quarterly follow up was done telephonically.

Technical Information and Interventions:

A study questionnaire was prepared after a detailed literature review of studies related to falls in the elderly. The study questionnaire included questions relating to the socio-demographic profile, comorbidities, physical activity, medication use and environmental assessment. This questionnaire was initially piloted over a small number of patients (n=50) and redundant questions were either removed or modified. The modified questionnaire was reviewed by subject experts and was approved for use in the full study.

All initial assessments were done at the participant's home. The research team (PI, two nurses) visited all recruited subjects at their home premises. The study questionnaire was administered by the PI by means of a face to face interview during house visits. In addition, height, weight and blood pressure readings were taken by the trained staff (nurses) that accompanied the PI. All subjects were advised to keep a diary in which they should note down and incidence of fall along with the date and time of fall, what the patient was doing when he fell, what caused the fall, whether it was witnessed fall or not and whether the fall had any consequences or complications. Three monthly follow up was done by telephonic conversation with enrolled subjects. Those who were not available over the phone were revisited via house visits. The data collection period was from August 2015 to April 2017.

Statistics:

We summarized demographic and social-economic variables to characterize the study population (Table 1). We presented the mean and standard deviation for normally distributed

continuous variables. Values are expressed in number and percentages. We used Chi square test to examine the association of categorical risk factors with prospective falls. All individual factors with a p value of <0.2 for association on bivariate analysis was selected for multivariate analysis. Multiple binary logistic regression was used to construct the prediction model for prospective falls. The cut-off point for statistical significance was set at an α-level of 5%. We reported the adjusted Odds Ratios (aOR) with 95% confidence intervals. Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago, USA).

Ethical approval:

We collected written informed consent from the consenting subjects before recruitment to the study and the same was documented for future reference. The consent contained the title, purpose, methods employed in the study, benefits to the subject as well as family and the interest of the respondent to participate on a voluntary basis to the study. The confidentiality of the study during the analysis was also mentioned in the consent. The consent process and study protocol was approved by the Institutional Ethics Committee (Institutional Ethics Committee Registration Number: ECR/129/Inst/KL/2013).

Results

Baseline Characteristics of the study population

We recruited a total of 1000 participants from 40 individual pre-designated clusters spread across a circular geographical area with the study institution as the centre point. The distribution of gender, age categories, weight status, education level, household living pattern and area of domicile are presented in Table 1. The mean age of the study subjects was 72.7(7.2) years. Among study participants, 568 (56.8%) were female, 87.4% were literate and 82% lived with family or caretakers. A total of 348 (34.8%) were either pre-obese or obese as per Asian Criteria of BMI classification.[16] The morbidity profile of the study population was published earlier.[17] The self-reported prevalence of diabetes(DM), coronary artery diseases(CAD) and cerebrovascular accidents (CVA) were 34.2%, 20.1%&5.3% respectively. Among study subjects, 768 (76.8%) were hypertensive as documented either by high values on house visit measurement or by current treatment for hypertension. Among hypertensives, a total of 528 subjects (68.8%) reported taking treatment for hypertension and remaining 240(31.2%) were newly detected during the baseline evaluation of the study.

Incidence of falls in the study population

A total of 201(20.1%) subjects reported a fall during the prospective follow up period of 12 months. The total fall episodes during the follow up period were 301. The overall incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 follow up years. The corresponding figures for elderly men and women separately were 21.2 (95% CI 18.5, 24.2) & 38.3 (95% CI, 34.6, 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85 were 27.4, 36.8 and 41.1 per 100 follow up years respectively. Among participants, more women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period, compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls) during the follow up.

Factors associated with prospective falls.

The association of baseline factors with a prospective history of falls during the follow up period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline variables, only gender and living arrangement showed a significant association with a prospective history of falls on bivariate comparisons. Females had a higher risk of fall when compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during daytime also had a higher risk of falls when compared to those living with family/caretaker (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors affecting locomotion was explored by bivariate analysis and is presented in **Table 3.** Among the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010), vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed significant associations with prospective falls on bivariate comparisons. A history of falls in the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p <0.001).

Among baseline factors only gender showed an association with recurrent falls on bivariate comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion

dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p <0.001), dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p = 0.038) and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001) showed an association with recurrent falls on bivariate comparisons.

In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%) reported taking anti diabetic medications and 69(6.9%) reported taking either benzodiazepines or other sedative drugs. There was no significant association for prospective falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

Independent Risk Factors for prospective falls

The final adjusted model with independent predictors of prospective falls in the elderly is presented as Table 4. Among the factors examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05-2.09, p=0.026), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13, p=0.012), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, p=0.001) and history of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, p<0.001) were found to be significantly associated with falls. The independent predictors for recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, p = 0.031), dependence in basic activities of daily living (OR 3.63, 95% CI 1.71, 7.70, p = 0.001), and history of falls in the previous year (OR 3.39, 95% CI 1.89, 6.05, p<0.001).

Discussion

This community based prospective cohort study provides details of 301 fall episodes experienced by 201 elderly subjects during a follow up period of one year from Ernakulam, Kerala, India. Approximately one in five elderly subjects in this age group reported a fall during the study period. There appears to be a sex based difference in the proportion that fell with one in four elderly women falling compared to one in six men during follow up. The results also suggest a dose response relationship between age and falls with more subjects falling in older age groups compared to relatively younger groups. In addition, every fourth

person who fell reported one or more falls following the index fall episode during the study period. The independent predictors for falls in the elderly included female sex, parkinsonism and related movement disorders, arthritis, dependence in basic activities of daily living, not using antihypertensive medicines, living alone during daytime and a history of fall in the preceding year. The corresponding predictors for recurrent falls included female sex, dependence in basic activities of daily living and a history of fall in the preceding year. To our knowledge, this is the only prospective cohort study done in India that focussed on falls in free living elderly who were assessed in the community setting.

The incidence of falls in the elderly from our study appears to be at the lower end of the spectrum as reported by western studies (29% to 40%).[4-9] Interestingly, our results are more similar to that reported by a prospective study among community dwelling elderly Chinese subjects.[18] The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-years for all elderly, women and men respectively. The proportion with recurrent falls in this study was also similar to our study (4.75% v/s 5.3%).

The risk factors for prospective falls in community dwelling elderly was examined by a recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.[14] Most of the prospective studies in the meta-analysis suggested that community dwelling elderly women are at higher risk for falls compared to their male counterparts. The pooled estimates for falls (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-analysis are in agreement with the current study.

Several prospective studies have reported higher risk for falls among elderly patients with Parkinsonism and/or related movement disorders similar to the current study. The meta-analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI, 1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't report any positive association between Parkinson's disease and recurrent falls, probably due to the small number of recurrent fallers (5.3%) in the cohort.

Our finding of high risk for falls among those elderly with arthritis is in concordance with several other studies.[19-22] Together these studies suggest that elderly with arthritis and/or chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis free peers.[22]

Several studies have reported that living alone during the daytime is a risk factor for falls in the elderly as suggested by the current study.[14] The meta-analysis is also in agreement with this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that examined the same.

Reduced BADL(Basic Activities of Daily Living) capability is also reported to be associated with falls in the elderly.[23] Yokoya et al recently concluded that higher frequency of leaving home, higher exercise levels and presence of interest in activities (e.g., meeting friends, shopping, working in the garden) were associated with a reduced risk for fall in community dwelling elders.[23] Maintaining and enhancing physical functions, principally walking ability and walking speed are critical for fall prevention among elderly.[24,25] Age appropriate exercises including those enhancing muscle strength and improving balance can probably reduce the incidence of falls among elderly.[25]

A history of falls in the previous year appears to be the most consistent risk factor across several studies.[14,25,26] Pooled data from several studies in the recent meta-analysis puts the risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).[14] Suzuki et al reported that five out of six elderly with a history of falls were anxious about another fall and one in three said that they did not venture out again due to fear of another fall.[25]

One notable finding in our study was the lack of association for falls with medication use for most groups of medications except for antihypertensive medications. This is in contrast to a meta-analysis of the impact of medication classes on falls in elderly.[27] Woolcott et al reported an OR of 1.41 (95% CrI, 1.20-1.71) for falls among elderly with benzodiazepine use.[27] The lack of association between sedatives use and falls in our study is probably due to the limited number of subjects reporting the use of the same (6.9%). We saw an inverse association between falls and the use of antihypertensive drug use in the current study. One probable reason could be the high proportion of uncontrolled hypertensives in the study population. This finding needs to be explored further in future studies.

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Conclusion

One in five community dwelling elderly citizens fall on an annual basis and one in four of those who fall are prone to fall again in the same calendar year. Female sex, movement disorders including parkinsonism, arthritis, dependence in basic activities of daily living, living alone during daytime and a history of falls in the previous year appear to predict a fall in the following year. Any intervention targeting a reduction in falls among the elderly need to focus on the modifiable risk factors like living alone at home during daytime, movement disorders and arthritis. We need to encourage mechanisms that may reduce dependence of elderly on basic activities of daily living. Attention should also be given to encourage both physical activity and interests in social activities among elderly subjects.

Competing Interests: Authors have no competing interests.

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)

Gender	
Male	432(43.2)
Female	568(56.8)
Age group	
65-75	648(64.8)
75-85	262(26.2)
>85	90(9.0)
Weight Status(BMI)	
Underweight(<18.5)	124(12.4)
Normal(18.5-22.9)	340(34.0)
Overweight(23-24.9)	188(18.8)
Pre Obese(25-29.9)	264(26.4)
Obese(>30)	84(8.4)
Education	
Graduate and above	132(13.2)
Diploma / Pre-degree	85(8.5)
Middle class / Primary	657(65.7)
Illiterate	126(12.6)
House Hold	
Living with family / caretaker	820 (82.0)
Living alone during daytime	145 (14.5)
Living alone	35 (3.5)
Domicile	
Urban	700(70.0)
Rural	300(30.0)

Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors	**Prospective falls**		**OR (95% CI)**	**P value**
	No Fall	**Fall**		

n(%)	n (%)	n (%)		
Gender				
Men **[432(43.2)]**	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women **[568(56.8)]**	434(76.4)	134(23.6)		
Age Group in years				
65-75 **[648(64.8)]**	528(81.5)	120(18.5)		
75-85 **[262(26.2)]**	208(79.4)	54(20.6)	1.14 (0.80-1.64)	0.468
>85 **[90(9.0)]**	63(70.0)	27(30.0)	1.89 (1.15 -3.09)	0.012
Diabetes [342(34.2)]				
No	532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes	267(78.1)	75(21.9)		
Hypertension (768(76.8))				
No	181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes	618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))				
No	622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes	177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))				
No	639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes	160(79.6)	41(20.4)		
Cerebrovascular Disease (53(5.3))				
No	762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
Yes	37(69.8)	16(30.2)		
Alcohol (177(17.7))				
No	654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
Yes	145(81.9)	32(18.1)		
Smoking (178(17.8))				
No	652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
Yes	147(82.6)	31(17.4)		
Living Arrangement				
Living with family/caretaker **(820(82))**	669(81.6)	151(18.4)		
Living alone during daytime **(145(14.5))**	109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone**(35(3.5))**	21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors	Prospective falls	OR (95% CI)	P value

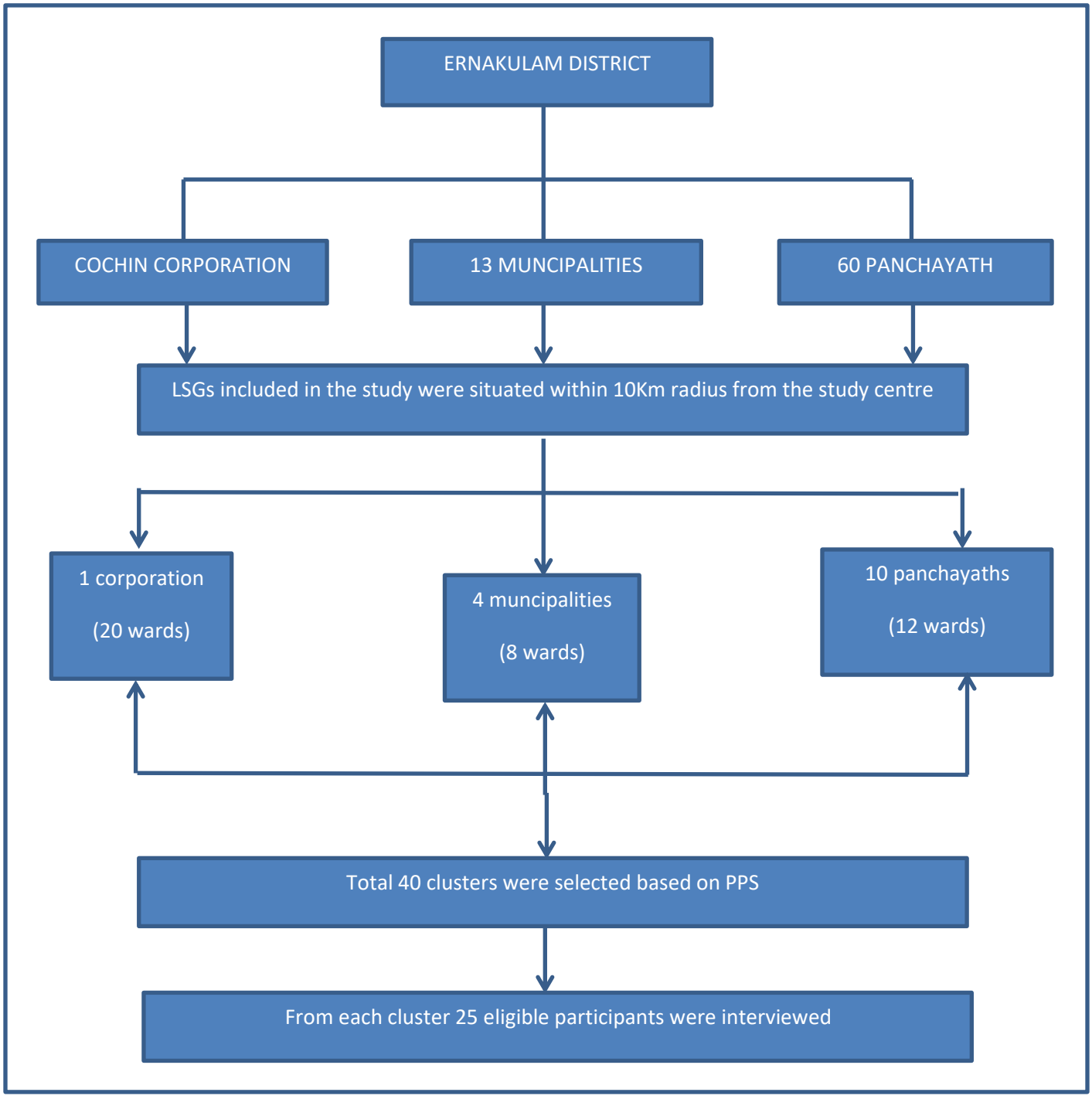
		No Fallers n (%)	Fallers n (%)		
Parkinsonism(28(2.8))					
	No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
	Yes	17(60.7)	11(39.3)		
Vertigo(388(38.8))					
	No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
	Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))					
	No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
	Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))					
	No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
	Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))					
	No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
	Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))					
	No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
	Yes	241(76.3)	75(23.7)		
Visual impairment (594(59.4))					
	No	326(80.3)	80(19.7)	1.04(0.76-1.43)	0.796
	Yes	473(79.6)	121(20.4)		
Not independent in Basic Activities of daily living (59(5.9))					
	Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
	No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))					
	Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
	No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))					
	Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
	No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))					
	Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
	No	617(84.4)	114(15.6)		

Table 4 Risk factors of falls in community dwelling elderly subjects

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		
Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

Figure

Fig.1 Flowchart of the Study Design



APPENDEX IV

INFORMED CONSENT

Introduction: Falls are a very common and often devastating problem in the elderly population. Most of these patients, who fall, end up getting injured, needing hospitalization or even surgical procedures. The prevalence of falls in the elderly is high and debilitating to the patients. However this aspect of health care is mostly neglected in our setup unless and until a person reports after a fall. Hence I feel this study will help us to assess the risk of fall in our population.

Name of project: **A PROSPECTIVE STUDY TO ASSESS THE PREVALENCE OF FALLS IN ELDERLY IN ERNAKULAM DISTRICT AND ITS ASSOCIATED RISK FACTORS OVER 1 YEAR**

Co coordinating center: Geriatric department, Amrita Institute of medical sciences, Kochi

Name of respondent.....

Address.....

Invitation and Purpose of the study:

We are conducting a study in which we are trying to understand the prevalence of fall in elderly in Kochi, Kerala, India and to find out the factors associated with these falls, with your permission, we would like to conduct this study. Please go through the details of the project below

Do I have to take part in this study?

Your participation in this study is voluntary. It is up to you to decide whether to participate in this study. If you change your mind, you are free to withdraw from the study at any time and without giving a reason. Refusal to participate will not involve any penalty or loss.

What do I have to do in this study? What is being studied?

If you agree to participate in this study, a questionnaire containing questions on environmental and lifestyle factors under study will be used to collect data. Trained investigators with the assistance of translators will administer the questionnaire. You will have to give answers to the questions asked. Follow up shall be done over phone where you have to say if you have fallen during the study period and the details of falls.

What are the Methods employed in the study?

A questionnaire containing questions on environmental and lifestyle factors under study. Basic physical parameters will be assessed, like height, weight, BMI and blood pressure. Memory status and depression status will be assessed using MMSE and GDS tools.

What are the risks in taking part in this study?

There are no risks in taking part in the study.

What are the Benefits?

The study will not provide you with any direct benefits. This study will put some light to the extent of this unrecognized problem .This information will help in prevention of such falls in elderly.

Is participation compulsory?

No. Taking part in this study is on a voluntary basis. If you have any doubt please do not hesitate to ask.

How will the information collected in the study be used?

The information collected will be kept completely confidential. At no point will we reveal the identity of the respondents when we analyze the data. Your information will be archived in a coded form. Your permission to the investigator to use this information does not automatically end at a particular time.

However your details will be released to any regulatory authorities if requested for legal/auditing purpose.

Problems or Questions:

If you have any question about the study, you may contact your investigator, whose details will be provided to you. You will also be asked to provide your address and contact details as we need to contact you during the study.

Name and Contact Details of the Investigator - Dr. Divyamol Sasidharan
Mob. No. 9995653009 Geriatrics Department
email:divz64@gmail.com AIMS, Kochi-682041

Name and contact details of local/Central ethics committee chairperson/member -
Dr. Santhi Kumar Nair, AIMS, Kochi-682041

I confirm that I have read the written information for study, "Prevalence of falls in elderly in Ernakulam district and its associated risk factors over 1 year in Kochi, Kerala, India.", and confirm that

- I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.
- I understand that I grant access to data to authorized persons described in the information sheet have been given time and opportunity to consider taking part in this study.
- I understand my participation is voluntary and that I am free to withdraw at any time, without giving reason
- I agree to take part in this study.

I confirm that I have been informed by my investigator that the information collected from me will be used for presentation /scientific publication and research analysis. I understand that such use is for advancement of further medical knowledge. I voluntarily agree to such use. I also understand that my identity will not be revealed in such presentation I express my willingness to the same. Having understood all the facts and the conditions stated above I accept and agree and hereby express my free and voluntary consent to Dr. Divyamol Sasidharan and his associates to participate in the study.

I understand that I have not given up any of my rights by signing this form. I will receive the full copy of the informed consent referred to above, including this signed statement with my signature below.

Signature of respondent:
Address:
Date:

Signature of witness:
Name of witness:
Address:
Date:

I have explained and made Mr. /Mrs. .....understand the above mentioned details of the study. -

Signature of investigator:

Name:

Address:

Date:

BMJ Open

Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India

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Secondary Subject Heading:	Epidemiology, Public health
Keywords:	Falls, Elderly, Community based study, Cohort Study, Kerala

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Title Page

Type of article: Original

Title of the article: **Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India**

Running title : Risk factors for falls among community dwelling elderly subjects in Kerala

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Title:

Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India

Abstract

Purpose : There is limited data regarding epidemiology and risk of falls in elderly in low middle income countries probably due to lack of awareness regarding the factors leading to falls and the consequences of fall related injuries in old in these countries.

Participants : Community dwelling elderly above 65years of age.

Findings to date : We recruited a total of 1000 participants. A total of 201(20.1%) subjects

reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 follow-up years. Female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), movement disorders including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05, 2.09, p=0.026), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13, p=0.012), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, p=0.001) and a history of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, p<0.001) predicted a fall in the following year.

Future plans: The Cohort is being followed up to study falls and its relation to mortality.

Keywords: **Falls, Elderly, Community based study, Cohort Study, Kerala**

Strengths and limitations of this study:

- The study was a prospective cohort study design with large sample size (n=1000).
- The study population represented both urban and rural population from different Socio Economic Scale levels.
- None of the participants were lost to follow up and a fall diary was used to avoid recall bias.
- The data is from a single study setting.
- The study has a short period of follow up (one year).

Introduction

Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent of the total population.[1] Unintentional injuries are reported to be the fifth leading cause of death globally in this population and falls constitute two out of every three deaths in this category.[2] The Kellogg International Working Group defined a fall as 'unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure'.[3]

Many prospective population-based studies have examined the epidemiology of falls in the community dwelling elderly across different settings. Environmental factors have been considered as having an association with falls in low middle income countries. Nutrition is not that well addressed among the elders in developing countries. Poor nutrition is a risk factor that could be contributing to the increase in falls in low middle income countries. Interventions that prevent falls are not accessible to a majority of elder population in such countries. Fall preventing interventions are not that freely available in many part of such countries.[4]

The reported incidence rates show wide variability from as low as 29% to as high as 40% in this population.[5-10]Various studies done in India have reported the prevalence of falls in community dwelling elderly ranging from 13-53%.[11-14] The incidence of recurrent falls (more than two episodes per calendar year) was reported to be 11 to 21% by Lord et al.[5]

The risk factors for falls in the elderly as reported by Lord et al can be grouped into seven major categories.[5]These include socio-demographic factors, balance and mobility factors, sensory and neuromuscular factors, psychological factors, medical factors, medication use, and environmental factors.[5] A recent meta-analysis by Deandrea et al pooled data from 74 prospective cohort studies that reported risk factors for prospective falls among community dwelling elders.[15] A prior history of falls, gait problems, walking aid use, vertigo, parkinson disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age group.[15]

The primary objective of our study was to report the incidence of falls in community dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective follow up schedule. The secondary objective was to identify factors that can predict a risk for future fall in community dwelling elders.

Methods:

Selection and Description of participants:

Design & Setting: The current study is a community based prospective cohort study that was conducted in an area within10 km radius from the study centre (Amrita Institute of Medical Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of

three years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, four municipalities and one corporation. The study area comes under Ernakulam district of Kerala, South India.

We calculated the sample size using a previously published study by Mitchell-Fearson et al which reported 21.7% prevalence for falls in the elderly.[16] We selected an alpha of 0.05 and an allowable error of 20% giving us a minimum sample size of 347 subjects. The design effect for the sampling method (multistage stratified random cluster sampling) was calculated using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC) of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We enrolled a total of 1000 participants anticipating significant sub group differences within the study sample.

Participants: We used stratified random cluster sampling method to select the participants. The sample was stratified at two levels, rural urban (level 1) and at the level of individual local self-governing units (LSGs, level 2). A total of 40 clusters using Probability proportional to size technique were selected randomly from the list of all available clusters within the defined geographical area. Each cluster was from an individual electoral ward within the LSGs. We selected 25 participants from each cluster. In each cluster, a random starting point was selected and households were visited in a sequential manner by the principal investigator and staff till 25 subjects were recruited. A flowchart on the study design used in the present study is shown in figure.1. The inclusion criteria included (i) minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the study area for a minimum of one year after assessment and (iv) ability to communicate in English/Malayalam language. The exclusion criteria included complete dependence for day to day activities.

Operational definitions:

Fall was defined as suggested by The Kellogg International Working Group as mentioned in the introduction.[3]

A recurrent fall was defined as fall of two or more times during the follow up period of one year.[5]

Patient and public involvement: Patients and the public were not specifically involved in the planning and execution of this study. However, they were informed of the need of the study and quarterly follow up was done telephonically.

Technical Information and Interventions:

A study questionnaire was prepared after a detailed literature review of studies related to falls in the elderly. The study questionnaire included questions relating to the socio-demographic profile, comorbidities, physical activity, medication use and environmental assessment. This questionnaire was initially piloted over a small number of patients (n=50) and redundant questions were either removed or modified. The modified questionnaire was reviewed by subject experts and was approved for use in the full study.

All initial assessments were done at the participant's home. The research team (PI, two nurses) visited all recruited subjects at their home premises. The study questionnaire was administered by the PI by means of a face to face interview during house visits. In addition, height, weight and blood pressure readings were taken by the trained staff (nurses) that accompanied the PI. All subjects were advised to keep a fall diary in which they should note down and incidence of fall along with the date and time of fall, what the patient was doing when he fell, what caused the fall, whether it was witnessed fall or not and whether the fall had any consequences or complications. Three monthly follow up was done by telephonic conversation with enrolled subjects for one year from first visit. Those who were not available over the phone were revisited via house visits by the research staff and hence no missing data was encountered in the study. In addition, the fall diaries of those who reported a fall from the same cluster were reviewed during these house visits. The data collection period was from August 2015 to April 2017.

Statistics:

We summarized demographic and social-economic variables to characterize the study population (Table 1). We presented the mean and standard deviation for normally distributed continuous variables. Values are expressed in number and percentages. We used Chi square test to examine the association of categorical risk factors with prospective falls. All individual factors with a p value of <0.2 for association on bivariate analysis was selected for multivariate analysis. Multiple binary logistic regression was used to construct the prediction

model for prospective falls. We selected Logistic regression after verifying lack of over-dispersion using the Pearson and deviance methods. The cut-off point for statistical significance was set at an α-level of 5%. We reported the adjusted Odds Ratios (aOR) with 95% confidence intervals. We encountered no missing data in the study. Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago, USA).

Ethical approval:

We collected written informed consent from the consenting subjects before recruitment to the study and the same was documented for future reference. The consent contained the title, purpose, methods employed in the study, benefits to the subject as well as family and the interest of the respondent to participate on a voluntary basis to the study. The confidentiality of the study during the analysis was also mentioned in the consent. The consent process and study protocol was approved by the Institutional Ethics Committee of Amrita Institute of Medical Sciences and Research centre. (Institutional Ethics Committee Registration Number: ECR/129/Inst/KL/2013).

Results

Baseline Characteristics of the study population

We recruited a total of 1000 participants from 40 individual pre-designated clusters spread across a circular geographical area with the study institution as the centre point of which 568 (56.8%) were female. The distribution of gender, age categories, weight status, education level, household living pattern and area of domicile are presented in Table 1. The mean age of the study subjects was 72.7(7.2) years. Among study participants, 568 (56.8%) were female, 87.4% were literate and 82% lived with family or caretakers. A total of 348 (34.8%) were either pre-obese or obese as per Asian Criteria of BMI classification.[17] The morbidity profile of the study population was published earlier.[18] The self-reported prevalence of diabetes(DM), coronary artery diseases(CAD) and cerebrovascular accidents (CVA) were 34.2%, 20.1%&5.3% respectively. Among study subjects, 768 (76.8%) were hypertensive as documented either by high values on house visit measurement or by current treatment for hypertension. Among hypertensives, a total of 528 subjects (68.8%) reported taking treatment for hypertension and remaining 240(31.2%) were newly detected during the baseline evaluation of the study.

Incidence of falls in the study population

A total of 201(20.1%) subjects reported a fall during the prospective follow up period of one year. The total fall episodes during the follow up period were 301. The overall incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 follow up years. The corresponding figures for elderly men and women separately were 21.2 (95% CI 18.5, 24.2) & 38.3 (95% CI, 34.6, 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85 were 27.4, 36.8 and 41.1 per 100 follow up years respectively. Among participants, more women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period, compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls) during the follow up.

Factors associated with prospective falls.

The association of baseline factors with a prospective history of falls during the follow up period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline variables, only gender and living arrangement showed a significant association with a prospective history of falls on bivariate comparisons. Females had a higher risk of fall when compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during daytime also had a higher risk of falls when compared to those living with family/caretaker (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors affecting locomotion was explored by bivariate analysis and is presented in **Table 3.** Among the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010), vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed significant associations with prospective falls on bivariate comparisons. A history of falls in the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p <0.001).

Among baseline factors only gender showed an association with recurrent falls on bivariate comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion

dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p <0.001), dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p = 0.038) and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001) showed an association with recurrent falls on bivariate comparisons.

In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%) reported taking anti diabetic medications and 69(6.9%) reported taking either benzodiazepines or other sedative drugs. There was no significant association for prospective falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

Independent Risk Factors for prospective falls

The final adjusted model with independent predictors of prospective falls in the elderly is presented as Table 4. The variables found to be significant(P value <0.2) in bivariate analysis with falls were age, sex, living arrangement, vertigo, parkinsonism, arthritis, urinary symptoms, constipation, knee pain, paresthesia of feet, history of fall in the previous year, dependence in basic and instrumental activities of daily living, use of assistive devices for movement, cognitive impairment, depression, use of antihypertensive medications and benzodiazepines. The same were included in the final model construction. Among the factors examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05-2.09, p=0.026), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13, p=0.012), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, p=0.001) and history of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, p<0.001) were found to be significantly associated with falls.

The factors included to assess the independent risk factors of recurrent falls were, female sex, vertigo, parkinsonism, arthritis and dependence in basic and instrumental activities of daily living and history of falls in the previous year. From the above, the independent predictors for recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, p = 0.031), dependence in basic activities of daily living (OR 3.63, 95% CI 1.71, 7.70, p = 0.001), and history of falls in the previous year (OR 3.39, 95% CI 1.89, 6.05, p<0.001).

Discussion

This community based prospective cohort study provides details of 301 fall episodes experienced by 201 elderly subjects during a follow up period of one year from Ernakulam, Kerala, India. Approximately one in five elderly subjects in this age group reported a fall during the study period. There appears to be a sex based difference in the proportion that fell with one in four elderly women falling compared to one in six men during follow up. The results also suggest a dose response relationship between age and falls with more subjects falling in older age groups compared to relatively younger groups. In addition, every fourth person who fell reported one or more falls following the index fall episode during the study period. The independent predictors for falls in the elderly included female sex, parkinsonism and related movement disorders, arthritis, dependence in basic activities of daily living, not using antihypertensive medicines, living alone during daytime and a history of fall in the preceding year. The corresponding predictors for recurrent falls included female sex, dependence in basic activities of daily living and a history of fall in the preceding year. To our knowledge, this is the only prospective cohort study done in India that focussed on falls in free living elderly who were assessed in the community setting.

The incidence of falls in the elderly from our study appears to be at the lower end of the spectrum as reported by western studies (29% to 40%).[5-10] Interestingly, our results are more similar to that reported by a prospective study among community dwelling elderly Chinese subjects.[19] The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-years for all elderly, women and men respectively. The proportion with recurrent falls in this study was also similar to our study (4.75% v/s 5.3%).

The risk factors for prospective falls in community dwelling elderly was examined by a recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.[15] Most of the prospective studies in the meta-analysis suggested that community dwelling elderly women are at higher risk for falls compared to their male counterparts. The pooled estimates for falls (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-analysis are in agreement with the current study.

Several prospective studies have reported higher risk for falls among elderly patients with Parkinsonism and/or related movement disorders similar to the current study. The meta-analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI,

1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't report any positive association between Parkinson's disease and recurrent falls, probably due to the small number of recurrent fallers (5.3%) in the cohort.

Our finding of high risk for falls among those elderly with arthritis is in concordance with several other studies.[20-23] Together these studies suggest that elderly with arthritis and/or chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis free peers.[23]

Several studies have reported that living alone during the daytime is a risk factor for falls in the elderly as suggested by the current study.[15] The meta-analysis is also in agreement with this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that examined the same.

Reduced BADL(Basic Activities of Daily Living) capability is also reported to be associated with falls in the elderly.[24] Yokoya et al recently concluded that higher frequency of leaving home, higher exercise levels and presence of interest in activities (e.g., meeting friends, shopping, working in the garden) were associated with a reduced risk for fall in community dwelling elders.[24] Maintaining and enhancing physical functions, principally walking ability and walking speed are critical for fall prevention among elderly.[25,26] Age appropriate exercises including those enhancing muscle strength and improving balance can probably reduce the incidence of falls among elderly.[26]

A history of falls in the previous year appears to be the most consistent risk factor across several studies.[15,26,27] Pooled data from several studies in the recent meta-analysis puts the risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).[15] Suzuki et al reported that five out of six elderly with a history of falls were anxious about another fall and one in three said that they did not venture out again due to fear of another fall.[26]

One notable finding in our study was the lack of association for falls with medication use for most groups of medications except for antihypertensive medications. This is in contrast to a meta-analysis of the impact of medication classes on falls in elderly.[28] Woolcott et al reported

an OR of 1.41 (95% CI, 1.20-1.71) for falls among elderly with benzodiazepine use.[28] The lack of association between sedatives use and falls in our study is probably due to the limited number of subjects reporting the use of the same (6.9%). We saw an inverse association between falls and the use of antihypertensive drug use in the current study. One probable reason could be the high proportion of uncontrolled hypertensives in the study population. This finding needs to be explored further in future studies.

The strengths of the current study include; prospective cohort study design, large sample size (n=1000), representative urban and rural population components, inclusion of participants from different Socioeconomic levels, no participants lost to follow up and use of a fall diary to avoid recall bias. However, the study included participants from a limited geographical setting and was able to follow up only for a shorter period (one year) and hence the generalisation of the study findings is limited.

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Conclusion

One in five community dwelling elderly citizens fall on an annual basis and one in four of those who fall are prone to fall again in the same calendar year. Female sex, movement disorders including parkinsonism, arthritis, dependence in basic activities of daily living, living alone during daytime and a history of falls in the previous year appear to predict a fall in the following year. Any intervention targeting a reduction in falls among the elderly need to focus on the modifiable risk factors like living alone at home during daytime, movement disorders and arthritis. We need to encourage mechanisms that may reduce dependence of elderly on basic activities of daily living. Attention should also be given to encourage both physical activity and interests in social activities among elderly subjects.

Competing Interests: Authors have no competing interests.

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)
Gender	
Male	432(43.2)
Female	568(56.8)
Age group	
65-75	648(64.8)
75-85	262(26.2)
>85	90(9.0)
Weight Status(BMI)	
Underweight(<18.5)	124(12.4)
Normal(18.5-22.9)	340(34.0)
Overweight(23-24.9)	188(18.8)
Pre Obese(25-29.9)	264(26.4)
Obese(>30)	84(8.4)
Education	
Graduate and above	132(13.2)
Diploma / Pre-degree	85(8.5)
Middle class / Primary	657(65.7)
Illiterate	126(12.6)
House Hold	
Living with family / caretaker	820 (82.0)
Living alone during daytime	145 (14.5)
Living alone	35 (3.5)
Domicile	

Urban	700(70.0)
Rural	300(30.0)

Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors n(%)	Prospective falls		OR (95% CI)	P value
	No Fall n (%)	Fall n (%)		
Gender				
Men **[432(43.2)]**	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women **[568(56.8)]**	434(76.4)	134(23.6)		
Age Group in years				
65-75 **[648(64.8)]**	528(81.5)	120(18.5)		
75-85 **[262(26.2)]**	208(79.4)	54(20.6)	1.14 (0.80-1.64)	0.468
>85 **[90(9.0)]**	63(70.0)	27(30.0)	1.89 (1.15 -3.09)	0.012
Diabetes [342(34.2)]				
No	532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes	267(78.1)	75(21.9)		
Hypertension (768(76.8))				
No	181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes	618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))				
No	622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes	177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))				
No	639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes	160(79.6)	41(20.4)		
Cerebrovascular Disease (53(5.3))				
No	762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
Yes	37(69.8)	16(30.2)		

Alcohol (177(17.7))				
No	654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
Yes	145(81.9)	32(18.1)		
Smoking (178(17.8))				
No	652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
Yes	147(82.6)	31(17.4)		
Living Arrangement				
Living with family/caretaker **(820(82))**	669(81.6)	151(18.4)		
Living alone during daytime **(145(14.5))**	109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone**(35(3.5))**	21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors	Prospective falls		OR (95% CI)	P value
	No Fallers n (%)	Fallers n (%)		
Parkinsonism(28(2.8))				
No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
Yes	17(60.7)	11(39.3)		
Vertigo(388(38.8))				
No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))				
No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))				
No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))				
No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))				
No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
Yes	241(76.3)	75(23.7)		
Visual impairment (594(59.4))				
No	326(80.3)	80(19.7)	1.04(0.76-1.43)	0.796
Yes	473(79.6)	121(20.4)		

Not independent in Basic Activities of daily living (59(5.9))	Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
	No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))	Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
	No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))	Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
	No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))	Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
	No	617(84.4)	114(15.6)		

Table 4 Risk factors of falls in community dwelling elderly subjects

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		
Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

Figure legends

Fig.1 Flowchart of the study design

Contributorship statement :-

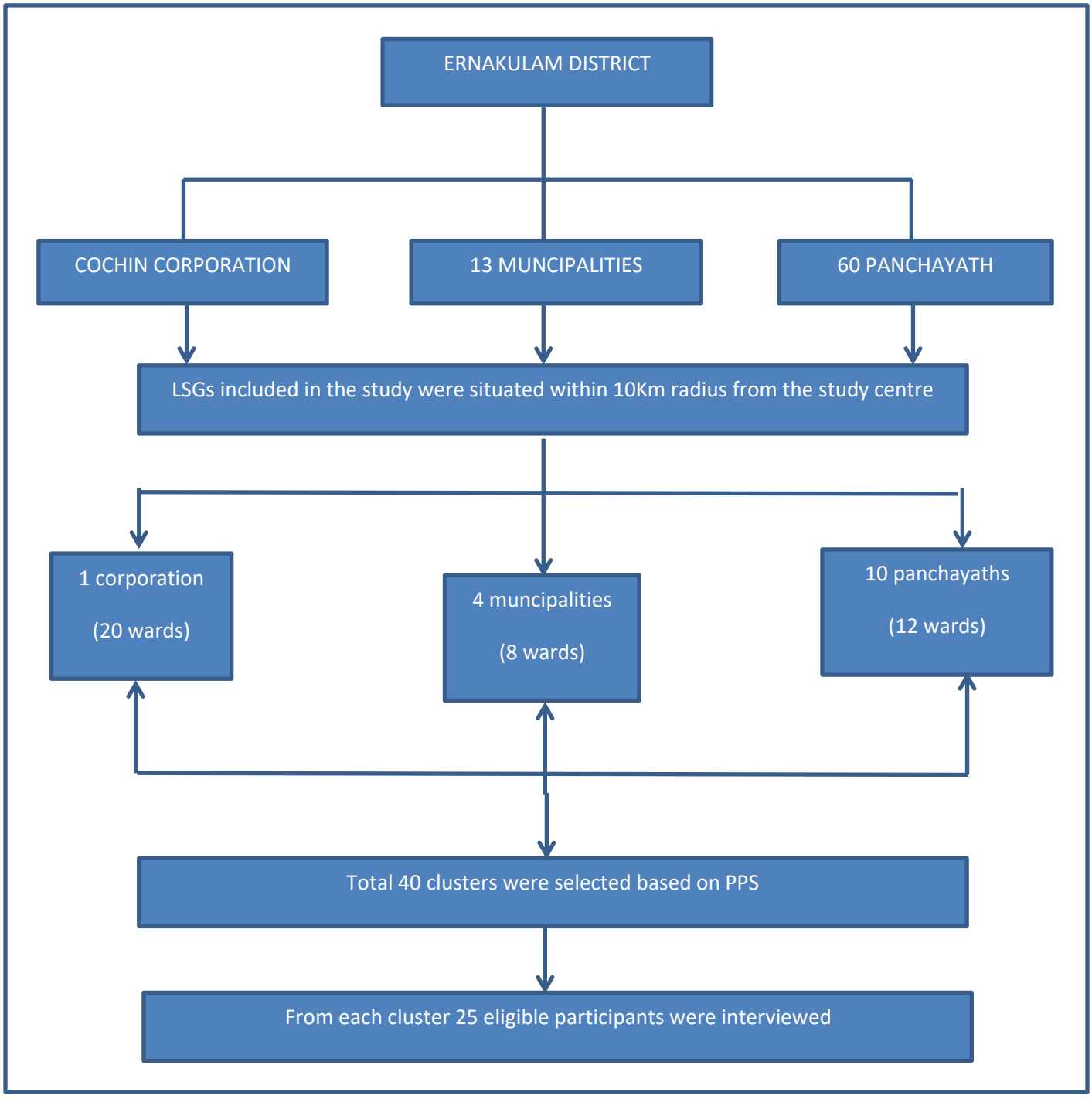
Divyamol K S and Priya Vijayakumar conceptualised the original idea. Divyamol K S and Manu Raj did review of literature and planned, conducted analysed and prepared manuscript of the research work. Priya Vijayakumar supervised the experiment and in final editing of the article. Sumi Soman and Libin Antony was involved in data acquisition and analysis. Abish Sudhakar and Conrad Kabali derived the models and analysed the data.

Data availability statement :-

All data relevant to the study are included in the article or uploaded as supplementary information.

Figure

Fig.1 Flowchart of the Study Design



STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

		Recommendation	Action taken
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 4, Line 50 & 51
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 4-5, Line 53-78
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5, Line 92-95 & 100-106
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6, Line 119-122
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6, Line 126
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6, Line 117-138
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 6&7, Line 139-151
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 7, Line 154-165
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	Page 7, Line 160-*177*
Bias	9	Describe any efforts to address potential sources of bias	Page 7, Line 147-151&170-174
Study size	10	Explain how the study size was arrived at	Page 6&7, Line 131-138
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8, Line 180-190
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 8, Line 181-186
		(*b*) Describe any methods used to examine subgroups and interactions	Not done
		(*c*) Explain how missing data were addressed	No missing data was encountered
		(*d*) If applicable, explain how loss to follow-up was addressed	No Loss to follow up was reported
		(*e*) Describe any sensitivity analyses	Not Applicable
Results			
Participants	13*	(a) 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	Page 9, Line 201-203 Refer Fig 1
		(b) Give reasons for non-participation at each stage	Not Applicable

		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14 *	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9, Line 201-214
		(b) Indicate number of participants with missing data for each variable of interest	No missing data
		(c) Summarise follow-up time (eg, average and total amount)	Page 8, Line 173-176
Outcome data	15 *	Report numbers of outcome events or summary measures over time	Page 9, Line 216-226
Main results	16	(*a*) 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 10, Line 228-257
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 11, Line 259-278
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 11-12, Line 280-300
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 13, Line 349-351
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 12&13, Line 301-343
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13, Line 346-349
Other information			
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 14, Line 356-357

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Title Page

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Title of the article: **Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India**

Running title : Risk factors for falls among community dwelling elderly subjects in Kerala

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Title:

Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India

Abstract

Objectives: There is limited knowledge regarding epidemiology and risk of falls in elderly living in low and middle income countries. The current study aims to report the incidence of falls among free living elderly population from Kerala, India.

Design: Prospective cohort study with stratified random cluster sampling.

Setting: The study location was Ernakulam, Kerala, India. We collected information via house visits using a questionnaire. The subjects were followed up prospectively for one year by phone at three monthly intervals and missing subjects by house visits.

Participants: Community dwelling elderly above 65years of age.

Results: We recruited a total of 1000 participants. A total of 201(20.1%) subjects reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 person years. Female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), movement disorders including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05, 2.09, p=0.026), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13, p=0.012), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, p=0.001) and a history of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, p<0.001) predicted a fall in the following year.

Conclusions: One in five community dwelling elderly fall annually and one in four who fall are prone to fall again in the next year. Interventions targeting falls among elderly need to focus on modifiable risk factors like living alone during daytime, movement disorders, arthritis and dependence on basic activities of daily living.

Keywords: **Falls, Elderly, Community based study, Cohort Study, Kerala**

Strengths and limitations of this study:

- The study was a prospective cohort study design with large sample size (n=1000).
- The study population represented both urban and rural population from different Socio Economic Scale levels.
- None of the participants were lost to follow up and a fall diary was used to avoid recall bias.
- The data is from a single study setting.
- The study has a short period of follow up (one year).

Introduction

Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent of the total population.[1] Unintentional injuries are reported to be the fifth leading cause of death globally in this population and falls constitute two out of every three deaths in this category.[2] The Kellogg International Working Group defined a fall as 'unintentionally

coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure'.[3]

Already over 70 % of the world's older population live in developing countries. The proportion will increase in coming decades due to increasing longevity in all regions of the world.[4] The incidence of falls as well as the consequences of falls have been higher in lower and middle income countries as compared to high income countries.[5-7] Each year an estimated 646 000 individuals die from falls globally of which over 80% are in low- and middle-income countries.[5] In 2010, for example, years lived with disability (YLDs) due to reported falls were 631.2 per 100,000 (population) in India and 674.4 per 100,000 in China, compared with 472.2 per 100,000 in the United States.[6] In that year, the global share of YLDs due to falls in adults aged 50 to 59 years was 66 % in developing countries and 34 % in high income developed countries. [7] Fall preventing interventions are not that freely available in many parts of low and middle income countries.[8]

Many prospective population-based studies have examined the epidemiology of falls in the community dwelling elderly across different settings. The reported incidence rates show wide variability from as low as 29% to as high as 40% in this population.[9-14]Various studies done in India too have reported the prevalence of falls in community dwelling elderly ranging from 13-53%.[15-18] The incidence of recurrent falls (more than two episodes per calendar year was reported to be 11 to 21% by Lord et al.[9]

The risk factors for falls in the elderly as reported by Lord et al can be grouped into seven major categories.[9]These include socio-demographic factors, balance and mobility factors, sensory and neuromuscular factors, psychological factors, medical factors, medication use, and environmental factors.[9] A recent meta-analysis by Deandrea et al pooled data from 74 prospective cohort studies that reported risk factors for prospective falls among community dwelling elders.[19] A prior history of falls, gait problems, walking aid use, vertigo, parkinson disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age group.[19]

The primary objective of our study was to report the incidence of falls in community dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective follow up schedule. The secondary objective was to identify factors that can predict a risk for future fall in community dwelling elders.

Methods:

Selection and Description of participants:

Design & Setting: The current study is a community based prospective cohort study that was conducted in an area within10 km radius from the study centre (Amrita Institute of Medical Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of three years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, four municipalities and one corporation. The study area comes under Ernakulam district of Kerala, South India.

We calculated the sample size using a previously published study by Mitchell-Fearson et al which reported 21.7% prevalence for falls in the elderly.[20] We selected an alpha of 0.05 and an allowable error of 20% giving us a minimum sample size of 347 subjects. The design effect for the sampling method (multistage stratified random cluster sampling) was calculated using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC) of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We enrolled a total of 1000 participants anticipating significant sub group differences within the study sample.

Participants: We used stratified random cluster sampling method to select the participants. The sample was stratified at two levels, rural urban (level 1) and at the level of individual local self-governing units (LSGs, level 2). A total of 40 clusters using Probability proportional to size technique were selected randomly from the list of all available clusters within the defined geographical area. Each cluster was from an individual electoral ward within the LSGs. We selected 25 participants from each cluster. In each cluster, a random starting point was selected and households were visited in a sequential manner by the principal investigator and staff till 25 subjects were recruited. A flowchart on the study design used in the present study is shown in figure.1. The inclusion criteria included (i)

minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the study area for a minimum of one year after assessment and (iv) ability to communicate in English/Malayalam language. The exclusion criteria included complete dependence for day to day activities.

Operational definitions:

Fall was defined as suggested by The Kellogg International Working Group as mentioned in the introduction.[3]

A recurrent fall was defined as fall of two or more times during the follow up period of one year.[9]

Patient and public involvement: Patients and the public were not specifically involved in the planning and execution of this study. However, they were informed of the need of the study and quarterly follow up was done telephonically.

Technical Information:

A study questionnaire was prepared after a detailed literature review of studies related to falls in the elderly. The study questionnaire included questions relating to the socio-demographic profile, comorbidities, physical activity, medication use and environmental assessment. This questionnaire was initially piloted over a small number of patients (n=50) and redundant questions were either removed or modified. The modified questionnaire was reviewed by subject experts and was approved for use in the full study.

All initial assessments were done at the participant's home. The research team (PI, two nurses) visited all recruited subjects at their home premises. The study questionnaire was administered by the PI by means of a face to face interview during house visits. In addition, height, weight and blood pressure readings were taken by the trained staff (nurses) that accompanied the PI. All subjects were advised to keep a fall diary in which they were instructed to note down any incidence of fall along with the date and time of fall, what the patient was doing when he fell, what caused the fall, whether it was a witnessed fall or not and whether the fall had any consequences or complications. A three monthly follow up was done by telephonic conversation with enrolled subjects for one year from first visit. Those who were not available over the phone were revisited via house visits by the research staff

and hence no missing data were encountered in the study. In addition, the fall diaries of those who reported a fall from the same cluster were reviewed during these house visits. The data collection period was from August 2015 to April 2017.

Statistics:

We summarized demographic and social-economic variables to characterize the study population (Table 1). We presented the mean and standard deviation for normally distributed continuous variables. All categorical variables are expressed in number and percentages. We used Chi square test to examine the association of categorical risk factors with prospective falls. All individual factors with a p value of <0.2 for association on bivariate analysis was selected for multivariate analysis. Multiple binary logistic regression was used to construct the prediction model for prospective falls. We selected Logistic regression after verifying lack of over-dispersion using the Pearson and deviance methods. The cut-off point for statistical significance was set at an α-level of 5%. We reported the adjusted Odds Ratios (aOR) with 95% confidence intervals. We encountered no missing data in the study. Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago, USA).

Ethical approval:

We collected written informed consent from the consenting subjects before recruitment to the study and the same was documented for future reference. The consent contained the title, purpose, methods employed in the study, benefits to the subject as well as family and the interest of the respondent to participate on a voluntary basis to the study. The confidentiality of the study during the analysis was also mentioned in the consent. The consent process and study protocol was approved by the Institutional Ethics Committee of Amrita Institute of Medical Sciences and Research centre. (Institutional Ethics Committee Registration Number: ECR/129/Inst/KL/2013).

Results

Baseline Characteristics of the study population

We recruited a total of 1000 participants from 40 individual pre-designated clusters spread across a circular geographical area with the study institution as the centre point of which 568 (56.8%) were female. The distribution of gender, age categories, weight status, education

level, household living pattern and area of domicile are presented in Table 1. The mean age of the study subjects was 72.7(7.2) years. Among study participants, 568 (56.8%) were female, 87.4% were literate and 82% lived with family or caretakers. A total of 348 (34.8%) were either pre-obese or obese as per Asian Criteria of BMI classification.[21] The morbidity profile of the study population was published earlier.[22] The self-reported prevalence of diabetes(DM), coronary artery diseases(CAD) and cerebrovascular accidents (CVA) were 34.2%, 20.1%&5.3% respectively. Among study subjects, 768 (76.8%) were hypertensive as documented either by high values on house visit measurement or by current treatment for hypertension. Among hypertensives, a total of 528 subjects (68.8%) reported taking treatment for hypertension and remaining 240(31.2%) were newly detected during the baseline evaluation of the study.

Incidence of falls in the study population

A total of 201(20.1%) subjects reported a fall during the prospective follow up period of one year. The total fall episodes during the follow up period were 301. The overall incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 person years. The corresponding figures for elderly men and women separately were 21.2 (95% CI 18.5, 24.2) & 38.3 (95% CI, 34.6, 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85 were 27.4, 36.8 and 41.1 per 100 person years respectively. Among participants, more women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period, compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls) during the follow up.

Factors associated with prospective falls.

The association of baseline factors with a prospective history of falls during the follow up period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline variables, only gender and living arrangement showed a significant association with a prospective history of falls on bivariate comparisons. Females had a higher risk of fall when compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during daytime also had a higher risk of falls when compared to those living with family/caretaker (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors

affecting locomotion was explored by bivariate analysis and is presented in **Table 3.** Among the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010), vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed significant associations with prospective falls on bivariate comparisons. A history of falls in the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p <0.001).

Among baseline factors only gender showed an association with recurrent falls on bivariate comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p <0.001), dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p = 0.038) and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001) showed an association with recurrent falls on bivariate comparisons.

In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%) reported taking anti diabetic medications and 69(6.9%) reported taking either benzodiazepines or other sedative drugs. There was no significant association for prospective falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

Independent Risk Factors for prospective falls

The final adjusted model with independent predictors of prospective falls in the elderly is presented as Table 4. The variables found to be significant(P value <0.2) in bivariate analysis with falls were age, sex, living arrangement, vertigo, parkinsonism, arthritis, urinary symptoms, constipation, knee pain, paraesthesia of feet, history of fall in the previous year, dependence in basic and instrumental activities of daily living, use of assistive devices for movement, cognitive impairment, depression, use of antihypertensive medications and benzodiazepines. The same were included in the final model construction. Among the factors examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, p =

0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05-2.09, p=0.026), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13, p=0.012), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, p=0.001) and history of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, p<0.001) were found to be significantly associated with falls.

The factors included to assess the independent risk factors of recurrent falls were, female sex, vertigo, parkinsonism, arthritis and dependence in basic and instrumental activities of daily living and history of falls in the previous year. From the above, the independent predictors for recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, p = 0.031), dependence in basic activities of daily living (OR 3.63, 95% CI 1.71, 7.70, p = 0.001), and history of falls in the previous year (OR 3.39, 95% CI 1.89, 6.05, p<0.001).

Discussion

The current study provides details of fall episodes experienced by free living elderly from Kerala, India during a prospective follow up of one year. Approximately one in five elderly subjects in this age group reported a fall during the study period. There appears to be a sex based difference in the proportion that fell with one in four elderly women falling compared to one in six men during follow up. The results also suggest a dose response relationship between age and falls with more subjects falling in older age groups compared to relatively younger groups. In addition, every fourth person who fell reported one or more falls following the index fall episode during the study period.

The independent predictors for falls in the elderly included female sex, parkinsonism and related movement disorders, arthritis, dependence in basic activities of daily living, not using antihypertensive medicines, living alone during daytime and a history of fall in the preceding year. The corresponding predictors for recurrent falls included female sex, dependence in basic activities of daily living and a history of fall in the preceding year. To our knowledge, this is the only prospective cohort study done in India that focussed on falls in free living elderly who were assessed in the community setting.

The incidence of falls in the elderly from our study appears to be at the lower end of the spectrum as reported by western studies (29% to 40%).[9-14] Interestingly, our results are more

similar to that reported by a prospective study among community dwelling elderly Chinese subjects.[23] The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-years for all elderly, women and men respectively. The proportion with recurrent falls in this study was also similar to our study (4.75% v/s 5.3%).

The risk factors for prospective falls in community dwelling elderly was examined by a recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.[19] Most of the prospective studies in the meta-analysis suggested that community dwelling elderly women are at higher risk for falls compared to their male counterparts. The pooled estimates for falls (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-analysis are in agreement with the current study.

Several prospective studies have reported higher risk for falls among elderly patients with Parkinsonism and/or related movement disorders similar to the current study. The meta-analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI, 1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't report any positive association between Parkinson's disease and recurrent falls, probably due to the small number of recurrent fallers (5.3%) in the cohort.

Our finding of high risk for falls among those elderly with arthritis is in concordance with several other studies.[24-27] Together these studies suggest that elderly with arthritis and/or chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis free peers.[27]

Several studies have reported that living alone during the daytime is a risk factor for falls in the elderly as suggested by the current study.[19] The meta-analysis is also in agreement with this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that examined the same.

Reduced BADL(Basic Activities of Daily Living) capability is also reported to be associated with falls in the elderly.[28] Yokoya et al recently concluded that higher frequency of leaving home, higher exercise levels and presence of interest in activities (e.g., meeting friends, shopping, working in the garden) were associated with a reduced risk for fall in community

dwelling elders.[28] Maintaining and enhancing physical functions, principally walking ability and walking speed are critical for fall prevention among elderly.[29,30] Age appropriate exercises including those enhancing muscle strength and improving balance can probably reduce the incidence of falls among elderly.[30]

A history of falls in the previous year appears to be the most consistent risk factor across several studies.[19,30,31] Pooled data from several studies in the recent meta-analysis puts the risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).[19] Suzuki et al reported that five out of six elderly with a history of falls were anxious about another fall and one in three said that they did not venture out again due to fear of another fall.[30]

One notable finding in our study was the lack of association for falls with medication use for most groups of medications except for antihypertensive medications. This is in contrast to a meta-analysis of the impact of medication classes on falls in elderly.[32] Woolcott et al reported an OR of 1.41 (95% CI, 1.20-1.71) for falls among elderly with benzodiazepine use.[32] The lack of association between sedatives use and falls in our study is probably due to the limited number of subjects reporting the use of the same (6.9%). We saw an inverse association between falls and the use of antihypertensive drug use in the current study. One probable reason could be the high proportion of uncontrolled hypertensives in the study population. This finding needs to be explored further in future studies.

Several studies have earlier suggested that the prevalence of falls in low and middle income countries are higher than that reported from high income countries.[4-6] The morbidity from falls and related events too appear to be higher in low and middle income countries compared to high income countries like US.[4-6] There appears to be low awareness about the consequences of falls in low and middle income countries. This could probably be due to the lack of data regarding falls reported from these regions. It is expected that the awareness related to falls will improve with dissemination of data from the current study as well as similar studies from this region. The same may also stimulate research into the interventional options to reduce fall related mortality and morbidity.

The strengths of the current study include; prospective cohort study design, large sample size (n=1000), representative urban and rural population components, inclusion of participants from different Socioeconomic levels, no participants lost to follow up and use of a fall diary

to avoid recall bias. However, the study included participants from a limited geographical setting and was able to follow up only for a shorter period (one year) and hence the generalisation of the study findings is limited.

Conclusion

One in five community dwelling elderly citizens fall on an annual basis and one in four of those who fall are prone to fall again in the same calendar year. Female sex, movement disorders including parkinsonism, arthritis, dependence in basic activities of daily living, living alone during daytime and a history of falls in the previous year appear to predict a fall in the following year. Any intervention targeting a reduction in falls among the elderly need to focus on the modifiable risk factors like living alone at home during daytime, movement disorders and arthritis. We need to encourage mechanisms that may reduce dependence of elderly on basic activities of daily living. Attention should also be given to encourage both physical activity and interests in social activities among elderly subjects.

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)
Gender	
Male	432(43.2)
Female	568(56.8)
Age group	
65-75	648(64.8)
75-85	262(26.2)
>85	90(9.0)
Weight Status(BMI)	
Underweight(<18.5)	124(12.4)
Normal(18.5-22.9)	340(34.0)
Overweight(23-24.9)	188(18.8)
Pre Obese(25-29.9)	264(26.4)
Obese(>30)	84(8.4)
Education	
Graduate and above	132(13.2)
Diploma / Pre-degree	85(8.5)
Middle class / Primary	657(65.7)
Illiterate	126(12.6)
House Hold	
Living with family / caretaker	820 (82.0)
Living alone during daytime	145 (14.5)

Living alone	35 (3.5)
Domicile	
Urban	700(70.0)
Rural	300(30.0)

Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors n(%)	**Prospective falls**		**OR (95% CI)**	**P value**
	No Fall n (%)	**Fall n (%)**		
Gender				
Men **[432(43.2)]**	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women **[568(56.8)]**	434(76.4)	134(23.6)		
Age Group in years				
65-75 **[648(64.8)]**	528(81.5)	120(18.5)		
75-85 **[262(26.2)]**	208(79.4)	54(20.6)	1.14 (0.80-1.64)	0.468
>85 **[90(9.0)]**	63(70.0)	27(30.0)	1.89 (1.15 -3.09)	0.012
Diabetes [342(34.2)]				
No	532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes	267(78.1)	75(21.9)		
Hypertension (768(76.8))				
No	181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes	618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))				
No	622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes	177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))				
No	639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes	160(79.6)	41(20.4)		
Cerebrovascular Disease				

(53(5.3))	No	762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
	Yes	37(69.8)	16(30.2)		
Alcohol (177(17.7))					
	No	654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
	Yes	145(81.9)	32(18.1)		
Smoking (178(17.8))					
	No	652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
	Yes	147(82.6)	31(17.4)		
Living Arrangement					
Living with family/caretaker **(820(82))**		669(81.6)	151(18.4)		
Living alone during daytime **(145(14.5))**		109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone**(35(3.5))**		21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors		**Prospective falls**		**OR (95% CI)**	**P value**
		No Fallers n (%)	**Fallers n (%)**		
Parkinsonism(28(2.8))					
	No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
	Yes	17(60.7)	11(39.3)		
Vertigo(388(38.8))					
	No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
	Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))					
	No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
	Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))					
	No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
	Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))					
	No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
	Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))	No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
	Yes	241(76.3)	75(23.7)		

Visual impairment (594(59.4))	No Yes	326(80.3) 473(79.6)	80(19.7) 121(20.4)	1.04(0.76-1.43)	0.796
Not independent in Basic Activities of daily living (59(5.9))	Yes No	766(81.4) 33(55.9)	175(18.6) 26(44.1)	3.45(2.01-5.92)	<0.001
Not independent in Instrumental activities of daily living (306(30.6))	Yes No	572(82.4) 227(74.2)	122(17.6) 79(25.8)	1.63(1.18-2.25)	0.003
Regular exercise or Yoga (342(34.2))	Yes No	281(82.2) 518(78.7)	61(17.8) 140(21.3)	1.25(0.89-1.74)	0.198
History of falls in the previous 1 year (269(26.9))	Yes No	182(67.7) 617(84.4)	87(32.3) 114(15.6)	2.59 (1.87 – 3.58)	<0.001

Table 4 Risk factors of falls in community dwelling elderly subjects

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		
Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

Figure legends

Fig.1 Flowchart of the study design

Contributorship statement :-

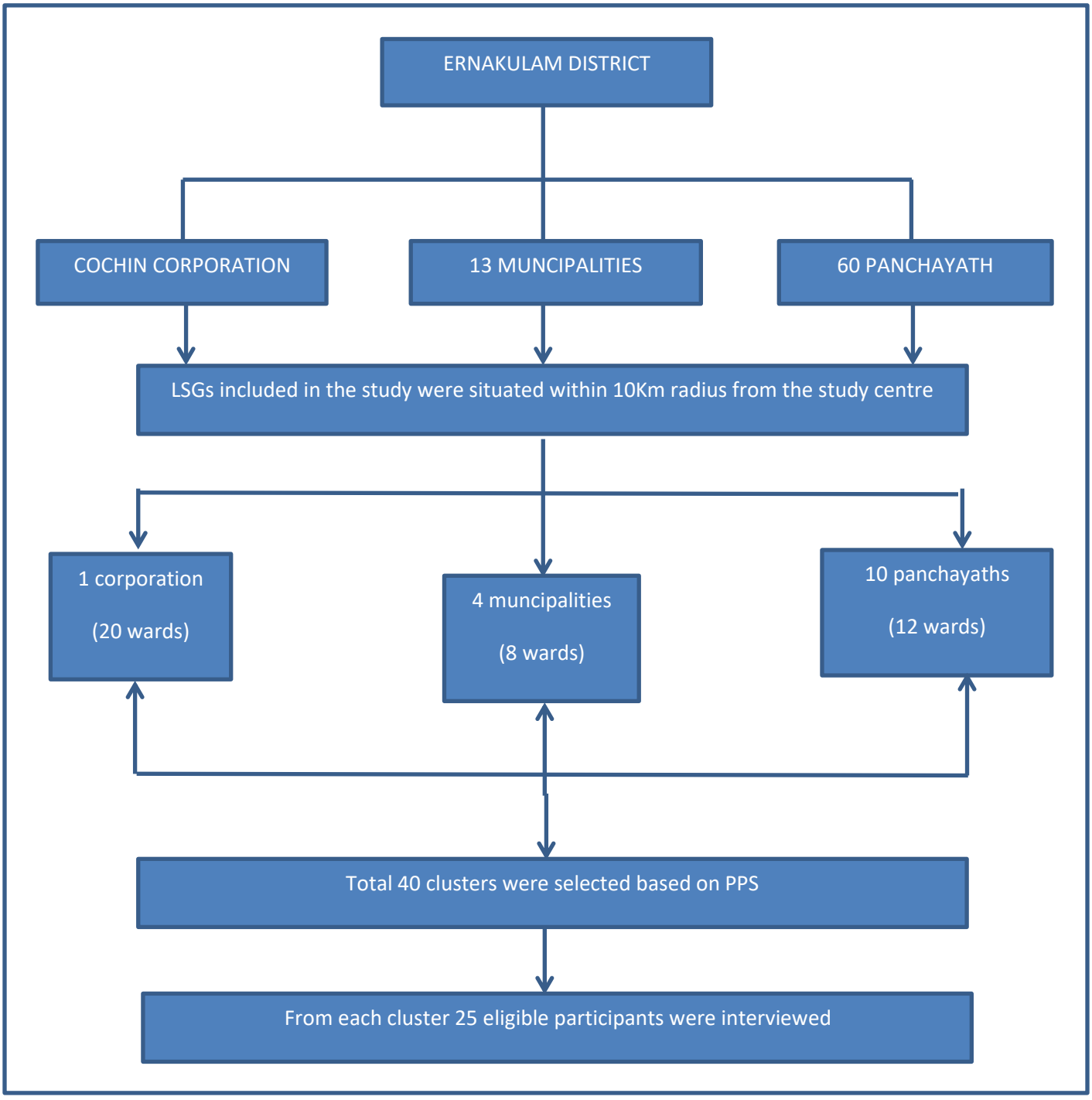
Divyamol K S and Priya Vijayakumar conceptualised the original idea. Divyamol K S and Manu Raj did review of literature and planned, conducted analysed and prepared manuscript of the research work. Priya Vijayakumar supervised the experiment and in final editing of the article. Sumi Soman and Libin Antony was involved in data acquisition and analysis. Abish Sudhakar and Conrad Kabali derived the models and analysed the data.

Data availability statement :-

All data relevant to the study are included in the article or uploaded as supplementary information.

Figure

Fig.1 Flowchart of the Study Design



STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

		Recommendation	Action taken
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 2, Line 50 & 51
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2-3, Line 53-73
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4, Line 86-103
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5, Line 120-123
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5, Line 127
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, Line 128-132
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5-6, Line 141-153
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6, Line 154-158
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	Page 6-7, Line 163-*181*
Bias	9	Describe any efforts to address potential sources of bias	Page 6-7, Line 173-176, 177-179
Study size	10	Explain how the study size was arrived at	Page 5, Line 133- 140
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 7, Line 183-194
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 7, Line 183-194
		(*b*) Describe any methods used to examine subgroups and interactions	Not done
		(*c*) Explain how missing data were addressed	No missing data was encountered
		(*d*) If applicable, explain how loss to follow-up was addressed	No Loss to follow up was reported
		(*e*) Describe any sensitivity analyses	Not Applicable
Results			
Participants	13*	(a) 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	Page 8, Line 206-208 Refer Fig 1
		(b) Give reasons for non-participation at each stage	Not Applicable

		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14 *	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 8, Line 207-219
		(b) Indicate number of participants with missing data for each variable of interest	No missing data
		(c) Summarise follow-up time (eg, average and total amount)	Page 6-7, Line 176-177
Outcome data	15 *	Report numbers of outcome events or summary measures over time	Page 8, Line 221-231
Main results	16	(*a*) 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 8-9, Line 232-262
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 09, Line 263-283
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 10, Line 286-292
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 13, Line 363-365
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11-12, Line 300-359
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13, Line 363-365
Other information			
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 13, Line 369-370

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Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India

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Title Page

Type of article: Original

Title of the article: **Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India**

Running title : Risk factors for falls among community dwelling elderly subjects in Kerala

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Title:

Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India

Abstract

Objectives: There is limited knowledge regarding epidemiology and risk of falls among the elderly living in low and middle income countries. In this situation, the current study aims to report the incidence of falls and associated risk factors among free living elderly population from Kerala, India.

Design: Prospective cohort study with stratified random cluster sampling.

Setting: The study location was Ernakulam, Kerala, India, and we collected information via house visits using a questionnaire. During the research, the subjects were followed up

prospectively for one year by phone at intervals of three months and missing subjects were contacted by house visits.

Participants: Community dwelling elderly above 65years of age.

Results: We recruited a total of 1000 participants out of which a total of 201(20.1%) subjects reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 person years. Female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), movement disorders including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05, 2.09, p=0.026), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13, p=0.012), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, p=0.001) and a history of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, p<0.001) predicted a fall in the following year.

Conclusions: One in five community dwelling senior citizen fall annually and one in four who fall are prone to fall again in the following year. Interventions targeting falls among the elderly need to focus on modifiable risk factors such as living alone during daytime, movement disorders, arthritis and dependence on basic activities of daily living.

Keywords: **Falls, Elderly, Community based study, Cohort Study, Kerala**

Strengths and limitations of this study:

- The study has a prospective cohort study design with a large sample size (n=1000).
- The study population represented both urban and rural population from different Socio Economic Scale levels.
- None of the participants were lost to follow up and a fall diary was used to avoid recall bias.
- The data are from a single study setting.
- The study has a short period of follow up (one year).

Introduction

Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent of the total population.[1] In this segment of the population, unintentional injuries are reported

to be the fifth leading cause of death globally and falls constitute two out of every three deaths in this category.[2] A fall is defined by The Kellogg International Working Group as 'unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure'.[3]

The incidence of falls and the consequences of falls have been higher in lower and middle income countries as compared to high income countries [4-6] mainly because fall preventing interventions are not that freely available in many parts of these countries.[7] Each year an estimated 646 000 individuals die from falls globally of which over 80% are in low- and middle-income countries.[4] In 2010, for example, years lived with disability (YLDs) due to reported falls were 631.2 per 100,000 (population) in India and 674.4 per 100,000 in China, compared with 472.2 per 100,000 in the United States.[5] In that year, the global share of YLDs due to falls in adults aged 50 to 59 years was 66 % in developing countries and 34 % in high income developed countries.[6] Clearly,the situation needs to be addressed urgently as already over 70 % of the world's older population live in developing countries and the proportion is likely to increase in the coming decades due to increasing longevity in all the regions of the world.[8]

Many prospective population-based studies have examined the epidemiology of falls in the community dwelling elderly across different settings. The reported incidence rates show wide variability from as low as 29% to as high as 40% in this population.[9-14] Furthermore, various studies done in India too have reported the prevalence of falls in community dwelling elderly ranging from 13-53%.[15-18] The incidence of recurrent falls (more than two episodes per calendar year was reported to be 11 to 21% by Lord et al.[9]

The risk factors for falls in the elderly as reported by Lord et al[9] can be grouped into seven major categories: socio-demographic factors, balance and mobility factors, sensory and neuromuscular factors, psychological factors, medical factors, medication use, and environmental factors.[9] A recent meta-analysis by Deandrea et al[19] pooled data from 74 prospective cohort studies that reported risk factors for prospective falls among community dwelling elders. A prior history of falls, gait problems, walking aid use, vertigo, parkinson

disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age group.[19]

The primary objective of our study was to report the incidence of falls in community dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective follow up schedule, and the secondary objective was to identify factors that can predict a risk for future falls in community dwelling elderly.

Methods:

Selection and Description of participants:

Design & Setting: The current study is a community based prospective cohort study that was conducted in an area within a radius of ten kilometres from the study centre (Amrita Institute of Medical Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of three years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, four municipalities and one corporation. The study area comes under Ernakulam district of Kerala, South India.

We calculated the sample size using a previously published study by Mitchell-Fearson et al which reported 21.7% prevalence for falls in the elderly.[20] We selected an alpha of 0.05 and an allowable error of 20% giving us a minimum sample size of 347 subjects. The design effect for the sampling method (multistage stratified random cluster sampling) was calculated using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC) of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We enrolled a total of 1000 participants anticipating significant sub group differences within the study sample.

Participants: We used stratified random cluster sampling method to select the participants. The sample was stratified at two levels, rural urban (level 1) and at the level of individual local self-governing units (LSGs, level 2). A total of 40 clusters using Probability proportional to size technique were selected randomly from the list of all available clusters within the defined geographical area. Each cluster was from an individual electoral ward within the LSGs. We selected 25 participants from each cluster. In each cluster, a random starting point was selected and households were visited in a sequential manner by the

principal investigator and staff till 25 subjects were recruited. A flowchart on the study design used in the present study is shown in figure.1. The inclusion criteria were: (i) minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the study area for a minimum of one year after assessment and (iv) ability to communicate in English/Malayalam language. The exclusion criteria included complete dependence for day-to-day activities.

Operational definitions:

A fall was defined as suggested by The Kellogg International Working Group as mentioned in the introduction.[3]

A recurrent fall was defined as falling of two or more times during the follow up period of one year.[9]

Patient and public involvement: Patients and the public were not specifically involved in the planning and execution of this study. However, they were informed of the need of the study and quarterly follow up which was to be done telephonically.

Technical Information:

A study questionnaire was prepared after a detailed review of the literature on studies related to falls in the elderly; however, the questionnaire was freshly prepared by us and not derived from other studies. The study questionnaire included questions relating to the socio-demographic profile, comorbidities, physical activity, medication use and environmental assessment. This questionnaire was initially piloted over a small number of patients (n=50) and the redundant questions were either removed or modified. The modified questionnaire was reviewed by subject experts and was approved for use in the full study.

All initial assessments were done at the participant's home. The research team (PI, two nurses) visited all the recruited subjects at their home premises. The study questionnaire was administered by the PI by means of a face-to-face interview during house visits. In addition, height, weight and blood pressure readings were taken by the trained staff (nurses) that accompanied the PI. All subjects were advised to keep a fall diary in which they were instructed to note down any incident of fall along with the date and time of the fall, what the patient was doing when he fell, what caused the fall, whether it was a witnessed fall or not

and whether the fall had any consequences or complications. A three monthly follow up was done by telephonic conversation with the enrolled subjects for one year from the first visit. Those who were not available over the phone were contacted via house visits by the research staff and hence no missing data were encountered in the study. In addition, the fall diaries of those who reported a fall from the same cluster were reviewed during these house visits. The data collection period was from August 2015 to April 2017.

Statistics:

We summarized demographic and social-economic variables to characterize the study population (Table 1). We presented the mean and standard deviation for normally distributed continuous variables. All categorical variables are expressed in number and percentages. We used Chi square test to examine the association of categorical risk factors with prospective falls. All individual factors with a p value of <0.2 for association on bivariate analysis was selected for multivariate analysis. Multiple binary logistic regression was used to construct the prediction model for prospective falls. We selected Logistic regression after verifying lack of over-dispersion using the Pearson and deviance methods. The cut-off point for statistical significance was set at an α-level of 5%. We reported the adjusted Odds Ratios (aOR) with 95% confidence intervals. We encountered no missing data in the study. Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago, USA).

Ethical approval:

We collected written informed consent from the consenting subjects before recruitment to the study and the same was documented for future reference. The consent contained the title, purpose, methods employed in the study, benefits to the subject as well as to their families. It was also made clear that participation in this research is purely voluntary. The confidentiality of the study during the analysis was also mentioned in the consent. The consent process and study protocol was approved by the Institutional Ethics Committee of Amrita Institute of Medical Sciences and Research centre. (Institutional Ethics Committee Registration Number: ECR/129/Inst/KL/2013).

Results

Baseline Characteristics of the study population

We recruited a total of 1000 participants from 40 individual pre-designated clusters spread across a circular geographical area with the study institution as the centre point. The distribution of gender, age categories, weight status, education level, household living pattern and area of domicile are presented in Table 1. The mean age of the study subjects was 72.7(7.2) years. Among the study participants, 568 (56.8%) were female, 87.4% were literate and 82% lived with family or caretakers. A total of 348 (34.8%) were either pre-obese or obese as per Asian Criteria of BMI classification.[21] The morbidity profile of the study population was published earlier.[22] The self-reported prevalence of diabetes(DM), coronary artery diseases(CAD) and cerebrovascular accidents (CVA) were 34.2%, 20.1%&5.3% respectively. Among the study subjects, 768 (76.8%) were hypertensive as documented either by high values on house visit measurement or by current treatment for hypertension. Among hypertensives, a total of 528 subjects (68.8%) reported taking treatment for hypertension and remaining 240(31.2%) were newly detected during the baseline evaluation of the study.

Incidence of falls in the study population

A total of 201(20.1%) subjects reported a fall during the prospective follow up period of one year. The total fall episodes during the follow up period were 301. The overall incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 person years. The corresponding figures for elderly men and women separately were 21.2 (95% CI 18.5, 24.2) and 38.3 (95% CI, 34.6, 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85 were 27.4, 36.8 and 41.1 per 100 person years respectively. Among the participants, more women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period, compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls) during the follow up.

Factors associated with prospective falls.

The association of baseline factors with a prospective history of falls during the follow up period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline variables, only gender and living arrangement showed a significant association with a prospective history of falls on bivariate comparisons. Females had a higher risk of fall when compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during

daytime also had a higher risk of falls when compared to those living with family/caretaker (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors affecting locomotion was explored by bivariate analysis and is presented in **Table 3.** Among the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010), vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed significant associations with prospective falls on bivariate comparisons. A history of falls in the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p <0.001).

Furthermore, among baseline factors only gender showed an association with recurrent falls on bivariate comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion, dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p <0.001), dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p = 0.038) and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001) showed an association with recurrent falls on bivariate comparisons.

In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%) reported taking anti diabetic medications and 69(6.9%) reported taking either benzodiazepines or other sedative drugs. There was no significant association for prospective falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

Independent Risk Factors for prospective falls

The final adjusted model with independent predictors of prospective falls in the elderly is presented as Table 4. The variables found to be significant(P value <0.2) in bivariate analysis with falls were age, sex, living arrangement, vertigo, parkinsonism, arthritis, urinary symptoms, constipation, knee pain, paraesthesia of feet, history of fall in the previous year, dependence in basic and instrumental activities of daily living, use of assistive devices for movement, cognitive impairment, depression, use of antihypertensive medications and

benzodiazepines. The same were included in the final model construction. Among the factors examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, p = 0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI 1.05-2.09, p=0.026), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00, 6.09, p<0.001), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13, p=0.012), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, p=0.001) and history of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, p<0.001) were found to be significantly associated with falls.

The factors included to assess the independent risk factors of recurrent falls were, female sex, vertigo, parkinsonism, arthritis and dependence in basic and instrumental activities of daily living and history of falls in the previous year. From the above, the independent predictors for recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, p = 0.031), dependence in basic activities of daily living (OR 3.63, 95% CI 1.71, 7.70, p = 0.001), and history of falls in the previous year (OR 3.39, 95% CI 1.89, 6.05, p<0.001).

Discussion

The current study provides details of fall episodes experienced by free living elderly from Kerala, India during a prospective follow up of one year. Approximately one in five elderly subjects in this age group reported a fall during the study period. There appears to be a sex based difference in the proportion that fell with one in four elderly women falling compared to one in six men during follow up. The results also suggest a dose response relationship between age and falls with more subjects falling in older age groups compared to relatively younger groups. In addition, every fourth person who fell reported one or more falls following the index fall episode during the study period.

The independent predictors for falls in the elderly included female sex, parkinsonism and related movement disorders, arthritis, dependence in basic activities of daily living, not using antihypertensive medicines, living alone during daytime and a history of fall in the preceding year. The corresponding predictors for recurrent falls included female sex, dependence in basic activities of daily living and a history of fall in the preceding year. To our knowledge, this is the only prospective cohort study done in India that focussed on falls in free living elderly who were assessed in the community setting.

The incidence of falls in the elderly from our study appears to be at the lower end of the spectrum as reported by western studies (29% to 40%).[9-14] Interestingly, our results are more similar to that reported by a prospective study among community dwelling elderly Chinese subjects.[23] The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-years for all elderly, women and men respectively. The proportion with recurrent falls in this study was also similar to our study (4.75% v/s 5.3%).

The risk factors for prospective falls in community dwelling elderly was examined by a recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.[19] Most of the prospective studies in the meta-analysis suggested that community dwelling elderly women are at higher risk for falls compared to their male counterparts. The pooled estimates for falls (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-analysis are in agreement with the current study.

Similar to the current study, several prospective studies have reported higher risk for falls among elderly patients with Parkinsonism and/or related movement disorders similar to the current study. The meta-analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI, 1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't report any positive association between Parkinson's disease and recurrent falls, probably due to the small number of recurrent fallers (5.3%) in the cohort.

Our finding of high risk for falls among those elderly with arthritis is in concordance with several other studies.[24-27] Together these studies suggest that the elderly with arthritis and/or chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis free peers.[27]

Several studies have reported that living alone during the daytime is a risk factor for falls in the elderly as suggested by the current study.[19] The meta-analysis is also in agreement with this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that examined the same.

Reduced capability for BADL(Basic Activities of Daily Living) is also reported to be associated with falls in the elderly.[28] Yokoya et al recently concluded that higher frequency

of leaving home, higher exercise levels and presence of interest in activities (e.g., meeting friends, shopping, working in the garden) were associated with a reduced risk for fall in community dwelling elders.[28] Therefore, maintaining and enhancing physical functions, principally walking ability and walking speed are critical for fall prevention among the elderly.[29,30] Age appropriate exercises including those enhancing muscle strength and improving balance can probably reduce the incidence of falls among the elderly.[30]

A history of falls in the previous year appears to be the most consistent risk factor across several studies.[19,30,31] Pooled data from several studies in the recent meta-analysis puts the risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).[19] Suzuki et al reported that five out of six elderly with a history of falls were anxious about another fall and one in three said that they did not venture out again due to fear of another fall.[30]

One notable finding in our study was the lack of association for falls with medication use for most groups of medications except for antihypertensive medications. This is in contrast to a meta-analysis of the impact of medication classes on falls in elderly.[32] Woolcott et al reported an OR of 1.41 (95% CI, 1.20-1.71) for falls among elderly with benzodiazepine use.[32] The lack of association between sedatives use and falls in our study is probably due to the limited number of subjects reporting the use of the same (6.9%). We saw an inverse association between falls and the use of antihypertensive drug use in the current study. One probable reason could be the high proportion of uncontrolled hypertensives in the study population. This finding needs to be explored further in future studies.

Several studies have earlier suggested that the prevalence of falls in low and middle income countries is higher than that reported from high income countries.[4-6] The morbidity from falls and related events too appear to be higher in low and middle income countries compared to high income countries like the US.[4-6] There appears to be low awareness about the consequences of falls in low and middle income countries. This could probably be due to the lack of data regarding falls reported from these regions. It is expected that the awareness related to falls will improve with dissemination of data from the current study as well as similar studies from this region. The same may also stimulate research into the interventional options to reduce fall related mortality and morbidity. Interventional studies to prevent falls in the elderly are very relevant to the state of Kerala as it has the maximum proportion of

elderly (12.6%) in India as per 2011 census.[33] This is much higher than the national average of 8.6%, making Kerala more appropriate for future intervention studies in this area.

The strengths of the current study include the following; prospective cohort study design, large sample size (n=1000), representative urban and rural population components, inclusion of participants from different socioeconomic levels, no participants lost to follow up and use of a fall diary to avoid recall bias. However, the study included participants from a limited geographical setting and was able to follow up only for a short period (one year), and hence the generalisation of the study findings is limited.

Conclusion

One in five community dwelling elderly citizens fall on an annual basis and one in four of those who fall are prone to fall again in the same calendar year. Female sex, movement disorders including parkinsonism, arthritis, dependence in basic activities of daily living, living alone during daytime and a history of falls in the previous year appear to predict a fall in the following year.

Any future intervention program targeting a reduction in falls among the elderly in India should start in Kerala due to the high proportion of elderly in the state and extend to similar states later. Such studies should focus on the modifiable risk factors such as living alone at home during daytime, movement disorders and arthritis as identified by the current study. We need to encourage mechanisms that may reduce dependence of the elderly for basic activities of daily living. Attention should also be given to encourage both physical and social activities among elderly subjects.

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)
Gender	
Male	432(43.2)
Female	568(56.8)
Age group	

65-75	648(64.8)
75-85	262(26.2)
>85	90(9.0)
Weight Status(BMI)	
Underweight(<18.5)	124(12.4)
Normal(18.5-22.9)	340(34.0)
Overweight(23-24.9)	188(18.8)
Pre Obese(25-29.9)	264(26.4)
Obese(>30)	84(8.4)
Education	
Graduate and above	132(13.2)
Diploma / Pre-degree	85(8.5)
Middle class / Primary	657(65.7)
Illiterate	126(12.6)
House Hold	
Living with family / caretaker	820 (82.0)
Living alone during daytime	145 (14.5)
Living alone	35 (3.5)
Domicile	
Urban	700(70.0)
Rural	300(30.0)

Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors	**Prospective falls**		**OR (95% CI)**	**P value**
n(%)	**No Fall n (%)**	**Fall n (%)**		
Gender				
Men **[432(43.2)]**	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women **[568(56.8)]**	434(76.4)	134(23.6)		

Age Group in years				
65-75 **[648(64.8)]**	528(81.5)	120(18.5)		
75-85 **[262(26.2)]**	208(79.4)	54(20.6)	1.14 (0.80-1.64)	0.468
>85 **[90(9.0)]**	63(70.0)	27(30.0)	1.89 (1.15 -3.09)	0.012
Diabetes [342(34.2)]				
No	532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes	267(78.1)	75(21.9)		
Hypertension (768(76.8))				
No	181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes	618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))				
No	622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes	177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))				
No	639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes	160(79.6)	41(20.4)		
Cerebrovascular Disease (53(5.3))				
No	762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
Yes	37(69.8)	16(30.2)		
Alcohol (177(17.7))				
No	654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
Yes	145(81.9)	32(18.1)		
Smoking (178(17.8))				
No	652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
Yes	147(82.6)	31(17.4)		
Living Arrangement				
Living with family/caretaker **(820(82))**	669(81.6)	151(18.4)		
Living alone during daytime **(145(14.5))**	109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone**(35(3.5))**	21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors	**Prospective falls**		**OR (95% CI)**	**P value**
	No Fallers n (%)	**Fallers n (%)**		
Parkinsonism(28(2.8))				
No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
Yes	17(60.7)	11(39.3)		

Vertigo(388(38.8))				
No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))				
No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))				
No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))				
No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))				
No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
Yes	241(76.3)	75(23.7)		
Visual impairment (594(59.4))				
No	326(80.3)	80(19.7)	1.04(0.76-1.43)	0.796
Yes	473(79.6)	121(20.4)		
Not independent in Basic Activities of daily living (59(5.9))				
Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))				
Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))				
Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))				
Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
No	617(84.4)	114(15.6)		

Table 4 Adjusted model for risk factors of falls in community dwelling elderly subjects(n=1000)

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		

Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in the previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

Figure legends

Fig.1 Flowchart of the study design

Contributorship statement :-

Divyamol K S and Priya Vijayakumar conceptualised the original idea. Divyamol K S and Manu Raj did review of literature and planned, conducted analysed and prepared manuscript of the research work. Priya Vijayakumar supervised the experiment and the final editing of the article. Sumi Soman and Libin Antony were involved in data acquisition and analysis. Abish Sudhakar and Conrad Kabali derived the models and analysed the data.

Data availability statement :-

All data relevant to the study are included in the article or uploaded as supplementary information.

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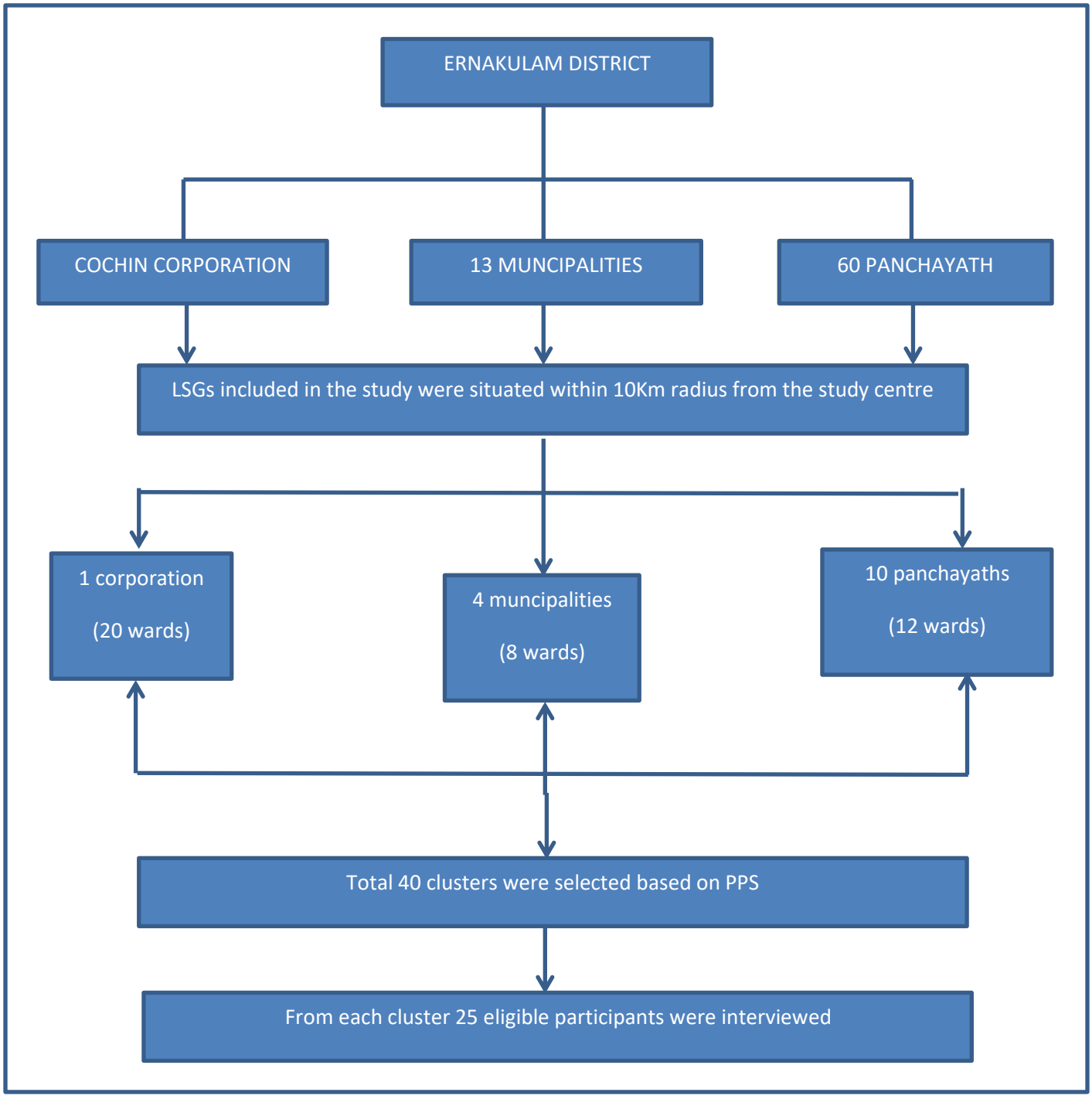
Figure

Fig.1 Flowchart of the Study Design



STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

		Recommendation	Action taken
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 2, Line 50 & 51
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2-3, Line 53-73
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4, Line 86-103
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5, Line 120-123
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5, Line 127
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, Line 128-132
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5-6, Line 141-153
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6, Line 154-158
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	Page 6-7, Line 163-*181*
Bias	9	Describe any efforts to address potential sources of bias	Page 6-7, Line 173-176, 177-179
Study size	10	Explain how the study size was arrived at	Page 5, Line 133- 140
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 7, Line 183-194
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 7, Line 183-194
		(*b*) Describe any methods used to examine subgroups and interactions	Not done
		(*c*) Explain how missing data were addressed	No missing data was encountered
		(*d*) If applicable, explain how loss to follow-up was addressed	No Loss to follow up was reported
		(*e*) Describe any sensitivity analyses	Not Applicable
Results			
Participants	13*	(a) 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	Page 8, Line 206-208 Refer Fig 1
		(b) Give reasons for non-participation at each stage	Not Applicable

		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14 *	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 8, Line 207-219
		(b) Indicate number of participants with missing data for each variable of interest	No missing data
		(c) Summarise follow-up time (eg, average and total amount)	Page 6-7, Line 176-177
Outcome data	15 *	Report numbers of outcome events or summary measures over time	Page 8, Line 221-231
Main results	16	(*a*) 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 8-9, Line 232-262
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 09, Line 263-283
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 10, Line 286-292
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 13, Line 363-365
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11-12, Line 300-359
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13, Line 363-365
Other information			
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 13, Line 369-370