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MATERNAL-FETAL MEDICINE

Trial of labor following cesarean in patients with bicornuate uterus: a multicenter retrospective study

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Abstract

Objective This study aimed to evaluate whether a trial of labor after cesarean delivery (TOLAC) in women with a bicornuate uterus is associated with increased maternal and neonatal morbidity compared to women with a non-malformed uterus.

Methods A multicenter retrospective cohort study was conducted at two university-affiliated centers between 2005 and 2021. Parturients with a bicornuate uterus who attempted TOLAC following a single low-segment transverse cesarean delivery (CD) were included and compared to those with a non-malformed uterus. Failed TOLAC rates and the rate of adverse maternal and neonatal outcomes were compared using both univariate and multivariate analyses.

Results Among 20,844 eligible births following CD, 125 (0.6%) were identified as having a bicornuate uterus. The overall successful vaginal delivery rate following CD in the bicornuate uterus group was 77.4%. Failed TOLAC rates were significantly higher in the bicornuate group (22.4% vs. 10.5%, $p<0.01$). Uterine rupture rates did not differ between the groups, but rates of placental abruption and retained placenta were significantly higher among parturients with a bicornuate uterus (9.8% vs. 4.4%, $p<0.01$, and 9.8% vs. 4.4%, $p<0.01$, respectively). Neonatal outcomes following TOLAC were less favorable in the bicornuate group, particularly in terms of neonatal intensive care unit admission and neonatal sepsis. Multivariate analysis revealed an independent association between the bicornuate uterus and failed TOLAC.

Conclusions This study found that parturients with a bicornuate uterus who attempted TOLAC have a relatively high overall rate of vaginal birth after cesarean (VBAC). However, their chances of achieving VBAC are significantly lower compared to those with a non-malformed uterus. Obstetricians should be aware of these findings when providing consultation to patients.

Keywords Trial of labor after cesarean (TOLAC) · Vaginal birth after cesarean (VBAC) · Bicornuate uterus · Müllerian anomalies · Uterine anomalies

What does this study add to the clinical work?

In parturients with a bicornuate uterus who attempt TOLAC, the likelihood of achieving VBAC is notably reduced when compared to individuals with a non-malformed uterus..

Introduction

In recent decades, a cesarean delivery (CD) has become the most common surgical procedure in modern obstetrics worldwide [1], with repeated CDs accounting for a substantial portion of these surgeries and carrying a distinct set of complications [2, 3]. The American College of Obstetricians and Gynecologists recognizes the trial of labor after

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cesarean (TOLAC) as a viable alternative to repeat CD for patients with a previous CD [4]. Given that most complications during TOLAC stem from failed attempts and subsequent intrapartum repeat CD [5–7], identifying the optimal candidates for successful TOLAC has been the focus of numerous studies [8–10].

Bicornuate uterus, the most common form of Müllerian duct anomalies, is estimated to affect approximately 0.4–1.2% of the general population [11–13] and exhibits a higher incidence among women with a history of infertility or recurrent miscarriages [14]. In parturients with Müllerian duct anomalies the rate of CD is significantly higher in this particular group of patients [15]. The combination of a scarred uterus and a uterine anomaly raises concerns about the outcome of TOLAC in this population.

Limited data are available regarding the evaluation of TOLAC in parturients with a malformed uterus, particularly in cases of a bicornuate uterus. Therefore, the objective of this study is to evaluate the success rate and safety of TOLAC among parturients with a bicornuate uterus.

Methods

Study design

A multicenter retrospective cohort study was conducted from 2005 to 2021, utilizing computerized medical records from two university-affiliated medical centers in Jerusalem, Israel. These medical centers collectively account for approximately 16% of all deliveries in Israel, with an average annual volume of 20,000 births.

Study population

The study enrolled parturients with singleton pregnancies who attempted a trial of labor following a single low-segment incision (LSTCS) between 24 and 42 weeks of gestation. Only those who had a primary CD and subsequent TOLAC at our medical centers were considered eligible. Exclusion criteria included, multifetal gestation, fetuses with major malformations, antepartum fetal death, planned CDs, non-vertex presentations, placenta accreta spectrum cases, and malformation of the uterus other than the bicornuate uterus.

Data collection and documentation

Both medical centers maintained electronic medical record databases, which were regularly updated by attending medical staff and periodically audited by trained technical personnel to ensure data validity and eliminate information bias. For this study, relevant maternal and neonatal records were extracted from the database, and personal information was anonymized before analysis.

Medical center protocols

Both medical centers followed similar departmental protocols in line with the TOLAC guidelines set forth by the Israeli Committee of Obstetrics and Gynecology. TOLAC was proposed to parturients with a history of a single LSTCS. Eligible participants were given a comprehensive briefing on the risks and benefits associated with both TOLAC and a repeat CD. Parturients choosing to attempt TOLAC were required to sign an informed consent, and continuous electronic fetal monitoring was mandatory throughout their labor.

For parturients with a history of one previous LSTCS who required labor induction, the induction was carried out using one of the following methods: a double-lumen balloon, amniotomy, or low-dose oxytocin. Prostaglandins post-CD were not employed at these medical centers.

The study group consisted of parturients attempting TOLAC with a bicornuate uterus, and they were compared to a control group of parturients attempting TOLAC with a non-malformed uterus.

Study outcomes

The primary outcome measure was the failed TOLAC rates, while secondary outcomes were adverse maternal and neonatal outcomes including uterine rupture or dehiscence, postpartum hemorrhage (PPH), blood product transfusion, maternal ICU admission, prolonged hospitalization, laparotomy, and hysterectomy among others.

Definitions

Uterine rupture was defined as a complete uterine scar rupture, characterized by a full-thickness defect with a direct connection between the peritoneal space and the uterine cavity, diagnosed during an exploratory laparotomy. Dehiscence of the uterine scar was defined as an incomplete uterine scar disruption where the serosa remains intact and the fetus, placenta, and umbilical cord remain contained within the uterine cavity. PPH was defined based on either estimated blood loss or transfusion of blood products and/or a drop in hemoglobin levels. Prolonged hospitalization was defined as a hospital stay exceeding 5 days for vaginal deliveries and 7 days for CD.

Ethical approval

The study was approved by the institutional ethics committee (IRB: 0036-23-SZMC). Given the retrospective nature of the study and the use of de-identified information, patient consent was waived.

Statistical methods

Statistical analysis involved describing nominal variables using proportions and comparing them using appropriate statistical tests such as the Chi-square test or Fisher's exact test. Continuous variables with a non-normal distribution were presented as means ± standard deviation (SD) or medians with interquartile ranges (IQR) and analyzed using the unpaired Student's *t*-test or Mann–Whitney test, depending on the distribution. Statistical significance was set at a *p*-value of less than 0.05.

The association between failed TOLAC and bicornuate uterus was assessed using a multivariate logistic regression model, reporting adjusted odds ratios (aOR) with 95% confidence intervals (CIs) to measure the strength of the association. All statistical tests were two-sided, and the analyses were performed using SPSS software (version 25, IBM, Armonk, NY).

Results

During the study period, a total of 20,844 eligible trials of labor after cesarean (TOLAC) deliveries were included in the analysis. Out of these, 125 cases (0.6%) were identified as having a bicornuate uterus and were assigned to the study group, while the remaining 20,719 cases (99.4%) had non-malformed uteruses and were assigned to the control group. Figure 1 presents a flow chart illustrating the composition of the study population.

Table 1 provides an overview of the general demographics and obstetric characteristics of the study population. It was observed that individuals attempting TOLAC with a bicornuate uterus were significantly younger with lower gravidity and parity order compared to the control group.

Table 2 presents the current delivery and obstetric characteristics of the study population.

Failed TOLAC rates were significantly higher in the bicornuate group (22.4% vs. 10.5%, $p < 0.01$), while the rates of uterine scar dehiscence and uterine rupture did not differ between the groups. In the non-malformed uterus group, there were 11 cases (0.1%) of hysterectomy, nine of which were due to uterine rupture and two due to failed TOLAC and massive surgical hemorrhage. The bicornuate group exhibited significantly higher rates of placental abruption as well as rates of retained placenta and prolonged hospitalization.

Table 3 presents the neonatal characteristics of both groups. Neonates born to parturients with a bicornuate uterus were born significantly earlier and had lower birth weights. The rates of neonatal intensive care unit (NICU) admission and sepsis were significantly higher in the bicornuate group. However, the remaining neonatal characteristics did not differ between the groups.

Table 4 displays the results of a multivariate logistic regression assessing the association between failed TOLAC and bicornuate uterus. The bicornuate uterus was found to be independently associated with failed TOLAC (adjusted odds ratio [aOR] 2.56, 95% confidence interval

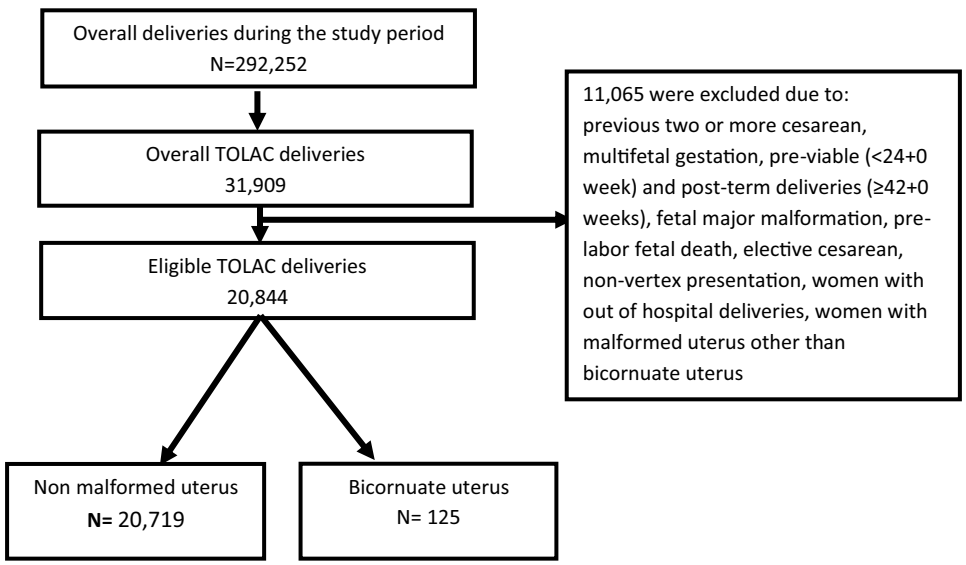

Fig. 1 Flow chart of the study group

TOLAC – Trial of labor after cesarean section

Table 1 Demographic and obstetric characteristics of the study population

	Non-malformed uterus $n=20,719$	Bicornuate uterus $n=125$	*P* value
Maternal age, years	31.5 ± 5.4	29.5 ± 5.1	< 0.01
Miscarriages, any	7608 (36.7%)	48 (38.4%)	0.70
Miscarriages > 3	1155 (5.6%)	6 (4.8%)	0.71
Gravidity	5 [3–7]	4 [3–5]	< 0.01
Parity	4 [3–6]	3 [2–4.5]	< 0.01
Interpregnancy interval, months	22.0 ± 19.6	21.2 ± 12.2	0.66
Fertility treatments	584 (2.8%)	4 (3.2%)	0.80
Hypertensive disorders of pregnancy	489 (2.4%)	3 (2.4%)	0.98
Diabetes (pregestational and gestational)	1167 (5.6%)	4 (3.2%)	0.24
Smoking	342 (1.8%)	1 (0.8%)	0.43
Obesity (BMI > 30)	1167 (5.6%)	4 (3.2%)	0.24
Anemia, Hb < 11gr/dL on admission	2201 (10.6%)	14 (11.2%)	0.83
Induction of labor	1543 (7.4%)	5 (4%)	0.14
Oxytocin augmentation of labor	12,856 (62%)	74 (59.2%)	0.51
Epidural analgesia	11,540 (55.7%)	69 (55.2%)	0.91
Meconium-stained amniotic fluid	3975 (19.2%)	13 (10.4%)	0.01
Second stage duration, minutes	30.2 ± 46.9	35.8 ± 52.7	0.25

Data are mean ± standard deviation; number (%); median [interquartile range]

Table 2 Current delivery and obstetric maternal outcomes of the study population

	Non-malformed uterus $n=20,719$	Bicornuate uterus $n=125$	*p*-value
Failed TOLAC	2175 (10.5%)	28 (22.4%)	< 0.01
Chorioamnionitis	296 (1.4%)	0 (0%)	0.18
Placental abruption	580 (2.8%)	8 (6.4%)	0.02
Vacuum assisted delivery	1601 (7.7%)	8 (6.4%)	0.58
Uterine rupture	70 (0.3%)	0 (0%)	0.52
Dehiscence of uterine scar	47 (0.2%)	1 (0.8%)	0.18
Retained placenta/placental fragments	830 (4.4%)	10 (9.8%)	< 0.01
Puerperal fever	383 (1.8%)	4 (3.2%)	0.26
Hemoglobin drop ≥ 3 g/dl	1734 (8.5%)	14 (11.2%)	0.28
Postpartum hemorrhage	2015 (9.7%)	16 (12.8%)	0.25
Blood products transfusion	305 (1.5%)	2 (1.6%)	0.91
Hysterectomy	11 (0.1%)	0 (0%)	0.80
Maternal ICU admissions	10 (0%)	0 (0%)	0.81
Hospitalization length, days	2.5 ± 1.3	3 ± 1.8	< 0.01
Prolonged hospital stays	265 (1.3%)	5 (4%)	< 0.01

Data are mean ± standard deviation; number (%); ICU Intensive-care unit, TOLAC Trial of labor after cesarean

[CI] 1.65–3.95). Preterm delivery (< 37 weeks), induction of labor, hypertensive disorders of pregnancy, and diabetes were found to be adversely associated with failed TOLAC, while parity and epidural analgesia were found to be favorably associated with failed TOLAC.

Discussion

In this retrospective cohort study assessing TOLAC outcomes in parturients with or without a bicornuate uterus revealed that failed TOLAC was significantly higher in the bicornuate uterus, while the rates of uterine rupture and dehiscence of uterine scar were comparable between the two groups. However, rates of placental abruption,

Table 3 Neonatal outcomes among the study population

	Non-malformed uterus $n=20{,}719$	Bicornuate uterus $n=125$	p-value
Gestational age at delivery	39.4 ± 1.8	38.7 ± 2.6	< 0.01
Neonatal birthweight	3335.6 ± 510.9	3139.2 ± 620.5	< 0.01
5-Minute Apgar score ≤ 7	332 (1.6%)	2 (1.6%)	1.00
NICU admission	945 (4.6%)	14 (11.3%)	< 0.01
Meconium aspiration syndrome	33 (0.2%)	0 (0%)	0.66
Jaundice	1276 (6.2%)	8 (6.4%)	0.91
TTN	285 (1.4%)	4 (3.2%)	0.08
Mechanical ventilation	253 (1.2%)	2 (1.6%)	0.70
Seizures	203 (1%)	2 (1.6%)	0.48
Sepsis	92 (0.4%)	2 (1.6%)	0.05
Encephalopathy	20 (0.1%)	0 (0%)	0.73
Perinatal Fetal Death	141 (0.7%)	1 (0.8%)	0.87

Data are mean ± standard deviation; number (%); *NICU* Neonatal intensive-care unit, *TTN* transient tachypnea of the newborn

Table 4 Multivariate logistic regression analysis for the association between Bicornuate uterus and failed trial of labor after cesarean (Adjusted Odds Ratio)

	p-value	aOR	95% CI	
Bicornuate uterus	< 0.01	2.56	1.65	3.95
Parity	< 0.01	0.79	0.74	0.84
Induction of labor	< 0.01	3.93	3.46	4.47
Epidural analgesia	< 0.01	0.54	0.49	0.59
Gestational age at delivery < 37 week	< 0.01	2.52	2.13	2.98
Hypertensive disorders of pregnancy	< 0.01	2.24	1.80	2.79
Diabetes (pregestational and gestational)	< 0.01	1.74	1.49	2.05

*CI*confidence interval, *aOR* adjusted odds ratio

retained placenta, and prolonged hospitalization were significantly higher. Otherwise, obstetrics and maternal outcomes were comparable. Notably, the presence of a bicornuate uterus was associated with adverse neonatal outcomes, including admission to the neonatal intensive care unit (NICU) and sepsis.

The ability to accurately predict successful TOLAC is crucial, as both maternal and neonatal morbidity is more common among those who experience failed TOLAC and require a repeat CD during labor. Our study findings revealed that failed TOLAC was significantly associated with the bicornuate uterus. Previous studies have reported varying rates of VBAC in relation to different types of Müllerian anomalies, including bicornuate, unicornuate, Didelphis, arcuate, and septate together. Two studies [16, 17] included a total of 190 patients with Müllerian anomalies, of them 91 with bicornuate uterus attempting TOLAC, indicating relatively high rates of successful VBAC ranging between 61.4% [17] and 80% [16]. Consistent with these findings, our institution also demonstrated an overall high VBAC rate (77.4%). However, when comparing this to the group with a non-malformed uterus, the rate of failed TOLAC was more than twice as high. This observation was held despite comparable main known risk factors for failed TOLAC [18], such as labor induction, duration of the second stage, and epidural analgesia, between the two groups. Furthermore, our study identified the bicornuate uterus as an independent risk factor for failed TOLAC, which contrasts with findings from other studies [17, 19]. Previous research has suggested that Müllerian anomalies are not an independent risk factor for failed TOLAC unless they are accompanied by other pregnancy complications, primarily fetal malpresentation. However, our study specifically focused on TOLAC outcomes in patients with a bicornuate uterus as a separate group, which could explain the difference in findings compared to previous studies. To our knowledge, this is the first study to examine TOLAC outcomes exclusively in patients with a bicornuate uterus, providing valuable insights into the unique challenges and risks associated with this specific uterine anomaly.

Given the hypothetical concern regarding the vector of contraction and the development of the lower segment of the uterus, ensuring the safety of trial of labor after cesarean (TOLAC) in the presence of Müllerian anomaly becomes of utmost importance [20]. The low rates of uterine rupture observed in our study align with previous studies conducted, which also did not find a higher incidence of uterine rupture in parturients with Müllerian anomalies attempting TOLAC [17, 21]. Nonetheless, a single retrospective study reported high rates of uterine rupture in this group (up to 8%) [16]. This particular study included 25 parturients attempting TOLAC with various Müllerian anomalies, and two of them experienced uterine rupture: one with a unicornuate

uterus and the other with a bicornuate uterus, both following induction with prostaglandin E2 gel. It is well-established that induction of labor is a recognized risk factor for uterine rupture, with higher rates associated with the use of prostaglandins [22]. Consequently, the use of prostaglandins is not permitted during TOLAC in our institution. These findings emphasize the importance of carefully considering the decision regarding the induction of labor in women with Müllerian anomalies and a history of previous CD.

Several studies [21, 23, 24] have confirmed a higher incidence of placental abruption in parturients with Müllerian anomalies. Additionally, two studies examining TOLAC in parturients with Müllerian anomalies [16, 17] found higher rates of placental abruption, although the difference did not reach statistical significance. Retained placental products are also documented complications associated with pregnancy in women with Müllerian anomaly uteri [19]. These adverse outcomes may be attributed to the abnormal anatomy of the uterus, which can result in abnormal placental vascularization [23, 25]. The rate of prolonged hospitalization which was significantly higher in the bicornuate uterus group, is likely due to the higher rate of NICU admissions followed by longer maternal stay in that group.

Our findings indicate that neonates born to parturients with a bicornuate uterus face a twofold increased risk of NICU admission and neonatal sepsis. This could potentially be attributed to the higher likelihood of failed TOLAC in this group. Additionally, this outcome may be influenced by the lower birthweight and earlier gestational age observed among neonates in the bicornuate uterus group. Existing literature [21, 23, 26, 27] supports our findings, showing that perinatal outcomes are less favorable for neonates born to parturients with Müllerian anomalies, with higher rates of preterm deliveries and lower birth weight.

Various studies have aimed to investigate whether obstetric outcomes are influenced by the specific type of Müllerian anomaly and the differences in the number of uterine cavities and orifices [23, 28]. In the era of personalized medicine, this study serves as a valuable counseling tool specifically for the sub-population of individuals with a bicornuate uterus.

This study possesses several notable strengths. Firstly, it is a large-scale population study, encompassing over 16% of all national births. This wide coverage enhances the generalizability of the findings. Furthermore, the database used in the study is continuously validated in real time, minimizing the potential for information bias. Lastly, by focusing on a specific subpopulation of Müllerian anomalies, the study provides valuable insights into the safety and chances of TOLAC within this particular sector. Despite implementing strict and specific inclusion criteria, a considerable number of participants still met the eligibility criteria, enhancing the study's validity.

Our study has several limitations that should be acknowledged. Firstly, the retrospective design of the study introduces inherent limitations and potential biases. Secondly, we recognize the limitation of our smaller sample size for bicornuate uterus cases, most probably related to the natural prevalence of bicornuate uterus worldwide. However, our findings are still significant. The current size was not powered to detect rare outcomes like uterine dehiscence or rupture, larger, multicenter studies are required to establish TOLAC safety in this regard. Additionally, important factors such as the indication for the first CD and prior uterine closure techniques, were not reported, despite their potential impact on the chances of failed TOLAC. Furthermore, it is worth noting that our study population had specific characteristics, particularly a high motivation for having large families. This may limit the generalizability of our study's results to populations with different characteristics. However, we believe that many parturients attempting TOLAC share certain common characteristics, which may still allow for some generalization of our findings.

Conclusions

In conclusion, our multicenter retrospective cohort study provides insights into TOLAC outcomes for parturients with a bicornuate uterus. Our findings suggest that TOLAC might be considered for these patients, but they do appear to face certain challenges not present in those with a non-malformed uterus. Notably, we observed increased rates of TOLAC failure, placental abruption, and retained placenta in the bicornuate group. Neonatal outcomes, such as NICU admission and neonatal sepsis, were also less favorable for this cohort. While our study offers essential information, it is important for obstetricians to interpret the data with caution. Personalized counseling should be provided to individuals with a bicornuate uterus, taking into account the specific risks and benefits based on our observations. Further research, preferably with larger sample sizes, is warranted to explore outcomes like uterine rupture in this population.

Author contributions All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission. RR, AH, MR: conceptualization, formal analysis, investigation and methodology, writing—original draft, and writing—review and editing. ZE, SGG, HYS: writing—review and editing.

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Data availability Data are available upon request by the Corresponding Author.

Declarations

Conflict of interest The authors declare that they have nothing to disclose and that they have no financial or non-financial conflict of interest.

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