# The Optimal Method for Labor Induction in Macrosomic Fetuses: Mechanical or Medical?

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**ABSTRACT** **Background:** Fetal macrosomia is a risk factor for operative vaginal delivery (VD), shoulder dystocia, obstructed labor, and cesarean section (CS). Induction of labor (IOL) may decrease these risks but also leads to longer labor, increasing the risk of CS. No data exist regarding the optimal method of IOL in macrosomic fetuses, and most studies are limited to the efficacy of medical induction.

**Objective:** To compare medical and mechanical IOL in macrocosmic fetuses.

**Methods:** This retrospective case-control study included pregnant women who underwent IOL and delivered macrosomic neonates at a tertiary center between 2010 and 2020. Women with non-cephalic presentation, prior CS, and multiple pregnancies were excluded. The primary outcome was the mode of delivery. Secondary outcomes included neonatal and maternal complications.

**Results:** A total of 247 women were included in the study, 188 underwent cervical ripening with prostaglandin E2 (PGE2) regimens and 59 with a double-balloon catheter. Higher rates of prior deliveries over 4000 grams and Oxytocin use during delivery were found in the mechanical induction group. No other clinically significant differences in demographic or clinical characteristics were identified. There were no statistically significant differences in the rates of VD or CS between the groups. The indications for CS were similar. Maternal and neonatal secondary outcomes were comparable.

**Conclusion:** PGE2 vaginal regimens and double catheter balloons are safe and effective methods for cervical ripening during IOL in term pregnancies with macrosomic neonates. The choice of cervical ripening method did not impact the mode of delivery or maternal and neonatal outcomes.

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**KEY WORDS:** cervical ripening, induction of labor, macrosomia

Induction of labor (IOL) is a common procedure in modern obstetrics. Conditions in which maternal or fetal well-being is at risk may require IOL [1,2]. The uterine cervix's condition, expressed by the BISHOP score, is examined to choose the suitable induction method. In cases of low BISHOP score cervical ripening is required, and prostaglandin E2 (PGE2) regiments or cervical ripening balloon are commonly used with similar safety and efficacy rates [3,4]. Moreover, in recent years, multiple studies have shown that elective induction of labor at 39 weeks of gestation may reduce primary cesarean section rates and maternal hypertensive diseases [5,6], and recently published new clinical recommendations suggest offering elective IOL [7].

Macrosomia is defined as a birthweight above 4000 grams at every gestational age [8,9] Macrosomia complicates approximately 8–10% of all pregnancies [8,10]. Macrocosmic pregnancies present with higher rates of maternal and fetal complications during delivery, higher rates of cesarean sections, postpartum hemorrhage, 3rd and 4th degree perineal tears, shoulder dystocia, and brachial plexus injuries.

The effectiveness of IOL in reducing adverse outcomes in cases of antepartum suspected macrosomia is debatable [11-13]. Still, due to the overall rise in IOL rates and the suggested benefits of IOL among macrosomic pregnancies, finding the optimal induction method in cases of unfavorable uterine cervix and macrosomic neonates is necessary since no evidence-based data exists.

We compared IOL by PGE2 vaginal regiments versus double catheter balloon for cervical ripening among macrosomic neonates in term pregnancies (37 to 42 + 6 weeks) in women who underwent induction of labor for various indications.

## PATIENTS AND METHODS

This retrospective case-control study included pregnant women at term who underwent IOL and delivered in our tertiary care center during 2010–2020. The study was approved by our local ethics committee (RMB-0638-19).

We included women who delivered macrosomic neonates and underwent IOL divided by the method of cervical ripening used, PGE2 vaginal regiments, or double catheter cervical balloon. The cervical ripening method was selected based on the department's protocol and the women's preferences. In the main analysis, we included deliveries of macrosomic neonates because most data investigating macrosomic deliveries relate to actual birth weight rather than estimated fetal weight [9]. The mechanical factors leading to the failure of vaginal deliveries, such as cephalopelvic disproportion (CPD) and complications like shoulder dystocia or prolonged labor, are directly related to the actual size and weight of the fetus at birth, rather than the estimated birth weight [8]. A sub-analysis of suspected macrosomic fetuses by ultrasound assessment prior to delivery was also performed.

Data were retrieved from the hospital's computerized database and completed and validated by the authors, all registered medical doctors. The data included information regarding the women's obstetrical and general medical history, peripartum information, and neonatal parameters.

We recruited term pregnant women with an indication for IOL who needed cervical ripening using prostaglandins or a double-balloon catheter (Cook Cervical Ripening Balloon, Cook OB/GYN, IN, USA; administered according to the manufacturer's guidelines). In the double-balloon catheter method, a mechanical ripening of the uterine cervix is performed. The catheter is inserted through the uterine cervix, and 80 cc of sterile fluid is placed above and below the cervical OS. The double balloon is left in place for up to 12 hours before it is removed. If active labor does not develop during the designated timeframe for prostaglandins or double balloon catheter action (12/24 hours and 12 hours, respectively), a vaginal examination is performed and additional doses of prostaglandins or another double balloon catheter are administered according to the protocols. Based on the progression of labor and in accordance with the department's protocol, an oxytocin infusion is added, and artificial rupture of membranes is performed.

Inclusion criteria involved term pregnant women who had delivered macrosomic neonates and underwent cervical ripening using the one of these methods. Exclusion criteria included multiple fetal gestations, combined methods for cervical ripening (e.g., prostaglandins and double balloon catheter), intra-uterine fetal death, and prenatally diagnosed fetal anomalies incompatible with life.

The study's primary outcome was the mode of delivery, vaginally (VD) or by cesarean section (CS). Secondary outcomes were maternal and neonatal adverse events and complications during delivery and the immediate postpartum period.

### STATISTICAL ANALYSIS

Descriptive statistics including means, standard deviations, and percentages were calculated for all parameters in the study. Differences between the two groups (medical induction vs. mechanical induction) for continuous parameters were evaluated by *t*-test or Mann Whitney U test when needed. For categorical parameters, we used Fisher's exact test. A logistic regression model was performed to predict CS delivery rates by adjusting several independent parameters: medical induction vs. mechanical induction, maternal body mass index, number of deliveries, previous macrosomic deliveries, maternal age, gestational age, and diabetes. Parameters with clinical relevance that affect the primary outcome and were identified as statistically significant in the univariate regression model were chosen for the multivariate regression model. A $P$-value < 0.05 was considered statistically significant. Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 28 (SPSS, IBM Corp, Armonk, NY, USA).

## RESULTS

Overall, 247 women were included in the study; 188 underwent cervical ripening by PGE2 regiments and 59 cervical ripening by a double balloon catheter. Demographic data and clinical characteristics comparisons between the groups are presented in Table 1. Overall, the two groups were comparable, and no major clinically significant difference was found. A higher rate of previous delivery above 4000 grams was found in the double balloon catheter group (27.1% vs. 12.2%, respectively, $P = 0.013$). In the PGE2 regiments group, more women underwent induction of labor due to post-term pregnancy (49.5% vs. 27.1%, respectively, $P = 0.0027$), while induction due to fetal heart rate decelerations was more common in the double balloon catheter group (16.9% vs. 7.4%, respectively, $P = 0.043$).

As shown in Table 2, there were no statistically significant differences in the rates of VD and CS between the double-balloon catheter or PGE2 regiments groups (for VD 78% vs. 69%, respectively, $P = 0.25$; for CS 15.5% vs. 25.5%, respectively, $P = 0.11$). The indication for CS was not statistically significantly different between the groups. Time from induction to delivery was also not statistically different between the groups.

**Table 1.** Maternal and delivery characteristics and maternal and neonatal outcome

| | | Medical induction, n=188 | Mechanical induction, n=59 | *P*-value |
|---|---|---|---|---|
| Maternal age at delivery, years | | 29.7 ± 4.7 | 31.9 ± 5.2 | 0.002 |
| Maternal BMI at delivery, kg/m$^2$ | | 32.70 ± 5.1 | 33.0 ± 6.4 | 0.76 |
| Maternal conditions | Pregestational diabetes, n (%) | 3 (1.6%) | 3 (5.1%) | 0.15 |
| | Gestational diabetes, n (%) | 25 (13.3%) | 10 (16.9%) | 0.52 |
| | Thyroid disorder, n (%) | 11 (5.9%) | 6 (10.2%) | 0.25 |
| | Coagulation disorder, n (%) | 2 (1.1%) | 4 (6.8%) | 0.03 |
| | Hypertension or Preeclampsia, n (%) | 13 (6.9%) | 3 (5.1%) | 0.77 |
| Prior delivery above 4000 grams, n (%) | | 23 (12.2%) | 16 (27.1%) | 0.013 |
| Number of deliveries | | 1.5 [1–2] | 2 [1–4] | < 0.001 |
| Gestation week at delivery, weeks | | 40.75 ± 0.9 | 40.21 ± 1 | < 0.001 |
| Interval between induction to delivery, hours | | 10 [6–17] | 14 [6–17] | 0.33 |
| Epidural use, n (%) | | 151 (80.3%) | 47 (79.7%) | 1 |
| Oxytocin administration during labor, n (%) | | 84 (44.7%) | 41 (69.5%) | < 0.001 |
| Maternal complications at delivery | Retained product of conception, n (%) | 18 (9.6%) | 10 (16.9%) | 0.12 |
| | Revisio of uteri, n (%) | 23 (12.2%) | 11 (18.6 %) | 0.21 |
| | Postpartum hemorrhage, n (%) | 9 (4.8%) | 1 (1.7%) | 0.46 |
| | 3rd and 4th degree perineal tears, n (%) | 3 (1.6%) | 0 | 1 |
| | Chorioamnionitis, n (%) | 12 (6.4%) | 3 (5.1%) | 1 |
| Blood transfusions, n (%) | | 1 (0.5%) | 1 (1.7%) | 0.421 |
| Episiotomy, n (%) | | 40 (21.3%) | 9 (15.3%) | 0.36 |
| Shoulder dystocia, n (%) | | 5 (2.7%) | 2 (3.4%) | 0.67 |
| Birthweight, grams | | 4014 ± 18 | 4037 ± 21 | 0.22 |
| APGAR score after 1 minute | | 8.73 ± 0.9 | 8.68 ± 1 | 0.73 |
| APGAR score after 5 minutes | | 9.81 ± 0.4 | 9.80 ± 0.6 | 0.88 |
| Umbilical cord sampling pH | | 7.26 ± 0.07 | 7.22 ± 0.07 | 0.067 |
| Fracture or neurologic compromise, n (%) | | 5 (2.7%) | 2 (3.4%) | 0.67 |
| NICU transfer, n (%) | | 5/186 (2.7%) | 1/59 (1.7%) | 0.66 |

BMI = body mass index, NICU = neonatal intensive care unit
*P* < 0.05 is considered significant
Values are presented as mean ± standard deviation for continuous variables, n (%) for categorical variables, and median [interquartile range] for non-normally distributed variables

Adjustment for confounding variables by multivariable logistic regression was performed [Table 4]. Besides the number of delivery (e.g., nulliparous women vs. multiparous women), no other statistically significant influence on the rates of CS and VD were found in the multivariate model.

There were no clinically significant differences in maternal or neonatal secondary outcomes [Table 1 and Table 3].

A subsequent analysis evaluated the mode of delivery as the primary outcome among women with a suspected macrosomic fetus who had undergone induction of labor by PGE2 regiments or double balloon catheter. Ultrasound estimation of the fetal weight evaluation was performed prior to delivery, and evaluations of 4000 grams and more were included in the analysis. As with the mac-

**Table 2.** Birth outcome

| | | Medical induction, n=188 | Mechanical induction, n=59 | *P*-value |
|---|---|---|---|---|
| Indication for induction of labor | Maternal*, n (%) | 40 (21.3%) | 12 (20.3%) | 0.88 |
| | Fetal**, n (%) | 155 (82.4%) | 51 (86.4%) | 0.47 |
| | Combined, n (%) | 7 (3.7%) | 4 (6.8%) | 0.30 |
| Mode of delivery | Vaginal delivery, n (%) | 130 (69.1%) | 46 (78.0%) | 0.25 |
| | Vacuum-assisted, n (%) | 10 (5.3%) | 4 (6.8 %) | 0.74 |
| | Cesarean section, n (%) | 48 (25.5%) | 9 (15.3%) | 0.11 |
| Indication for Cesarean section | Failed induction, n (%) | 7 (12.1%) | 1 (7.6%) | 1 |
| | Non-reassuring fetal heart rate, n (%) | 17 (29.3%) | 6 (46.2%) | 0.33 |
| | Prolonged 2nd stage, n (%) | 22 (37.9%) | 2 (15.4%) | 0.19 |
| | Arrest of dilatation, n (%) | 9 (15.5 %) | 1 (7.7%) | 1 |
| | Maternal request, n (%) | 1 (1.7%) | 0 | 1 |
| | Severe preeclampsia, n (%) | 2 (3.4%) | 0 | 1 |

*Hypertension or preeclampsia, diabetes, coagulation disorder, intrahepatic cholestasis of pregnancy
**Prolonged pregnancy, oligohydramnios, non-reassuring fetal heart rate, decreased fetal movements, poor obstetric history, suspected abruption of placenta, suspected macrosomia, other
*P* < 0.05 is considered significant
Values are presented as mean ± standard deviation for continuous variables and n (%) for categorical variables

rosomic birthweight-induction group, no statistically significant differences were found in the mode of delivery between PGE2 regiments and double balloon catheter (for VD 67% vs. 81%, respectively, $P = 0.13$; for CS 17% vs. 11%, respectively, $P = 0.42$) [Table 4].

**Table 3.** Suspected macrosomic fetuses prior to delivery by ultrasound assessment: delivery outcome

| | Medical induction, n=75 | Mechanical induction, n=37 | *P*-value |
|---|---|---|---|
| Vaginal delivery, n (%) | 50 (66.6 %) | 30 (81.1%) | 0.13 |
| Vacuum-assisted, n (%) | 12 (16.0%) | 3 (8.1%) | 0.38 |
| Cesarean section, n (%) | 13 (17.3%) | 4 (10.8%) | 0.42 |

NS, not significant; n, number
$P < 0.05$ is considered significant

## DISCUSSION

In this study, we demonstrated that the method of cervical ripening used for IOL in women giving birth to macrosomic neonates did not increase the risk for CS. There was no statistically significant difference in the rates of VD and CS between IOL by PGE2 regiments or double balloon catheter. Secondary fetal and maternal outcomes were also comparable between the two groups. Moreover, an analysis of women with suspected macrosomic neonates by ultrasound assessment before delivery demonstrated the same trend with no higher rates of CS.

Previous studies and systematic reviews have shown that both methods of cervical ripening for IOL are considered effective and safe. They have similar CS rates. In addition, Du et al. [14] and Diguisto and colleagues [15], who tested IOL in fetuses at all weight ranges, demonstrated a similar rate of CS when using the two methods. These studies strengthen our findings that having fetal macrosomia should not influence the IOL method chosen.

Moreover, having comparable rates of secondary outcomes strengthens the similarity between the two methods by demonstrating that no specific methods lead to higher rates of typical complications common in macrosomic deliveries, such as immediate postpartum hemorrhage (PPH), 3rd and 4th degree perineal lacerations, shoulder dystocia, and obstructed labor. Compared to previous work by Beta and co-authors [9], rates of common complications such as shoulder dystocia, PPH, and OASIS were even lower in our cohort, emphasizing the safety of IOL in macrosomic pregnancies.

Assessment of time from induction to delivery also did not result in a statistically significant difference between the two methods, in contrast to the results of and Diguisto co-authors [15] and Zhao et al. [16], where PGE2 regiments demonstrated a shorter time to delivery. This discrepancy requires further investigation.

The rates of oxytocin treatment were statistically significantly different between the two groups. These findings are consistent with those presented in a Cochrane systematic review [17], which compared mechanical induction of labor to vaginal PGE2, as well as in a meta-analysis published by Liu et al. [18] This difference can be explained by the distinct modes of action of the two induction methods.

In this cohort, the rates of uterine revisions and retained products of conception (RPOC) were higher than reported in other studies, such as the one by Ashwal et al. [19] and a systematic review by Favilli and colleagues [20], which evaluated the general population. The use of IOL with PGE2 or extra-amniotic balloon, oxytocin, and epidural analgesia were identified as risk factors for RPOC. In our study cohort, the rate of these conditions was notably high, which may have contributed to the elevated rates of RPOC and uterine revisions observed.

In an era of rising rates of IOL for various reasons,

**Table 4.** Logistic regression model

| | Univariate model | | | Multivariate model | | |
|---|---|---|---|---|---|---|
| | Odds ratio | *P*-value | 95%CI | Odds ratio | *P*-value | 95%CI |
| Medical induction vs. mechanical induction | 1.90 | 0.106 | 0.87–4.16 | 1.47 | 0.373 | 0.62–3.47 |
| Number of deliveries: 1 vs. 2 or more | 8.83 | 0.001 | 4.19–18.60 | 11.24 | 0.0001 | 4.34–29.41 |
| Prior delivery above 4000 grams, yes vs no | 4.20 | 0.021 | 1.24–14.22 | 1.04 | 0.95 | 0.25–4.31 |
| Maternal age at delivery | 0.93 | 0.049 | 0.88–1.00 | 1.05 | 0.18 | 0.97–1.14 |

95%CI = 95% confidence interval

including macrosomic fetuses, these data supply essential and reassuring information for obstetricians and women undergoing IOL. Having equal vaginal delivery rates enables medical professionals to offer more treatment options based on patient preferences and other clinical characteristics.

Despite the small numbers, examining the indication for CS in the two groups showed no statistically significant difference in the rate of fetal distress or obstructed labor between the two groups [Table 4]. This fact highlights that despite the two different mechanisms of action, both methods have similar complication profiles as demonstrated by meta-analyses by Zhao et al. [16], Chen et al. [3], and Diguisto et al. [15], which compared several cervical ripening methods.

The generalizability of our results is limited due to the number of women included in each cohort group and its retrospective nature. While assessing the management of macrosomic deliveries, we refer to the actual birth weight in contrast to the estimated fetal weight. This dataset limits the guidelines given to doctors deciding on IOL, who have only weight estimations for decision-making.

We included a cohort of macrosomic fetuses defined by ultrasound estimation. We showed no statistically significant differences in the mode of delivery between the two groups. Still, further randomized controlled trials and a larger cohort are required to obtain more sustained results.

## CONCLUSIONS

Both PGE2 regiments and double balloon catheter are equally safe methods of IOL by cervical ripening and lead to a similar rate of VD and can be offered to women with macrosomic fetuses.

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**References**

1. Coates D, Makris A, Catling C, et al. A systematic scoping review of clinical indications for induction of labour. *PLoS One* 2020; 15 (1): e0228196.
2. Middleton P, Shepherd E, Morris J, Crowther CA, Gomersall JC. Induction of labour at or beyond 37 weeks' gestation. *Cochrane Database Syst Rev* 2020; 7 (7): CD004945.
3. Chen W, Xue J, Peprah MK, et al. A systematic review and network meta-analysis comparing the use of Foley catheters, misoprostol, and dinoprostone for cervical ripening in the induction of labour. *BJOG* 2016; 123 (3): 346-54.
4. Levine LD. Cervical ripening: Why we do what we do. *Semin Perinatol* 2020; 44 (2): 151216.
5. Grobman WA, Rice MM, Reddy UM, et al; Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal–Fetal Medicine Units Network. Labor induction versus expectant management in low-risk nulliparous women. *N Engl J Med* 2018; 379 (6): 513-23.
6. Migliorelli F, De Oliveira SS, Martínez de Tejada B. The ARRIVE Trial: Towards a universal recommendation of induction of labour at 39 weeks? *Eur J Obstet Gynecol Reprod Biol* 2020; 244: 192-5.
7. Society of Maternal-Fetal (SMFM) Publications Committee. Electronic address: pubs@smfm.org. SMFM Statement on Elective Induction of Labor in Low-Risk Nulliparous Women at Term: the ARRIVE Trial. *Am J Obstet Gynecol* 2019; 221 (1): B2-B4.
8. Macrosomia: ACOG Practice Bulletin, Number 216. *Obstet Gynecol* 2020; 135 (1): e18-e35.
9. Beta J, Khan N, Khalil A, Fiolna M, Ramadan G, Akolekar R. Maternal and neonatal complications of fetal macrosomia: systematic review and meta-analysis. *Ultrasound Obstet Gynecol* 2019; 54 (3): 308-18.
10. Salihu HM, Dongarwar D, King LM, Yusuf KK, Ibrahimi S, Salinas-Miranda AA. Trends in the incidence of fetal macrosomia and its phenotypes in the United States, 1971-2017. *Arch Gynecol Obstet* 2020; 301 (2): 415-26.
11. Magro-Malosso ER, Saccone G, Chen M, Navathe R, Di Tommaso M, Berghella V. Induction of labour for suspected macrosomia at term in non-diabetic women: a systematic review and meta-analysis of randomized controlled trials. *BJOG* 2017; 124 (3): 414-21.
12. Vitner D, Bleicher I, Kadour-Peero E, et al. Induction of labor versus expectant management among women with macrosomic neonates: a retrospective study. *J Matern Fetal Neonatal Med* 2020; 33 (11): 1831-9.
13. Boulvain M, Irion O, Dowswell T, Thornton JG. Induction of labour at or near term for suspected fetal macrosomia. *Cochrane Database Syst Rev* 2016; 2016 (5): CD000938.
14. Du YM, Zhu LY, Cui LN, Jin BH, Ou JL. Double-balloon catheter versus prostaglandin E2 for cervical ripening and labour induction: a systematic review and meta-analysis of randomised controlled trials. *BJOG* 2017; 124 (6): 891-9.
15. Diguisto C, Le Gouge A, Arthuis C, et al; Groupe de Recherche en Obstétrique et Gynécologie (GROG). Cervical ripening in prolonged pregnancies by silicone double balloon catheter versus vaginal dinoprostone slow release system: The MAGPOP randomised controlled trial. *PLoS Med* 2021; 18 (2): e1003448.
16. Zhao G, Song G, Liu J. Safety and efficacy of double-balloon catheter for cervical ripening: a Bayesian network meta-analysis of randomized controlled trials. *BMC Pregnancy Childbirth* 2022; 22 (1): 688.
17. de Vaan MD, Ten Eikelder ML, Jozwiak M, et al. Mechanical methods for induction of labour. *Cochrane Database Syst Rev* 2023; 3 (3): CD001233.
18. Liu YR, Pu CX, Wang XY, Wang XY. Double-balloon catheter versus dinoprostone insert for labour induction: a meta-analysis. *Arch Gynecol Obstet* 2019; 299 (1): 7-12.
19. Ashwal E, Melamed N, Hiersch L, Wiznitzer A, Yogev Y, Peled Y. The incidence and risk factors for retained placenta after vaginal delivery-a single center experience. *J Matern Fetal Neonatal Med* 2014; 27 (18): 1897-900.
20. Favilli A, Tosto V, Ceccobelli M, et al. Risk factors for non-adherent retained placenta after vaginal delivery: a systematic review. *BMC Pregnancy Childbirth* 2021; 21 (1): 268.