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Keywords:	10-Group Classification System, Cesarean Section, Tanzania, Robson classification, Neonatal outcome

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Abstract

Objective: Caesarean section rates have increased worldwide over the last decades. In 2015, WHO proposed the use of the 10-group classification as a global standard for assessing, monitoring and comparing caesarean section rates. The aim of our work was to assess the pattern of CS rates according to the Robson Classification and describe maternal and perinatal outcomes by group in a District Hospital in Tanzania.

Design: Observational retrospective study

Setting: District Hospital in Tanzania

Participants: 3012 delivered in Tosamaganga Hospital from 1st January to 30th June 2014 and from 1st March to 30th November 2015.

Results: The institutional CS rate was 35.2% of all births in an obstetric population of about 90% in Robson groups 1 through 5. More than 40% of all CS in the hospital occurred in Groups 1 and 3 and the most frequent indication to perform CS was for previous scar (39,2%). Major contribution to severe neonatal outcome was given by Group 1 (27.7%), Group 10 (24.5%) and Group 3 (19,1%).

Conclusion: A high CS rate was registered in Tosamaganga Hospital, particularly in low risk Groups as 1 and 3. The analysis of Robson Classification and the neonatal outcomes may indicate the need to improve management of labour and to provide timely referral to prevent women from arriving in hospital in critical conditions.

Keywords

10-Group Classification System; Cesarean Section; Tanzania; Robson classification; Neonatal outcome;

Strengths and limitations of this study

- The study uses data from a rural setting, giving the opportunity to compare it with other contexts in the country.
- The availability of outcome data, indication for CS and data on who performed the CS allowed a more contextualized interpretation of CS rates in each group.
- The combination of two different period of 2014 and 2015 increase the sample and avoid to have seasonal differences.
- Data derived from handwritten records and some information may not be accurate.
- The analysis permit to propose potential strategies to address the overuse of caesarean birth.

Introduction

Cesarean section (CS) is a lifesaving operation used when obstetric pathologies or urgent conditions preclude a vaginal delivery[1]. The cesarean section rate is widely considered an important global indicator for measuring access to obstetric services[2] and safe and timely care for mothers and newborns. Ensuring access to CS is an essential strategy to reduce maternal mortality[3] and to reach the Sustainable Development Goal number 3[4].

However, as a surgical operation, this procedure is associated with increased risk of maternal morbidity, such as postpartum haemorrhage, blood transfusions, hysterectomy or even death, and the uterine scar can increase the risk of uterine rupture, placenta previa or accreta in subsequent pregnancies[5-7]. These risks are higher in settings without access to safe surgery or with capacity to treat complications safely. Compared with vaginal delivery, CS also entails more health personnel and higher costs for hospitals and society too[8]. Nevertheless, in the past three decades CS rates have steadily increased in many countries, especially middle and high income countries, and have become an important and controversial public health concern[9, 10]. In 1985 the World Health Organization (WHO) stated that ''There is no justification for any region to have a caesarean section (CS) rate higher than 10–15%''. This statement was justified upon data mainly from northern European countries which achieved good maternal and perinatal outcomes with that rate of CS[11]. Numerous studies have analyzed the relationship between CS rate and maternal and neonatal mortality trying to define the optimal limit/range associated with minimum maternal and perinatal risks[12-15], but there are multiple limitations in all approaches that limit the interpretation of results[16]. In 2015 a new WHO policy statement superseding the previous 1985 restated that "every effort should be made to provide caesarean sections to women in need, rather than striving to achieve a specific rate"[17] acknowledging the lack of a universal ideal CS rate.

However, the worldwide rising CS rate trend is widely regarded as a concern considering the above-mentioned health and socio-economic consequences as well as the unknown ecologic or intergenerational consequences. In addition, the increase of CS is not confined to high- or middle-income countries. Low-income countries are suffering the consequences of the unequal rise of CS. In these countries, inequalities are exacerbated by the unnecessary overuse of CS in some facilities, settings or groups of women which coexist with others where high levels of maternal and perinatal mortality are the consequence of lack of access to CS.

Efforts have been placed in the design of effective strategies to reduce unnecessary CS. Facing this challenge, it is essential to study the population of women undergoing CS, to identify high risk groups for poor outcomes and to investigate the reasons for these trends in different groups and settings[18]. For many decades, the lack of a standard and internationally accepted classification system for CS has precluded a more effective progress in understanding the raising trend and act upon it. The ten-group Robson Classification system is now recommended by WHO and FIGO for assessing, monitoring and comparing CS rates within healthcare facilities over time and between facilities[17, 19]. The Robson Classification is simple, clinically relevant, accountable, replicable and verifiable[20], all critical characteristics for a classification system.

The aim of our work was to assess the pattern of CS rates according to the Robson Classification and describe maternal and perinatal outcomes by group in a District Hospital in Tanzania. Based on these data, we propose potential strategies to address the overuse of caesarean birth and provide lessons learnt with applicability for other low-income countries and setting on how to use the classification.

Methods

Design and participants

This was an observational retrospective study, conducted in a District Hospital in Tanzania. We included all women delivered in Tosamaganga Hospital from 1st January to 30th June 2014 and from 1st March to 30th November 2015. We choose to combine these periods because in these selected months an Obstetrics and Gynecology resident doctor was responsible for the completeness of patient’s charts. In addition, this selection gave us the possibility to increase our study population and avoid seasonal bias. Each woman was categorized into one of ten groups, using the Robson Classification.

Setting

St. John of the Cross Tosamaganga Hospital belongs to the Roman Catholic Church, Diocese of Iringa, and since 2007 is used as a Council Designated Hospital for Iringa District Council, according to an agreement with the Local Government Authorities (LGAs) which is renewed every 5 years in the context of the Private Public Partnership (PPP). Tosamaganga Hospital, supported by Doctors with Africa CUAMM, an Italian NGO, is the only C-EmONC (Comprehensive Emergency Obstetric and Newborn Care) Center in Iringa Rural District, with an estimated population of 265.000 inhabitants.

During the study period, in Tosamaganga hospital about 2300 deliveries occurred every year. The hospital had a total of 165 beds; maternity department had 48 beds divided in Obstetrics (12 beds), Vaginal Post-Partum (18 beds), Caesarean Section Post-Partum (18 beds), Labour Room and a small neonatal resuscitation room.

In the district, other smaller health facilities were present (10 Health Center and 62 dispensaries), but none of them was allowed to perform CS.

The maternity department had 2 functioning operating theatres, one for the major and one for minor surgery intervention (e.g. Dilation and Curettage, dressing).

Human resources allowed to perform CS during the study included 1 Gynecologist, 1 Medical Doctor (MD) and 5 Assistant Medical Officers (AMO). Maternity staff was composed also by 10 midwives divided into three shifts (3 during the morning, 2 in the afternoon, 2 during the night) and 1 Clinical Officer.

Variables and Data Collection

For each woman giving birth in the hospital, we collected data on maternal age, obstetric history (parity, previous caesarean section), foetal presentation, gestational age, final mode of delivery (simple vaginal delivery-SVD, operative vaginal delivery-OVD, Cesarean section-CS) and onset of labour (spontaneous, induced, pre-labour CS).

For each woman who underwent to CS, one of the following mutually exclusive indication for CS was assigned: urgent or emergency CS (considering eclamptic, abrupio placenta, uterine rupture), mechanical or dynamic dystocia, previous scar, malpresentation, cephalopelvic disproportion, foetal distress, breech, twins and others. If there were more than one indication, the priority was given according to the order in the list. We collected maternal outcomes (death before discharge) and neonatal outcomes (birth weight, Apgar score at 1 and 5 minutes, death before discharge).

We also registered if patient had been formally referred from village-level dispensaries or rural Health Center or self-referred.

Because of the elevated number of missing or wrong date for last menstrual period (LMP), we used birth weight ≥ 2500 gr as a proxy for gestational age ≥37 weeks[21]. This adaptation has been suggested and previously used for the Robson Classification in settings where accurate assignment of gestational age may be challenging[22-24].

Exclusion criteria was birth weight <500 gr (proxy for gestational aged <22 weeks) and incomplete information on obstetric history, mode of delivery and onset of labour. Congenital anomalies were included. For twin deliveries, only the outcome of the first twin was considered.

The cesarean delivery rate was defined as the number of cesarean deliveries over the total number of live births[9, 15]. The maternal mortality rate was defined as the number of maternal deaths over the total number of women giving birth regardless of birth outcome. We defined a neonatal composite outcome: severe neonatal outcome as the total number of stillbirth, early neonatal death (death of a live born neonate, by discharge or day 7 of life whichever occur first) and birth discharged alive with Apgar score at 5 min < 7. Available data did not allow to differentiate fresh and macerated stillbirth. Deaths occurring after discharge were not captured. During the 2015 study period (from 1st March to 30th November) information was also collected on who performed CS (Gynecologist, medical doctor-MD, assistant medical doctor-AMD).

Each woman was categorized into one of ten groups using the Robson Classification. We used the recommended subdivision for groups 2 and 4 into induced labour (2a or 4a) and pre-labour CS (2b or 4b). Group 5 was also divided into 5.1 (women with only one previous CS) and 5.2 (women with two or more previous CS)[25]. Intrapartum and postpartum perinatal mortality has been analyzed by type of delivery and using the Robson Classification.

Patient and Public Involvement

No patients/public were involved in defining the research question or the outcome measures, nor were they involved in the design and implementation of the study. There are no plans to involve patients/public in the dissemination of the results.

Results

From 1st January to 30th June 2014 and from 1st March to 30th November 2015, 3052 women gave birth in the Tosamaganga hospital. Of these, 3012 (98.7%) deliveries had complete information and were included in the Robson classification. The institutional CS rate was 35.2% of all births.

Table 1 summarizes the characteristics of the study population: the mean age was 25,6 years (range 14-45 years). Among all deliveries, 1691 women were multiparous (56.1%), 370 (12,3%) had one previous CS, 111 (3,7%) two previous CS, 38 (1,3%) had 3 or more (Table 1).

Table 1: Characteristics of women delivered during the study period in Tosamaganga Hospital, Tanzania (n=3012).

Maternal Age	*Mean*	25,6
	Range	14-45
Parity	*Nulliparous (%)*	1321 (43.9%)
	Multiparous (%)	1691 (56.1%)
Previous CS	*No Previous CS (%)*	2493 (82.8%)
	One Previous CS (%)	370 (12.3%)
	Two Previous CS (%)	111 (3.7%)
	Three or more previous CS (%)	38 (1.3%)
Referral status	*Self admitted (%)*	2844 (94.4%)
	Referred from other facilities (%)	168 (5.6%)

Table 2 presents the Robson Classification. Almost 90% of the women admitted for birth in this hospital were women in groups 1 through 5 and about two-thirds in groups 1 through 4. Among nulliparous women with term singleton fetus in cephalic presentation (n=1184), 1128 (95.3%) went into labour spontaneously, 32 (2.7%) were induced and 24 (2%) had a pre-labour CS (Table 2 and 3). Similarly, among multiparous women with term singleton fetus in cephalic presentation (n=1019), 974 (95.6%) went into labour spontaneously, 21 (2%) were induced and 24 (2.4%) had a pre-labour CS.

Women admitted in the hospital for birth with term singleton fetus in cephalic presentation entering labour spontaneously represent 70% of the obstetric population and have CS rates of 27.4% and 15.1% in nulliparous and multiparous, respectively.

Table 2: The Robson Reporting Table and Neonatal outcomes, Tosamaganga Hospital, Tanzania, 2014-2015.

Group		Number of CS in group	Number of women in group	Group Size (%)	Group CS Rate (%)	Absolute group contribution to overall CS rate (%)	Relative contribution of group to overall CS rate (%)	Stillbirth [N stillbirth/ N women (%)]	Early neonatal death* [N neonatal deaths/N women (%)]	Apgar < 7 at 5 minutes [N live birth Apgar <7/N women (%)]
1	Nulliparous, single cephalic, term pregnancy, in spontaneous labour	309	1128	37,5%	27,4%	10,3%	29,2%	9 (0,8%)	28 (2,5%)	24 (2,1%)
2	Nulliparous, single cephalic, term pregnancy, induced labour or elective CS	35	56	1,9%	62,5%	1,2%	3,3%	8 (14,3%)	-	1 (1,8%)
3	Multiparous (excluding prev. CS), single cephalic, term pregnancy, in spontaneous labour	147	974	32,3%	15,1%	4,9%	13,9%	16 (1,6%)	13 (1,3%)	13 (1,3%)
4	Multiparous (excluding prev. CS), single cephalic, term pregnancy, induced labour or elective CS	25	45	1,5%	55,6%	0,8%	2,4%	7 (15,6%)	-	1 (2,2%)
5	One previous CS, single cephalic, term pregnancy	404	463	15,4%	87,3%	13,4%	38,1%	5 (1,1%)	2 (0,4%)	8 (1,7%)
6	All nulliparous breeches	13	21	0,7%	61,9%	0,4%	1,2%	2 (9,5%)	2 (9,5%)	3 (14,3%)
7	All multiparous breeches (including prev. CS)	16	32	1,1%	50,0%	0,5%	1,5%	5 (15,6%)	4 (12,5%)	-
8	All multiple pregnancies (including prev. CS)	48	77	2,6%	62,3%	1,6%	4,5%	3 (3,9%)	7 (9,1%)	-
9	All abnormal lies (including prev. CS)	30	30	1,0%	100,0%	1,0%	2,8%	1 (3,3%)	1 (3,3%)	3 (10%)
10	All single cephalic, preterm (including prev. CS)	33	186	6,2%	17,7%	1,1%	3,1%	22 /11,8%)	17 (9,1%)	15 (8,1%)
	TOTAL	**1060**	**3012**	**100%**	**35,2%**	**35,2%**	**100%**	**78 (2,6%)**	**74 (2,5%)**	**68 (2,3%)**
Unclassifiable: 40 cases, 1,3% (40/3052)										

* Early neonatal death was defined as the death of a live born neonate, by discharge or day 7 of life whichever occur first)

Table 3: Groups 2, 4 and 5 subdivisions

Group		Number of CS in group	Number of women in group	Group Size (%)	Group CS Rate (%)	Absolute group contribution to overall CS rate (%)	Relative contribution of group to overall CS rate (%)
2a	Nulliparous, single cephalic, S37 weeks, induced	11	32	1,1%	34,4%	0,4%	1,0%

2b	Nulliparous, single cephalic, S37 weeks, CS before labour	24	24	0,8%	100,0%	0,8%	2,3%
4a	Multiparous (excluding prev. CS), single cephalic, S37 weeks, induced	1	21	0,7%	4,8%	0,0%	0,1%
4b	Multiparous (excluding prev. CS), single cephalic, S37 weeks, CS before labour	24	24	0,8%	100,0%	0,8%	2,3%
5.1	One previous CS, single cephalic, S37 weeks	272	327	10,9%	83,2%	9,0%	25,7%
5.2	Two or more previous CS, single cephalic, S37 weeks	132	136	4,5%	97,1%	4,4%	12,5%

Women in Group 5 (previous CS) constitute about 15% of the obstetric population of the hospital with a CS rate of 87%. Two-thirds of these women had just one previous CS while one-third had two or more CS (Table 2 and 3).

Overall, the most frequent indication to perform CS was one or more previous CS (39,2%), followed by dystocia (22,3%) and fetal distress (12,8%) (Table 4).

Table 4: Indication for CS in the study population

Previous scar	416	39,2%
Mechanical or dynamic dystocia	236	22,3%
Foetal distress	136	12,8%
Breech	22	2,1%
Twins	28	2,6%
Malpresentation	41	3,9%
CPD	90	8,5%
Urgent or Emergency CS	50	4,7%
Others	41	3,9%
Total number of CS	**1060**	**100,0%**

The management of the women with previous CS is shown in Fig 1. During the study there were 519 (17.2%) women with one or more previous CS. Among them, 153 (29.5%) had an elective pre-labour CS while the rest (70.5%) went into labour spontaneously. None of these women were induced. Among those who entered labour spontaneously, 71 (19,4%) had a SVD, while 295 (80.6%) had a CS. The indication recorded for the CS was “previous CS” in 97,4%

of the women who had a pre-labour CS and 90,5% of the women who went into labour spontaneously (Figure 1).

More than 40% of all CS in the hospital occurred in Groups 1 and 3. Since the CS rate was particularly high for Group 1 (27,7%) and Group 3 (15,2%), we analyzed deeply the indication for CS in these 2 groups (Figure 2) The majority of them were performed for dystocia (44,3% in Group 1; 55,1% in Group 3).

We registered two maternal deaths (one in Group 1 and one in Group 5) and 152 perinatal deaths (5%) of which 78 (2,6%) were stillbirth and 74 (2,5%) were neonatal deaths. About 70% of all perinatal deaths occurred in groups 1 (37 deaths), group 3 (29 deaths) and 10 (39 deaths).

We analyzed 220 cases of severe neonatal outcome (stillbirth, neonatal deaths and live birth with Apgar score < 7 after 5 minutes) by mode of delivery using the Robson Classification as shown in Table 5. Major contribution to severe neonatal outcome was given by Group 1 (27.7%), Group 10 (24.5%) and Group 3 (19,1%). Considering the incidence in each category, the groups with the highest severe neonatal outcome rate were Group 6 (33.3%), Group 10 (29%) and Group 7 (28,1%) indicating a high risk for newborn in breech deliveries.
The incidence of severe neonatal outcome was similar when analyzed by mode of delivery. Majority of adverse neonatal outcome in these groups occurred performing SVD.

Table 5: Distribution of severe neonatal outcomes stratified by Robson Groups.

	Severe neonatal outcomes/women in group	% of Severe neonatal outcomes	Relative contribution of group to the overall severe neonatal outcomes	Proportion of Severe neonatal outcome delivered by SVD* / total SVD		Proportion of Severe neonatal outcome delivered by OVD** / total OVD		Proportion of Severe neonatal outcome delivered by CS / total CS	
1	61/1128	5,4%	27,7%	43/799	5,4%	1/20	5,0%	17/309	5,5%
2	9/56	16,1%	4,1%	7/19	36,8%	0/2	0,0%	2/35	5,7%
3	42/974	4,3%	19,1%	27/818	3,3%	1/9	11,1%	14/147	9,5%
4	8/45	17,8%	3,6%	7/20	35,0%	-	-	1/25	4,0%
5	15/463	3,2%	6,8%	1/58	1,7%	0/1	0,0%	14/404	3,5%
6	7/21	33,3%	3,2%	6/8	75,0%	-	-	1/13	7,7%
7	9/32	28,1%	4,1%	7/16	43,8%	-	-	2/16	12,5%

8	10/77	13,0%	4,5%	4/29	13,8%	-	-	6/48	12,5%
9	5/30	16,7%	2,3%	-		-	-	5/30	16,7%
10	54/186	29,0%	24,5%	47/153	30,7%	-	-	7/33	21,2%
Total	**220/3012**	**7,3%**	**100,0%**	**149/1920**	**7,8%**	**2/32**	**6,3%**	**69/1060**	**6,5%**

* SVD: simple vaginal delivery as a final mode of delivery

** OVD: operative vaginal delivery

We conducted a descriptive analysis on a subset of women who underwent CS during the 2015 study period. Information on who performed the CS and its indication was available for 574 of 616 (93.1%) CS conducted. Most of the CS were performed by a Medical Doctor (66,6%; 382) while 25.8% (148) were conducted by an Assistant Medical Officer, and 7.7% (44) by a gynecologist. This distribution remains when stratifying by Robson groups and by indication of CS (See Appendix).

Discussion

Our analysis of 3012 deliveries in a rural District Hospital in Tanzania using the Robson classification showed a 35% overall CS rate in an obstetric population of about 90% in Robson groups 1 through 5. These groups are, arguably, low-risk women but present high CS rates such as 27.4% and 15.1% in Group 1 and Group 3, respectively, whom are women at term with a single fetus in cephalic presentation without a previous CS who have entered labour spontaneously.

High CS rates have been reported in other studies in Tanzania[23, 26] (31% in Muhimbli Hospital, 35% in Kilimangiaro Christian Medical Center) probably because of the role of a referral hospital to target high risk pregnancy. This hypothesis could be confirmed by the higher CS rate in women referred from other facilities (63,7% in our study). Sørbye described this situation in KCMC[27] comparing patients referred and self-referred, having a CS rate of 55% and 26,9% respectively. However the referral system seems to have a poor role on our context since only 5,6% of the women were referred (vs 20% in Sørbye study).

Nilsen et al.[26] hypothesizes that poor quality of care at dispensaries and health centers level contributes excessively to raise the number of preventable CS in women who are referred late and in critical condition so at arrival an emergency CS is the only possible action[28]. In addition, several studies highlight the inadequacy of obstetric and neonatal care services at primary level in Tanzania[29, 30, 31]. Kruk et al. in a 2009 study conducted in the Kusulu district[32] shows that 42.2% of women who give birth in peripheral units bypassed the nearest services (dispensaries) to go to higher level facilities (health centers), governmental or private facilities. 61.4% of women giving birth at home had a government dispensary in the village, but chose not to go there for the delivery.

Studies conducted by Straneo et al. in Tosamaganga catchment area showed high rates of institutional birth coverage, probably facilitated by the high health facility density[33]. But parallel to this, a conflict between coverage and quality of delivery care has been registered, with poorest women accessing lower level health services for delivery, which offer worse quality of care, due to limited caseloads and poor staffing[34].

Comparing the study population according the Robson Classification with other similar settings, Tosamaganga Hospital shows a bigger size of Group 5 (15,4% vs 8,8% in the population of Muhimbli Hospital 2000-2011) and a smaller size of preterm births (6.2% vs 14,6%), while similar is the size of Group 2 and 4 confirming probably the low induction rate in both contexts.

We analyzed data according to the interpretation guidelines published by WHO[25, 35] (Table 6).

Table 6: Interpretation of the Robson Classification

Quality of data	• The CS rate of the group is 100% signifying a good quality of data
Type of population	• The size of Groups 1 + 2 (39.5%) is within the expected range. However, the ratio of the size of Group 1 versus Group 2 is very high (20.1). In the WHO Multicountry Study reference population (population in the WHO study with relatively low CS rates and, at the same time, with good outcomes of labour and childbirth), this ratio was found to be 6.3[25, 36]. Similarly, the ratio of the size of Group 3 versus Group 4 is 21.6; very high compared with the 6.3 in the WHO study[25, 36]. Both high rates probably indicate the need to increase inductions in these groups of women (term with singleton fetus in cephalic presentation) or even not performing sufficient pre-labour CS. This is consistent with the high CS rates found in groups 1 and 3, and our data on stillbirth and neonatal deaths. Despite being the lower risk groups, of the total 152 perinatal deaths during the study period, 37 (24%) and 29 (19%) occurred in Groups 1 and 3, respectively. Only group 10 had a higher number of perinatal deaths with 39 (25.7%) but this is a high risk group with the women with singleton pregnancies in cephalic presentation preterm.

	• The size of Groups 3 + 4 is 33.9%. Since Tanzania have a high fertility rate, we were expecting a higher number of multiparous. This can be explained by a very high size of Group 5 (15.4%) with a CS rate of 87%, which contributes to about 38% of all CS conducted in the hospital. • The size Groups 6 + 7 is 1.6% which is below the expected range for breeches. Moreover the ratio of Group 6/Group 7 is 0.5 is unusual since breeches are more frequent in nulliparas than multiparas. This could indicate errors in data collection due potentially to some misclassification of nulliparous women with breech presentation under Group 1. • The size of Group 10 is 6.2% slightly higher than that proposed by Robson (5%) and that found in the WHO Study (4.2%). Even if Tosamaganga is a referral hospital, only 168 deliveries (5,6%) were referred of which 107 (63,7%) delivered by CS. For this reason, we consider that the higher size of group 8 and 10 cannot be justified by a particularly high risk population. • Malnutrition and other concurrent diseases could have caused growth retardation and errors in pregnancy dating based on neonatal weight.
Caesarean section rate	• In all groups, the CS rates are higher than the expected range[25, 36]. • It has been proposed that CS rates in Group 1 of about 10% are achievable. However, the high ratio of Group 1 versus Group 2 mentioned above may be responsible for the high CS rate in this group (27.4%). If insufficient number of women are induced or have a necessary pre-labour CS, it is more likely than these women will need a CS at a later stage of labour. In addition, the high CS rate in Group 2 is not caused by the size of Group 2b (pre-labour CS, only 0.8% of the population), but mainly by a very low size of Group 2a (1.1% of the population) and by the poor success for induction with a consequent high C/S rate also in this group (34.4%). Similar arguments apply to Group 3 and 4. The high CS rate in Group 4 (55,5%) is not justified by the high size of Group 4b (representing only 0,8% of the population) but by the small size of Group 4a (only 0.7% of the population). Particularly in Group 1 and Group 3, a large number of CS were performed with the diagnosis of dystocia. This could suggest a poor quality of diagnosis of dystocia and sub-optimal management of the active phase of labor. • The very high CS rate in Group 5 (87.2%) is not justified by the proportion of women with 2 or more CS (Group 5.2) who represent one-third of the population of this group. CS rates in women with one (group 5.1) and two or more CS (group 5.2) are both high 83.2% and 97%, respectively, indicating the common practice to perform C/S in women with previous scar. These rates contrast markedly with the 50-60% rates considered appropriately by Robson guideline and the 74.4% found in the WHO Study[25, 36]. Nevertheless, an assessment of the hospital capacity to offer safe Trial of Labour after CS (TOLAC) would be crucial before recommending more women to be offered a trial of labour. Vaginal birth after cesarean (VBAC) was minimally practiced probably because of the inadequate number of midwives to attend the women in labour. Moreover the lack of information around the previous caesarean delivery (how was

	performed and complication occurred) may have increased the fear of doctors to offer TOLAC. • Looking at the higher risk groups, CS rate in Group 8 is within the expected range, while the CS rate in Group 10 is lower than expected, probably indicating a high rate of spontaneous preterm labour or a high incident of low birth weight (since newborn weight was used as a proxy for gestational age)[25, 36]. • Considering the contribution of the groups to the overall CS rate, Group 1, 2 and 5 represent 70.6% of all CS, higher than the expected, and among this, Group 5 contribute for 38.1% indicating, as already mentioned, a very high C/S rate in the previous years.

Among 152 perinatal deaths, 78 were stillbirth. The highest incidence of severe neonatal outcome was recorded in Group 6, 7 and 10, therefore breech deliveries and preterm deliveries were the most at risk in our hospital.

As has been shown by other studies in similar setting[37], a higher risk for adverse neonatal outcome in breech vaginal deliveries compared with breech CS has been registered in Tosamaganga Hospital, suggesting sub-optimal management of breech presentation and the need for training

In addition, a good antenatal care program would help women to approach the facility earlier and would prevent risk factors for preterm birth, report and manage pregnancies with fetuses in breech presentation and also decrease the number of intrapartum deaths and macerated fetuses.

In Tosamaganga hospital most of the CS were performed by in charge of the delivery room, namely the Medical Doctor (MD) and the Assistant Medical Doctor (AMO), which cover all duty calls. The Gynecologist was involved in case of emergency and complicated elective or intrapartum CS. In all Robson categories, the highest CS rate was performed by the MD. Again, this suggests the need for an obstetric and gynecological training for the staff and a better supervision by the gynecologist. Nyamtema et al. analyzed the work of MD, AMD and midwives in 10 rural health centers in Tanzania[38]. Based on the Tanzanian national guidelines and WHO recommendations[39], 37% of CS were considered unjustified and potentially preventable. After a staff training program and close supervision, the proportion of unjustified CS decreased from 30% to 17% in HCs and from 37% to 20% in hospitals[38].

Strengths and limitations

This study uses data from a rural setting, giving the opportunity to compare with other contexts in the country. The availability of outcome data and the indication for CS allowed a more contextualized interpretation the interpretation of CS rates in each group. Moreover, the availability of data on who performed the CS gives the possibility to address appropriately any improvement interventions. There are a number of limitations to this study. The data were derived from handwritten records and some information may not be accurate. Because of missing data we included in the study two different period of 2014 and 2015, therefore there is discontinuity in data collection. We have chosen to combine the two periods to increase the sample and not have seasonal differences. Some variables were not available in patient's charts and registers (i.e. length of labour, difference between Macerated Stillbirth (MSB) and Fresh Stillbirth (FSB). Perinatal mortality can be underreported because Early neonatal deaths occurred after the discharge were not captured. Lastly, since the determination of gestational age was not reliable, we used birth weight as proxy.

Conclusion

A high CS rate was registered in Tosamaganga Hospital although the obstetric population attended was not considered of particular high risk for a referral hospital. The analysis of the data using the Robson classification showed that Groups 1 and 3 (women at term with a single fetus in cephalic presentation who entered labour spontaneously) were larger than anticipated and presented very high CS rates. The large size of these groups and the high CS rates combined with the stillbirth and neonatal mortality rates seen in the hospital, may indicate insufficient induction rates and the need to provide timely referral so that women reach to the hospital earlier before their condition is too critical.

Efforts to improve care and outcomes should invest in the training of medical and nursing staff to improve the management of labour, with a correct use of the partogram and in particular for a judicious use of oxytocin augmentation for the management of prolonged labor. Training on management of breeches and TOLAC would also be a priority to improve quality of intrapartum care in the hospital.

Figure 1. Management of women with one or more previous CS during the study period.

Figure 2. Indication for CS in Group 1 and Group 3.

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Patient consent: Not required

Ethics approval: This study was approved by the hospital review board, who, in agreement with the "Declaration of Helsinki", waived the need for patient written consent, given the retrospective nature of the study and the collection of anonymized data.

Data sharing statement: Data essential for conclusion are included in this manuscript. Additional data can be obtained from the corresponding author on reasonable request.

Disclaimer: The views expressed in this publication are the sole responsibility of the authors and do not necessarily reflect the views of the affiliated organizations.

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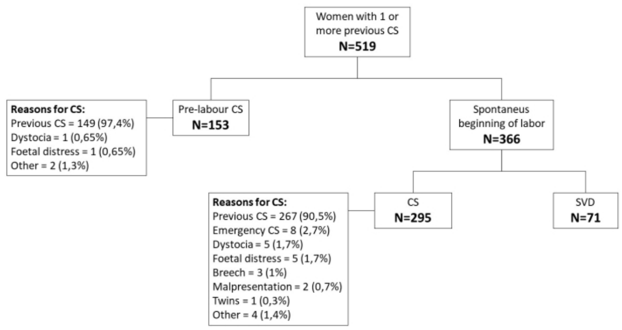
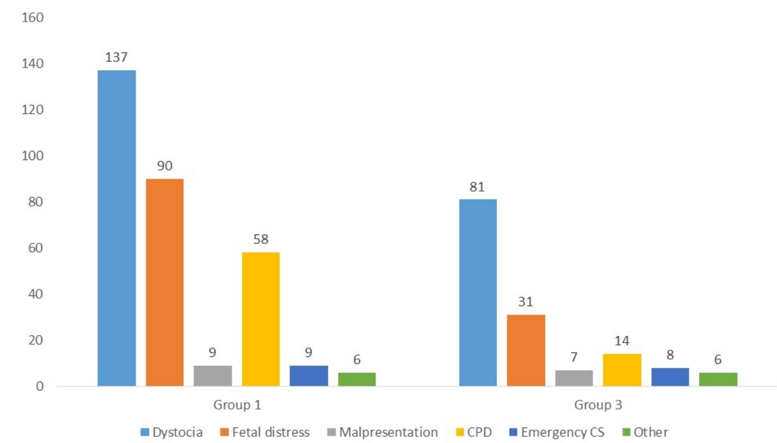


Management of women with one or more previous CS during the study period.

602x338mm (96 x 96 DPI)

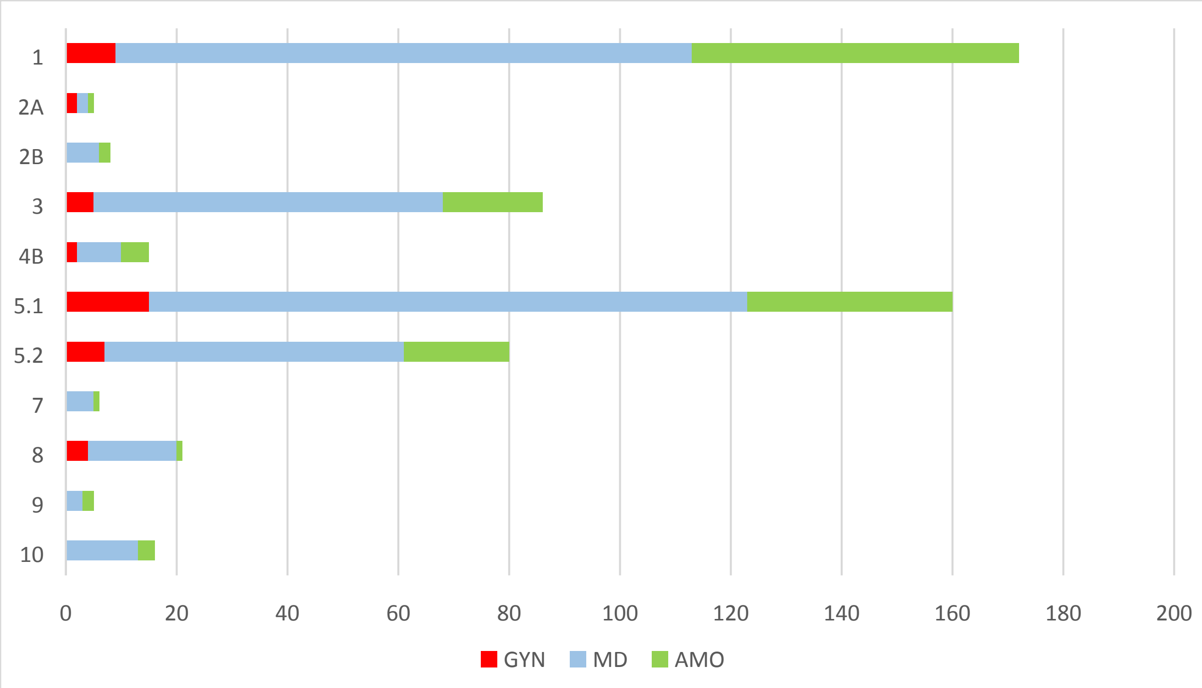


Indication for CS in Group 1 and Group 3.

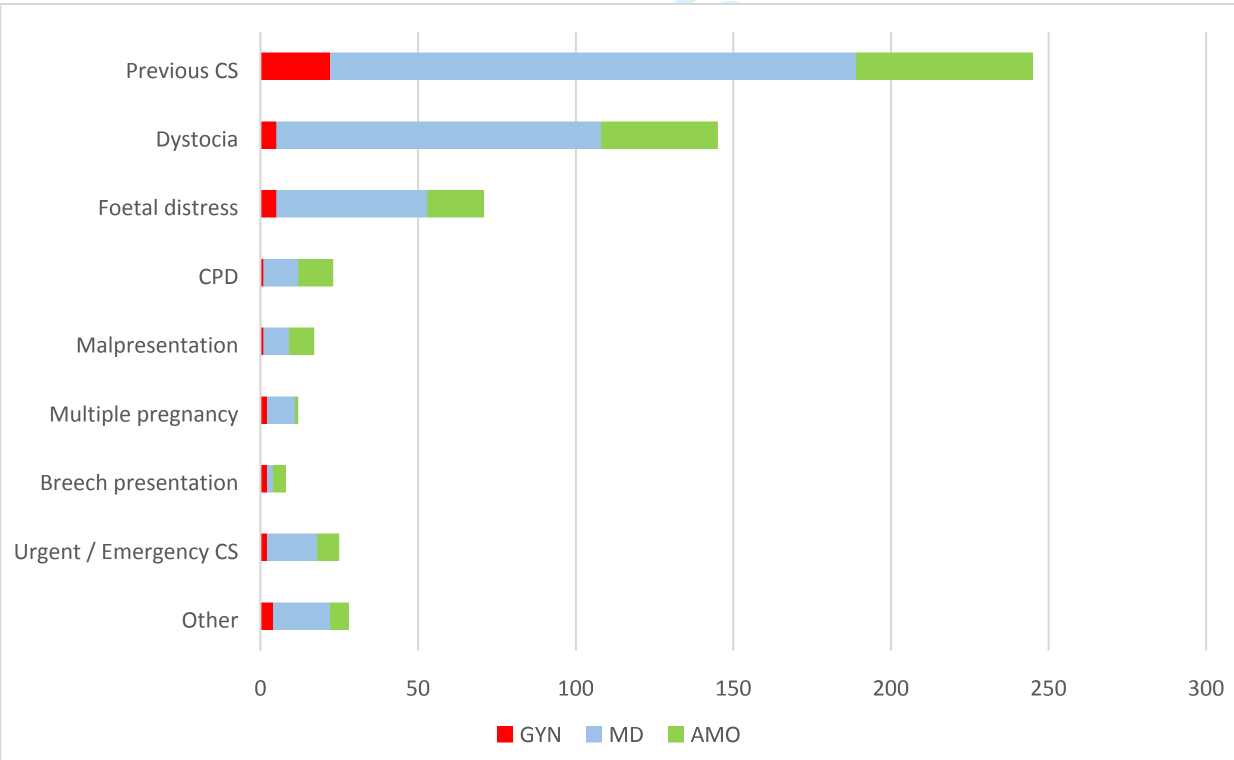
338x190mm (96 x 96 DPI)

APPENDIX

Appendix 1: Distribution of CS among health professionals stratified in the Robson Classification.



Appendix 2: Distribution of CS among health professionals according to indication for CS



Robson Classification System applied in a rural District Hospital in Tanzania

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Comments
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	P. 2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	P. 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P. 5
Objectives	3	State specific objectives, including any prespecified hypotheses	P. 5
Methods			
Study design	4	Present key elements of study design early in the paper	P. 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pp. 5,6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	P. 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pp. 6,7
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	Pp. 6,7
Bias	9	Describe any efforts to address potential sources of bias	Pp. 5,6,7
Study size	10	Explain how the study size was arrived at	P. 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P. 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	P. 5
		(*b*) Describe any methods used to examine subgroups and interactions	P. 5
		(*c*) Explain how missing data were addressed	P. 7
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*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	Pp. 7,8
		(b) Give reasons for non-participation at each stage	P. 7
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	Table 1

		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	Participant with incomplete data were not considered in the analysis
Outcome data	15*	Report numbers of outcome events or summary measures	Table 2, Table 5
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	Not applicable
		(*b*) Report category boundaries when continuous variables were categorized	Done
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Pp 8-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	P. 12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	P. 16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Table 6, p. 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	P. 15
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	P. 18

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Analysis of Caesarean Section and neonatal outcome using the Robson classification in a rural district hospital in Tanzania

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Keywords:	10-Group Classification System, Cesarean Section, Tanzania, Robson classification, Neonatal outcome

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Analysis of Caesarean Section and neonatal outcome using the Robson classification in a rural district hospital in Tanzania

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Abstract

Objective: Caesarean section (CS) rates have increased worldwide in recent decades. In 2015, the World Health Organization (WHO), proposed the use of the 10-group classification as a global standard for assessing, monitoring and comparing CS rates both within health care facilities over time, and between them. The aim of this study was to assess the pattern of CS rates according to the Robson classification and describe maternal and perinatal outcomes by group at the Tosamaganga Hospital in rural Tanzania.

Design: Observational retrospective study.

Setting: St. John of the Cross Tosamaganga Hospital, a referral centre in rural Tanzania.

Participants: 3012 women who gave birth in Tosamaganga Hospital from 1 January to 30 June 2014 and from 1 March to 30 November 2015.

Results: The overall CS rate was 35.2%, and about 90% of women admitted for labour were in Robson Groups 1 through 5. More than 40% of the CS carried out in the hospital were performed on nulliparous women at term with a single fetus in cephalic presentation (Groups 1 and 3), and the most frequent indication for the procedure was previous uterine scar (39,2%). The majority of severe neonatal outcomes were observed in Groups 1 (27.7%), 10 (24.5%) and 3 (19.1%).

Conclusion: We recorded a high CS rate in Tosamaganga Hospital, particularly in low-risk patients groups (Robson 1 and 3). Our Robson classification and neonatal outcomes analysis suggests the need to improve labour management at the hospital, and to provide timely referrals in order to prevent women from arriving there in critical conditions.

Keywords

10-Group Classification System; Caesarean Section; Tanzania; Robson classification; Neonatal outcome;

Strengths and limitations of this study

- Our study used data from a rural setting, that can be compared with analogous data obtained in other settings in the country.
- The availability of outcome data, indication and data on who performed the Caesarean Section made possible a more contextualized interpretation of Cesarean Section rates in each group.
- The combination of two different periods of 2014 and 2015 enlarged the sample size and allowed us to avoid seasonal bias.
- The data was collected from handwritten records, thus some of the information may not be accurate.
- Due to missing data, it was not possible to analyse the details of the Caesarean Section decision-making process.

Introduction

Caesarean section (CS) is a lifesaving procedure performed when an urgent obstetric condition precludes vaginal delivery[1]. The CS rate is widely considered an important global indicator for measuring access to obstetric services[2] and safe and timely care for mothers and newborns. Ensuring access to CS is an essential strategy to reduce maternal mortality[3] in order to achieve the target of Sustainable Development Goal number , i.e. reducing the number of maternal deaths to less than 70 per 100,000 live births by 2030[4].

As surgical procedure, CS is associated with increased risk of maternal morbidity, including postpartum haemorrhage, blood transfusion, hysterectomy and even death, while a uterine scar can increase the risk of uterine rupture, placenta previa or placenta accreta in subsequent pregnancies[5-7]. These risks are higher in settings that lack access to safe surgery and/or the capacity to treat complications safely. Compared with vaginal delivery, CS also necessitates more health personnel and entails higher costs both for hospitals and for society[8]. Nevertheless, over the past three decades CS rates have increased steadily in many countries, especially middle- and high-income ones, a phenomenon that has become a major public health concern[9, 10]. In 1985, the World Health Organization (WHO) stated that ‘‘There is no justification for any region to have a caesarean section rate higher than 10–15%’’. This statement was justified based on review of data mainly from northern European countries which had achieved good maternal and perinatal outcomes with that CS rate[11]. Numerous studies have analysed the relationship between the CS rate and maternal and neonatal mortality, attempting to define the optimal limit/range associated with minimum maternal and perinatal risks[12-15], but the multiple limitations in each of these approaches has limited the interpretation of results[16]. In 2015, a new WHO policy statement superseding the earlier one did not recommend any specific rate as “optimal”, recommending instead that “Every effort should be made to provide caesarean sections to women in need, rather than striving to achieve a specific rate”[17].

Nevertheless, the above-mentioned health and socio-economic impact as well as the unknown ecological and intergenerational consequences of the worldwide trend of increasing CS rate mean that it continues to be a widespread concern. The increase in CS deliveries is being seen not only in high- and middle-income countries, but also in low-income ones. Moreover, the increase has not been equally distributed across income or residency strata; in low-income countries, inequalities are exacerbated by the unnecessary overuse of CS in or among some facilities, settings or patients groups alongside others where the lack of access to the procedure leads to high levels of maternal and perinatal mortality[18].

Efforts have been made to devise effective strategies to reduce unnecessary CS. In order to better face this challenge, it is essential to study the population of women who undergo CS, to identify high-risk groups for poor outcomes, and to investigate the reasons for these trends in different groups and settings[19]. For many decades, the lack of a standard and internationally-accepted CS classification system made it difficult to fully understand the growing trend and act upon it. The ten-group Robson classification system now recommended by WHO and the International Federation of Gynecology and Obstetrics (FIGO) for assessing, monitoring and comparing CS rates within healthcare facilities over time as well as between them[17, 20] is simple, clinically relevant, accountable, replicable and verifiable[21], all critical characteristics for such a system.

The aim of our work was to assess the pattern of CS rates according to the Robson classification and to describe maternal and perinatal outcomes by group in a rural district hospital in Tanzania. Based on these data, we propose potential strategies to address the overuse of CS procedures.

Methods

Design and participants

This was an observational retrospective study conducted in a rural district hospital in Tanzania. We included the women who gave birth in Tosamaganga Hospital from 1 January to 30 June 2014 and from 1 March to 30 November 2015. During these two periods, an Italian obstetrics and gynecology resident doctor was available to support the hospital's maternity staff and ensure the completeness of patient charts. Because the resident doctor was absent in the labour ward from July 2014 to February 2015, the information routinely collected in that period was considered inadequate for analysis and thus could not be included. Foetal position and information on previous deliveries are two important variables for the Robson classification which were not collected and recorded systematically and routinely.

In addition, combining the two periods made it possible to increase our study population and avoid seasonal bias due to the dry and rainy season. We used the Robson classification to categorize each of the women into one of ten groups. A full description of this classification system has been provided in the Supplementary File.

Setting

St. John of the Cross Tosamaganga Hospital belongs to the Roman Catholic Church, Diocese of Iringa, and is supported in terms of governance and human resources by Doctors with Africa CUAMM (Collegio Universitario Aspiranti Medici Missionari), an Italian non governmental organisation (NGO). Although the hospital is a private facility, it has been officially integrated into the Tanzanian public health system since 2007 in the context of the Private Public Partnership (PPP) framework and is recognised as a Council

Designated Hospital for Iringa District Council. Tosamaganga Hospital is the only Comprehensive Emergency Obstetric and Newborn Care (CEmONC) Center in Iringa Rural District, serving an estimated population of 265,000 inhabitants.

Tosamaganga Hospital handles approximately 2,300 deliveries a year. The hospital had a total of 165 beds, 48 of which were in the maternity department, including 12 Obstetrics, 18 in Vaginal Post-Partum and 18 in Caesarean Section Post-Partum. There was also a Labour Room and a small neonatal resuscitation room. There was no anesthesiologist in the hospital. Pediatric Ward (32 beds) was served by only one pediatrician present during the day in and on-call at night.

The maternity department had two functioning operating theatres, one for major and one for minor surgical procedures (e.g. dilation and curettage, dressing). Midwives monitored labour progression with the use of a partograph, and the foetal heart rate was checked through intermittent auscultation done with a Pinard. An ultrasound machine was available, but not routinely used for labour assistance. The human resources allowed to perform CS during the study included a gynecologist, a medical doctor (MD) and five assistant medical doctors (AMD). The maternity staff included ten midwives divided over three shifts (3 in the morning, 2 in the afternoon and 2 at night) as well as a clinical officer. In addition to Tosamaganga Hospital, there were 10 health centres and 62 dispensaries in the district. None of them ware allowed to perform CS.

Variables and Data Collection

The data was collected retrospectively from hospital registers (Labour Room, Maternity Ward and Operating Theatre) and patients charts in a Microsoft Excel data-extraction form specifically designed for this study (see Supplementary File). All data sources were compared to verify the quality of the information. For each woman who gave birth in the hospital, we collected data on maternal age, obstetric history (parity, previous caesarean section), foetal presentation, gestational age (using the date of the last menstrual period – LMP) and onset of labour (spontaneous, induced, pre-labour CS). Final mode of delivery was classified into two categories: vaginal delivery and caesarean section. Vaginal delivery could have been either (1) simple vaginal delivery which included all vaginal deliveries not requiring forceps or vacuum although they may have had episiotomy; and (2) operative vaginal delivery which included all vaginal deliveries that required forceps or vacuum.

For each woman who underwent a CS, a single indication was assigned as the one for use the procedure. When more than one indication was recorded in the woman's records and hospital charts, the authors selected only one for the analysis. This was done according to a pre-defined hierarchy devised for this study based on earlier proposals in the literature[19, 22-23]: (1) urgent or emergency CS (considering eclamptic, abrupio placentae, uterine rupture), mechanical or dynamic dystocia; (2) previous scar(s); (3) malpresentation; (4) cephalopelvic disproportion; (5) foetal distress; (6) breech; (7) twins; and others. We collected maternal outcomes (death before discharge), neonatal outcomes (birth weight, Apgar score at 1 and 5 minutes, death before discharge) and referral status (formally referred from village-level dispensaries, rural health centres or self-referred).

Because the date of last menstruation period (LMP) was missing form most of the records (n=2,444; 81.1%), we used birth weight ≥ 2500 g as a proxy for gestational age ≥37 weeks[24]. This adaptation has been suggested and previously used for the Robson classification in settings where it is challenging to assign gestational age accurately[25-27].

Exclusion criteria were birth weight <500 g (proxy for gestational aged <22 weeks). No data was collected on congenital malformations and all cases were included. For twin deliveries, only the first twin's outcome was taken into account.

The caesarean delivery rate was defined as the number of caesarean deliveries over the total number of live births[9, 15]. The maternal mortality rate was defined as the number of maternal deaths over the total number of women who gave birth regardless of birth outcome. We defined a neonatal composite outcome: severe neonatal outcome as the total number of stillbirths, early neonatal deaths (death of a live born neonate, by discharge or day 7 of life whichever occurred first) and birth discharged alive with an Apgar score at 5 min of < 7. The data available did not allow us to differentiate between fresh and macerated stillbirths. Deaths occurring after discharge were not captured. During the 2015 study period (1 March to 30 November), information was also collected on who performed the CS (gynecologist, medical doctor-MD, assistant medical doctor-AMD).

Each woman was categorized into one of ten groups using the Robson classification[28]. We used the recommended subdivision for Groups 2 and 4 into induced labour (2a or 4a) and pre-labour CS (2b or 4b). Group 5 was also divided into 5.1 (women with only one previous CS) and 5.2 (women with two or more previous CS)[28]. We analysed intrapartum and postpartum perinatal mortality by type of delivery and using the Robson classification.

Patient and Public Involvement

No patients/or members of the public were involved in the definition of the research question or outcome measures, nor in the design and implementation of the study. We have no plans to involve patients/members of the public in the dissemination of the study's results.

Results

From 1 January to 30 June 2014 and from 1 March to 30 November 2015, 3,052 women gave birth in the Tosamaganga Hospital. Complete information was available for 3,012 (98.7%) of these deliveries, all of which were included in the Robson classification. The CS rate in the population included in our analysis was 35.2% of all births.

Table 1 summarizes the characteristics of the study population. The mean age of the women was 25.6 years (range 14-45 years). Among all deliveries, 1,691 women were multiparous (56.1%), 370 (12.3%) had undergone one previous CS, 111 (3.7%) two previous CS, and 38 (1,3%) had undergone 3 or more (Table 1).

Table 1: Characteristics of women delivered during the period from January to June 2014 and March to November 2015 in Tosamaganga Hospital, Tanzania (n=3012).

Maternal Age	*Mean*	25.6
	Range	14-45
Parity	*Nulliparous (%)*	1,321 (43.9%)
	Multiparous (%)	1,691 (56.1%)
Previous CS	*No previous CS (%)*	2,493 (82.8%)
	One previous CS (%)	370 (12.3%)
	Two previous CS (%)	111 (3.7%)
	Three or more previous CS (%)	38 (1.3%)
Referral status	*Self-admitted (%)*	2844 (94.4%)
	Referred from other facilities (%)	168 (5.6%)

CS: Caesarean section

Table 2 shows the Robson classification. Almost 90% of the women admitted for delivery in this hospital were women classified into Groups 1 through 5 and about two-thirds into Groups 1 through 4.

Of the nulliparous women with a term singleton fetus in cephalic presentation (n=1,184), 1,128 (95.3%) went into labour spontaneously, 32 (2.7%) were induced, and 24 (2%) had a pre-labour CS (Tables 2 and 3). Similarly, of the multiparous women with a term singleton fetus in cephalic presentation (n=1,019), 974 (95.6%) went into labour spontaneously, 21 (2%) were induced and 24 (2.4%) had a pre-labour CS.

Women admitted to the hospital for delivery with a term singleton fetus in cephalic presentation who entered labour spontaneously accounted for 70% of the obstetric population. They had CS rates of 27.4% and 15.1% in nulliparous and multiparous, respectively.

Table 2: The Robson Reporting Table and neonatal outcomes by Robson group, Tosamaganga Hospital, Tanzania, January - June 2014 and March - November 2015.

Group*		Number of CS** in group	Number of women in group	Group Size (%)	Group CS Rate (%)	Absolute group contribution to overall CS rate (%)	Relative contribution of group to overall CS rate (%)	Stillbirth [N stillbirth/ N women (%)]	Early neonatal death*** [N neonatal deaths/N women (%)]	Apgar < 7 at 5 minutes [N live birth Apgar <7/N women (%)]
1	Nulliparous, single cephalic, term pregnancy, in spontaneous labour	309	1,128	37.5%	27.4%	10.3%	29.2%	9 (0.8%)	28 (2.5%)	24 (2.1%)
2	Nulliparous, single cephalic, term pregnancy, induced labour or elective CS	35	56	1.9%	62.5%	1.2%	3.3%	8 (14.3%)	-	1 (1.8%)
3	Multiparous (excluding prev. CS), single cephalic, term pregnancy, in spontaneous labour	147	974	32.3%	15.1%	4.9%	13.9%	16 (16%).	13 (1.3%)	13 (1.3%)
4	Multiparous (excluding prev. CS), single cephalic, term pregnancy, induced labour or elective CS	25	45	1.5%	55.6%	0.8%	2.4%	7 (15.6%)	-	1 (2.2%)
5	One previous CS, single cephalic, term pregnancy	404	463	15.4%	87.3%	13.4%	38.1%	5 (1.1%)	2 (0.4%)	8 (1.7%)
6	All nulliparous breeches	13	21	0.7%	61.9%	0.4%	1.2%	2 (9.5%)	2 (9.5%)	3 (14.3%)
7	All multiparous breeches (including prev. CS)	16	32	1.1%	50.0%	0.5%	1.5%	5 (15.6%)	4 (12.5%)	-

8	All multiple pregnancies (including prev. CS)	48	77	2.6%	62.3%	1.6%	4.5%	3 (3.9%)	7 (9.1%)	-
9	All abnormal lies (including prev. CS)	30	30	1.0%	100.0%	1.0%	2.8%	1 (3.3%)	1 (3.3%)	3 (10%)
10	All single cephalic, preterm (including prev. CS)	33	186	6.2%	17.7%	1.1%	3.1%	22 /11.8%)	17 (9.1%)	15 (8.1%)
	TOTAL	**1,060**	**3,012**	**100%**	**35.2%**	**35.2%**	**100%**	**78 (2.6%)**	**74 (2.5%)**	**68 (2.3%)**
Unclassifiable: 40 cases, 1.3% (40/3,052)										

* Birth weight ≥ 2500 g was used as proxy for GA >37 weeks

** CS: Caesarean Section

*** Early neonatal death was defined as the death of a live born neonate, by discharge or day 7 of life (whichever occurred first)

Table 3: The Robson classification Table showing only the subdivisions in Groups 2, 4 and 5, Tosamaganga Hospital, Tanzania, January - June 2014 and March - November 2015.

Group*		Number of CS** in group	Number of women in group	Group Size (%)	Group CS Rate (%)	Absolute group contribution to overall CS rate (%)	Relative contribution of group to overall CS rate (%)
2a	Nulliparous, single cephalic, S37 weeks, induced	11	32	1.1%	34.4%	0.4%	1.0%
2b	Nulliparous, single cephalic, S37 weeks, CS before labour	24	24	0.8%	100.0%	0.8%	2.3%
4a	Multiparous (excluding prev. CS), single cephalic, S37 weeks, induced	1	21	0.7%	4.8%	0.0%	0.1%
4b	Multiparous (excluding prev. CS), single cephalic, S37 weeks, CS before labour	24	24	0.8%	100.0%	0.8%	2.3%

5.1	One previous CS, single cephalic, S37 weeks	272	327	10.9%	83.2%	9.0%	25.7%
5.2	Two or more previous CS, single cephalic, S37 weeks	132	136	4.5%	97.1%	4.4%	12.5%

* Birth weight ≥ 2500 g was used as proxy for GA >37 weeks.

** CS: Caesarean Section

We analysed and interpreted the Robson Table and the data according to the Robson classification interpretation guidelines published by WHO[28, 29] which is shown in Table 4.

Table 4: Interpretation of the Robson classification in Tosamaganga Hospital, Tanzania, January - June 2014 and March - November 2015 following the WHO Robson Classification Interpretation Manual.

Quality of data	• The Caesarean Section (CS) rate of the group is 100% indicating a good quality of data
Type of population	• The size of Groups 1 + 2 (39.5%) is within the expected range. However, the ratio of the size of Group 1 versus that of Group 2 is very high (20.1). In the WHO Multicountry Study reference population (population in the WHO study with relatively low CS rates as well as good labour and childbirth outcomes), this ratio was found to be 6.3[28, 30]. Similarly, the ratio of the size of Group 3 versus that of Group 4 is 21.6 - very high compared with the 6.3 in the WHO study[28, 30]. Both high rates probably indicate the need to increase inductions in these groups of women (term with singleton fetus in cephalic presentation) or even to avoid performing pre-labour CS. This is consistent with the high CS rates found in Groups 1 and 3 and our data on stillbirth and neonatal deaths. Despite their being lower-risk groups, 37 (24%) and 29 (19%) of the total 152 perinatal deaths that occurred during the study period were in Groups 1 and 3, respectively. Only Group 10 had a larger number of perinatal deaths with 39 (25.7%) but this is a high-risk group where the women had singleton pregnancies in cephalic presentation preterm. • The size of Groups 3 + 4 is 33.9%. Since Tanzania haa a high fertility rate, we expected a higher number of multiparous women. This can be explained by the very high size of Group 5 (15.4%) with a CS rate of 87%, which contributes to about 38% of all the CS performed in the hospital. • The size Groups 6 + 7 is 1.6%, which is below the expected range for breeches. Moreover, the ratio of Group 6/Group 7 (0.5) is unusual since breeches are more frequent in nulliparas than multiparas. This could indicate errors in data collection due potentially to misclassification of nulliparous women with breech presentation into Group 1. • The size of Group 10 is 6.2% is slightly higher than that proposed by Robson (5%) and that found in the WHO Study (4.2%). Even if Tosamaganga Hospital is a referral hospital, only 168 women (5.6%) were referred, 107 (63.7%) of whom delivered by

	CS. For this reason, we consider that the larger sizes of Groups 8 and 10 cannot be justified by a particularly high-risk population. • Malnutrition and other concurrent diseases may have caused growth retardation and errors in pregnancy dating based on neonatal weight.
Caesarean section rate	• In all groups, the CS rates are higher than the expected range[28, 30]. • It has been proposed that CS rates in Group 1 of about 10% are achievable. However, the abovementioned high ratio of Group 1 versus Group 2 may be responsible for the high CS rate(27.4%) in this group. If insufficient numbers of women are induced or have necessary pre-labour CS, it is more likely that these women will need a CS at a later stage of labour. In addition, the high CS rate in Group 2 is not caused by the size of Group 2b (pre-labour CS, only 0.8% of the population), but mainly by a very low size of Group 2a (1.1% of the population) and by the poor success for induction with a consequent high C/S rate (34.4%) in this group as well. Similar arguments apply to Groups 3 and 4. The high CS rate in Group 4 (55.5%) is not justified by the high size of Group 4b (which accounted for only 0,8% of the population), but by the small size of Group 4a (just 0.7% of the population). Particularly in Groups 1 and 3, a large number of CS were performed with the diagnosis of dystocia. This might indicate a poor quality of diagnosis of dystocia and sub-optimal management of the active phase of labour. • The very high CS rate in Group 5 (87.2%) is not justified by the proportion of women with 2 or more CS (Group 5.2) who make up one-third of this group. CS rates in women with one CS (Group 5.1) and two or more CS (Group 5.2) are both high (83.2% and 97%, respectively), indicating the common practice of performing CS in women with previous scar. These rates contrast markedly with the 50-60% rates considered appropriate by the Robson guideline and the 74.4% found in the WHO Study[28, 30]. Nevertheless, an assessment of the hospital's capacity to offer safe trial of labour after CS (TOLACs) is crucial prior to making recommendation that more women be offered one Vaginal birth after caesarean (VBAC) was minimally practiced probably due to the inadequate number of midwives available to attend women in labour. Moreover, the lack of information regarding previous caesarean deliveries (how they were performed and whether or not complications occurred) may have exacerbated doctor's fear regarding whether to offer a TOLAC. • Looking at the higher-risk groups, the CS rate in Group 8 is within the expected range, while the CS rate in Group 10 is lower than expected, probably indicating a high rate of spontaneous preterm labour or a high incident of low birth weight (since newborn weight was used as a proxy for gestational age)[28, 30]. • Considering the contribution of the groups to the overall CS rate, Groups 1, 2 and 5 account for 70.6% of all CS, a higher percentage than expected, and of that figure, Group 5 accounts for 38.1% indicating, as already mentioned, a very high CS rate in the previous years.

Women in Group 5 (previous CS) constituted about 15% of the obstetric population of the hospital, with a CS rate of 87%. Two-thirds of these women had undergone just one previous CS while one-third had undergone two or more CS (Tables 2 and 3).

Overall, the most frequent indication for performing a CS was one or more previous CS (39.2%), followed by dystocia (22.3%) and then foetal distress (12.8%) (Table 5).

Table 5: Indication for Caesarean Section in the study population, Tosamaganga Hospital, Tanzania, January - June 2014 and March - November 2015.

Previous scar	416	39.2%
Mechanical or dynamic dystocia	236	22.3%
Foetal distress	136	12.8%
Breech	22	2.1%
Twins	28	2.6%
Malpresentation	41	3.9%
Cephalopelvic disproportion (CPD)	90	8.5%
Urgent or Emergency Cesarean Section	50	4.7%
Others	41	3.9%
Total number of Cesarean Section	**1,060**	**100.0%**

The management of the women with previous CS is shown in Figure 1. During the study there were 519 (17.2%) women with one or more previous CS. One hundred and fifty three (153) of them (29.5%) had an elective pre-labour CS, while the rest (70.5%) went into labour spontaneously. None of these women were induced. Among those who entered labour spontaneously, 71 (19.4%) had a SVD, while 295 (80.6%) had a CS. The indication recorded for the CS was "previous CS" in 97.4% of the women who had a pre-labour CS and 90.5% of the women who went into labour spontaneously (Figure 1).

More than 40% of all CS in the hospital occurred in Groups 1 and 3. Since the CS rate was particularly high for Group 1 (27.7%) and Group 3 (15.2%), we carried out an in depth analysis regarding the indication for the CS in these two groups (Figure 2) The majority of them were performed for dystocia (44.3% in Group 1; 55.1% in Group 3). Among the 168 women referred from other facilities, 107 (63.7%) delivered by CS.

We recorded two maternal deaths (one in Group 1 and one in Group 5) and 152 perinatal deaths (5%) of which 78 (2.6%) were stillbirths and 74 (2.5%) were neonatal deaths. About 70% of all perinatal deaths occurred in Groups 1 (37 deaths), 3 (29 deaths) and 10 (39 deaths). We analysed 220 cases of severe neonatal outcome (stillbirths, neonatal deaths and live births with Apgar score < 7 after 5 minutes) by mode of delivery using the Robson classification as shown in Table 6. A major contribution to severe neonatal outcome was made by Groups 1 (27.7%), 10 (24.5%) and 3 (19.1%). Considering the incidence in each category, the groups with the highest severe neonatal outcome rate were Groups 6 (33.3%), 7 (28.1%), indicating a high risk for newborn in breech deliveries, and 10 (29%) for preterm babies. The incidence of severe neonatal outcome was similar when analysed by mode of delivery. The majority of adverse neonatal outcomes in these groups occurred while performing simple vaginal delivery.

Table 6: Distribution of severe neonatal* outcomes by Robson group classification.

Group	Number of severe neonatal outcomes/number of women in group	Proportion of severe neonatal outcomes	Relative contribution of group to the overall severe neonatal outcomes	Proportion of severe neonatal outcome in simple vaginal deliveries** / total simple vaginal deliveries		Proportion of severe neonatal outcome in operative vaginal deliveries*** / total operative vaginal deliveries		Proportion of severe neonatal outcome in CS**** / total CS	
1	61/1,128	5.4%	27.7%	43/799	5.4%	1/20	5.0%	17/309	5.5%
2	9/56	16.1%	4.1%	7/19	36.8%	0/2	0.0%	2/35	5.7%
3	42/974	4.3%	19.1%	27/818	3.3%	1/9	11.1%	14/147	9.5%
4	8/45	17.8%	3.6%	7/20	35.0%	-	-	1/25	4.0%
5	15/463	3.2%	6.8%	1/58	1.7%	0/1	0.0%	14/404	3.5%

6	7/21	33.3%	3.2%	6/8	75.0%	-	-	1/13	7.7%
7	9/32	28.1%	4.1%	7/16	43.8%	-	-	2/16	12.5%
8	10/77	13.0%	4.5%	4/29	13.8%	-	-	6/48	12.5%
9	5/30	16.7%	2.3%	-		-	-	5/30	16.7%
10	54/186	29.0%	24.5%	47/153	30.7%	-	-	7/33	21.2%
Total	**220/3012**	**7.3%**	**100.0%**	**149/1,920**	**7.8%**	**2/32**	**6.3%**	**69/1,060**	**6.5%**

* Severe Neonatal Outcome includes stillbirths, neonatal deaths and live births with Apgar score < 7 after 5 minutes

** Simple vaginal delivery: vaginal deliveries not requiring forceps or vacuum, although episiotomy may have been done.

*** Operative vaginal delivery: vaginal deliveries that required forceps or vacuum.

**** CS: Caesarean Section

We conducted a descriptive analysis on a subset of women who underwent CS during the 2015 study period. Information on the individual who performed the CS and the indication for the CS was available for 574 of the 616 CS conducted (93.1%). Most of the CS were performed by a medical doctor (66.6%; 382) while 25.8% (148) were conducted by an AMD, and 7.7% (44) by a gynecologist. This distribution remains when stratifying by Robson groups and by CS indication (see Supplementary File).

Discussion

Our analysis of 3,012 deliveries in a rural district hospital in Tanzania using the Robson classification showed a 35% overall CS rate in an obstetric population of about 90% in Robson Groups 1 through 5. These groups were arguably composed of low-risk women, but they presented high CS rates e.g. 27.4% and 15.1% in Groups 1 and 3, respectively, who were women at term with a single foetus in cephalic presentation without previous CS who entered labour spontaneously.

High CS rates have been reported in other studies conducted in Tanzania[26, 31] (for example 31% at the Muhimbli Hospital and 35% in Kilimanjaro Christian Medical Center - KCMC) probably because of the role played by a referral hospital in targeting high-risk pregnancies. This hypothesis could be confirmed by the higher CS rate in women referred from other facilities (63.7% in our study). Sørbye described the situation at the KCMC[32] comparing patients who were referred and self-referred, with CS rates of 55% and 26.9%

respectively. However, the referral system seems to have played a minimal role in the setting of our study since only 5.6% of the women were referred (versus 20% in the Sørbye study).

Nilsen et al.[31] hypothesises that poor quality of care at the dispensary and health centre level contributes to increasing the number of preventable CS in women who are referred late and in critical condition, meaning that by the time they get to the medical facility an emergency CS is the only possible action[33]. In addition, several studies have highlighted the inadequacy of obstetric and neonatal care services at the primary level in Tanzania[34, 35, 36]. In a 2009 study conducted in the Kusulu district[37], Kruk et al. showed that 42.2% of women who gave birth in peripheral units bypassed the nearest services (dispensaries) in favor of higher level facilities (health centres), governmental or private facilities. 61.4% of women who gave birth at home had a government dispensary in the village, but chose not to go there for their deliveries.

Studies conducted by Straneo et al. in the Tosamaganga catchment area showed high rates of institutional birth coverage, probably facilitated by the high health facility density[38]. However, coverage and quality do not always go together and the poorest women were reported accessing lower level health services for birth where quality of care is sub-optimal due to limited caseloads and poor staffing[39].

Comparing our study population according to the Robson classification with those in similar settings, Tosamaganga Hospital shows a bigger size of Group 5 (15.4% compared to 8.8% in Muhimbli Hospital[26]) and a smaller size of preterm births (6.2% versus 14,6%), while the size of Group 2 and 4 was similar, a probable confirmation of the low induction rate in both settings.

Severe neonatal outcomes were recorded for 220 newborns, almost half of them in Groups 1 and 3, which may indicate that a high CS rate in these groups did not guarantee better quality of care and was not accompanied by better neonatal outcomes. This is consistent with the phenomenon of "Perinatal Paradox" which has been described in the literature[40, 41], as the inconsistency between "our superb ability to care for the individual patient and our dismal failure to address the problems of the larger society"[41]. The overuse of unnecessary technology in low-risk women translates in that the growing number of surgical procedures being performed are not associated with significant improvements in terms of maternal and neonatal outcomes.

Among 152 perinatal deaths, 78 were stillbirths. The highest incidence of severe neonatal outcome was recorded in Groups 6, 7 and 10, therefore in our hospital breech deliveries and preterm deliveries were the most at risk. As has been shown by other studies in similar setting[42], a higher risk for adverse neonatal outcome in breech vaginal deliveries compared with breech CS was recorded in Tosamaganga Hospital, suggesting sub-optimal management of breech presentation and the need for training to improve the skills of the providers. In addition, it underlines the need for appropriate, high-quality antenatal healthcare programs to encourage women to come to the facility earlier in order to identify, monitor and better manage risk factors for preterm birth, pregnancies with fetuses in breech presentation and also decrease the number of intrapartum deaths and macerated fetuses.

In Tosamaganga Hospital most of the CS were performed by the personnel in charge of the delivery room, namely the MD and the AMD, who handled all duty calls. The gynecologist was involved in case of emergency and complicated elective or intrapartum CS. In all Robson categories, the highest CS rate was performed by the MD. Again, this suggests the need for obstetric and gynecological training for the staff and a closer supervision by the gynecologist. Nyamtema et al. analysed the work of the MD, AMD and midwives in ten rural health centres in Tanzania[43]. Based on Tanzanian national guidelines and WHO recommendations[44], 37% of CS were considered unnecessary and preventable. After a staff training program was carried out and closer supervision provided, the proportion of unnecessary CS fell from 30% to 17% in HCs and from 37% to 20% in hospitals[43].

Strengths and limitations

This study used data from a rural setting that can be compared with analogous population type described in other settings in the country. The availability of outcome data and the indication for CS made possible a more contextualized interpretation of CS rates in each group. Moreover, the availability of data on who performed the CS made it possible to specifically intervene in this aspect where appropriate. There were a number of limitations to this study. The data was collected retrospectively from handwritten records and some of the information may not have been recorded accurately. Because of deficient routine data collection, we included two different time periods (January - June 2014 and March - November 2015) in the study, meaning that there was discontinuity in data collection. Combining the two periods enlarged our sample size and allowed us to avoid bias due to seasonal differences. Some variables were not available in patient charts and registers (e.g. length of labour, who made the decision to perform the CS, or whether the stillbirth were macerated or fresh). Perinatal mortality may have been underreported since early neonatal deaths occurring after discharge were not recorded. Data on congenital malformations was not available, making the interpretation of neonatal outcomes more difficult. Lastly, in the absence of reliable data on gestational age, we used birth weight as a proxy, a technique found in the literature on earlier studies conducted in low-resource settings.

Conclusion

We found a high CS rate at Tosamaganga Hospital even though the obstetric population served was not considered particularly high-risk for a referral hospital. Our analysis of the data using the Robson classification showed that Groups 1 and 3 (women at term with a single foetus in cephalic presentation who entered labour spontaneously) were larger than anticipated and presented very high CS rates. The large size of these groups and high CS rates combined with the stillbirth and neonatal mortality rates seen in the hospital may indicate insufficient induction rates and the need to provide more timely referrals so that women will get to the hospital before their conditions have become too critical.

Efforts to improve care and outcomes should include greater investment in the training of medical and nursing staff to improve the management of labour, with a correct use of the partograph and in particular for the judicious use of oxytocin augmentation in the management of prolonged labour. Training on the management of breeches and TOLAC should also be a priority in order to improve the quality of intrapartum care in the hospital.

Figure 1. Management of women with one or more previous cesarean sections (CS) during the study period.

Figure 2. Indication for Caesarean Section (CS) in Group 1 and Group 3.

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Patient consent: Not required

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Data sharing statement: Data essential for conclusion are included in this manuscript. Additional data can be obtained from the corresponding author on reasonable request.

Disclaimer: The views expressed in this study are the sole responsibility of the authors and do not necessarily reflect the views of their affiliated organizations.

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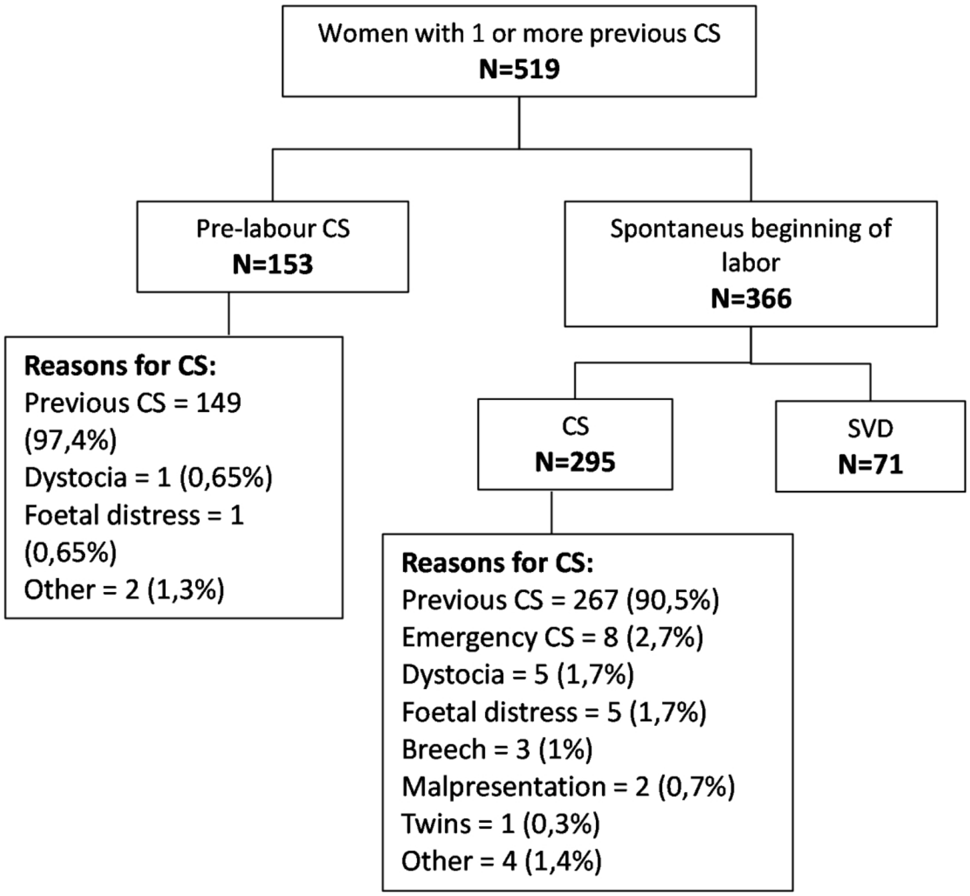
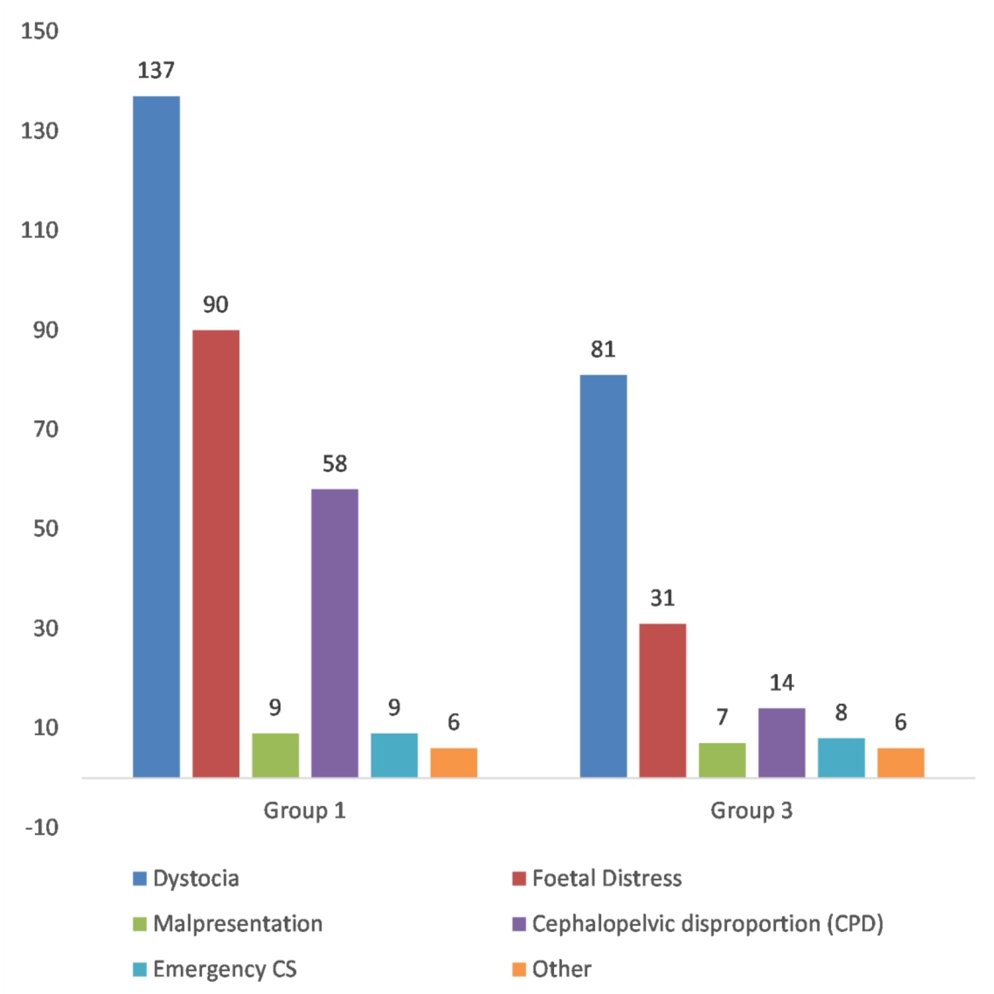
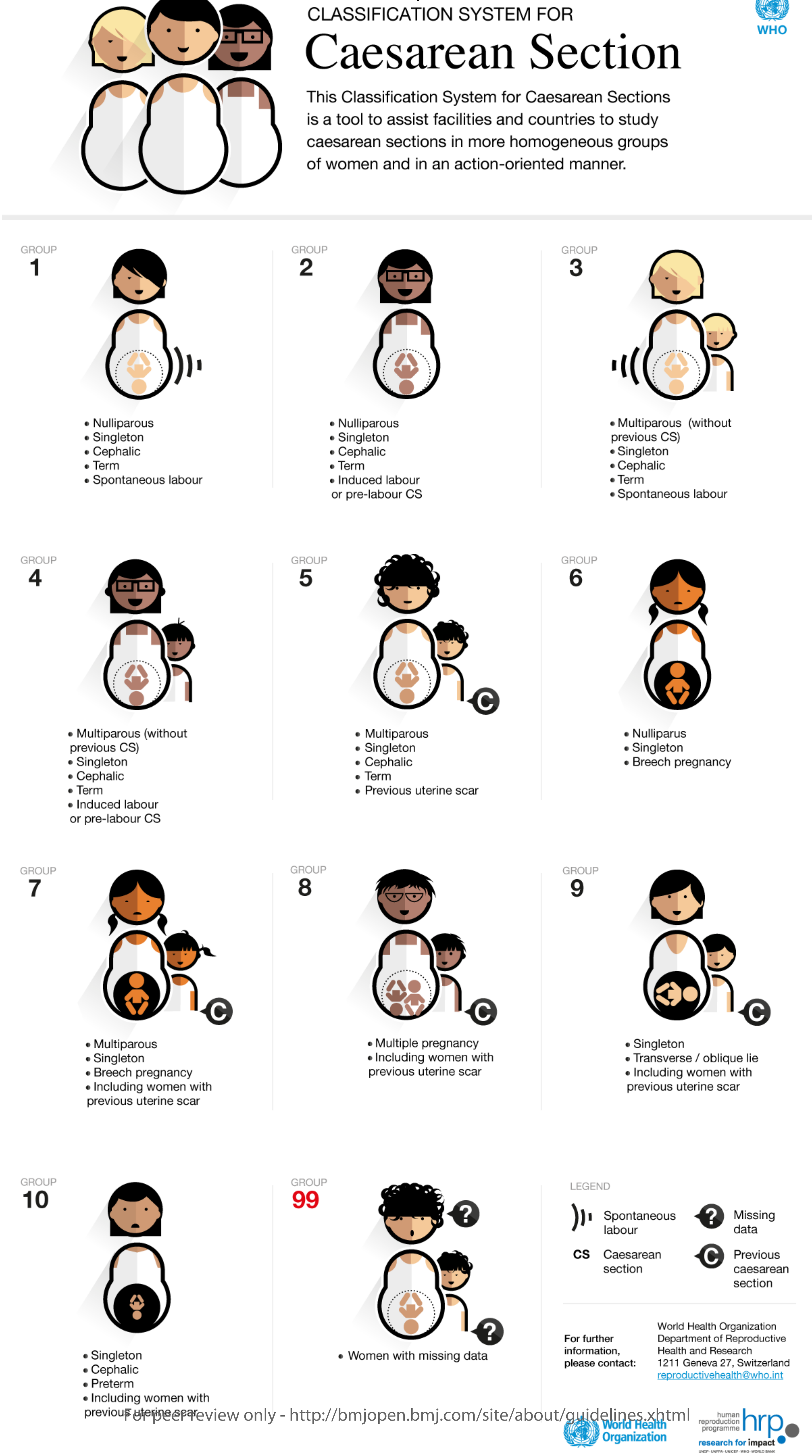


Management of women with one or more previous cesarean sections (CS) during the study period.

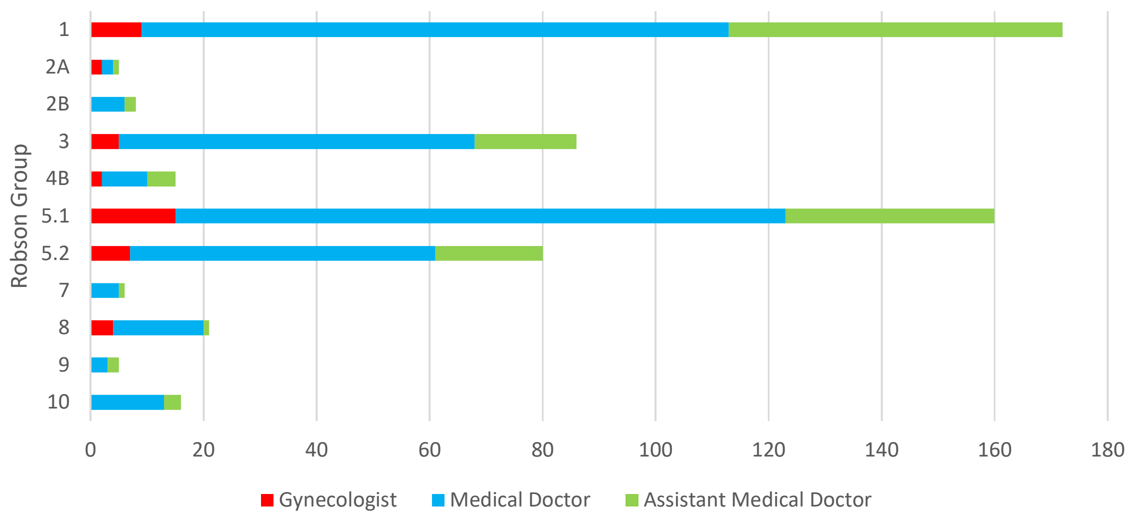


Indication for Caesarean Section (CS) in Group 1 and Group 3.

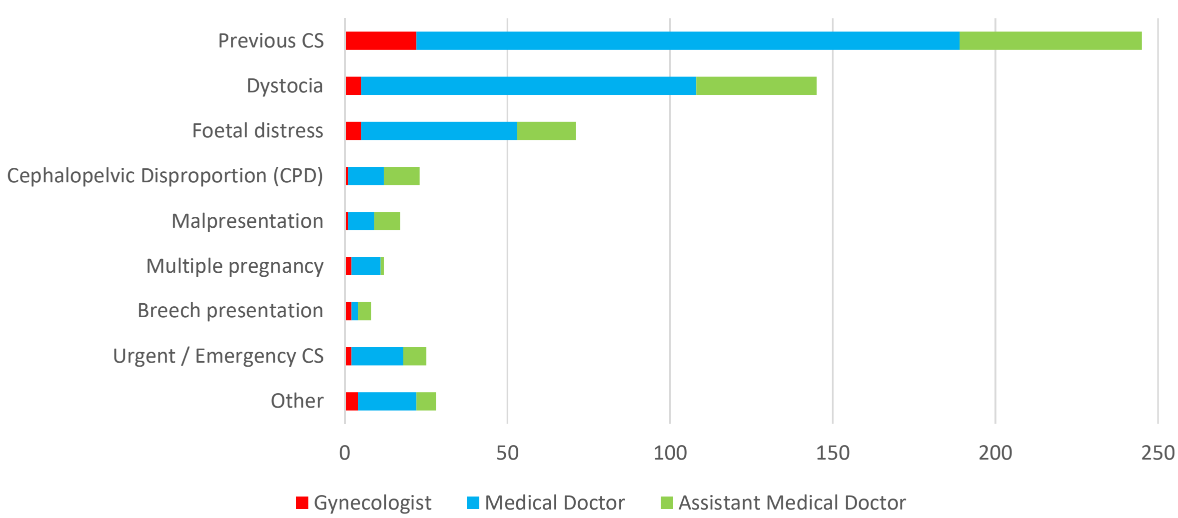

CLASSIFICATION SYSTEM FOR
Caesarean Section
WHO
This Classification System for Caesarean Sections is a tool to assist facilities and countries to study caesarean sections in more homogeneous groups of women and in an action-oriented manner.
GROUP 1
• Nulliparous
• Singleton
• Cephalic
• Term
• Spontaneous labour
GROUP 2
• Nulliparous
• Singleton
• Cephalic
• Term
• Induced labour or pre-labour CS
GROUP 3
• Multiparous (without previous CS)
• Singleton
• Cephalic
• Term
• Spontaneous labour
GROUP 4
• Multiparous (without previous CS)
• Singleton
• Cephalic
• Term
• Induced labour or pre-labour CS
GROUP 5
• Multiparous
• Singleton
• Cephalic
• Term
• Previous uterine scar
GROUP 6
• Nulliparus
• Singleton
• Breech pregnancy
GROUP 7
• Multiparous
• Singleton
• Breech pregnancy
• Including women with previous uterine scar
GROUP 8
• Multiple pregnancy
• Including women with previous uterine scar
GROUP 9
• Singleton
• Transverse / oblique lie
• Including women with previous uterine scar
GROUP 10
• Singleton
• Cephalic
• Preterm
• Including women with previous uterine scar
GROUP 99
• Women with missing data
LEGEND
Spontaneous labour
Missing data
CS Caesarean section
Previous caesarean section
For further information, please contact:
World Health Organization
Department of Reproductive Health and Research
1211 Geneva 27, Switzerland
reproductivehealth@who.int
World Health Organization
human reproduction programme hrp
research for impact
UNDP · UNFPA · UNICEF · WHO · WORLD BANK

Graphs on distribution of CS among health professional

Graph 1: Distribution of Cesarean Section (CS) among health professionals stratified in the Robson Classification.



Graph 2: Distribution of Cesarean Section (CS) among health professionals according to indication.



TOSAMAGANGA HOSPITAL – Deliveries according to Robson Classification

Date ________________________________

ID Number __________________________

Age _________________________________

Parity ________________________________

Previous CS ☐ Yes number: ______________ ☐ No

Referred? ☐ Yes ☐ No

Labour ☐ spontaneous ☐ Induced ☐ Elective CS

Presentation ☐ cephalic ☐ breech ☐ oblique / transverse lie

Fetal number ☐ Single pregnancy ☐ multiple pregnancy

Mode of delivery ☐ SVD ☐ AVD (Vacuum or forceps) ☐ CS

If CS, Indication:
- ☐ dystocia
- ☐ previous CS
- ☐ foetal distress
- ☐ breech
- ☐ twins
- ☐ malpresentation
- ☐ CPD
- ☐ Urgent CS/emergency (eclampsia, uterine ropture, placenta abruprio/previa..)
- ☐ other ________________________

Birth weight ______________________________

Neonatal outcome ☐ Live birth ☐ Still birth ☐ Fresh ☐ Macerated ☐ Neonatal Death

APGAR 0 ____________

APGAR 1 ____________

Maternal outcome: ☐ Alive ☐ Dead

Robson Classification System applied in a rural District Hospital in Tanzania

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Comments
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	P. 2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	P. 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P. 5
Objectives	3	State specific objectives, including any prespecified hypotheses	P. 5
Methods			
Study design	4	Present key elements of study design early in the paper	P. 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pp. 5,6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	P. 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pp. 6,7
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	Pp. 6,7
Bias	9	Describe any efforts to address potential sources of bias	Pp. 5,6,7
Study size	10	Explain how the study size was arrived at	P. 5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P. 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	P. 5
		(*b*) Describe any methods used to examine subgroups and interactions	P. 5
		(*c*) Explain how missing data were addressed	P. 7
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*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	Pp. 7,8
		(b) Give reasons for non-participation at each stage	P. 7
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	Table 1

		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	Participant with incomplete data were not considered in the analysis
Outcome data	15*	Report numbers of outcome events or summary measures	Table 2, Table 5
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	Not applicable
		(*b*) Report category boundaries when continuous variables were categorized	Done
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Pp 8-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	P. 12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	P. 16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Table 6, p. 15
Generalisability	21	Discuss the generalisability (external validity) of the study results	P. 15
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	P. 18

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.