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Prevalence and predictors of failure in labor induction among pregnant women delivered in Northern-Tanzania 2000-2015: A Registry-based Retrospective Cohort Study

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Abstract

Background
The proportion of induced deliveries is increasing steadily among referral hospitals of Tanzania. However, there is limited information regarding the failure rates of this important obstetric intervention. Factors that are associated with failure rate have also not been well documented. This information is important for practicing clinicians as it may help to understand some maternal and fetal characteristics that contribute to failure in labor induction and thereby provide women with timely alternative modes of delivery. This may reduce morbidities and mortalities related to emergency Cesarean deliveries following induction of labor. This study aimed to determine the prevalence and factors associated with failure in labor induction among women who delivered at KCMC hospital in Northern-Tanzania.

Methods
A hospital-based retrospective cohort study was designed using maternally-linked data from Kilimanjaro Christian Medical Centre (KCMC) medical birth registry among women who delivered singleton babies from 2000 to 2015. All deliveries that were induced using any method were included. Failure in labor induction was defined as inability to achieve vaginal delivery after labor induction. Women with missing information on induction of labour status were excluded from analysis. Data analysis was performed using Stata version14.0. Relative risk and 95% Confidence Interval for factors associated with failed induction were estimated using Log-binomial regression models. Robust variance estimations were used to take into account for repeated deliveries from the same woman.

Results
A total of 11,483 deliveries were analyzed. The rate of failed labor induction (fIOL) was 19%. Independent predictors of fIOL include primiparity (RR = 1.83; 95% CI: 1.57 – 2.14), pre-pregnancy obesity (RR =1.58; 95% CI: 1.33-1.67), fetal macrosomia (RR = 5.30; 95% CI: 2.47 – 11.37) and rural residence (RR =1.20; 95% CI: 1.08 – 1.34).

Conclusion
Numerous factors were associated with fIOL. Assessment of these factors and preparation for alternative delivery mode prior an intervention is warranted to reduce adverse pregnancy outcomes related to failed labor induction.

Key words: Labor Induction, Failed labor induction, Predictors, Tanzania.

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Background

Induction of labor (IOL) is a medical technique which is done to artificially initiate uterine contractions before its spontaneous onset [1]. The main goal of IOL is to achieve vaginal delivery and it is only recommended when the benefits of delivery outweighs the risks of continuing the pregnancy [2,3,4]. The medical risks to be considered for this intervention include maternal, fetal or social or the combination of these [5,6]. Maternal indications include gestational diabetes, preeclampsia, prolonged pregnancy, and premature rupture of membrane (PROM). Fetal indications include fetal distress, intrauterine growth retardation (IUGR), and intrauterine fetal death (IUFD). Social factors for IOL include mostly non-medical ones such as specialist's service availability and others [7].

The intervention has been shown to be conducted mostly in High Income Countries where about 20% - 30% of all deliveries are preceded by induction [6] while African countries the overall rate in the seven selected countries (Algeria, Angola, DR Congo, Kenya, Niger, Nigeria and Uganda) was found to be only 4.4% ranging from 1.4% in Niger to 6.8% in Algeria [8,9]. IOL has a number of clinical advantages such as decreasing the number of still births, reducing chorioamnionitis, and most importantly lowering Cesarean Section rates without increasing adverse pregnancy outcomes as it has been the priority consideration in Low Income Countries where resources are limited [10–12]. However this intervention is not without risks and it may fail and lead to adverse health experiences to the mother, newborn or both [4].

There is scanty information on the failure rate of Labor Induction and hence the maternal and fetal characteristics that predicts its failure in Sub-Saharan Africa including Tanzania. Evidences generated from this study will help clinicians to well identify the subjects with the high chances of being victims of failure in this intervention and hence be in a position to take precautionary measures such as preparation for cesarean section (CS), assisted vaginal delivery and others. This study aimed to determine the prevalence and factors associated with failure in labor induction among women who delivered at KCMC hospital in Northern-Tanzania.

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Methods

Study design and setting

A hospital-based retrospective cohort study was designed, using birth registry data which collects information from all women delivered at Kilimanjaro Christian Medical Centre (KCMC) hospital birth registry from 2000 to 2015. The hospital is one of the four zonal referral which is well known of its excellence in serving not only the indigenous of Kilimanjaro region but also significant amount of people from the nearby regions such as Tanga, Manyara and Arusha. About 4,000 deliveries are recorded annually at this facility and 20% of these admissions are referral cases while the remaining proportion is self-referrals. Since the establishment of the birth registry at KCMC in 2000, the hospital has been recording every information on pregnancy, delivery as well as the information of the newborn in an electronic database.

This information is obtained through personal interviews conducted by the specially trained nurse-midwives within 24 hours after delivery in case of uncomplicated pregnancies or on the second or third day in case of CS delivery or other pregnancy complications. Major themes in the questionnaire include: socio-demographic attributes of the child's mother and father, health status before pregnancy, the mother's health during pregnancy, information concerning the delivery, and on the health status of the newborn. In this computerized system, each birth is assigned its own unique registration number.

Study Population

Women whose labor was induced at KCMC Hospital from the year 2000 to 2015 and with the complete reproductive history in the medical birth registry were included. We excluded women who delivered spontaneously and those with missing information on whether IOL was conducted, as well as those with no record on the mode of delivery achieved since the mode of delivery was used as the definition of failure or success of IOL intervention.

Data collection methods and tools

We made use of the standardized questionnaire which enabled us to capture information regarding maternal socio-demographic, health status of the mother before and during pregnancy as well as information concerning delivery. Demographic information includes age, occupation, education level, and place of residence, marital status, tribe, religion and many others. Some of the health information before and during pregnancy that were captured in this database include presence of chronic or serious diseases, family practices, smoking and alcohol behavior, drugs taken on regular basis plus many others. Information on delivery includes mode of delivery, blood loss, use of induction, method of induction used, use of analgesics and mother's health at delivery. The questionnaire also has information on the health status of the newborn such as presentation, sex, birth weight Apgar score, birth defects and Neonatal ICU admissions.

The interview is conducted by the specially trained nurse-midwives in 24 hours after delivery or on the second or third day depending how ready is the mother to provide response. The completed questionnaires are then entered into the computerized database.

Definition of the Outcome Variable

The question as to when does IOL intervention said to have failed is still debatable. There has been no standard definition of failed labor induction (fIOL) to date. Some literatures define it as failure to progress to active phase of labor [13–15], inability to achieve cervical dilatation of >4cm after 12 hours of oxytocin administration [16], inability to end up with vaginal delivery after labor induction [17,18] plus many others. This study defined failure of IOL as a failure to give birth vaginally after any trial of inducing labor. Hence, all mothers whose labor were induced but ended up with CS delivery were considered victims of the failure of the intervention.

Data analysis

Data analysis was performed using Stata version 14. Mean and SD was used to describe continuous variable and comparison of proportions was performed by Pearson chi-square ($\chi 2$) for categorical variables to determine associations between demographic variables and the IOL. Multivariable Log-binomial regression model was used to estimate the odds ratios (ORs) for IOL with 95% confidence intervals (CIs). A p-value of less than 20% was considered statistically significant for inclusion in multivariable analysis.

We used mothers as the primary unit for our analysis and conducted a clustered analysis technique with robust estimation of variances to account for the correlation between repeated observations of the same woman.

Ethical considerations

This study acquired an ethical approval from Kilimanjaro Christian Medical University College Research and Ethics Committee with the reference number 985. Informed consent was also obtained from all mothers before conducting an interview. The study also adhered to confidentiality as patients' names were not used anywhere but rather the information of all participants were coded by the unique hospital registration numbers.

Results

The summary of demographic as well as obstetric characteristics of women who underwent labor induction is summarized in (**Table 1**). After performing necessary exclusion (**Figure 1**) a total of 11,483 deliveries were analyzed. The mean maternal age was 27 (SD=6) years and most of these mothers were 20 to 30 years of age. About 50% of these women had a primary education and more than 80% were married while more than half (57%) of all deliveries came from primiparous women. The institution uses oxytocin most frequently in inducing deliveries as it accounted for about 90% followed by prostaglandins (7%). Missing observations of about 90% were observed in indications for IOL, however for the subjects with recorded information on indications for IOL (n=1088)

it was seen that 50% of these were indicative of Preeclampsia while Pre-Labor Rupture of Membrane (PROM) accounted for 34%.

Table 1 : Demographic and Obstetric characteristics of women underwent labor induction from 2000 to 2015 at KCMC Hospital, Northern Tanzania

SOCIAL-DEMOGRAPHICS CHARACTERISTICS		OBSTETRIC CHARACTERISTICS	
Variable	**Frequency (%) N=11,483**	**Variable**	**Frequency (%) N=11,483**
Maternal age (years)*	27 ± 6	**Birth weight(Kg)***	3.17 ± 0.73
Maternal age (years)		**Birthweight (Kg)**	
<20	1085 (09.45)	<1.8	300 (02.61)
20-30	6753 (58.81)	1.8-2.5	883 (07.69)
30-35	2280 (19.86)	2.5-3.5	7408 (64.51)
>35	1353 (11.78)	3.5-4.0	2398 (20.88)
Missing	12 (0.10)	>4.0	494 (04.30)
Educational Status		**Gestational age(Weeks)**	
None	142 (01.24)	Extreme Preterm	35 (00.30)
Primary	5739 (49.98)	Very Preterm	162 (01.41)
Secondary	1499 (13.05)	Mod. Preterm	967 (08.42)
Higher	4078 (35.51)	Term	8303 (72.31)
Unknown	8 (00.07)	Post term	1204 (10.49)
Missing	17 (00.15)	Missing	812 (7.07)

Religion		**Delivery modes**	
Catholic	4446 (38.72)	Vaginal delivery	8988 (78.27)
Protestants	4696 (40.90)	Cesarean delivery	2495 (21.73)
Muslim	2271 (19.78)		
Others	37 (0.32)		
Missing	33 (0.29)		
Mothers tribe		**Indication for IOL**	
Chagga	6498 (56.59)	Post-dates	123 (1.07)
Pare	1328 (11.56)	PROM	366 (3.19)
Masai	150 (01.31)	Eclampsia	13 (0.11)
Others	3491 (30.40)	Preeclampsia	551 (4.80)
Missing	16 (0.14)	GDM	5 (0.04)
		Abrupti o Placenta	30 (0.26)
		Missing	10395 (90.53)
Marital status		**Method of IOL**	
Married	9832 (85.62)	Amniotomy	8 (0.07)
Not Married	1627 (14.17)	Oxytocin	10289 (89.60)
Missing	24 (0.21)	Prostaglandin	761 (6.63)
		Missing	425 (3.70)
BMI		**Parity**	
Normal	1594 (13.88)	Nulliparous	6555 (57.08)
Underweight	1654 (14.40)	Multiparous	4928 (42.92)
Overweight	2171 (18.91)		
Obese	1542 (13.43)		
Missing	4522 (39.38)		

Figure1: Schematic diagram for sample size estimation

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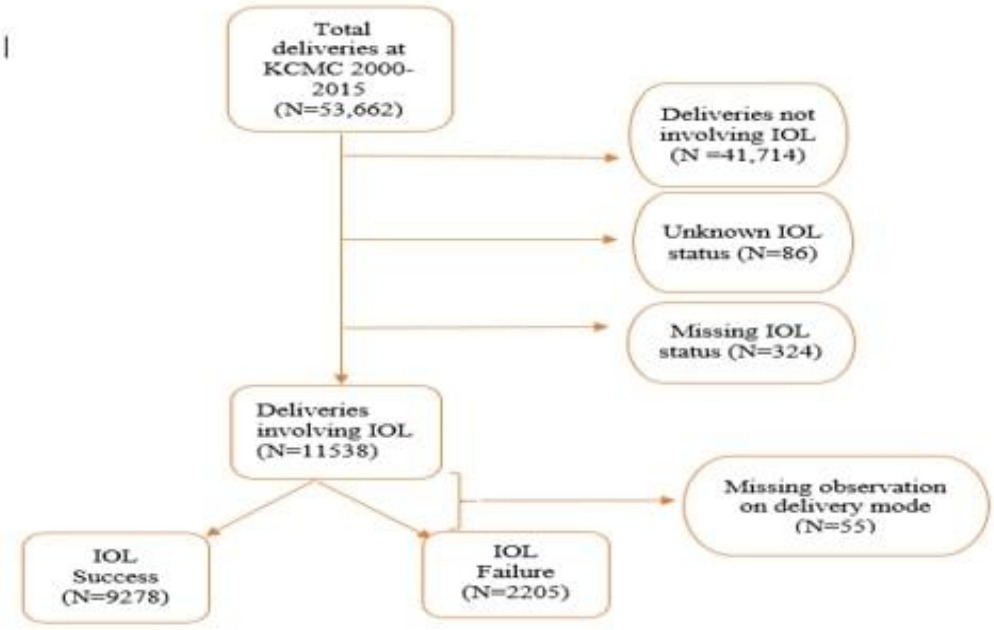

Prevalence of Failure of IOL

Among 11,483 deliveries analysed, 2205 (19.2%) deliveries experienced failure in IOL intervention. There was a variation in frequency of fIOL according to parity, gestational age, maternal BMI, and birth weight of the new born. The proportion of fIOL increased with an increase of BMI and birth weight of the newborn showing the linear trend. Obese women had the highest proportion of fIOL compared to other BMI categories (**Figure 2**). Similarly, increase in the infant birth weight was related with an increased proportion of fIOL as shown in **Figure 6** below. Mothers who gave birth to big babies (>4Kg) had the highest proportion (31.78%) of fIOL compared to other birth weight categories (**Figure 3**). Primiparous women showed higher proportion of failure rate (66%) compared to multiparous women 34% (**Figure 4**).

Figure 2: Failure in labor induction by BMI categories

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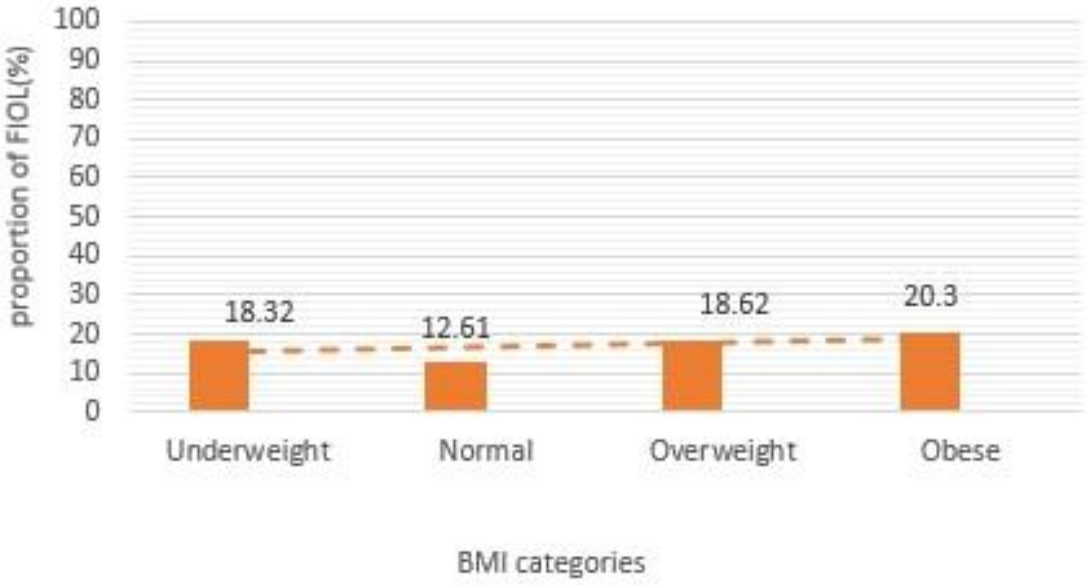

Figure 3: Failure in labor induction by birthweight

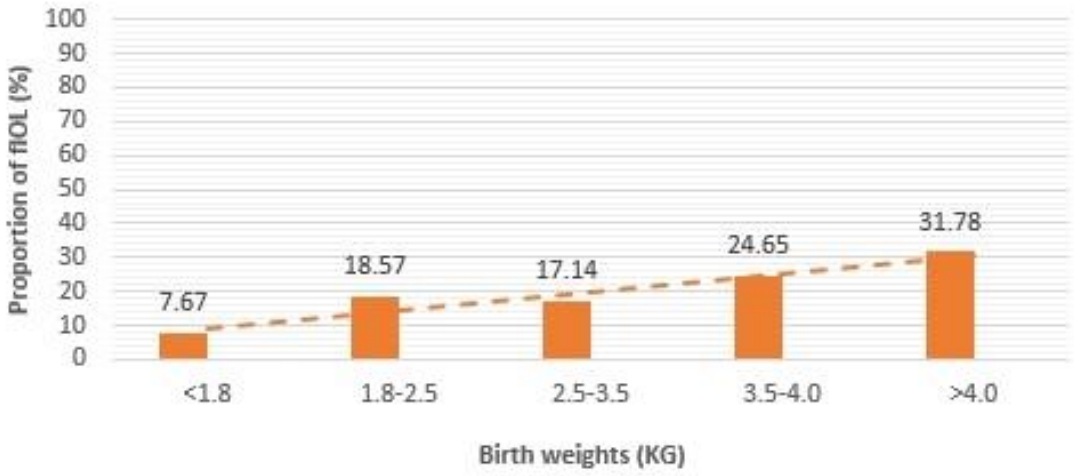

Figure 4: Failure in labor induction by parity

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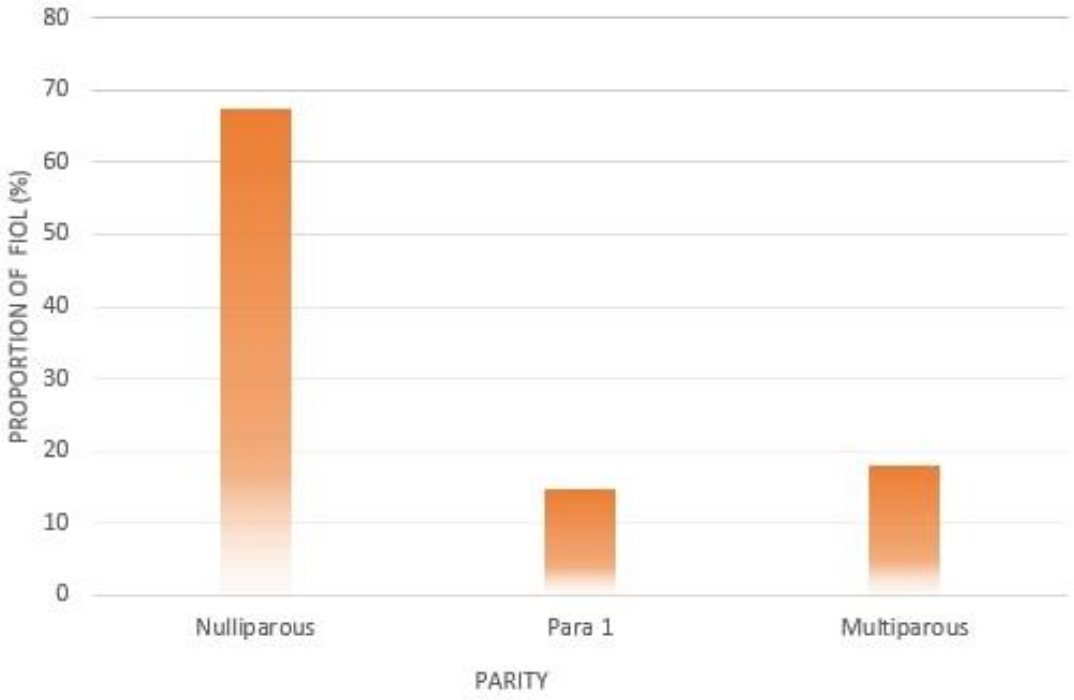

Trend in Prevalence of Failed Labor Induction

The trends in prevalence of Induced deliveries and prevalence of failure in IOL at KCMC have been displayed in (**figure 5**) and (**figure 6**) respectively. It is shown that there was a steep downfall of IOL at this institution from 2007 (30.77%) to 2009 (7.54%). A steady increase labor induction started to increase from the year 2009 (7.54%) and achieved a peak of 28.43% in 2014. The trend in fIOL has been displayed in (**figure 6)**. There had been irregular ups and downs of the prevalence of fIOL at KCMC from the period of 2000 to 2004 where it started to decline steadily up to the year 2007. Since the year 2012, there was a steady increase in proportion of fIOL cases to the year 2015 (**figure 6**). This might be predicting an alarming situation on the success of this important intervention in the future hence creating a great need to conduct more and more studies in this specific area.

Figure 5: Trend of induced deliveries from 2000 – 2015 at KCMC

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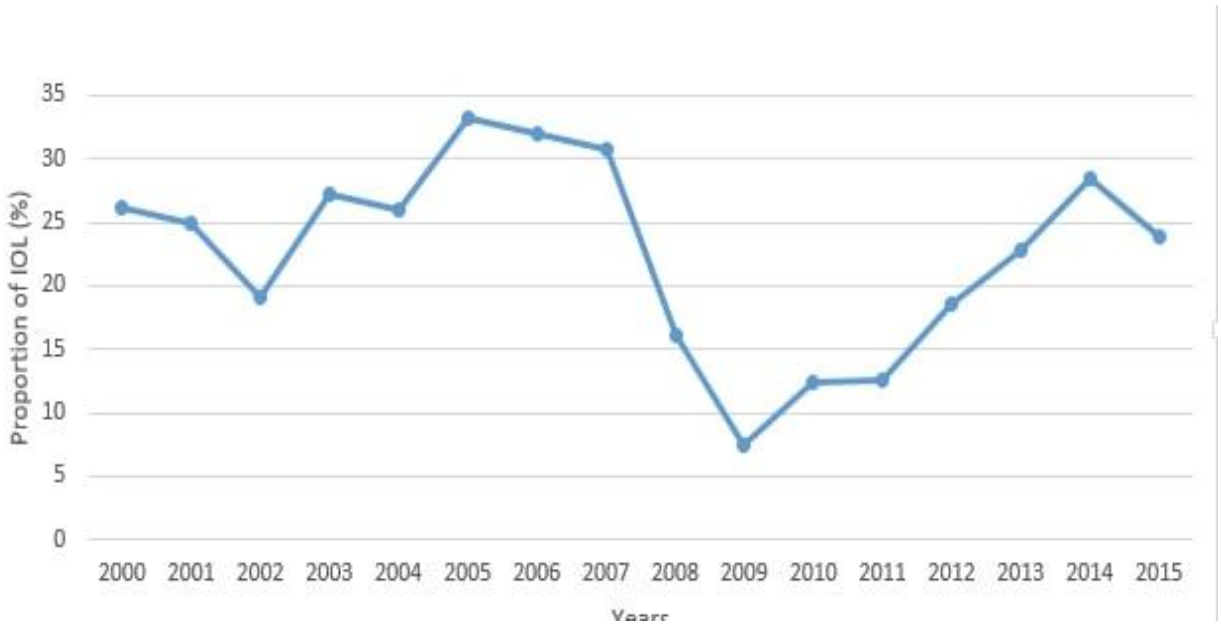
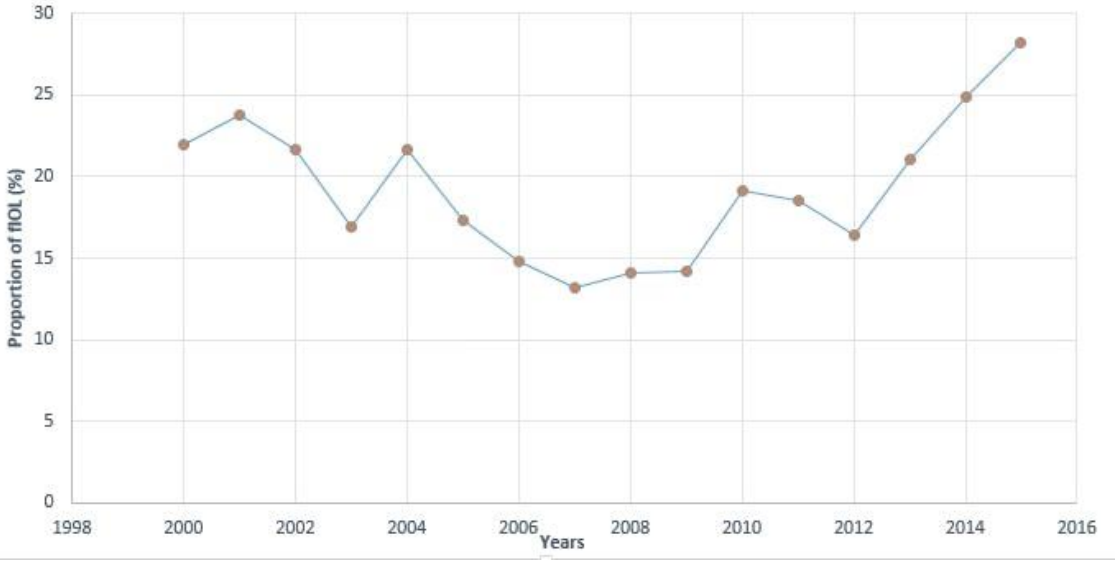


Figure 6: Trend of failed labor induction from 2000 – 2015 at KCMC



Risk factors for failure in IOL

The bivariate analysis for association between failure in IOL and risk factors have been displayed in (Table 2)**.** Factors such as parity, gestational age, residence, birth weight of

the newborn and maternal BMI were found statistically significant in bivariate analysis. These significant factors at the level of 5% are the ones that were used in the multivariable log-binomial regression modelling. We abandoned the variable for indications of IOL during the adjusted model building due to the fact that it had a huge number of missing observations (>80%) which could influence the final model and eventually leading to incorrect inferences. The results from multivariable regression fro association between failure in IOL and its predictors are displayed in (Table 3)**.** In the adjusted analyses Women who were primiparous were seen to have 72% increased risk of failing in IOL compared to multiparous women. We also saw that women whose gestational age was extremely preterm and very preterm at the time of induction were 20% and 13% reduced risk of experiencing failure in this intervention respectively compared to those whose pregnancy were at term during IOL. However, this association did not reach statistical significance. We found strong association between maternal BMI and fIOL. Obese women (BMI ≥ 30Kg/m^2) had 60% increased risk of experiencing failure in IOL compared to those whose BMI were normal (BMI ≥ 18 and <25 Kg/m^2). The study also found a statistically significant association between the birth weights and the risk of fIOL. We found that the more the weight of the fetus the higher the likelihood of a mother to failed in IOL. Specifically, fetal macrosomia (birth weight of ≥4kg) was associated with 89% increased risk of fIOL compared to normal birth weight (2.5-3.9) Kg. The adjusted analysis for association between mother's residence and fIOL shows that being in rural locality subjects a mother into 20% increased risks of failure in IOL intervention.

Table 2 : Bivariate analyses for risk factors associated with Failure in Labor Induction at KCMC Hospital from 2000 to 2015 (N=11,483).

Characteristics	Induction Status	x^2

	Success (n=9278)	Failed (n=2205)	P-value
Parity			
Primiparous	5069 (77.33)	1486 (22.67)	
Multiparous	4209 (85.41)	719 (14.59)	<0.001
Gestational Age			
Term	6691(80.59)	1612 (19.41)	
Extreme Preterm	31 (88.57)	4 (11.43)	
Very Preterm	148 (91.36)	14 (08.64)	
Moderate Preterm	804 (83.14)	163 (16.86)	
Post term	930 (77.24)	274 (22.76)	
Missing	674 (83.00)	138 (17.00)	<0.001
Maternal age (years)	873 (80.46)	212 (19.54)	
<20	5416 (80.20)	1337 (19.80)	
20-30	1863 (81.71)	417 (18.29)	
30-35	1116 (82.48)	237 (17.52)	
>35	10 (83.33)	2 (16.67)	0.251
Missing			
Residence			
Rural	3565 (79.56)	916 (20.44)	
Urban	5224 (81.51)	1185 (18.49)	
Semi-Urban	473 (82.84)	98 (17.16)	
Missing	16 (72.73)	6 (27.27)	0.029
Birth Weight			
<1800	277 (92.33)	23 (07.67)	
1800-2500	719 (81.43)	164 (18.57)	
2500-3500	6138 (82.86)	1270(17.14)	

3500-4000	1807 (75.35)	591(24.65)	
>4000	337 (68.22)	157 (31.78)	<0.001
Body Mass Index			
Underweight	1351 (81.68)	303 (18.32)	
Normal	1393 (87.39)	201 (12.61)	
Overweight	1771 (81.58)	400 (18.42)	
Obese	1229 (79.70)	313 (20.30)	
Missing	3534 (78.15)	988 (21.85)	<0.001
Indications of IOL			
Post-dates	111 (90.24)	12 (9.76)	
PROM	197 (53.83)	169 (46.17)	
Eclampsia	12 (92.31)	1 (7.69)	
Preeclampsia	459 (83.30)	92 (16.7)	
GDM	3 (60.0)	2 (40.0)	
Abruptio Placenta	15 (50.0)	15 (50.0)	
Missing	8481(81.59)	1914 (18.41)	<0.001

Table 3 : Crude and Adjusted analyses on predictors of fIOL among women underwent labor induction from 2000 to 2016 at KCMC Hospital (Log-binomial regression).

	CRUDE ANALYSES		ADJUSTED ANALYSES	
Variable	**Crude RR (95% CI)**	**P-value**	**RR $_{adj}$ (95% CI)**	**P-value**

Parity				
Multiparous	1		1	
Primiparous	1.55 (1.43-1.69)	<0.001	1.79 (1.60-2.01)	<0.001
Gestational Age				
Term	1		1	
Extreme	0.59 (0.23-1.48)	0.261	0.79 (0.23-2.88)	0.727
Preterm	0.45 (0.27-0.74)	0.002	0.87 (0.39-1.91)	0.681
Very Preterm	0.87 (0.75-1.01)	0.059	1.10 (0.91-1.34)	0.323
Moderate	1.17 (1.05-1.31)	0.006	1.03 (0.87-1.21)	0.752
Preterm				
Post-term				
Body Mass Index				
Normal	1		1	
Underweight	1.45 (1.23-1.71)	<0.001	1.42 (1.19-1.68)	<0.001
Overweight	1.46 (1.25-1.71)	<0.001	1.43 (1.22-1.68)	<0.001
Obese	1.61 (1.37-1.89)	<0.001	1.60(1.35-1.90)	<0.001
Birth				
Weight(grams)	0.98 (0.85-1.13)	0.769	1.02 (0.83-	0.865
1800-2500	1		1.25)	
2500-4000	0.40 (0.27 –	<0.001		0.004
<1800	0.60)	<0.001	0.32 (1.15-0.70)	<0.001
>4000	1.67 (1.46 –		1.89 (1.58-2.27)	
	1.92)			
Residence				
Urban	**1**		1	
Rural	1.11 (1.04-1.20)	0.006	1.20 (1.08-1.34)	0.001

Maternal age				
<20	1			
20-30	1.01(0.89-1.15)	0.842	-	-
30-35	0.94(0.81-1.09)	0.384		
>35	0.90(0.76-1.06)	0.200		

Discussion

The study has found the prevalence of failure in IOL to be 19.2%. The likelihood of failure in IOL intervention was significantly associated with primiparous condition, obesity, fetal macrosomia, and being living in a rural area. Despite the limited number of studies failure of IOL we managed to find few studies and they were somewhat consistent with our results, for example the study conducted in Hawassa Public Health facility and Jimma Hospital in Ethiopia found prevalence of fIOL to be 17.3% and 21.4% respectively and the one done in Pakistan with the prevalence of 21.4% [20–22].

We found parity, maternal BMI, birth weight, and residence as independent predictors of fIOL. The finding of this study shows that primiparous women have an increased proportion and at more risk in failure of the intervention compared to their counterpart. These findings are in line with other studies such as one done at Birmingham Hospital in the University of Alabama which found bigger proportion (25%) of primiparous women with fIOL compared to 9% proportion of multiparous women that fIOL., the one done at University of Mississippi Medical Centre which found prime women to have about 4 times the risk of fIOL compared to multiparous, and also a study in Nepal found increased proportion (41%) of failed IOL in primiparous women compared to 24% in multiparous women [23,24]. It is possible that primiparous women are different from multiparous women in pre-induction cervical effacement as well as response to ripening methods In addition primiparous women have no labor experience hence the appropriate rate of cervical collagen fibre dissolution is rather hard to attain compared to women with multiple labor experience [25].

Obese condition was another predictor for fIOL. The findings were consistent with the one done in at Kathmandu medical College in Nepal where the higher risks (44.4%) of failure in IOL were observed among obese women [24]. This failure seen in obese women might be due to the fact that the obesity condition is characterized by accumulation of adipose tissues in the abdomen which mechanically obstruct the labor as a result interferes with feto-placental circulation leading to fetal distress and eventually failure in a vaginal delivery.

We also found that suspected fetal macrosomia increases the likelihood of failure in IOL. This incidences of this condition has been increasing in the last 50 years and it is now reported to reach up to 9% of the general hospital population [25,26]. We found that macrosomic condition increases the risk of failure in IOL intervention. These findings are comparable with study at Atrium Medical Centre in Netherlands where big babies condition was associated with twice (AOR 2.38; 95% CI 1.45-3.91) the risk of fIOL [27]. Similarly the study done in Al-Shaikh *et al* at King Khalid University Hospital also found an increased risk 55% increased risk of fIOL to macrsomia conditions while the one done in Jimma Specialized Hospital twice the risk of fIOL to mothers with big babies compared with those whose babies had normal weight [22,28]. The increased risk of fIOL on macrosomic infants may be explained by labor obstruction that is caused by conditions such as shoulder dystocia. This situation may eventually lead to failure in vaginal delivery and hence necessitate CS.

We also found that women who reside in rural areas of Northern Tanzania are 20% more likely to experience failure in IOL intervention compared to those in urban locality. We found no studies that tried to link mother's location and the failure of IOL. We thought this attribute might be an important predictor in our final predictive model due to the differences in health care between rural and urban communities in Tanzania. We suspected that those coming from urban are likely to pay visits for ANC and more medical

advices that eventually improved their pregnancy outcomes compared to those in the rural area.

Limitations of the study

The use of the birth registry which is well maintained and rich in information as well as study subjects for more than 15 years gave this study more credits. We were able to include more than 10,000 deliveries and hence attain >90% power to detect the effect of predictors on failure in labor induction. This facilitated generalizability of the findings to other similar settings. Despite these strengths, we highlighted selection bias as one of the potential and common problem in hospital-based studies. The prevalence of fIOL reported in this study might be underestimated since other women might be attending other health facilities for delivery. Bishop score as one of the important attribute in predicting IOL failure was not found in this database hence not included.

Similarly, indication for IOL could also provide a useful contribution to our final model but the variable had >80% missing observation hence were not used in the final model building.

Conclusions

The prevalence of fIOL was found to be 19.2%. This score is still high and indicates a significant burden especially in a resource-limited setting like Tanzania since the medical infrastructures are not adequate and preparations for emergent situations such as CS are somewhat not up to standard. As the study found predictors for fIOL to be nulliparity, pre-pregnancy obesity, fetal macrosomia and residence, it underscores a need to review the execution of IOL services taking into consideration the factors that highly predicts the failure before performing IOL and eventually be in a position to prepare for emergency.

List of Abbreviations

BMI, Body Mass Index

CS, Caesarean Section

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fIOL, failure of Induction of Labor
GDM, Gestational Diabetes Mellitus
ICU, Intensive Care Unit
IOL, Induction of Labor
IUFD, Intra-Uterine Fetal Death
IUGR, Intra-Uterine Growth Restriction
KCMC, Kilimanjaro Christian Medical University College
KCMUCo, Kilimanjaro Christian Medical University College
PROM, Pre-labor Rapture of Membrane
RR, Relative Risk
WHO, World Health Organization

Declaration

Competing Interests

Not Applicable

Funding

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Ethics approval and consent to participate

The study has ethical approval from the KCMUCo Ethical Committee with reference number 985. Confidentiality was observed as the study participants' names in the database are all coded using special ID numbers to ensure anonymity.

Availability of data and materials

The dataset analyzed in this study are not publicly available as KCMC-hospital is holding a complete authority and ownership of the data. However, these data are available from the corresponding author on a reasonable request.

Authors' Contribution

CST Proposed, designed, analyzed and drafted the manuscript.

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