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Misoprostol vaginal insert and Foley catheter in labour induction — single center retrospective observational study of obstetrical outcome

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ABSTRACT

Objectives: Induction of labour is one of the most common procedures used in obstetrics and its prevalence tends to increase. In patients with an unripe cervix (Bishop score < 7) pre-induction procedures are used before the start of oxytocin induction. Currently there is no consensus among scientific societies on the optimal way of pre-induction. We have conducted a single-centre retrospective observational study comparing obstetric induction results of patients after 37 weeks of gestation who were pre-induced with misoprostol vaginal insert (MVI) with 200 µg of misoprostol (Misodel — Ferring Pharmaceuticals Poland) or Foley catheter (20 F, 60 mL baloon).

Material and methods: We have reviewed the medical records of 503 patients (group A pre-induced MVI — 135 patients, group B pre-induced Foley catheter — 368 patients) who were in a single, full-term pregnancy, pre-induced due to unripe cervixes (Bishop score < 7) with a Foley catheter or Misodel (MVI 200 µg). We compared obstetric results between groups.

Results: Group A patients had a lower chance of using oxytocin in labour induction/augmentation (OR = 0.21 95% CI = 0.13–0.32), and a greater chance of surgical delivery by caesarean section (OR = 2.14 95% CI = 1.42–3.23) and vacuum extraction (OR = 3.29 95% CI = 1.08–10.00). Group A patients also had a greater chance of abnormal CTG (OR = 2.66 95% CI = 1.5–4.7) compared to group B. The groups did not differ in terms of meconium stained amniotic fluid and postpartum haemorrhage. The percentage of children born with a pH from umbilical cord blood < 7.2 and < 7.1 and newborns of medium general condition (Apgar 4–7) did not differ between the groups.

Conclusions: Neonatological results of children from Foley catheters and MVI induced delivery do not differ. Patients pre-induced with MVI rarely require labour augmentation with oxytocin. MVI-preinduced patients have a better chance of having a delivery by CS or VE compared to the Foley catheter.

Key words: misoprostol; induction of labour; dinoproston; cervical ripening; Foley catheter

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INTRODUCTION

Induction of labour (IOL) is a procedure whose prevalence varies dramatically from country to country and may range from 1.4% to 35.5% [1]. In countries with high levels of economic development, it is used in about 1 in 5 pregnant women after the 37th week of pregnancy [2]. It is undoubtedly a procedure reducing the mortality and morbidity of newborns and pregnant women in the case of specific complications in pregnancy and should be used when, in the opinion of the clinician, the risk associated with waiting for spontaneus onset of labour is greater than the risks associated with shortening the duration of pregnancy by IOL. It seems to be generally accepted that for unripe cervix (usually defined by Bishop score < 7) cervical ripening (pre-induction of labour) is necessary. At present, there is no consensus among scientific societies in the world on the optimal method of IOL, and the differences in local recommendations mainly concern cervical ripening methods due to their diversity.

Objectives

Comparison of obstetric results of patients pre-induced with misoprostol vaginal insert which contains 200 µg of misoprostol slowly released 7 µg/hour for 24 hours (Misodel — Ferring Pharmaceuticals Poland) with patients in whom a Foley catheter was used to pre-induce labour. (20 F, 60 mL).

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MATERIAL AND METHODS

We reviewed the medical records of 503 patients who delivered in the Department of Gynecology and Obstetrics of the Provincial Hospital Complex in Kielce between 4.03.2017 and 21.07.2018. All labours were induced. Indications for labour induction were in accordance with the recommendations of the Polish Society of Gynaecologists and Obstetricians [3]. The study included patients with single, full-term pregnancy (completed 37 weeks of pregnancy) who had unripe cervixes (Bishop score < 7) at the time of the decision on labour induction. MVI 200 (misoprostol vaginal insert with 200 micrograms of misoprostol) — (group A — 135 patients) or Foley catheter (group B — 368 patients) 20 F thick with 60 mL of saline balloon filling were used for labour pre-induction. Patients were sent to the delivery room at the start of regular contraction and cervical dilation of 3–4 cm or 20–24 hours after pre-induction in the absence of the start of labour. Oxytocin was used for induction and labour stimulation in a low-dose protocol, at 4–6 cm dilation amniotomy was performed. The groups were compared for obstetric results: — Apgar scores in one minute, pH from venous cord blood — in quantitative terms, as well as the percentage of children born with pH < 7.2 and < 7.1.

Table 1. Characteristics of groups

	A (n = 135)	B (n = 368)	
age [years] (mean ± SD)	27.5 ± 4.15	28.37 ± 4.72	p = 0.43
pluripara	17.78%	20.92%	p = 0.48
gestational age (median, IQR)	40 (0.8)	40 (0.8)	p = 0.93
Membranes rapture before pre-induction	17.05%	0%	p < 0.01
epidural analgesia	15%	21%	p = 0.06

SD — standard deviation; IQR — interquartile range

We compared the percentage of meconium stained amniotic fluid (MSAF), surgical deliveries [vacuum extraction (VE) and cesarean section (CS)], postpartum haemorrhage (PPH), and the duration of stay in the delivery room. We performed the statistical analysis using Statistica 13.1 (StatSoft Poland). For continuous variables we presented the arithmetic mean when the distribution was close to normal and as a median for skewed distributions. Standard deviation and interquartile range were used as measures of scatter, respectively. We compared the groups when the assumptions of near-normal distribution and equal variance were met with the Student's t-test, and when the above-mentioned criteria were not met with the Kruskallis-Wallis U test. In case of qualitative variables, we presented the data as a percentage of events in a given group and the quotient of chances of group A vs. B (OR), and compared the groups using Pearson's $\chi 2$ test, and in case of small expected numbers we used Yates correction. The differences were considered statistically significant in case of $p < 0.05$.

RESULTS

The demographic characteristics of the groups were presented in Table 1.

The groups did not differ in terms of age, fertility, median gestational age and the percentage of patients who received epidural analgesia. The Foley catheter was not used for patients with pre-labour rapture of membranes (PROM). In group A, the percentage of patients with amniotic fluid drainage prior to MVI insertion was 17.05% (23 patients). The total percentage of CS was 32% and VE 2.5%.

The results of the comparison of groups A and B are presented in Table 2.

Among patients in group A compared to group B, oxytocin was used significantly less frequently in the stimulation or induction of labour [26% vs 62% (p < 0.001, OR = 0.21 95%

Table 2. Comparison of groups

	A (n = 135)	B (n = 368)	p	OR (95% CI)
oxitocin stimulation/induction	26%	62%	p < 0.001	0.21 (0.13–0.32)
time at delivery room [h] (median, IQR)	8.75 (7.83)	8.16 (5.58)	p = 0.13	N/A
cesarean section	45.19%	27.72%	p < 0.001	2.14 (1.42–3.23)
unreassuring fetal heart rate pattern	24.55%	10.88%	p < 0.001	2.66 (1.5–4.7)
arrested labour and failed induction	19.26%	13.59%	p = 0.11	1.51 (0.90–2.55)
vacuum extraction	5.19%	1.63%	p = 0.02	3.29 (1.08–10.00)
postpartum haemorrhage	2.22%	2.17%	p = 0.97	1.02 (0.26–3.19)
meconium stained amniotic fluid	12.59%	12.50%	p = 0.97	1.00(0.55–1.82)
pH (median, IQR)	7.358 (0.085)	7.374 (0.068)	p < 0.01	N/A
pH < 7.2	3.70%	2.17%	p = 0.33	1.73 (0.55–5.38)
pH < 7.1	0%	0%	N/A	N/A
Apgar 4–7 points	2.96%	1.63%	p = 0.34	1.83 (0.51–6.61)

CI = 0.13–0.32)]. Considering only the patients and groups A and B, whose labour ended in natural ways, the difference is similar (28.3% vs. 67.67%, p < 0.001, OR = 0.18 95% CI = 0.10–0.33). Patients pre-induced with MVI compared to the group pre-induced with Foley catheter had a significantly higher chance of completion of labour through CS (OR = 2.14 95% CI 1.42–3.23) as well as VE (OR = 3, 29.95% CI = 1.08–10), the most common indication for operative labour in group A was nonreassuring fetal heart rate tracing, which was statistically more frequent in comparison to group B (OR = 2.66 95% CI = 1.5–4.7). Among patients in group A and B who gave birth by nature the chance for VE was more than 5 times higher (9.46% vs 1.88%, p = 0.001, OR = 5.45 95% CI = 1.62–17.72). Groups A and B did not differ in terms of the most frequent indication for operative delivery, *i.e.* incorrect fetal CTG recording as well as frequency of MSAF and PPH. The median pH in group A was significantly lower, although both values were within the norm range (7.35 vs 7.37 p = 0.008), groups A and B did not differ in terms of the percentage of newborns born with pH < 7.2 and < 7.1. Patients in groups A and B did not differ in terms of the time they spent in the delivery room. In the whole study group, there were no newborns born in severe condition (defined as Apgar scores in 1 minute of life ≤ 3). Therefore, we compared groups in terms of the percentage of newborns born in general medium condition (Apgar 4–7 points in 1 minute), the groups did not differ significantly.

DISCUSSION

Although induction of labor (IOL) is one of the most common interventions in obstetrics, the proportion of patients who will undergo this procedure may increase significantly in the coming years. Post-term pregnancy is one of the most common indications for induction of labour. The practice of post-term induction differs between countries [4], but usually in low-risk pregnancies this procedure is not used until the 41st week of pregnancy. A multi-centre randomized study published in 2018 indicates that induction of a low-risk pregnancy at 39th week of pregnancy may reduce the percentage of caesarean sections, hypertension-related pregnancy complications, improve patient satisfaction and through the reduction of pain without compromising neonatal outcomes [5]. Following the results of the this ARRIVE study [5]. The Society for Maternal-Fetal Medicine concluded that it is reasonable to offer elective induction to low-risk nulliparous women who are ≥ 39 + 0 weeks of gestation [6]. In the year preceding the publication in the United States, delivery after the 41st week of gestation concerned about 7% of pregnancies, and between 40 and 41 weeks of gestation about 25% of pregnancies [7]. The implementation of the results of the ARRIVE study into clinical practice may result in a significant increase in the IOL percentage in the future, through additional qualification for induction of labour of approximately 30% of pregnant women. Additional factors like increasing population rate of obesity and age of procreation will also take their role in this process [8]. Due to the large scale of the problem, research is needed to optimize the entire process of IOL in terms of woman and child safety as well as cost-effectiveness. One of the pre-induction methods used in patients with an unripe cervix is MVI. It is a therapeutic system applied to the posterior vaginal vault releasing misoprostol (prostaglandin E1 analogue — PGE1) at a dose of about 7 µg per hour for a period of 24 hours (the total dose of misoprostol is 200 µg). The unquestionable advantage of the preparation is the ease of removal in the case of complications occurring during the application and the possibility of use at the outflow of amniotic fluid, moreover, the preparation is registered from the end of 36 weeks of pregnancy. MVI is removed from the vagina at the beginning of labour or at 4 cm cervical dilation, 30 minutes after the removal of the preparation, an infusion of oxytocin can be started. In the Phase 3 key study for product registration, the product was used in patients [9] in whom cervical maturity was assessed to be 4 or less on the Bishop scale. There are no studies in the literature that directly compare the efficacy and obstetric performance of Foley catheter-induced patients to MVI, but there are studies to evaluate other forms of misoprostol in IOL. The 2016 meta-analysis showed that vaginal use of misoprostol tablets (compared to Foley catheter, vaginal dinoprostone and oral misoprostol) is associated with the highest chance of vaginal delivery within 24 hours and the highest risk of uterine hyperstimulation and abnormal CTG recording [10]. The main advantage of MVI is its ease of removal in case of the above-mentioned complications. The risk of developing hyperstimulation in a patient pre-induced with MVI is about 13% and is one of the most common complications [9]. One of the studies [11] to analyze the use of MVI for pharmacoeconomic purposes used an indirect comparison of MVI with the Foley catheter for prenatal pre-induction in accordance with Bucher's method [12]. In the study cited, dinoprostone vaginal insert (DVI — 10 mg of dinoprostone in insert releasing 0.3 mg/h —Propess, Cervidil) was the common comparator. The median time needed to achieve active phase of labour with MVI was 44% lower than with Foley catheter (95% CI 33.5–54.3%), there were no differences in the percentage of patients who gave birth vaginally, percentage of CS , frequency of PPH, MSAF and chorioamnionitis. In the group of MVI pre-induced patients, less frequent prenatal oxytocin before delivery was used (RR = 0.5 95% CI 0.39–0.62). The risk of tachysystole was almost 40 times higher compared to the Foley catheter (RR = 39.91 95% CI = 5.02–317.5) [11]. In our cohort of patients, these correlations were similar, the chance of using oxytocin was about 5 times lower in the group of

patients who were pre-induced with MVI compared to those pre-induced with Foley catheter, this regularity applied both to patients who gave birth vaginally and to those who had a CS. The limitation of our study involves the lack of data about induction to delivery time (ID — time), it only includes the time the patient spent in the delivery room, which did not differ significantly. This value is less useful especially in the context of cost-effectiveness studies. The Expadite randomized study [9] comparing MVI with DVI revealed no differences in the percentage of caesarean sections between groups and the percentage of CS in the MVI group was 26%. However, observational studies in the Polish population indicate a higher percentage of CS. In one of the works in the Polish cohort of patients published by Jagielska et al. [13] the percentage of caesarean sections was 40.58% in the primagravida and 16.13% in the plurigravida group, and the overall percentage of caesarean sections in the group of patients induced by MVI was 33%, which is lower than in our cohort. However, in the study cited above [12], the proportion of plurigravidas to the primagravidas in the studied group (31/69 = 0.45) was higher, and in our studies it was lower (24/111 = 0.21), (p = 0.018). Numerous studies show that vaginal childbirth in the history is one of the strongest predictive factors of induction efficiency and occurs in most of the predictive models published in the literature [14, 15]. In our opinion, this proportion is crucial if we want to compare the percentage of caesarean sections between individual studies. This study demonstrates the high effectiveness of misoprostol in the form of MVI as the only method without the need to augment the delivery, however, the higher risk of surgical delivery compared to Foley catheter brings some concern. Clinical and biochemical condition of newborns did not differ significantly between groups. The question remains open whether this situation was influenced by the increased number of obstetric interventions (CS and VE) undertaken by supervising obstetricians. The limitation of the study is also related to the lack of division of patients according to the indications for induction of labour.

CONCLUSIONS

Neonatological results of children from births induced with Foley catheter and MVI 200 do not differ.

Patients pre-induced with MVI 200 less frequently require oxitocin augumentation of labor.

MVI 200 pre-induced patients have a greater chance of delivery by CS and VE compering to patients pre-induced with Foley catheter.

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