

# A Trial of Labor after Cesarean Section with a Macrosomic Neonate. Is It Safe?

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## Abstract

**Objective** This study aimed to determine whether a trial of labor after cesarean section (TOLAC) with a macrosomic neonate is associated with adverse outcomes.

**Study Design** A retrospective cohort study was conducted in a population motivated for TOLAC. Women attempting TOLAC with a neonatal birth weight >4,000 g were compared with women attempting TOLAC with neonatal birth weights between 3,500 and 4,000 g. The primary outcome was TOLAC success. Secondary outcomes included mode of delivery, uterine rupture, postpartum hemorrhage (PPH), shoulder dystocia, obstetric anal sphincter injury (OASI), Apgar's score <7 at 5 minutes, and umbilical artery pH <7.1. Data were analyzed using Fisher's exact test and Chi-square test.

**Results** Overall, 375 women who underwent TOLAC with a neonate weighing >4,000 g comprised the study group. One thousand seven hundred and eighty-three women attempting TOLAC with a neonate weighing 3,500 to 4,000 g comprised the control group. There were no clinically significant differences between the groups for maternal age, gestational age, parity, and vaginal birth after cesarean (VBAC) rate. There were no significant differences in the rates of successful TOLAC (94 vs. 92.3%,  $p = 0.2$ , odds ratio [OR] = 0.8, 95% confidence interval [CI]: 0.5, 1.2), operative vaginal delivery (7.4 vs. 5.3%,  $p = 0.18$ , OR = 0.7, 95% CI: 0.4, 1.1), uterine rupture (0.4 vs. 0%,  $p = 0.6$ ), PPH (3.2 vs. 2.3%,  $p = 0.36$ , OR = 1.4, 95% CI: 0.7, 2.7), OASI (0.8 vs. 0.2%,  $p = 0.1$ , OR = 3.6, 95% CI: 0.8, 1.6), Apgar's score <7 at 5 minutes (0 vs. 0.4%,  $p = 0.37$ ), and umbilical artery pH <7.1 (0.5 vs. 0.7%,  $p = 1.0$ , OR = 0.73, 95% CI: 0.2, 3.2). Women with a neonate weighing >4,000 g had a significantly increased risk of shoulder dystocia (4 vs. 0.4%,  $p < 0.05$ , OR = 9.2, 95% CI: 3.9, 22).

**Conclusion** Women attempting TOLAC with a macrosomic neonate are not at increased risk for failed TOLAC, operative vaginal delivery, uterine rupture, PPH, or OASI but are at risk of shoulder dystocia. This information may aid in prenatal counseling for women considering TOLAC with a macrosomic fetus.

## Keywords

- ▶ macrosomia
- ▶ a trial of labor after cesarean
- ▶ TOLAC
- ▶ cesarean delivery

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## Key Points

- TOLAC with fetal macrosomia does not increase the risk of uterine rupture.
- TOLAC with fetal macrosomia is associated with high chances of VBAC.
- TOLAC with fetal macrosomia is not associated with adverse neonatal outcomes.

A trial of labor with a macrosomic fetus is described in the literature as associated with adverse outcomes for both mother and neonate, including an unplanned operative delivery,<sup>1</sup> uterine rupture,<sup>2</sup> postpartum hemorrhage (PPH),<sup>2</sup> obstetric anal sphincter injury (OASI),<sup>3</sup> shoulder dystocia,<sup>4</sup> and low Apgar's scores.<sup>5</sup> The risk of these outcomes rises with increasing birth weight above 4,000 g.<sup>6</sup>

Rising rates of maternal obesity and pregestational and gestational diabetes have led to an increased prevalence of macrosomia (birth weight >4,000 g) worldwide.<sup>7</sup> In parallel, there is a global trend of rising rates of cesarean deliveries. In 2019, more than 31% of deliveries in the United States were by cesarean delivery.<sup>8</sup> Consequently, the question regarding the optimal mode of delivery in women with a previous cesarean delivery and suspected macrosomia has become more pertinent.

One strategy that has been employed to reduce the rate of cesarean deliveries is the consideration of a trial of labor after cesarean section (TOLAC) in selected candidates. While a successful TOLAC is associated with a lower maternal and neonatal morbidity rate than a planned repeat cesarean delivery, a failed TOLAC is associated with an even greater risk of adverse outcomes. Therefore, the ideal candidate for TOLAC is one in whom the risks of adverse outcomes, mainly uterine rupture, are low and the chances of success are high.

Previous studies<sup>9–14</sup> have demonstrated that patients undergoing TOLAC with a macrosomic fetus are less likely to achieve vaginal birth after cesarean (VBAC) than patients with a nonmacrosomic fetus, with success rates reported in the literature ranging from 38 to 85%.<sup>9–14</sup> Furthermore, there are conflicting data regarding whether these patients are also at increased risk of uterine rupture.<sup>9–14</sup> Recent guidelines from the American College of Obstetrics and Gynecology do not consider macrosomia a contraindication to TOLAC. However, considering current estimated and previous birth weights is recommended when counseling patients regarding the mode of delivery after a previous cesarean delivery.<sup>15</sup> Similarly, the Royal College of Obstetrics and Gynecology advises, “a cautious approach due to a lack of safety and efficacy data.”<sup>16</sup>

This study aims to assess the safety and feasibility of a TOLAC in women with a macrosomic neonate and will help answer the question of increasing clinical relevance; should TOLAC be attempted in suspected macrosomia?

## Materials and Methods

A retrospective cohort study was conducted at Mayanei Hayeshua Medical Center (MHMC) over 7 years. MHMC is a teaching hospital affiliated with Tel Aviv University. The labor delivery ward has around 11,000 deliveries per year

and a cesarean delivery rate of 10%. Absolute contraindications to TOLAC in our center include a clinical or sonographic estimated fetal weight of >4,500 g and a prior uterine incision other than a lower segment transverse incision. Before a TOLAC attempt, patients are counseled regarding their chances of success, risk of uterine rupture, and other adverse maternal and neonatal outcomes.

The study and control groups consisted of women who underwent a trial of labor after one previous cesarean delivery with a single neonate weighing more than 4,000 g and a neonate weighing between 3,500 and 4,000 g, respectively.

The primary outcome was TOLAC success. Secondary outcomes included the mode of vaginal delivery (spontaneous or operative), uterine rupture, PPH, shoulder dystocia, OASI, neonatal Apgar's score <7 at 5 minutes, and umbilical artery pH <7.1.

Data were collected from the computerized patient database. Demographic data and maternal and neonatal outcomes for each group were compared.

A statistical power analysis was performed. With an  $\alpha = 0.05$  and power = 0.80, the projected sample size needed to detect a 6% difference in TOLAC success rate is approximately 1,668 in the control group and 268 in the study group. Thus with our proposed sample size of 1,783 in the control group and 375 in the study group, our study is powered to detect significant differences in the primary outcome of TOLAC success.

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp. Data were analyzed using Fisher's exact test and Chi-square test.

The local ethical review board approved the study.

## Results

During the study period, there were 81,000 deliveries at our center. The study group comprised 375 women who underwent TOLAC and delivered a neonate weighing above 4,000 g. The control group was composed of 1,783 women undergoing TOLAC who delivered a baby weighing between 3,500 and 4,000 g.

There were statistically significant, however, not clinically significant differences between the groups for maternal age ( $33.2 \pm 5.3$  vs.  $32.4 \pm 5.2$  years), gestational age ( $40.2 \pm 1.0$  vs.  $39.9 \pm 1.0$  weeks), and parity ( $4.9 \pm 2.8$  vs.  $4.4 \pm 2.6$ ) in the study versus control groups, respectively. There were no significant differences between the groups for the number of previous VBAC section ( $1.7 \pm 2.0$  vs.  $1.8 \pm 1.9$ ; **Table 1**).

There were no significant differences between groups for the primary outcome: TOLAC success (92.3 vs. 94%  $p = 0.2$ ,

**Table 1** Comparison of demographic characteristics of the women undergoing TOLAC with a macrosomic fetus (>4,000 g) and a fetus weighing between 3,500 and 4,000 g

Variable	Macrosomia (375)	Nonmacrosomia (1,783)	p-Value
Maternal age (y)	33.2 ± 5.3	32.4 ± 5.2	<0.05
Gestational age at delivery (wk)	40.2 ± 1.0	39.9 ± 1.0	<0.05
Parity (n) <sup>a</sup>	4.9 ± 2.8	4.4 ± 2.6	<0.05
VBAC (n) <sup>a</sup>	1.7 ± 2.0	1.8 ± 1.9	0.5

Abbreviations: TOLAC, trial of labor after cesarean delivery; VBAC, vaginal birth after cesarean delivery.

<sup>a</sup>Continuous variable reported as means ± standard deviation.

odds ratio [OR] = 0.8, 95% confidence interval [CI]: 0.5, 1.2) nor in the rates of the secondary outcomes, including operative vaginal delivery, uterine rupture, OASI, Apgar's score <7 at 5 minutes, and umbilical artery pH <7.1 (→ Table 2).

Women who underwent TOLAC with a neonate weighing above 4,000 g had a statistically significant increased risk of shoulder dystocia (4 vs. 0.4%  $p < 0.05$ , OR = 9.2, 95% CI: 3.9, 22) compared with women with a neonate weighing between 3,500 and 4,000 g (→ Table 2). Of all the cases of shoulder dystocia in this study, there were two cases of Erb's palsy, one in each group and one case of a clavicle fracture in the study group. The remaining cases of shoulder dystocia had an uneventful postnatal course.

In a subgroup analysis of 212 women who attempted TOLAC with no history of vaginal births, there were also no significant differences in the primary outcome of TOLAC

**Table 2** Maternal and neonatal outcomes in patients undergoing a trial of labor after cesarean delivery with and without a macrosomic neonate

	n (%)	p-Value	Odds ratio	95% CI
Successful TOLAC		0.2	0.8	0.5, 1.2
3,500–4,000 g	1,676 (94)			
> 4,000 g	346 (92.3)			
Spontaneous vaginal delivery		0.86	0.86	0.7, 1.4
3,500–4,000 g	1,544 (86.6)			
> 4,000 g	326 (86.9)			
Operative vaginal delivery		0.18	0.7	0.4, 1.1
3,500–4,000 g	132 (7.4)			
> 4,000 g	20 (5.3)			
Cesarean delivery		0.21	1.3	0.9, 2.0
3,500–4,000 g	107 (6)			
> 4,000 g	29 (7.7)			
Postpartum hemorrhage		0.36	1.4	0.7, 2.7
3,500–4,000 g	41 (2.3)			
> 4,000 g	12 (3.2)			
OASI		0.1	3.6	0.8, 16
3,500–4,000 g	4 (0.2)			
> 4,000 g	7 (0.8)			
Uterine rupture		0.6	N/A	N/A
3,500–4,000 g	7 (0.4)			
> 4,000 g	0 (0)			
pH < 7.1 (n) <sup>a</sup>		1.0	0.73	0.2, 3.2
3,500–4,000 g	13 (0.7)			
> 4,000 g	2 (0.5)			
Apgar's score <7 at 5 minutes (n)		0.37	N/A	N/A
3,500–4,000 g	8 (0.4)			
> 4,000 g	0 (0)			
Shoulder dystocia		<0.05	9.2	3.9, 22
3,500–4,000 g	8 (0.4)			
> 4,000 g	15 (4)			

Abbreviations: CI, confidence interval; N/A, not available; TOLAC, trial of labor after cesarean delivery.

<sup>a</sup>Umbilical cord pH.

**Table 3** Maternal and neonatal outcomes in patients undergoing a trial of labor after cesarean delivery with and without a macrosomic neonate and no previous vaginal births (subgroup analysis)

	<i>n</i> (%)	<i>p</i> -Value	Odds ratio	95% CI
Successful TOLAC		0.09	0.49	0.24, 1.0
3,500–4,000 g	185 (80.2)			
> 4,000 g	27 (67.5)			
Spontaneous vaginal delivery		0.23	1.5	0.78, 3.0
3,500–4,000 g	127 (55.5)			
> 4,000 g	18 (45)			
Operative vaginal delivery		0.84	0.86	0.39, 1.9
3,500–4,000 g	58 (25.3)			
> 4,000 g	9 (22.5)			
Cesarean delivery		0.09	2.0	0.97, 4.2
3,500–4,000 g	44 (19.2)			
> 4,000 g	13 (32.5)			
Postpartum hemorrhage		1	N/A	N/A
3,500–4,000 g	1 (0.4)			
> 4,000 g	0			
OASIS		N/A	N/A	N/A
3,500–4,000 g	0			
> 4,000 g	0			
Uterine rupture		0.61	N/A	N/A
3,500–4,000 g	7 (0.4)			
> 4,000 g	0 (0)			
pH < 7.1 ( <i>n</i> ) <sup>a</sup>		N/A	N/A	N/A
3,500–4,000 g	0			
> 4,000 g	0			
Apgar's score <7 at 5 minutes ( <i>n</i> )		1.0	N/A	N/A
3,500–4,000 g	3 (1.3)			
> 4,000 g	0 (0)			
Shoulder dystocia				
3,500–4,000 g	0	N/A	N/A	N/A
> 4,000 g	0			

Abbreviations: CI, confidence interval; N/A, not available; OASIS, obstetric anal sphincter injuries; TOLAC, trial of labor after cesarean delivery.

<sup>a</sup>Umbilical cord pH.

success (67.5 vs. 80.8%  $p = 0.09$ , OR = 0.49, 95% CI: 0.24, 1.03). There was also no significant difference in the rate of operative vaginal delivery, uterine rupture, OASIS, shoulder dystocia, Apgar's score <7 at 5 minutes, and umbilical artery pH <7.1 (–Table 3).

## Discussion

Our results demonstrate that women undergoing a TOLAC with a neonate weighing >4,000 g have the same chances of achieving a VBAC as women with a nonmacrosomic neonate and are not at increased risk of experiencing adverse maternal outcomes, including unplanned operative delivery, uterine rupture, PPH, and OASIS, nor are they at increased risk of having adverse neonatal outcomes including umbilical artery pH < 7.1

and Apgar's scores of <7 at 5 minutes. Specific analysis of the group that is considered most challenging from a prelabor counseling point of view, women who attempt TOLAC and do not have a prior vaginal delivery, similarly demonstrated no differences in the primary or secondary outcomes,

The data regarding TOLAC outcomes with a macrosomic neonate are limited, despite the increasing prevalence of this clinical scenario. Results from studies that have been conducted regarding the safety and feasibility of TOLAC with macrosomia report success rates of 38 to 85%, with conflicting results regarding whether there is an increased risk of uterine rupture or increased adverse maternal or neonatal outcomes.<sup>9–14</sup>

Our study demonstrates that a trial of labor with a macrosomic neonate is as likely to succeed as with a nonmacrosomic neonate (>92%). This contrasts with the literature which has

reported a lower VBAC rate overall (60–80%),<sup>15</sup> lower success rates in macrosomic TOLAC (38–85%), and a significant reduction in TOLAC success in macrosomic compared with nonmacrosomic cohorts.<sup>9–13</sup> Furthermore, Elkousy et al<sup>12</sup> demonstrated a strong relationship between neonatal birth weight and TOLAC success ranging from 38% with a neonatal birth weight above 4,250 to 68% for neonates weighing less than 4,000 g.

This discrepancy in results is possible for several reasons. One is due to the characteristics of our study population. Factors that modify the chances of achieving a successful TOLAC in patients with macrosomia include the presence of previous vaginal delivery,<sup>12</sup> previous VBAC,<sup>12</sup> indication for previous cesarean delivery,<sup>12</sup> and the use of oxytocin.<sup>11</sup> The women in our cohort had an average parity of five and two previous VBACs, both factors that have been shown to increase the chances of TOLAC success.<sup>17</sup> Indeed, in our subgroup analysis of patients who had no history of vaginal delivery, TOLAC success rates were reduced to 80.8% in patients without a macrosomic neonate and 67.5% in patients with a macrosomic neonate. Regardless, these numbers are higher than published in the literature.

Patients undergoing a trial of labor with a macrosomic fetus are more likely to experience arrest disorders of the active phase. This seems to be the case in TOLAC as well, with one study reporting that the most common reason cited for failed TOLAC in patients with a macrosomic neonate was a “failure to progress.”<sup>10</sup> Due to a desire for higher parity in our population, women and attending physicians are highly motivated for TOLAC, with a TOLAC rate >90% in our center. This may affect the threshold for terminating the trial of labor due to a failure to progress, and extra time is given to the patients to progress, facilitating more patients to achieve VBAC with no increase in adverse neonatal and maternal outcomes. Further research is needed to determine whether patients undergoing a trial of labor with a macrosomic neonate have a different partogram, such as has been described in twin deliveries.<sup>18</sup>

Another reason why our study demonstrated high TOLAC success in both study groups may be since our study population was created based on neonatal birth weights and not estimated fetal weight. It has been well described that fetal weight estimations do not correlate well with actual birth weights, particularly in patients with macrosomia. Indeed, one study reported that 82% of neonatal macrosomia was undetected by clinical estimation of estimated fetal weight before birth.<sup>19</sup> Similarly, in our study, it is likely that physicians attending the delivery assessed fetal weight as appropriate for gestational age and allowed a trial of labor. They were again less likely to terminate a trial of labor or avoid operative vaginal delivery.

Whether TOLAC with a macrosomic neonate increases the risk of uterine rupture is a matter of debate. Most studies have not demonstrated an increased risk of uterine rupture.<sup>9–11,13,14</sup> However, the most extensive study to date investigating the effect of birth weight on TOLAC outcomes<sup>12</sup> did report an increased risk of uterine rupture in patients undergoing TOLAC with a neonatal birth weight of

>4,000 g compared with a neonatal birth weight <4,000 g (2.8 vs. 1.2%) with the highest risk of uterine rupture (3.6%) reported in the group with a macrosomic neonate and no previous vaginal deliveries. In our cohort, there were no cases of uterine rupture in the patients undergoing TOLAC with a macrosomic neonate, and the rupture rate was 0.4% in the nonmacrosomic group. There were no statistically significant differences between the two groups for uterine rupture. Our results are in line with most studies that do not demonstrate an increased risk of rupture in TOLAC with a macrosomic neonate. However, due to the rarity of uterine rupture, particularly in a parous population, our study was not powered to detect any differences in uterine rupture.

A significantly increased risk for shoulder dystocia was demonstrated within the macrosomic compared with the nonmacrosomic TOLAC population (OR=9.2). This result was expected as it has been widely documented that the risk of shoulder dystocia increases with increasing neonatal birth weight<sup>20</sup> in patients undergoing a trial of labor regardless of whether they have had a previous cesarean section or not.

Our study is one of the largest to date to investigate the effect of macrosomia on TOLAC outcomes. Our study reports both maternal and neonatal outcomes and used as a control group, patients undergoing TOLAC without a macrosomic fetus in whom TOLAC is generally considered safe and widely encouraged.

## Conclusion

Our study demonstrates that TOLAC with a macrosomic neonate is safe, feasible, and has a high chance of success. Although having a macrosomic neonate increases the risk of shoulder dystocia, other obstetric and adverse perinatal outcomes, particularly those related to a TOLAC attempt are not more likely to occur when the neonate is macrosomic. This data can be used to counsel patients and assist in decision-making in the increasingly common dilemma regarding whether to undergo a trial of labor after cesarean when there is suspicion of fetal macrosomia.

### Ethical Approval

This study was conducted in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments. The local ethical committee approved the study. Since the study was retrospective, there was a waiver from informed consent by the local ethical committee.

### Authors' Contributions

M.L.: project development, data collection, and first draft manuscript writing.

L.K.-L.: Project development, data collection, and review of the final version of the manuscript.

R.C.: data collection and review of the final version of the manuscript.

J.H.: data collection and review of the final version of the manuscript.

S.P.: project development, supervision, and first draft manuscript writing.

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#### Conflict of Interest

None declared.

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