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Labor induction outcomes with vaginal misoprostol in high-risk pregnancies at a tertiary center in the metropolitan region of Rio de Janeiro, Brazil

Výsledky indukce porodu vaginálním misoprostolem u vysoce rizikových těhotenství v terciárním centru v metropolitní oblasti města Rio de Janeiro v Brazílii

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Summary: Objective: To analyze the main indications for induction of labor with vaginal misoprostol in high-risk pregnancies as well as the main variables associated with failed induction in a tertiary center in the metropolitan region of Rio de Janeiro, Brazil. **Methods:** A retrospective cohort study analyzed the medical records of pregnant women who underwent induction of labor. Inclusion criteria were singleton pregnancy, gestational age ≥ 34 weeks, Bishop score ≤ 6, fetuses in cephalic presentation, and no contraindications for the use of vaginal misoprostol. The labor induction protocol consisted of vaginal misoprostol 25 mcg every 6 hours, with a maximum of eight doses (200 mcg) to ripen the cervix if Bishop's score was ≤ 6. **Results:** A total of 88 cases of labor induction were analyzed. Main indications for labor induction were preeclampsia and gestational hypertension (N = 28; 31.8%), chronic arterial hypertension (N = 19; 21.6%), and gestational diabetes mellitus (N = 12; 13.6%). We observed that vaginal delivery was associated with the number of vaginal misoprostol doses (P = 0.000348). The most common indications for cesarean section were failure of labor induction (N = 21; 40%) and suspected acute fetal distress (N = 17; 33%). We did not observe a statistical difference between indication of labor induction and mode of delivery. There were no fetal deaths. Six neonates were admitted to the neonatal intensive care unit (NICU), one for respiratory distress, one for preterm delivery, and four for hypoglycemia. There was no statistical difference in the rate of NICU admission between delivery modes (P = 0.692). **Conclusion:** The main indication for cesarean section in this study was induction failure, indicating the need to review and continuously monitor the protocol to increase success rates without compromising perinatal outcomes.

Key words: induction of labor – high-risk pregnancies – cesarean section – perinatal outcomes

Introduction

Labor induction is the process of artificially stimulating the uterus to induce labor. It is recommended when the benefits of labor may outweigh the perinatal risks [1]. Studies have been conducted on induction of labor over the past 20 years. The use of this procedure has increased worldwide in recent decades, especially in developed countries [1]. There are issues that make it difficult to compare results, such as heterogeneity in inclusion criteria, gestational age, and types of induction methods used. What most of these studies have in common was that they were conducted in normal-risk pregnancies at term [2].

A review of 34 randomized clinical trials involving more than 21,500 participants compared induction of labor at 41 weeks' gestation and expectant management for spontaneous onset of labor. Most pregnancies were low-risk and

Souhrn: **Cíl:** Cílem je nalyzovat hlavní indikace pro indukci porodu vaginálním misoprostolem u vysoce rizikových těhotenství, a také hlavní proměnné související se selháním indukce v terciárním centru v metropolitní oblasti města Rio de Janeiro v Brazílii. **Metodika:** Retrospektivní kohortová studie analyzovala lékařské záznamy těhotných žen, které podstoupily indukci porodu. Kritéria pro zařazení byla jednočetné těhotenství, gestační věk ≥ 34 týdnů, Bishopovo skóre ≤ 6, plody v cefalické prezentaci a žádné kontraindikace pro použití vaginálního misoprostolu. Protokol indukce porodu sestával z vaginálního misoprostolu 25 mcg každých 6 hod, s maximálně osmi dávkami (200 mcg) k dozrání děložního čípku, pokud bylo Bishopovo skóre ≤ 6. **Výsledky:** Celkem bylo analyzováno 88 případů indukce porodu. Hlavními indikacemi pro indukci porodu byly preeklampsie a gestační hypertenze (n = 28; 31,8 %), chronická arteriální hypertenze (n = 19; 21,6 %) a gestační diabetes mellitus (n = 12; 13,6 %). Pozorovali jsme, že vaginální porod byl spojen s počtem dávek vaginálního misoprostolu (p = 0,000348). Nejčastější indikací k císařskému řezu bylo selhání indukce porodu (n = 21; 40 %) a podezření na akutní tíseň plodu (n = 17; 33 %). Statistický rozdíl mezi indikací vyvolání porodu a způsobem porodu jsme nezaznamenali. Nedošlo k žádnému úmrtí plodu. Šest novorozenců bylo přijato na neonatální jednotku intenzivní péče (NICU), jeden pro dechovou tíseň, jeden pro předčasný porod a čtyři pro hypoglykemii. Mezi jednotlivými způsoby porodu nebyl statistický rozdíl v míře přijetí na NICU (p = 0,692). **Závěr:** Hlavní indikací pro císařský řez v této studii bylo selhání indukce, což ukazuje na nutnost revize a průběžné sledování protokolu pro zvýšení úspěšnosti bez ohrožení perinatálních výsledků.

Klíčová slova: indukce porodu – riziková těhotenství – císařský řez – perinatální výsledky

induced labor was associated with a reduced risk of cesarean section and perinatal death [3]. A study of 6,106 low-risk nulliparous women treated in 41 hospitals concluded that elective induction of labor at 39 weeks did not result in a higher incidence of adverse perinatal outcomes than expectant management. The incidence of cesarean section was lower in the induction group than in the expectant management group [4].

One issue to consider is the increased number of high-risk pregnancies. The prevalence of pre-eclampsia and eclampsia reported in a systematic review was 4.6 and 1.4% [5]. In a five-center study to predict pre-eclampsia in low-risk singleton pregnancies, the incidence of pre-eclampsia was 7.5% [6]. In a Brazilian study of 873 participants, the most common recommendations for labor induction were hypertension (37.5%), premature rupture of ovular membranes (23%), gestational age ≥ 41 weeks (18.3%), and diabetes mellitus (12.6%) [7].

Labor induction is not a risk-free procedure. There is no consensus on the best method of induction. Given the paucity of data on the most appropriate regimens for high-risk pregnancies, protocols used in low-risk pregnancies are generally extrapolated and applied to a wide range of clinical conditions [2].

The primary objective of this study was to analyze the main indications for cesarean section in high-risk pregnancies undergoing the protocol of labor induction with a pharmacological method (vaginal misoprostol). The secondary objective was to analyze the variables associated with cesarean section in cases of failed induction.

Methods

This was an observational and retrospective study that analyzed the medical records of participants who used vaginal misoprostol during their hospitalization at the Antonio Pedro University Hospital, Niterói, metropolitan region of Rio de Janeiro, Brazil, between January 1, 2021 and December 31, 2021. This study was approval by the Ethics Committee of Fluminense Federal University (CAAE No. 58047722.3.0000.5243) on June 12, 2023. The defining conditions of high-risk pregnancies were related to reproductive history (such as prematurity, fetal growth restriction, fetal death), clinical conditions prior to pregnancy (chronic arterial hypertension, diabetes mellitus, heart disease, kidney disease, cancer, etc.), and complications in the current pregnancy (such as hypertensive disorders, gestational diabetes mellitus, fetal growth restriction, placenta previa, etc.).

The data were analyzed in three groups according to maternal and fetal conditions at the time of hospitalization: low-risk pregnancies, pregnancies complicated by pregnancy-related conditions, and pregnancies with maternal clinical complications.

Inclusion criteria were: pregnant women with an indication for induction of labor, singleton pregnancy, gestational age ≥ 34 weeks, Bishop score ≤ 6, fetuses in cephalic presentation, and no contraindications for the use of vaginal misoprostol. Medical records without data on vaginal examination upon admission, pregnant women in the active phase of labor upon admission, placenta previa, vasa previa, severe placental insufficiency, active genital herpes, other contraindications to vaginal delivery and to the use of vaginal misoprostol (previous cesarean section, previous uterine surgery, cerebral vascular disease, coronary disease, and hypersensitivity to any of the components of misoprostol) were excluded.

Data collected from the medical records were: age, gestational age (calculated from the date of the last menstrual period and/or ultrasound examination until 20 weeks of gestation), parity, indication for labor induction, Bishop's score at admission, number of doses of misoprostol administered, time between first dose and onset of uterine activity, time between first dose and delivery, mode of delivery, indication for cesarean section, Apgar score at the 5th min, and

admission to the neonatal intensive care unit (NICU).

The labor induction protocol consisted of vaginal application of misoprostol 25 mcg every 6 hours, with a maximum of eight doses (200 mcg) to ripen the cervix if Bishop's score was ≤ 6. Prior to induction, all participants were assessed for fetal well-being by basal cardiotocography and Obstetric Doppler ultrasound. Cervical effacement failure was defined as the persistence of a Bishop score ≤ 6 after one cycle of treatment [8]. Failure of labor induction was defined as failure to reach the active phase of labor (two to four uterine contractions lasting 45 s every 10 min, cervical effacement of at least 80%, and progressive cervical dilation of 5 cm). Failure of induction was defined as at least 15 hours of oxytocin and rupture of the ovular membranes, either spontaneously or by amniotomy [9].

Dystocia due to lack of progression of labor was defined when, after the onset of the active phase of labor, there was no progression to the second stage after 12 hours of active labor in primiparous women and 10 hours in multiparous women. Tachysystole was defined as the occurrence of more than five contractions every 10 min for at least 20 min. Hypertonia was defined as a contraction lasting at least 2 min.

Suspicion of impaired intrapartum fetal well-being was defined by changes in cardiotocographic recordings: reduced or higher than expected heart rate, reduced variability, absence of accelerations and presence of late or prolonged decelerations [10]. Successful induction was defined as achieving vaginal delivery after the induction procedure.

Data were compiled in an Excel 2010 spreadsheet (Microsoft Corp., Redmond, WA, USA) and analyzed using the R program, version 3.6.1 (www.r-project.org). The Chi-squared or Fisher's exact test was used to assess the association between delivery mode and categorical variables, depending on the frequencies observed; in the case of numerical variables, their differences between the two delivery modes were assessed using the Mann-Whitney test. P-values < 0.05 were considered statistically significant.

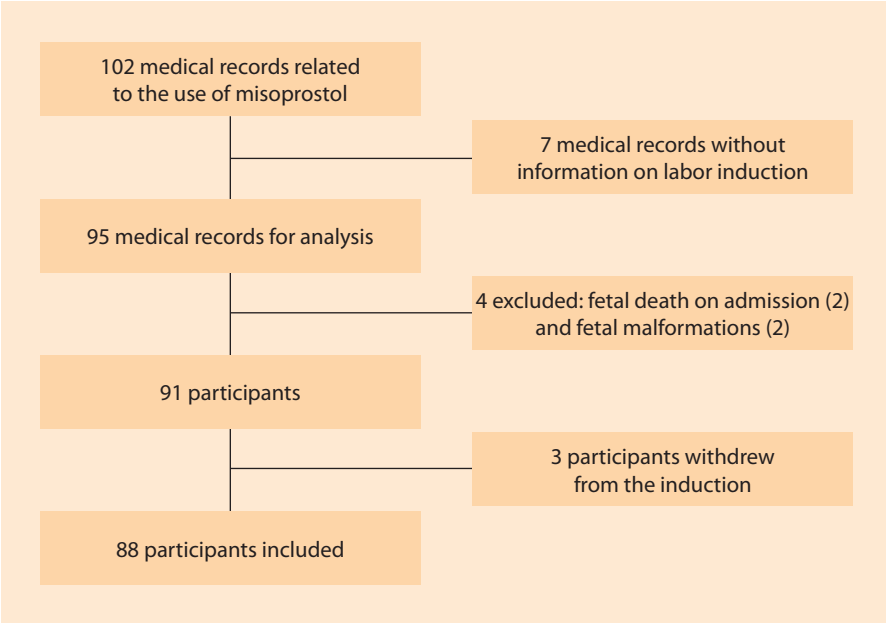

Fig. 1. Flowchart of the included participants.
Obr. 1. Vývojový diagram zahrnutých účastníků.

Results

The service provided a list of 102 medical records related to the use of vaginal misoprostol at a dose of 25 mcg. Seven medical records with no information on induction of labor were excluded. Seven participants were excluded from the final analysis: two cases of fetal death prior to induction (as it would not be possible to analyze the primary objective); two cases whose fetuses had multiple structural malformations (which alters the progression of labor); and of the participants who began labor induction, three (3.2%) gave up and underwent cesarean section. A total of 88 cases of labor induction were analyzed (Fig. 1).

Typical pregnancy complications were preeclampsia and gestational hypertension (N = 28; 31.8%), gestational diabetes mellitus (N = 12; 13.6%), premature rupture of ovular membranes (N = 8; 9.0%), fetal growth restriction (N = 6; 6.8%), and oligohydramnios (N = 3; 3.4%). Maternal clinical complications were chronic arterial hypertension (N = 19; 21.6%) and type 1 and 2 diabetes mellitus, either alone or in association with arterial hypertension and fetal growth restriction (N = 9; 10.2%). Other complications included sickle cell anemia and ulcerative colitis.

The characteristics of the participants before induction of labor are detailed in Tab. 1. All participants had an unfavorable cervix (Bishop's score ≤ 6) upon enrollment. Tab. 2 provides information about the labor induction procedure: number of doses of vaginal misoprostol, time from first dose to onset of regular uterine activity, and time from first dose of vaginal misoprostol to delivery.

Tab. 3 shows the comparison between maternal characteristics and mode of delivery after the labor induction procedure. We observed that vaginal delivery was associated with the number of vaginal misoprostol doses (P = 0.000348).

The most common indication for cesarean section was failure of labor

Tab. 1. Characteristics of the participants before induction of labor.
Tab. 1. Charakteristika účastnic před indukcí porodu.

Characteristics	Median	Interquartile range (25^{th}–75^{th})
Maternal age (years)	27.5	24–32
Number of pregnancies	2	1–3
Number of previous deliveries	0	0–1
Gestational age		
(weeks + days)	38+4	37+6 to 39+3
Bishop score	3	2–4

Tab. 2. Number of doses of vaginal misoprostol, time between the first dose and the beginning of uterine activity, time between the first dose and delivery.
Tab. 2. Počet dávek vaginálního misoprostolu, doba mezi první dávkou a začátkem děložní činnosti, doba mezi první dávkou a porodem.

Characteristics	Median	Interquartile range (25^{th}–75^{th})
Number of vaginal misoprostol doses	3	2–6
Time between the first dose and the beginning of uterine activity (hours)	12	10–24
Time between first dose and delivery (hours)	20	12.75–28.00
Apgar score at the 5^{th} minute	9	8–9

induction (N = 21; 40%). Suspected of acute fetal distress was the second most common indication (N = 17; 33%). Other indications were: arrest of progression, difficult-to-control hypertension, uterine dyskinesia, anomalous presentation, and difficult-to-control hyperglycemia (N = 14; 27%).

Tab. 4 correlates the indications for labor induction with the mode of delivery. We did not observe a statistical difference between indication of labor induction and mode of delivery.

There were no fetal deaths. Six neonates were admitted to the NICU, one for respiratory distress, one for preterm delivery, and four for hypoglycemia. There was no statistical difference in the rate of NICU admission between delivery modes (P = 0.692).

Discussion

Labor induction in this study resulted in 41% of vaginal deliveries and 59% of cesarean sections. The main indications for cesarean section were failed induction and suspected fetal acute distress. Among the variables analyzed, the only one that showed a statistical difference for successful labor induction was the number of doses of vaginal misoprostol (median 2.5 doses in vaginal deliveries and 5 doses in cesarean sections).

The protocol used in this study to induce labor with 25 mcg of vaginal misoprostol every 6 hours is one of the options recommended by the World Health Organization (WHO) [11]. Misoprostol is a synthetic prostaglandin that mimics the changes in the cervix that precede spontaneous labor (activation of collagenase, remodeling of the extracellular matrix) stimulating uterine contractions [12].

A retrospective Brazilian study of induction of labor with misoprostol in 412 pregnancies at 40 weeks and premature rupture of ovular membranes at > 34 weeks of gestation recorded 69% of vaginal deliveries. The main indications for cesarean section were failure of induction (10.9%), fetal bradycardia (10.7%), and arrest of progression (7.8%). In 83% of cases, the time from labor induction to delivery was less than 30 hours. The statistically significant factors predicting successful labor induction were Bishop's score four and five and previous vaginal delivery [13]. Another retrospective Brazilian study analyzed the variables that influence the success rate of induction of labor with vaginal misoprostol. Of the 873 participants, 40.8% were low-risk, 36.3% had hypertensive disorder, and 14.6% had diabetes mellitus. The non-operative vaginal delivery rate was 72%. The main indications for cesarean section were acute fetal distress (34.85%) and failed induction (19.09%). Upon admission, maternal age < 24 years, previous vaginal delivery, advanced gestational age, and greater cervical dilatation were associated with a higher likelihood of non-operative vaginal delivery. During hospitalization, this outcome was associated with fewer vaginal examinations, amniotomy or premature rupture of ovular membranes with clear fluid, and shorter induction times [7].

In a US study comparing expectant management with induction of labor at 39 weeks in low-risk pregnancies, the rate of vaginal delivery was even higher, at 81.4% [4]. A meta-analysis of randomized clinical trials comparing misoprostol with dinoprostone (synthetic prostaglandin E2) for induction of labor at 37 weeks found 65.1% of vaginal deliveries within 24 hours in the misoprostol group [12]. Several factors may have contributed to the lower rate of vaginal deliveries in this study than reported in the literature such as: gestational age at admission < 39 weeks, Bishop's score < 4, occurrence of maternal and/or fetal morbidity, and method of labor induction used.

In a prospective multicenter study of induction of labor with vaginal prostaglandins, the time to the onset

of active labor was significantly longer in diabetic women, and 32% of pregnancies ended in cesarean section. The mechanism by which labor was prolonged is unknown. Factors such as changes in uterine contractility and the effect of arachidonic acid on the cervix have been suggested [14]. In a study comparing the outcomes of labor induction with dinoprostone and cervical balloon in pregnant women with fetal growth restriction, the overall rate of vaginal delivery was 62.3% and 84.5%, resp. The rate of vaginal delivery within 24 hours of induction was 50.6% in the dinoprostone group and 74.6% in the cervical balloon group [15]. A study comparing adverse outcomes of labor induction with and without the use of prostaglandins in pregnant women with fetal growth restriction showed that the overall rate of cesarean section was higher in the group of participants who used prostaglandins [16].

The limitations of this study are that it is a retrospective study and it was not possible to obtain information on the body mass index (BMI) of the participants. Although these data were not available, it was observed that a large proportion of patients using our service had a BMI above 30 kg/m^2. A systematic review and meta-analysis examined the influence of maternal obesity on the process of labor induction. Pregnant women with obesity had longer induction times, used higher doses of prostaglandins, and had cesarean section rates almost twice as high as pregnant women with a normal BMI [17].

Considering that our service is a regional reference for high-risk pregnancies, the maternal and fetal conditions requiring induction of labor at a gestational age < 39 weeks, as well as an unfavorable cervix at admission, still persist. The fact that only three participants (3.2%) abandoned induction suggests a good acceptance of the vaginal delivery proposal by service users. Ways to improve the success of induction include revising the protocol and expanding the methods used to induce labor. Depending on the profile of our patients, the dose of misoprostol used may need to be adjusted. The American College of Obstetrics and Gynecology (ACOG) recommends the use of vaginal misoprostol for labor induction at doses ranging from 25 mcg to 50 mcg. A randomized clinical trial is underway to determine whether the 50 mcg dose reduces the time to onset of labor in obese women compared with the standard 25 mcg dose [18]. Mechanical methods for induction of labor include transcervical balloon placement (or Foley catheter), hygroscopic dilators, and sweeping of the membranes. The WHO recommends the use of a balloon for induction of labor at term, as well as a balloon associated with

Tab. 3. Maternal characteristics and mode of delivery after labor induction procedure.
Tab. 3. Charakteristiky matky a způsob porodu po jeho indukci.

Maternal characteristics	Vaginal delivery	Cesarean section	P-value
Age (years)			
median	29	27	
interquartile range (25th–75th)	24–33	24–31.25	0.286
Number of pregnancies			
median	2	2	
interquartile range (25th–75th)	1–3	1–1.98	0.416
Number of previous deliveries			
median	1	0	
interquartile range (25th–75th)	0–2	0–1	0.131
Gestational age (weeks)			
median	38+5	38+2	
interquartile range (25th–75th)	38+1 to 39+3	37+3 to 39+2	0.085
Bishop score			
median	3	3	
interquartile range (25th–75th)	2–4	2–3	0.222
Number of vaginal misoprostol doses			
median	2.5	5	
interquartile range (25th–75th)	2–4	3–7.2	0.000348
Time between the first dose and the beginning of uterine activity (hours)			
median	12	12	
interquartile range (25th–75th)	8–19.5	12–24	0.380
Apgar score at the 5th minute			
median	9	9	
interquartile range (25th–75th)	8–9	8–9	0.700

Tab. 4. Indications for labor induction according to the mode of delivery.
Tab. 4. Indikace k indukci porodu podle jeho způsobu.

Indications for labor induction	Cesarean section	Vaginal delivery	P-value
	52	36	0.692
Post-term pregnancy	1 (1%)	0	
Pregnancy related conditions	33 (63%)	24 (67%)	
Maternal clinical conditions	18 (34%)	12 (33%)	

oxytocin, especially in situations where it is important to avoid uterine hyperstimulation or when there is a contraindication to the use of misoprostol [11].

A randomized clinical trial compared four labor induction protocols: misoprostol, Foley catheter, simultaneous misoprostol and Foley catheter, and simultaneous Foley catheter and oxytocin. The combination of methods resulted in a shorter time to delivery, with the misoprostol/Foley catheter combination recording the shortest time (13 hours). There was no difference in cesarean section rates or perinatal outcomes between the groups [19]. In this study, the variable associated with successful induction was the number of doses of misoprostol. One way to adjust the protocol would be to reduce the induction time with misoprostol from 48 to 24 hours. The use of 24-hour observation protocols has the potential to reduce the length of hospital stay in the event of induction failure.

Conclusion

In conclusion, there is currently no evidence to define the superiority of one method of labor induction over another. There is a lack of studies with different groups of pregnant women, such as those with hypertensive disorders, obese women, and fetal growth restriction. The main indication for cesarean section in this study was induction failure, indicating the need to review and continuously monitor the protocol to increase success rates without compromising perinatal outcomes.

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I v ekonomicky horších časech musí být připraven na **financování rozvoje medicínských technologií** a jejich dostupnosti – této výzvě aktuálně čelí všechny vyspělé země světa.

PharmDr. Jiří Samek,
odborný garant – ombudsman

Náš cíl

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- **osvětová činnost** v oblasti medicínských technologií a zdravotní, resp. zdravotně sociální politiky,
- organizace **kulatých stolů**, diskusních panelů, **vzdělávacích a osvětových akcí** v oblasti medicínských technologií a zdravotní, resp. zdravotně sociální politiky.

Činnost spolku Ombudsman zdravotní péče, z.s., **podporují zdravotní pojišťovny ČR**.

Připojte se svými náměty a potřebami i vy:

- na webových stránkách **www.ombudsmanzdravotnipece.cz**
- na e-mailové adrese **ombudsman@ombudsmanzdravotnipece.cz**

** Ombudsman dostupnosti zdravotní péče, z.s., není primárně založen k řešení konkrétních případů neposkytnutí adekvátní zdravotní péče a dalších otázek, které jsou v kompetenci pacientského ombudsmana, nemocničních ombudsmanů či obdobných institucí.*