Outcomes of Trial of Labor versus Elective Repeat Cesarean Delivery in Women with a Previous Cesarean Delivery

Safinaz Abdelrahman, MD* Arjumand Qamaruddin, MD* Sara Khadeer, MD* Zainab Al-Jufairi, MHPE, FRCOG**

ABSTRACT

Objective: To compare the maternal and fetal outcomes of trial of labor (TOLAC) versus elective repeat caesarean delivery (ERCS) in women with a previous caesarean delivery in our institution.

Methods: All women with a singleton gestation and a prior cesarean delivery in maternity department at Salmaniya medical complex, Manama, Kingdom of Bahrain during the period between June 2017 to July 2018 have been included. Baseline characteristics as well as maternal and perinatal outcomes between women who underwent TOLAC versus ERCS were compared in retrospective descriptive and comparative study

Results: This study included 586 women, two thirds (n=347, 59.2%) underwent trial for normal delivery during which more than half succeeded (n=199, 57.3%) and the rest went for emergency cesarean section (n=148, 42.7%). The second group preferred elective cesarean section (n=239, 40.8%). Women in both groups TOLAC and ERCS are very comparable in term of age which was nearly identical on average (31 years vs. 31.2 years). Those in TOLAC arm had significantly higher number of previous normal vaginal delivery compared to ERCS arm (167, 48.1%) vs. (49, 20.5%), p<0.0001). The proportion of diabetes mellitus patients was 2.3 times higher in the elective cesarean section group than those who underwent trial of labor (4.6% vs. 2%). Also, the proportion of subjects with hypertension was 3.3 times higher in the ERCS group than the TOLAC group with a statistically significant difference (3.8% vs. 1.2%, p=0.046). The two groups were compared against various maternal and fetal outcomes and turned to be quite similar except for the total blood loss and ultimately the need for blood transfusion which was associated more with ERCS.

Conclusion: In our population, after first cesarean delivery; diabetes mellitus and systemic hypertension appears as a potent driven factors for ELCS while the major driven factor for TOLAC is previous normal delivery with overall moderate success rate. No major differences in maternal and fetal outcomes but risk of bleeding is more in ELCS.

Key words: TOLAC, VBAC, ERCS, Previous cesarean section

INTRODUCTION

The incidence of cesarean section (CS) is increasing dramatically in the Kingdom of Bahrain. The mean incidence was reported to be 9.1% for the period 1982-1993 but according to a recent study the incidence rose from 16% in 2004 to 31.5% in $2015^{1.2}$. In April 2015 the World Health Organization (WHO) stated that there is no justification for any region to have a rate higher than 15% as there is no evidence that mortality rates improve when the rate exceed this range. Bahrain is no exception because CS rate is increasing globally³. Canada's C-section rate has increased dramatically in the past two decades from 17% of all births in 1995 to nearly 27% in 2010^4 . In US the rate is $32, 9\%^5$. Western Europe countries like Switzerland, France and UK reported relatively better rates ranging between $21-26\%^6$.

The primary obstetric indication for Cesarean in many countries is repeat Cesarean birth. This contributes 28% to the overall Cesarean rate in Australia, 40% in the USA and 29% in the UK. Interestingly, in Bahrain the most common indication for CS for many decades was cephalo-pelvic disproportion and malpresentation (37.4%) followed by

Senior Resident
 Obstetrics and Gynecology Department
 Salmaniya Medical Complex (SMC)

 ** Consultant Obstetrics and Gynecology Salmaniya Medical Complex (SMC), Bahrain.
 E-mail: zaljufairi@gmail.com fetal distress (27.4%) and then previous cesarean (14.3%) while in a recent study of cesarean sections in Bahrain previous CS came first on the list to be the most potent indication for CS with a rate of (31.5%) followed by failure to progress (18.6%) and fetal distress (17.9%)^{2,7,8}.

For most of the 20th century, 'Once a Cesarean, always a Cesarean' was the rule worldwide⁹. The percentage of women who attempt vaginal delivery after prior cesarean delivery has fall off because of concern about safety. The risks associated with a trial of labor in women with a prior history of cesarean section delivery, as compared with elective repeated cesarean delivery without labor, are uncertain¹⁰.

Most of women who have had a history of previous cesarean delivery have the option to choose between a trial of labor after cesarean (TOLAC) delivery or elective repeat cesarean delivery (ERCD) in a subsequent pregnancy¹¹. Planned TOLAC may result in a successful labor with vaginal birth (VBAC) or an emergency cesarean section and there for decision making regarding mode of delivery must take into consideration the patient's personal preferences, obstetric history, scientific data on risks and benefits of TOLAC versus PRCD, and availability of TOLAC in the selected birth setting¹².

During antenatal counseling of pregnant women with a previous cesarean section who do not have a medical indication for a repeat cesarean, the decision-making is between TOLAC and ERCD. Much rumination is important for taking this decision, particularly the chance of succeeding with VBAC without complications balanced against the risk of an adverse neonatal outcome, uterine rupture and maternal complications¹³.

There is an overall increase in the rate of cesarean section on maternal request and its contribution to the rise in the cesarean delivery incidence still uncertain. The American committee of obstetrics and gynecology recommended vaginal delivery in the absence of maternal and fetal indication for cesarean section¹⁴.

The consensus of the National Institute for Health and Care Excellence (NICE), Royal College of Obstetricians and Gynecologists (RCOG) and American College of Obstetricians and Gynecologists (ACOG) that planned VBAC is a clinically safe choice for the majority of women with a single previous lower segment cesarean delivery¹⁴.

An obstetrician should be involved in the counseling regarding mode of delivery and the decision should be finalized by 36 weeks of pregnancy in most cases. Having information regarding the probability of successful VBAC will improve the decision-making process regarding the mode of delivery¹⁵.

Over the last decades, VBAC grew in popularity. However, the rational of this trend was to enable a trial of labor after a previous Cesarean delivery, but the benefit of this approach has been questioned in many studies Also, there is no evidence from randomized controlled trials to support a recommendation of ERCD for non-medical reasons at term¹⁶.

In view of considerable discrepancies with regard to the safest mode of delivery for a mother with a history of a prior Cesarean delivery and her fetus, we conducted this study to compare the outcomes of trial of labor versus elective repeat caesarean delivery in women with a previous caesarean delivery in our institution.

OBJECTIVES

To compare the maternal and fetal outcomes of trial of labor (TOLAC) versus elective repeat caesarean delivery (ERCS) in women with a previous cesarean delivery in our institution.

METHODS

Study Population: All women with a singleton gestation and a prior cesarean delivery in maternity department at Salmaniya medical complex, Manama, Kingdom of Bahrain during the period between June 2017 to July 2018 have been included. Baseline characteristics as well as maternal and perinatal outcomes between women who underwent a trial of labor versus women who had an elective repeated cesarean delivery were compared in retrospective descriptive and comparative study. Ethical approval from secondary health research committee was obtained prior conducting this study.

Data Collection: The medical files of all women who had a prior cesarean delivery and a singleton pregnancy at 20 weeks or more of gestation with a birth weight of at least 500g in Salmaniya medical complex (SMC) during the study period have been reviewed.

The study population has been identified by searching the electronic system of discharge summaries in medical records of the hospital. The extracted data from the files including the demographic and basic characteristics, the non-obstetric medical history as well as the maternal and perinatal outcomes were analyzed. The registry of mortality and morbidity in the department been reviewed also.

Exclusion criteria include any medical condition precluding a trial of labor such as a prior classical (up-and-down) or "inverted T" incision, breech or transverse presentation, placenta previa, prior myomectomy, non-reassuring patterns in the antepartum fetal heart rate and genital herpes.

Statistical Analysis: Descriptive statistics reported as frequency and percentage for categorical data. Chi square test or Fischer's exact test used to compare the two study groups. Continuous data reported as mean and standard deviation and compared by Student's t test. The statistical software package SPSS-20 for windows used to perform the statistical analysis and for producing graphs and plots. The statistical significance threshold was set at 5%

RESULTS

This study included 586 women, 347 (59.2%) underwent trial of labor and 239 had elective cesarean section (40.8%) figure 1. Those patients who had trial of labor more than half succeeded (n=199, 57.3%) and the rest went for emergency cesarean section (n=148, 42.7%) (Figure 2).







Figure 2: Percentages of EMCS and NVD of patient who had TOLAC

Table 1:	: Baseline	characteristics	of women	undergoing	trial o	of labor	or an	elective	cesarean	section
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Characteristics	TOLAC N=347	ERCS N=239	p-value	
Maternal age (Yrs) M±SD (95%CI)	31.0±5(30.5-31.5)	31.2±5.2(30.6-31.9)	0.561	
18 - 34 years - n (%) (95%CI)	260(59.5%) (54.7%-64.1%)	177(40.5%) (35.9%-45.3%)	0.912	
\geq 35 years – n (%) (95%CI)	87(58.4%) (50%-66.7%)	62(41.6%) (33.6%-50%)		
Nationality – n (%) (95%CI)				
Bahraini	215(59.7%) (54.5%-64.8%)	145(40.3%) (35.2%-45.5%)	0.752	
Non-Bahraini	132(58.4%) (51.7%-64.9%)	94(41.6%) (35.1%-48.3%)		
Gestational history-M±SD (95%CI)				
Gravida	3.45±1.3 (3.2-3.6)	2.91±1.7 (2.7-3.1)	<0.0001**	
Parity	1.97±0.8 (1.8-2.1)	1.3±1.4 (1.3-1.5)	<0.0001**	
Abortion	0.47±0.9 (0.3-6)	0.51±0.8 (0.4-0.6)	0.625	
Living	1.94±0.8 (1.8-2)	1.38±1.3 (1.3-1.5)	<0.0001**	
Type of pregnancy – n (%) (95%CI)				
Spontaneous	344(99.1%) (97.5%-99.8%)	232(97.1%) (94.1%-98.8%)	0.210	
Assisted reproductive technique	3(0.9%) (0.2%-2.5%)	7(2.9%) (1.2%-5.9%)		
Inter pregnancy interval (Yrs)-M±SD (95%CI)	3.2±1.5(3-3.3)	3.4±2(3.2-3.7)	0.095	
Gestational age (Weeks) - M±SD (95%CI)	38.3±2.2(38.1-38.6)	37.9±1.8(37.7-38.2)	0.020**	
Induction of labor- n (%) (95%CI)	48(13.8%) (10.4%-17.9%)	0(0%)	< 0.0001*	
Previous normal vaginal delivery– n (%) (95%CI)	167(48.1%) (42.8%-53.5%)	49(20.5%) (15.6%-26.2%)	<0.0001*	

a. M±SD: Mean±Standard Deviation, b. n (%): Number of subjects (Percentage of subjects)

*Statistically significant difference with Chi square test of independence at Alpha 0.05

**Statistically significant difference with T-test of independent samples at Alpha 0.05

The mean age of women who underwent TOLAC was 31.0 ± 5 years (95% CI: 30.5- 31.5). While the mean age of women who had ERCS was 31.2 ± 5.2 years (95% CI: 30.6- 31.9). The difference between the two groups was not statistically significant (p value 0.561) (Table 1).

The majority of our patients were Bahraini (n=360, 61.4%) and 226 (38.6%) were non-Bahraini. The nationality seems to be nonrelated to the patient's choice to undergo a trial of labor or elective cesarean section (p value 0.753) (Table 1).

There are significant differences between the two groups in term of their gestational histories. Those underwent trial for labor had significantly higher number of previous gestations $(3.45\pm1.3 \text{ vs. } 2.91\pm1.73, p<0.0001)$ **Figure 3**, higher number of previous births $(1.97\pm0.8 \text{ vs. } 1.3\pm1.4, p<0.0001)$, and higher number of living children $(1.94\pm0.8 \text{ vs. } 1.38\pm1.3, p<0.0001)$. However, they did not significantly differ in the type of pregnancy and the inter pregnancy intervals. (P value 0.095)



Figure 3: Comparisons of 95% CI of gestational history of women with TOLAC Vs ERCS

Women who had history of previous normal vaginal delivery are more likely to elect TOLAC. Forty eight percent (167) women with previous normal vaginal delivery undergone TOLAC as compared to 20.5% (49) who had ERCS. The difference between the two groups was statistically significant (p value < 0.0001) (Figure 4).



Figure 4: History of previous vaginal delivery of TOLAC Vs ERCS

Women tried normal labor had significantly higher gestational age when compared to those who had elective cesarean section $(38.3\pm2.2 \text{ vs. } 37.9\pm1.8, \text{ p}=0.020)$ (Figure 5).

Women who underwent elective cesarean section had significantly higher number of past medical illnesses as twice as their counter parts who agreed for trial of labor (OR 2.1(1.2-3.2)). The proportion of diabetes mellitus patients was 2.3 times higher in the elective cesarean section group than those who underwent trial of labor (4.6% vs. 2%), however, this difference did not achieve the statistical significance (p=0.083). The proportion of subjects with hypertension was 3.3 times higher in the elective cesarean group than the other group with a statistically significant difference (3.8% vs. 1.2%, p=0.046) (**Table 2**).



Figure 5: Comparison of gestational age between TOLAC and ERCS

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Comorbidities	TOLAC N=347	ERCS N=239	Odds Ratio OR (95% CI)	p-value
Past medical history	37(10.7%)	47(19.7%)	2.1(1.2-3.2)	0.002*
History of diabetes mellitus	7(2%)	11(4.6%)	2.3(0.89-6.1)	0.083
History of hypertension	4(1.2%)	9(3.8%)	3.3(1-11)	0.046*
Antenatal complications	92(26.5%)	66(27.6%)	1.1(0.7-1.5)	0.767

*Statistically significant difference with Chi square test of independence at Alp

The prevalence of antenatal complications among the two groups was nearly identical (27.6% vs. 26.5%, OR 1.1) with no significant difference (p=0.767).

The most common indication for emergency cesarean section among those who had trail of labor was fetal distress (53.4%) followed by failure to progress (24.3%). Other indications included scar tenderness and failed induction of labor (**Table 3**).

 Table 3: Indication of emergency cesarean section among the patients

 who had TOLAC

Indication	N=148	%
Failed induction of labor	3	1.2%
Failure to progress	36	24.3%
Fetal distress	79	53.4%
Good size baby	1	0.7%
Patient request	11	07.5%
Scar tenderness	18	12.2%

The two groups were compared against various maternal outcomes and turned to be quite similar except for the total blood loss and ultimately the need for blood transfusion. Subjects underwent trial for labor had significantly lower amount of blood loss during delivery (M=312ml, SD=255.8ml, Min=120ml, Max=2500ml) compared to their

elective cesarean counterparts (M=466ml, SD=211ml, Min=300ml, Max=1800ml). The difference between the two means is statistically significant as confirmed with the One-way ANOVA test (F=69.5, df=1, p<0.0001). This ultimately reflected on their need for blood transfusion as higher proportion of the elective cesarean group required blood transfusion than those who went for trial of labor (8.4% vs. 3.5%, OR 0.4 (0.2-0.8)) with a statistically significant difference (p=0.018). In other words, going for trial of labor had reduced the need for blood transfusion by 60% if to be compared with going for elective cesarean section (**Figure 6**).

However, no significant differences were observed in the rest of maternal outcomes such as: wound infection, puerperal fever, uterine rupture, and operative injury. However, there were three cases of complete uterine rupture in TOLAC as compared to none in the ERCS group, but the difference was not significant (p value 0.076). Fortunately, there was no patient required hysterectomy in both groups and no maternal death reported (**Table 4**).



Figure 6: Total blood loss among TOLAC Vs ERCS

The two groups did not differ significantly in any of the fetal outcomes and showed nearly identical results on average. In term of baby's wellbeing, both groups recorded identical medians at 1-minute Apgar score assessment (Md=9 and Md=9) and (Md=10, Md=10) at 5-minutes Apgar score. The proportion of newborns with Apgar score \geq 7 at the first 1 minute was slightly higher in the elective cesarean group when compared to their trial of labor counterparts (97.1% vs. 93.9%), however, this difference was not statistically significant. A very similar finding applies at 5 minutes Apgar score assessment.

The average birth weight for babies born for mothers underwent elective cesarean section was slightly higher than those of who were born with trial of labor but the difference was not significant (3.2 ± 0.6 vs. 3.0 ± 0.6 , p=0.052) as confirmed with Mann-Whitney test (U=37546, Z=-1.94, p=0.052). As for the rest of the outcomes: neonatal sepsis, NICU admission, stillbirth, neonatal death, and other complication, all go in the same vein with very negligible differences that did not reach the statistical significance (Table 5).

DISCUSSION

The vast majority of evidence support to encourage TOLAC with subsequent vaginal birth after cesarean (VBAC) is an important mechanism to reduce the overall cesarean rate¹⁷. Our study included 586 women all of them are sharing the history of previous one cesarean section, about 59.2 % elect a trial of normal vaginal delivery and 42.7% underwent for elective cesarean section. The success rate of VBAC is 43% up to 80%. In our study the success rate was 57.3% which is within the same range¹⁸⁻²⁰.

Maternal outcomes	TOLAC	ERCS	Odds Ratio	p-value	
	N=347	N=239	OR (95% CI)		
Total blood loss (ml) - M±SD	312±255.8	466.5±211	-	<0.0001*	
Blood transfusion – n (%)	12(3.5%)	20(8.4%)	0.4(0.2-0.8)	0.018**	
Wound infection – n (%)	17(4.9%)	17(7.1%)	0.7(0.3-1.3)	0.291	
Puerperal fever – n (%)	14(4%)	7(2.9%)	0.72(0.2-1.8)	0.496	
Operative injury –n (%)	1(0.3%)	3(1.3%)	0.2(0.02-2.2)	0.207	
Uterine rupture – n (%)	3(0.9%)	0(0%)	-	0.076	
Scar dehiscence – n (%)	12(3.5%)	10(4.2%)	0.8(0.3-1.9)	0.662	
Hysterectomy – n (%)	0(%)	0(0%)	-	-	
Maternal death – n (%)	0(%)	0(0%)	-	-	

Table 4: Maternal Outcomes in TOLAC Vs ERCS

*Statistically significant difference with One-way ANOVA test at Alpha 0.05

**Statistically significant difference with Chi Square test at Alpha 0.0Baby's outcomes comparisons

Table 5: Fetal Outcomes in TOLAC VS ERCS

Fetal outcomes	Trial of Labor	Elective Cesarean	Odds Ratio	p-value
	N=347	N=239	OR (95% CI)	
Apgar score at 1 minutes- MD±IQR ^a	9.0±0	9.0±0	-	0.789*
Apgar score \geq 7 at 1 minutes– n (%)	326(93.9%)	232(97.1%)	0.9(0.7-1.2)	0.785**
Apgar score at 5 minutes- MD±IQR	10±0	10±0	-	0.309*
Apgar score \geq 7 at 5 minutes– n (%)	336(96.8%)	239(100%)	0.9(0.7-1.2)	0.270**
Birth weight – M±SD	3.0±0.6	3.2±0.6	-	0.052^{t}
Neonatal sepsis- n (%)	0(0%)	1(0.4%)	-	0.408**
Admission to NICU-n (%)	29(8.4%)	19(7.9%)	1.1(0.5-1.9)	0.998**
Still birth – n (%)	5(1.5%)	0(0%)	-	0.083**
Neonatal death-n (%)	4(1.2%)	2(0.8%)	1.3(0.2-7.5)	0.712**
Other complications – n (%)	27(7.8%)	11(4.6%)	1.7(0.8-3.4)	0.153**

a: MD±IQR (Median ± Inter-Quartile Range)

*Statistically insignificant difference with Mood's median test at Alpha 0.05 **Statistically insignificant difference with Chi Square test at Alpha 0.05 IStatistically insignificant difference with Mann-Whitney test at Alpha 0.05

In a study conducted by Regan J et al, they give a trial of labor only for 16.6 % of patient with a previous cesarean section, and they reported a success rate of 68%, so this can justify the higher rate of VBAC in comparison to ours as they give a TOLAC for a small percent of the patient²¹.

This study showed that there was a great difference between the two groups in the number of gravidity, parity and living issues as it shows that patient who underwent for trial of labor have a higher number of these three aspects. In TOLAC group has a higher number of vaginal births which is the most independent factor for successful vaginal delivery, that's mean our practice following the global guideline by giving them a chance to go for trial of labor, also we noticed it is one of the driven factors for the patient to go for TOLAC with p value <0.0001. This has been observed in other studies which consistently report a history of vaginal delivery have a higher likelihood of VBAC, it's the same finding for a study conducted by Tessmer-Tuck JA^{20,21}.

In contrast to the patient who elect ERCS we figure out that the proportion of subjects with hypertension was 3.3 times higher in the ERCS than TOLAC with a statistically significant difference (p value 0.046). Same findings had been detected by Srinivas et al²². Also we found that the proportion of diabetes mellitus is 2.3 times higher among this group, that's mean diabetes is a significant driven factor for those women to go for repeated cesarean section and this may be related to increase the incidence of diabetes in Bahrain and in Gulf Area²³, according to this result we should try to control diabetes during

antenatal period to participate in reduction of cesarean section rate, as it will decrease indication of macrosomic babies, but the potential risk for shoulder dystocia, should be discussed with the candidates for TOLAC.

Many studies do not consider gestational and pregestational diabetes a contraindication to TOLAC. But in view of that the overall rate of VBAC appears to be lower in women with diabetes compared with nondiabetic women undergoing TOLAC this had been approved by Regan J et al²⁴.

The main consideration regarding maternal wellbeing in view of trial of labor after a previous cesarean section is to avoid a major complication such as uterine rupture which will lead to fetal and maternal morbidity or death. Fortunately, in our study there were no maternal deaths, a similar finding reported by Flamm et al. On the other hand, Guise et al. observed that maternal mortality was significantly increased for elective repeat cesarean delivery at 0.013% compared with 0.004% for trial of labor^{19,25}.

In this study there were three complete uterine rupture in TOLAC as compared to none in ERCS. Though the difference was not significant between both groups but this can be explained by small number of uterine ruptures. Previous studies reported the incidences of uterine rupture in women with prior CS ranged from 0.22% to $1.69\%^{26,27}$. Guise et al, reported Landon et al²⁸.

One of the risk factors for rupture of uterus is an induction of labor in this study 48(13.8%) patient who underwent for TOLAC required induction for labor. Two of this group had uterine rupture as compared to one uterine rupture in spontaneous labor and the relative risk of uterine rupture after induction of labor in TOLAC group was high (12.45). This finding supported by other two studies done by Sandhu et al, and Al-Jufairi et al, who found that the rise of uterine rupture was associated with the increasing rate of cesarean and induction of labor and accordingly they recommended to use induction of labor judiciously to prevent catastrophic uterine rupture^{29,30}. Palatnik et al concluded that induction of labor at 39 weeks, was associated with a greater chance of VBAC but also of uterine rupture when compared to expectant management³¹.

On the other hand, we found that there was no significant statistical difference between the two groups in term of scar dehiscence and inter pregnancy interval, this supported by the same finding of Trojano et al, as they concluded the inter-pregnancy interval of <24 months is not associated with a decreased success of VBAC, therefore short inter pregnancy interval shouldn't negatively influence the patient decision to go for TOLAC³².

We found that women who underwent trial for labor had significantly lower amount of blood loss during delivery compared to their elective cesarean counterparts (p<0.0001). This ultimately reflected on their need for blood transfusion as higher proportion of the elective cesarean group required blood transfusion than those who went for trial of labor (OR 0.4, p value 0.018). In other words, going for trial of labor had reduced the need for blood transfusion by 60%. Wesley et al has the same findings³³.

Our results showed that there was no significant difference between TOLAC versus ERCS in term of Apgar score, neonatal outcome and admission to NICU (Table 5).

In line with our findings are studies conducted by Charitou A. and Li et al as they noticed there was no significant difference in neonatal outcomes between the two groups^{34,35}.

Other studies had variable findings of neonatal outcomes. A study conducted by Fagerberg et al showed that perinatal and neonatal mortality rates were higher with TOLAC than ERCS¹⁶. In contrast to this finding, Kamath et al found that a successful TOLAC had a lower rate of neonatal complications in term of NICU admission and resuscitation in comparison to those born by ERCS³³.

In view of the different neonatal outcomes between the patient who had a trial of labor and those who underwent for elective cesarean section in many studies, worrisome of the patient with previous one cesarean section regarding neonatal outcome should not drag them to go for ERCS specially in our institution, as there is no difference between the two groups in neonatal outcomes³¹.

Most of the patients are not keen for TOLAC to avoid neonatal morbidity and adverse fetal outcomes³⁴, however we should counsel them that the success rate of TOLAC is high for women undergoing systematic prenatal assessment and close management during labor with less blood loss and non-serious maternal and neonatal complications compared with ERCS³⁵

CONCLUSION

In our population, after first cesarean delivery; diabetes mellitus and systemic hypertension appear as potent driven factors for ERCS while the major driven factor for TOLAC is previous normal delivery with overall moderate success rate. No major differences in fetal outcomes but blood loss and blood transfusion are more in ERCS.

LIMITATIONS

The number of patients maybe underpowered but we think it is reasonable as we covered all the cases fulfilling the criteria over one year. Also, being a single centre experience; but worth mentioning that it is the major hospital in Bahrain that cover approximately two thirds of deliveries in our country.

Authorship Contribution: All authors share equal effort contribution towards (1) substantial contributions to conception and design, analysis and interpretation of data; (2) drafting the article and revising it critically for important intellectual content; and (3) final approval of the manuscript version to be published. Yes.

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Competing Interest: None.

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