Association between first birth cesarean delivery and adverse maternal-fetal outcomes in the second pregnancy: a registry-based study in Northern Tanzania

Raziya Gaffur (rfgaffur@gmail.com)
kilimanjaro Christian Medical University Collge
Eusebious Maro
kilimanjaro Christian Medical University Collge
Bariki Mchome
kilimanjaro Christian Medical University Collge
Micheal Mahande
kilimanjaro Christian Medical University Collge
Lyasimana Ndaninginan
kilimanjaro Christian Medical University Collge
Benjamin Asubiojo
kilimanjaro Christian Medical University Collge

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Association between first birth cesarean delivery and adverse maternal-fetal outcomes in the second pregnancy: a registry-based study in Northern Tanzania

Raziya Gaffur[1,2] , Bariki Mchome [1,2], Lyasimana Lithaneninn Ndaninginan[1,2], Benjamin Asubiojo [1,2] , Michael Johnson Mahande[3*] and Eusebious Maro[1,2]

[1] Kilimanjaro Christian Medical University College, P.O Box 2240, Moshi Tanzania

[2]Department of Obstetrics and Gynecology, Kilimanjaro Christian Medical Center, P.O Box 3010, Moshi Tanzania

[3]Institute of Public Health, Department of Epidemiology and Biostastics, Kilimanjaro Christian Medical University College, P.O Box 2240, Moshi Tanzania

***Corresponding author**:

RG: rfgaffur@gmail.com

Emails:

BM: barikimchome@gmail.com

LLH: lyasimana@yahoo.com

BA: remson712@gmail.com

MJM: jmmahande@gmail.com

EM: sebiwilly@gmail.com

Abstract

Background: Cesarean delivery is the commonest obstetric surgery and surgical intervention to save lives of the mother and/or the new-borns. It has been accepted as safe procedure, yet it has increased risk of adverse maternal and fetal outcomes. The rise in rate of cesarean delivery has been a major public health concern worldwide. Previous caesarean section has been associated with repeated cesarean delivery, causing potential adverse maternal-fetal outcomes in the subsequent pregnancy. We aimed to examine the relationship between first birth cesarean delivery and adverse maternal-fetal outcomes in the subsequent pregnancy among women who delivered at Kilimanjaro Christian Medical Centre in Northern Tanzania.

Methods: A retrospective cohort study was conducted using maternally-linked data from Kilimanjaro Christian Medical Centre. All women who had singleton second delivery between the years 2011 to 2015 were studied. A total of 5,984 women with singleton second delivery were analysed. Multivariable log-binomial regression was used to determine the association between first cesarean delivery and maternal-fetal outcome in subsequent pregnancy.

Results: Cesarean delivery in the first birth was associated with an increased risk of adverse maternal and fetal outcomes in the subsequent pregnancy. These included repeated cesarean delivery (ARR 1.19; 95% CI: 1.05-1.34), pre/eclampsia (ARR 1.38; 95% CI: 1.06-1.78), gestational diabetes Mellitus (ARR 2.80; 95% CI: 1.07-7.36), uterine rupture (ARR 1.56; CI: 1.05-2.32), peri-partum hysterectomy (ARR 2.28; CI: 1.04-5.02) and preterm birth (ARR 1.21; CI: 1.05-1.38).

Conclusion: Women with CD in their first pregnancy had an increased risk of repeated CD and other adverse maternal-fetal outcomes. Findings from a present study highlight the importance of devising regional specific measures to mitigate unnecessary primary caesarean delivery. Additionally, this information may serve as a basis to guide mode of delivery counselling prior to Trial of labour after caesarean delivery.

Keywords: Caesarean delivery, Maternal -Fetal outcomes, Tanzania

Introduction

Globally, the rising rate of cesarean delivery (CD) has been a major public health concern to the public health worldwide [1]. There are wide variations in respect to the management of pregnancy in women with previous cesarean delivery and more specifically CD in the first birth between high-income and low-income countries [2]. Over the three decades, evidence showed a worldwide spiked rate of CD ranging from 6-40% [3], and primary CD being the most common indicator among women with previous CD [4, 5]. Most recent CD rate in Tanzania was estimated to be 6%, with an estimated rate of 11% for Kilimanjaro region while KCMC hospital had a CD rate ranging between 29.9-35.5% [6–8]

In 2015, two thirds of the global maternal deaths were reported to occur in Sub-Saharan Africa (SSA), and the maternal mortality ratio is estimated to be twice the global average of 546 per 100,000 live births [9]. The CD rate in SSA has been stagnant at 3.5% compared to the increasing CD rate globally, yet the maternal death after CD is fifty times higher compared to high income countries [9].

A major challenge is that previous CD is one of the leading indication for the repeated caesarean section [10]. Physicians and midwives often fail to counsel women appropriately during their antenatal care who have had CD with their first pregnancy. Indeed, many of these women report in labor with limited or no knowledge regarding the possibility of a trial of labor [10]. In addition to this, inability to adequately monitor the fetus and safely augment the progress of labor when the choice is to proceed with a trial of labor is challenging [10, 11].

Worldwide, studies have demonstrated the complex association of first CD with maternal and fetal morbidity and mortality in the subsequent pregnancy. These include increased risks of repeated CD, pre-eclampsia, placenta previa, placenta abruption, post-

partum haemorrhage, uterine rupture, peri-partum hysterectomy, preterm birth, unexplained antepartum fetal death, and low birth weight [3, 12–18]. Extensive studies on previous CD and its association with maternal and fetal complications have been conducted in many African countries. However, due to the increasing number of CD, it is imperative to study the risks of the first CD which can then be communicated to the patient for their future reproductive planning. This study aimed to examine the association between first birth cesarean delivery and maternal-fetal outcomes in the subsequent pregnancy among women who delivered at Kilimanjaro Christian Medical Centre in Northern Tanzania.

Materials and Methods

Study design and setting

This was a hospital based retrospective cohort study which was designed using maternally-linked data from Kilimanjaro Christian Medical Centre (KCMC) medical birth registry. We reviewed a five years' data from 1st January, 2011 to 31st December 2015. KCMC is among one the three Zonal Referral hospitals and teaching hospital in Tanzania, located in the North zone of Tanzania, in Kilimanjaro region, within Moshi Municipal. The hospital receives women from the local community and referred cases from the nearby regions including Arusha, Manyara, Tanga, and Singida. The average number of deliveries per year is between 4000-4800 deliveries. The average percentage of cesarean deliveries is 28.8% in KCMC [19].

Data source and Data collection

The KCMC Medical Birth Registry system was established in 1999 as collaboration between Kilimanjaro Christian Medical College, Moshi, Tanzania and the University of Bergen, Norway through the support of the Norwegian Council for Higher education program for Development Research (NUFU) project, it has commenced since 2000. Women who delivered at KCMC undergo a prospective interview with standardized questionnaire within

24 hours of delivery or later in case of any delivery complications. The interview is conducted by the trained midwives at the department of Obstetrics and Gynaecology. The details of the procedure has been described elsewhere [20]. Information regarding birth outcomes, delivery mode, obstetric history and socio-demographic is recorded in the birth registry, including neonates admitted at neonatal care unit. For those who delivered their first birth at KCMC, we linked the mother's record with the child's by unique number, which is assigned to every woman who delivers at KCMC.

Study population

Data for 19,670 women delivered within the years 2011 to 2015 were obtained from KCMC birth registry. Of these, 13,211 women were multiparous. We included data for women with complete information of the second singleton delivery during the study period, and whose records were available at KCMC medical birth registry. These women were further classified into two groups, those with first birth CD and spontaneous vaginal delivery (SVD). We excluded women with missing information on the mode of delivery in their first and second pregnancies. The total of 13,722 women were excluded according to our exclusion criteria. The remaining, 5948 women had singleton deliveries in the second birth, 4367(73.4%) had SVD in their first birth and 1581(26.6%) had caesarean delivery in their first birth and were constituted the final sample size and were analysed (Figure **1**).

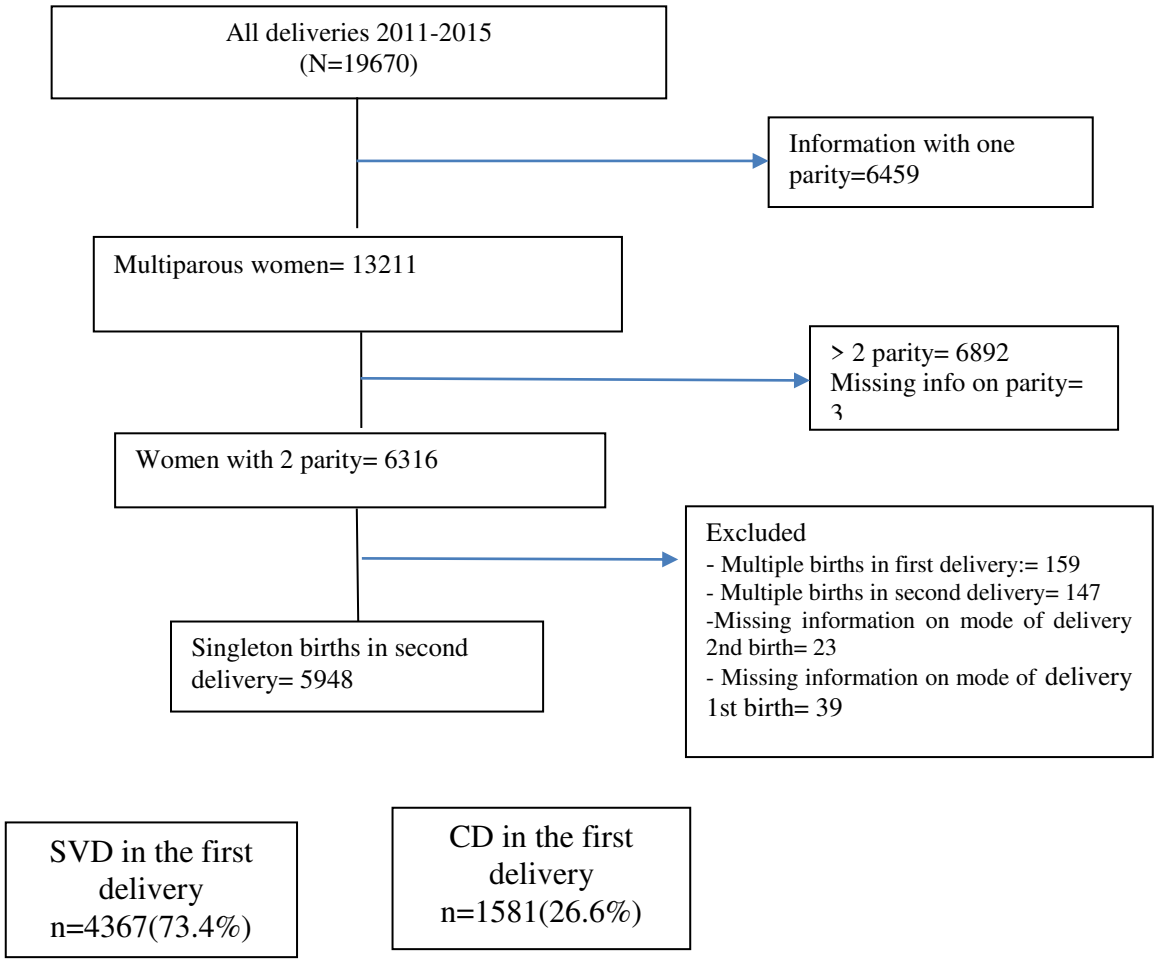

Figure 1 : Flow diagram for participants' selection (sample size estimation)

Study variables and definitions

Dependent variable

The outcome variables of this study were adverse maternal and fetal outcomes in the subsequent pregnancy. Adverse maternal outcomes include Cesarean delivery, Abruption placenta, Placenta Previa, Postpartum haemorrhage, Pre/eclampsia, Gestational Diabetes Mellitus, Uterine Rupture and Peri-partum- Hysterectomy. Adverse fetal outcomes include Apgar score less than 7 in 5 minutes, neonatal care admission, low birth weight, fetal macrosomia, preterm birth, still birth and neonatal death before 24 hours.

Independent variables

The main exposure of interest was first birth cesarean delivery. It was defined as cesarean delivery preformed during the first pregnancy for the first time. Other covariates include maternal age which originally were recorded as continuous and then was categorized into 15-19 years, 20-29 years, 30-39 years and ≥ 40 years, maternal education, Body Mass Index (BMI) was calculated as ante-natal care booking body weight in kg/ height in metres squared, then was categorized according to the World Health Organization standard; Normal weight 18.5-24.9 kg/m^2, underweight < 18.5 kg/m^2, overweight 25.0-29.9 kg/m^2 and obese ≥30 kg/m^2. Gestational age at delivery was recorded in weeks as continuous, and then was categorized as 28-32weeks, 33-36 weeks and ≥ 37 weeks. Inter-pregnancy interval was calculated from year of delivery in the first pregnancy to the year of subsequent pregnancy which was recorded as continuous, and then was converted into months: < 24 months, 24-36 months, 37-60 months and > 60 months. Referral status was divided into three categories: home, district hospital and regional hospital. Obstetric outcomes in first birth such as Pre/eclampsia, Epilepsy, GDM, anaemia, heart disease, still birth, macrosomia, low birth weight and preterm birth were assessed in both groups.

Statistical analysis

Data analysis was performed using STATA version 13.0. Descriptive statistics were summarized using mean and standard deviation continuous variables while frequency and proportion was used to summarize the categorical variables. The chi-square test was used to determine the association between the first birth CD with baseline maternal and obstetric characteristics in bivariate analysis. Both crude relative risk (CRR) and Adjusted relative risk (ARR) with 95% confidence intervals for the association between the first birth CD and maternal-fetal outcomes in the subsequent delivery were estimated using Multivariable log-binomial regression model. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was approved the Kilimanjaro Christian Medical University College Research and Ethics Committee (ethical clearance certificate number: 2346). Permission to use the medical registry data was obtained from the director of KCMC. All study participants were informed that they had the right to withdraw any time during the interview without giving any reason. Verbal consent was sought was obtained from all participants prior the interview.

Results

Characteristics of the study participants

The demographic characteristics of the study participants are shown in Table **1**. The mean age was 28.3 (SD=5.4) years. The mean booking BMI for women who had SVD and CD was [24.7 ($SD = 3.5$) kg/m^2 and 25.3 ($SD = 4.4$) kg/m^2], respectively. Majority of women 653(41.3%) with CD in their first delivery were overweight. In respect to gestation age at time of delivery, in both groups, majority had delivered at term 3408(78.0%) and 1187(75.1%) for SVD and CD respectively. More women (62.4%) with CD in the first birth had inter-pregnancy interval between 37-60 months which was higher compared to SVD (55.5%) group and had significant difference.

Table 1 : Baseline characteristics of the study participants with singleton birth in the second pregnancy (N=5948)

Characteristics	Women with first birth SVD (n=4367)		Women with first birth CD (n=1581)		P-value
	n	%	n	%	
Age [Mean, SD]	**[28.3, 5.4]**		**[28.3, 5.4]**		
Maternal Age					
15-19	163	3.7	63	4.0	0.822
20-29	2483	56.9	911	57.6	
30-39	1617	37.0	574	36.3	
≥40	104	2.4	33	2.1	
Education					
None formal	64	1.5	27	1.7	0.685
Primary education	1844	42.2	689	43.6	
Secondary education	1126	25.8	398	25.2	
Higher education	1333	30.5	467	29.5	
Religion					

Christian	3476	79.6	1243	78.6	0.604
Muslim	865	19.8	326	20.6	
Others	26	0.6	12	0.8	
Occupation					
Housewife	517	11.8	186	11.8	0.444
Farmer	650	14.9	209	13.2	
Business	1454	33.3	554	35.0	
Employed	1376	31.5	490	31.0	
Others e.g students, retired	370	8.5	142	9.0	
Residency					
Urban	2584	59.2	937	59.3	0.947
Rural	1783	40.8	644	40.7	
Tribe					
Chagga	2242	51.3	793	50.2	0.857
Pare	527	12.1	200	12.7	
Maasai	93	2.1	35	2.2	
Others	1505	34.5	553	35.0	
Booking BMI (kg/m^2)					
Underweight	131	3.0	70	4.4	**<0.0001**
Normal	2058	47.1	649	41.0	
Overweight	1762	40.3	653	41.3	
Obesity	416	9.5	209	13.2	
[Mean, SD]	**[24.7, 3.5]**		**[25.3, 4.4]**		
ANC visit					
≥4	2882	66.0	1057	66.9	0.535
<4	1485	34.0	524	33.1	
Gestation age at delivery					
28-32	130	3.0	49	3.1	**0.047**
33-36	829	19.0	345	21.8	
≥37	3408	78.0	1187	75.1	
[Mean, SD]	**[37.9, 2.3]**		**[37.8, 2.3]**		
Inter-pregnancy Interval					
<24 months	15	0.3	7	0.4	**<0.0001**
24-36 months	1200	27.5	338	21.4	
37-60 months	2423	55.5	987	62.4	
>60 months	729	16.7	249	15.7	
Referral					
Home	3508	80.3	1227	77.6	0.566
District hospital	707	16.2	289	18.3	
Regional hospital	152	3.5	65	4.1	

First birth obstetric characteristic of study participants

The obstetrics characteristics of the first birth between women who had CD and those without are shown in Table **2**. Majority of the women had term deliveries in both groups (73.1% vs. 68.8%, for those with CD and SVD in their first pregnancy respectively). Women who had

SVD in their first pregnancy were less likely to experience risk of preeclampsia and GDM than those who had CD [(4.0% vs. 5.5 %) and (0.3% vs. 0.8%)], respectively. They were also less likely to give birth to infant with macrosomia than their counterparts (11.0% vs.7.5%). Furthermore, women who had first birth by SVD had more stillbirth and preterm birth babies compared with their counterparts who had delivered by CS in their first pregnancy [(5.1% vs. 3.4%) and (29.0% versus 25.4%)], respectively.

Table 2 : First birth obstetric characteristic of study participants (N=5948)

Characteristics	Women with first birth SVD (n=4367)		Women with first birth CD (n=1581)		P-value
	n	%	n	%	
Maternal Characteristics					
Gestation age					
28-32	95	2.2	25	1.6	0.005
33-36	1269	29.1	401	25.4	
≥37	3003	68.8	1155	73.1	
Medical Conditions					
Pre/Eclampsia					
Yes	173	4.0	87	5.5	0.010
No	4194	96.0	1494	94.5	
Epilepsy					
Yes	37	0.8	11	0.7	0.564
No	4330	99.2	1570	99.3	
GDM					
Yes	11	0.3	13	0.8	0.002
No	4356	99.7	1568	99.2	
Anaemia					
Yes	48	1.1	20	1.3	0.595
No	4319	98.9	1561	98.7	
Heart Disease					
Yes	47	1.1	20	1.3	0.542
No	4320	98.9	1561	98.7	
Fetal characteristics					
Still birth					
Yes	222	5.1	54	3.4	0.007
No	4145	94.9	1527	96.6	
Macrosomia*					
Yes	326	7.5	174	11.0	<0.0001
No	4041	92.5	1407	89.0	
Low birth weight**					
Yes	371	8.5	138	8.7	0.776
No	3996	91.5	1443	91.3	
Preterm birth					
Yes	1268	29.0	401	25.4	0.005
No	3099	71.0	1180	74.6	

*Birth weight ≥4000 grams; ** Birth weight ≤2500grams

Association between first birth cesarean delivery and adverse maternal outcomes in the subsequent pregnancy

The relationship between first birth cesarean delivery and adverse maternal outcomes has been displayed in Table **3**. Women with first birth CD had an increased risk of having CD [ARR1.19 (95% CI: 1.05-1.34)]; pre/eclampsia [ARR1.38(95% CI: 1.06-1.78)], GDM [ARR 2.80 (95% CI: 1.07-7.36)], uterine rupture [ARR1.56 (95%CI: 1.05-2,32)] and peri-partum hysterectomy [ARR2.28 (95% CI: 1.04-5.02)] in their subsequent pregnancy as compared to their counterparts who had SVD. The association between CD in the first pregnancy and placenta abruption, placenta previa, and PPH was not statistically significant (Table **3**).

Table 3: Association between first birth cesarean delivery and adverse maternal outcomes in the subsequent pregnancy (N=5948)

Maternal outcomes	Women with first birth SVD* (n=4367)	Women with first birth CD (n=1581)	CRR (95% CI)	ARR (95% CI)
Cesarean delivery	1568(35.9)	648(41.0)	1.24(1.10-1.39)	1.19(1.05-1.34)[a]
Placental abruption	73(1.7)	32(2.0)	1.22(0.80-1.85)	
Placental previa	80(1.8)	37(2.3)	1.28(0.87-1.90)	
PPH	291(6.7)	122(7.7)	1.17(0.94-1.45)	
Pre/eclampsia	207(4.7)	109(6.9)	1.49(1.17-1.89)	1.38(1.06-1.78)[b]
GDM	15(0.3)	14(0.9)	2.59(1.24-5.38)	2.80(1.07-7.36)[b]
Uterine rupture	82(1.9)	43(2.7)	1.46(1.01-2.12)	1.56(1.05-2.32)[b]
Peripartum hysterectomy	18(0.4)	15(0.9)	2.31(1.16-4.60)	2.28(1.04-5.02)[a]

*Reference group
CRR: Crude Relative Risk; ARR: Adjusted Relative Risk; CI: Confidence Interval
[a] :Adjusted by Maternal age, Booking BMI, Gestation age, Inter-pregnancy interval, also current and previous pre/eclampsia and GDM
[b] :adjusted by maternal age, gestational age, Booking BMI, inter-pregnancy interval, previous GDM, and pre/eclampsia

Association between first birth cesarean delivery and adverse fetal outcomes in the subsequent pregnancy

In unadjusted analysis, having first cesarean delivery was associated with preterm birth in the subsequent pregnancy [CRR1.18 (95% CI: 1.03-1.34)]. In multivariable model, the association between first birth cesarean delivery in the first pregnancy and preterm birth in the second pregnancy also remained significant [ARR1.21 (95% CI: 1.05-1.38)]. However, there were no significant difference in terms in LBW, macrosomia, Low Apgar sore in 5th minute, still birth and early neonatal death between women with previous CD and those without (Table **4**).

Table 4 : Association between first birth cesarean delivery and adverse fetal outcomes in the subsequent pregnancy (N=5948)

Adverse outcomes	*Women with first birth SVD (n=4367	Women with first birth CD (n=1581)	CRR(95%CI)	ARR(95%CI)
Preterm birth	959(22.0)	394(24.9)	1.18(1.03-1.34)	1.21(1.05-1.38)[a]
Neonatal unit admission	650(14.9)	219(13.9)	0.92(0.77-1.08)	0.90(0.74-1.09)[b]
Macrosomia	257(5.9)	72(4.6)	0.76(0.58-0.99)	0.72(0.55-0.95)[c]
Low birth weight	417(9.5)	165(10.4)	1.10(0.91-1.33)	0.96(0.78-1.18)[d]
Low Apgar score in 5 minutes (n=5771)	89(2.1)	36(2.3)	1.12(0.75-1.65)	1.06(0.71-1.58)[e]
Still birth	128(2.9)	49(3.1)	1.06(0.75-1.47)	0.95(0.67-1.36)[f]
Neonatal death in 24 hours	35(0.8)	20(1.3)	1.58(0.91-2.75)	1.72(0.73-4.03)[g]

CRR: Crude Relative Risk; ARR: Adjusted Relative Risk; CI: Confidence Interval

*Reference group

[a] adjusted by the current preeclampsia GDM Macrosomia, LBW, and previous preterm

[b] adjust by Preeclampsia, GDM, Macrosomia, LBW, Apgar score in 5 and Preterm

[c] adjusted by macrosomia in the first birth, pre/eclampsia, GDM, stillbirth, and preterm in the second birth

[d] adjusted by LBW in the first birth, pre/eclampsia, GDM, and Preterm in the second birth

[e] adjusted by preeclampsia, GDM, LBW, Preterm, abruption placenta in the second birth

[f] adjusted by stillbirth in the first birth, preeclampsia, GDM, , Macrosomia, Preterm and abruption placenta in the second birth

[g] adjusted by preeclampsia, GDM, macrosomia, LBW, Apgar score in 5 Preterm, and Abruption placenta in the second birth

Discussion

In the present study, CD in the first pregnancy was associated with increased recurrence of CD in the subsequent pregnancy. It was also associated with higher risk of adverse maternal and fetal outcomes in the subsequent pregnancy. We found that women with previous CD had nearly 2-fold increased risk of repeated CD in their subsequent pregnancy.

The finding in our study is consistent with previous studies done in China and Germany[3, 12]. The reason for high repeated CD for example in China was due to 'two child policy', leading to increase in maternal request for CD, to get the next precious baby. In the present study, the high repeated CD could be explained by the nature of the studied population and conducted at the tertiary hospital that receive pregnant women in different state and conditions of labor, whereby to perform CD maybe best possible form of mode of delivery for the attending physician. In addition to this the dilemma and pressure on the doctors is fact that the physician may have not attended to the patient prior and also inadequate information on the first CD before the labor.

In consistent with other studies, this study revealed that first birth CD is associated with significant increased risk of adverse outcomes: pre/eclampsia, GDM, uterine rupture and peri-partum hysterectomy. Supporting the finding to this study, specifically on pre/eclampsia, study in USA and Peru has shown 3 folds high and almost one half high risk respectively in the subsequent pregnancy [14, 21]. Contrary to this evidence, [3] did not identify any risk in this relationship. Although the mechanism underlying this association is unclear, the most likely explanation is that cesarean section scar leads to change in the endometrium; hence the pathophysiology for pre/eclampsia is supported by poor trophoblast invasion, less vascularization and incomplete remodelling of spiral arteries [22, 23]. However, in our study we could not do subgroup analysis in respect to indications of cesarean delivery especially for the first delivery and difference in race and ethnicity as incidence of pre/eclampsia is higher in African-American women [24]. Another finding is the risk of uterine rupture in the

subsequent pregnancy in women with first birth CD. Worth mentioning, is higher number of uterine ruptures with limited peri-partum hysterectomy. This disparity is possibly due to repairs of some uterine rupture which were not captured in the registry [13, 14]

Furthermore, this study also found association of first birth CD and increased risk of developing GDM and peri-parturm hysterectomy in the subsequent pregnancy. Although this association is statically significant, the explanation that could account for this, especially for GDM is the small number of events, thus wide confidence interval. Despite this, [3] had similar association with larger events. Similar to pre/eclampsia, GDM could be associated with increasing placenta mass which directly influenced anti-insulin hormones production. [24].

In relation to maternal outcomes, our findings show that there were some association between first birth CD and placenta abruption, placenta previa and PPH, however not significant, which is consistent with other analysis in respect to placenta previa and PPH [13], however contrary to [3, 16]. Possible explanation that may have influenced our finding might be missing information on complication in the first birth which may have influenced the current pregnancy and furthermore our data did not classify the types of placenta previa.

On the aspect of fetal outcomes, we found that, women with first birth CD has 1.21(CI 95%: 1.05-1.38) higher risk of having preterm birth in the subsequent pregnancy similar to a systemic review [25]. This association is explained by the changes in the intra-uterine structure and its microenvironment, although the pathogenesis of this event is unclear [25]. However, inability to control for other possible confounders such as premature rupture of membranes, infections or cigarette smoking which could lead to preterm delivery was a limitation that could have given different view to our finding. Also the recorded preterm birth, was not categorized as either induced or spontaneous and on the other hand, availability

of neonatal care at KCMC could reflect the results in our study, as most preterm deliveries are referred at KCMC.

Strengths and limitations

Our study included data for five years; therefore, it had large scale sample size. And our analysis was strictly restricted to women with first and second singleton pregnancies, thereby eliminating potential confounding effect of parity and multiple gestation pregnancy. It being a retrospective study design, we could not capture many important factors that would helped us in better analysis, such indications of previous and current cesarean delivery, history of myomectomy, history of previous placental abruption, where was the first cesarean delivery performed and on the other hand, possibility of leading to inappropriate documentation of certain clinical condition, such as birth-weight, gestational age. KCMC being a tertiary hospital, thus more complicated cases being referred here, may be leading to referral bias and it is hospital based, therefore may not be generalized the population.

Conclusion

In view of our finding, cesarean delivery in the first birth does appear to increase risk of repeated cesarean delivery and other adverse outcomes in the subsequent pregnancy. We emphasise clinician to balance the risk and benefit of cesarean delivery in the first and future births, and encourage the counselling to the women the risks of cesarean delivery at ante-natal clinic.

Abbreviation

ANC: Ante-natal care; BMI: Body Mass Index; CD: Cesarean delivery; CI: Confidence Interval; GDM: Gestational Diabetes Mellitus; KCMC: Kilimanjaro Christian Medical Centre; LBW: Low birth weight; PPH: Post-partum Haemorrhage; SSA: Sub-Saharan Africa; SVD: Spontaneous vaginal delivery.

Ethical approval and consent to participants

The interviews are conducted after the delivery, a verbal informed consent was sought. Oral information is given by the midwives before conducting the interview regarding the birth registry and the data collected and the use of data for research purposes. After the consent, the women were free to opt not to reply any specific questions during the interview. The Ethical Clearance was approved by Health Research and Ethics committee of Kilimanjaro Christian Medical University College, with ethical clearance certificate No. 2346.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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Competing interests

The authors declare that they have no competing interests.

Authors 'contributions

RG had the concept idea of the study, design study, data analysis, manuscript preparation and with continuous revision, and was supervised EM and BM. MJM, BA and LHH helped in reviewing the article. All authors read and approved the final manuscript

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Figures

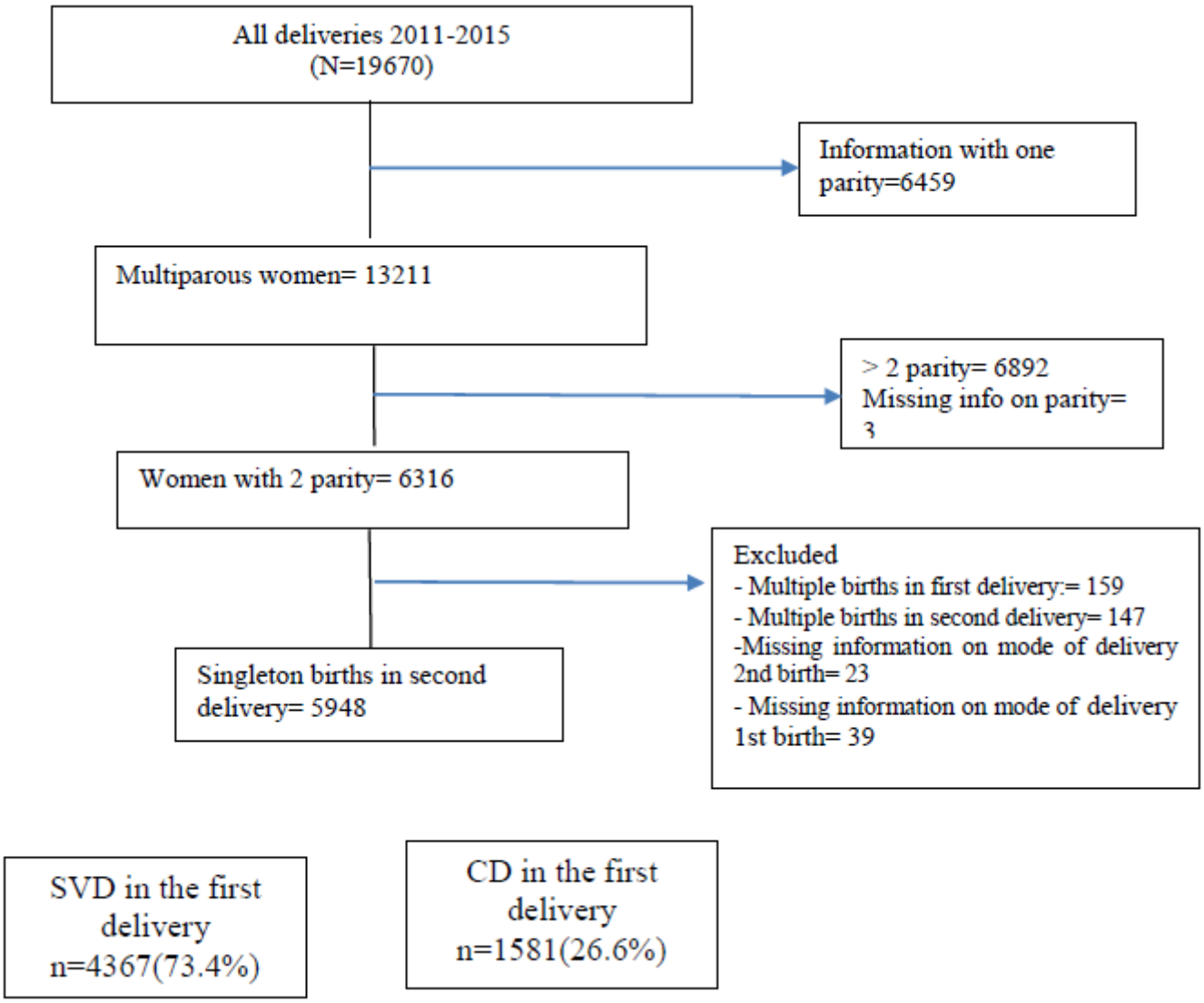

Figure 1

Flow diagram for participants' selection (sample size estimation)

Supplementary Files

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