

Offering women a choice in induction of labour in case of an unfavorable cervix: a prospective cohort study

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Abstract

Objective: To evaluate women's choice in the method of labour induction between oral misoprostol, PGE2 pessary and the Foley catheter. To compare women's satisfaction according to their choice and to identify factors associated with patient satisfaction. **Design:** Prospective cohort study. **Setting:** Tertiary hospital in Toulouse, France, from July 2019 to October 2020. **Population:** All women admitted for labour induction at term, by either oral misoprostol, PGE2 pessary or Foley catheter. **Methods:** Women chose their preferred method. Before and after the delivery, they were asked to argument their choice and to evaluate their satisfaction through the use of questionnaires. **Main outcome measures:** Global level of satisfaction. **Results:** Of the 520 women included, 67,5% of women chose oral Misoprostol compared to 21% PGE2 pessary and 11.5% the Foley catheter. Regarding global satisfaction, we found no significant difference between the three groups: 78,4%, 68,8% and 71,2% (p=0,091) for respectively oral misoprostol, PGE2 pessary and Foley catheter. Factors that seem to improve women's satisfaction were nulliparity (OR = 2.03, 95%CI [1.19 - 3.53]), delivery within 24 hours after the start of induction (OR = 3.46, 95%CI. [2.02 - 6.14]) and adequate information (OR = 4.21,95%CI [1.86 - 9.64]). Factors associated with lower satisfaction rates were postpartum hemorrhage (OR = 0.51, 95%CI [0.30 - 0.88]) and caesarean section (OR = 0.31, 95%CI [0.17 - 0.54]). **Conclusion:** Women satisfaction rates were not different between the three methods, when chosen by the patients themselves. These finding should encourage caregivers to promote shared decision making when possible.

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Running title: Women's choice for labour induction

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Methods Women chose their preferred method. Before and after the delivery, they were asked to argument their choice and to evaluate their satisfaction through the use of questionnaires.

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Results Of the 520 women included, 67,5% of women chose oral Misoprostol compared to 21% PGE2 pessary and 11.5% the Foley catheter. Regarding global satisfaction, we found no significant difference between the three groups: 78,4%, 68,8% and 71,2% ($p=0,091$) for respectively oral misoprostol, PGE2 pessary and Foley catheter. Factors that seem to improve women's satisfaction were nulliparity (OR = 2.03, 95%CI [1.19 - 3.53]), delivery within 24 hours after the start of induction (OR = 3.46, 95%CI. [2.02 - 6.14]) and adequate information (OR = 4.21, 95%CI [1.86 - 9.64]). Factors associated with lower satisfaction rates were postpartum hemorrhage (OR = 0.51, 95%CI [0.30 - 0.88]) and caesarean section (OR = 0.31, 95%CI [0.17 - 0.54]).

Conclusion Women satisfaction rates were not different between the three methods, when chosen by the patients themselves. These finding should encourage caregivers to promote shared decision making when possible.

Tweetable abstract By offering women the choice about the method of labour induction, the level of satisfaction is similar for oral misoprostol, PGE2 pessary and Foley catheter.

Keywords

Induction of labour, satisfaction, choice, misoprostol, Foley catheter, intra vaginal prostaglandin E2, PGE2 pessary

INTRODUCTION

Several methods of labour induction have been described, including oral misoprostol, PGE2 pessary and Foley catheter. Nowadays, involving women in their own care appears essential, especially in obstetrical care such as labour induction.

The labour induction rate increased from 9.6% in 1990 to 27.1% in 2018 in the United States. This rate even rises to 37.8% in nulliparous women ^{1,2}. In England and Wales, induction of labour accounts for more than one in five deliveries, and this rate has been increasing over the past 20 years in high-income countries^{3,4}. More than 60% of the total number of labour inductions need cervical ripening ^{5,6}. Finally, the recent demonstration of a potential benefit of elective induction of labour at 39 weeks may increase this trend and underline the importance of asking about women satisfaction and their place in the decision about the method⁷.

Most of the published studies compare induction methods one by one. However, neither the PROBAAT II trial⁸ nor a large meta-analysis of 96 randomized controlled trials⁹, could find a significant difference in obstetrical or neonatal outcome between each method of cervical ripening. In a recent meta-analysis, Alfrevic et al. reported that none of the methods is superior to the others regarding perinatal outcomes³. Management of labour induction with cervical ripening is very heterogeneous and can even vary within maternity wards, according to national guidelines and local practices. Standardizing practices was one of the objectives of the French and English guidelines in 2008^{10,11}. Therefore, the identification of the best outcome is essential

since different outcome measures have been used such as delivery within 24 hours, caesarean rate and total duration of labour induction.

In modern obstetrics, it is essential to consider women's opinions and to involve them in medical decision making, as it is associated with higher satisfaction rates^{11, 12,13}.

Several studies discussed women satisfaction concerning delivery by comparing spontaneous labour to induction of labour. These studies showed that labour induction might be associated with lower satisfaction¹⁴. However, no study has ever evaluated women satisfaction regarding labour induction after offering women the choice of the method of cervical ripening.

Lastly, Coates et al emphasized the importance of shared decision-making between clinicians and women and stated that the physician should empower women to be involved in decision-making such as induction of labour¹⁵. Therefore we decided to engage women in the decision-making process of the choice of the method of cervical ripening in our tertiary center.

The objective of our study was to evaluate women's choice in the method of cervical ripening and to compare women satisfaction according to their choice.

MATERIALS AND METHODS

Study design and participants

This is a prospective cohort study carried out at the Paule de Viguier Hospital in Toulouse from July 2019 until October 2020. This hospital is a tertiary care center for neonatal care with 5200 newborns born each year.

The medical healthcare professionals implemented a new protocol in February 2019 in order to offer women the choice of the method of labour induction.

In order to optimize our patient care and to facilitate the women's choice, a booklet with information on the three different methods of labour induction was available in French and English, written in collaboration with patients, midwives and obstetricians. The booklet described the three different methods of cervical ripening and the most important steps of labour induction.

The protocol of labour induction offered three of the cervical ripening methods available in France: oral misoprostol, PGE2 pessary and balloon catheter. The supra cervical balloon corresponds to a Foley catheter. The balloon is inserted vaginally up until it reaches a supra cervical level and it is filled with 60ml of saline water. PGE2 pessary, prostaglandin E2, is a vaginal insert, and is placed in the vagina by a midwife. Misoprostol is an oral tablet of 25 micrograms taken every two hours as long as the patient is not in labour, up until a dose of 200 mcg (eight tablets) in total. Whatever the method chosen, after 24 hours of cervical ripening without labour, induction of labour by amniotomy and oxytocin was started in a delivery room.

The study period started four months after the implementation of the new labour induction protocol in order to allow the medical staff to become familiar with this new protocol. During the six months before the beginning of the study, we decided to evaluate women satisfaction about cervical ripening and labour induction without offering them the possibility to choose.

During the study period, we included all pregnant women admitted for labour induction with a singleton pregnancy at term (37 – 41 +6 weeks) requiring cervical ripening by either oral misoprostol or PGE2 pessary or Foley catheter.

Exclusion criteria were: any contra-indication to one of the three methods of labour induction, women under 18 years old and patients with no understanding of French or English language. For the use of Foley Catheter, rupture of membranes, coagulation disorder, HIV infection, Hepatitis B or C infection were the main contra-indications. PGE2 pessary contra-indications were intrauterine growth restriction (<3rd centile), history of caesarean delivery or multiparity (strictly more than three). Misoprostol specific contra-indications were severe hepatic or renal insufficiency or previous caesarean section. All participants were included after

obtaining written informed consent. Intra partum surveillance was similar for all patients and conform to local protocols.

Women's satisfaction was evaluated with the use of a questionnaire available in French and English. The questionnaires were based on the items in the Labour Agency Scale, an instrument measuring expectancies and experiences of personal control during childbirth¹⁶. In addition, we used the items studied to develop the CEQ (Childbirth Experience Questionnaire) and QACE (Questionnaire for Assessing the Childbirth Experience) questionnaires. The CEQ measures different aspects of maternal satisfaction with labour and birth¹⁷. The QACE questionnaire identifies women with a negative experience of childbirth¹⁸. Finally, we also included the items of the EXIT score, an instrument for assessing women's experience of induction of labour described by Beckman et al¹⁹.

The first part of the questionnaire was filled in the day of the decision of labour induction and evaluated the women's motivations for their choice (Table S1). We also evaluated their satisfaction about the given information on a five levels scale from 'not at all satisfied' to 'very satisfied'. Finally, we evaluated their satisfaction of being able to choose themselves and the anxiety generated by this choice.

The second part of the questionnaire was given 24 to 72 hours after the delivery and before discharge. This part of the questionnaire evaluated women's satisfaction related to labour induction, pain relief management and their feelings concerning duration of labour induction. Finally, patients were asked to decide which method they would choose for a potential new labour induction in a next pregnancy and if they would recommend the method of their choice.

Outcomes

Global satisfaction regarding the induction of labour was rated on a scale from one to four. Primary outcome was the global level of satisfaction treated as a binary variable: women were considered satisfied if they scored a three or more and unsatisfied if they scored a two or less¹⁶.

Secondary outcomes included satisfaction regarding quality of the given information, pain, duration of labour induction, the delivery itself and an evaluation of anxiety. The satisfaction regarding the quality of the given information, delivery and anxiety were rated on a scale from one to four or five and the variable were analyzed as for the primary outcome.

For the pain and duration of labour induction variables, there were three possible answers, it was less, more or as painful or longer than expected.

Statistical analysis

We compared the characteristics of women, pregnancies and deliveries using Chi-square test or Fisher exact tests for categorical variables and Analysis of variance (ANOVA) or Kruskal-wallis test for quantitative variables, as appropriate. Potential confounders, that might influence both the choice of method of induction and the satisfaction, were determined from previous literature and clinical knowledge. To assess the association between method of induction and satisfaction regarding induction of labour, while controlling for confounders, we used a multivariable logistic regression model. Confounders included in the regression model were: obesity, parity, history of labour induction and indication for labour induction.

Finally, to identify factors associated with global satisfaction, we performed a multivariable logistic regression with stepwise selection. Variables included in the initial regression model were: obesity, parity, history of labour induction, induction method, indication for labour induction, adequate information, satisfaction regarding pain management, assisted vaginal delivery, cesarean delivery, postpartum hemorrhage and delivery within 24 hours after the start of induction. Odds ratios were expressed with their 95% confidence interval. All tests were two-sided with p-values 0.05 defined as statistically significant. All analyses were performed using R STUDIO version 1.0.136.

The lack of data on women's choice of labour induction did not allow for sample size calculation. Based on the study of Ten Eikelder ML et al., we planned to include more than 500 women. In their study, 502

patients were included and the authors assessed experience and preferences among term women undergoing induction of labour with oral misoprostol or Foley catheter ²⁰.

The protocol was approved by the French ethics committee for research in obstetrics and gynaecology (CE-ROG, reference number 2019-OBS-0602).

RESULTS

During the study period, 1210 women underwent labour induction. 538 (42.9%) met the inclusion criteria and were included in our study. The final responsive rate was 96.7%, thus 520 women in total.

The main indications for labour induction were prolonged pregnancy (37,9%) gestational diabetes (26,0%) and maternal pathologies such as gestational cholestasis, diabetes or placental vascular diseases (18,8%). There was a very low rate of induction of labour on-demand at 39 weeks (1,15%).

Maternal characteristics are reported in Table 1. Maternal age, pre-pregnancy BMI, ethnicity, pre-existing and/or pregnancy comorbidity, gestational age at induction and initial Bishop score were comparable between groups. Regarding obstetrical outcomes, there was no difference between the three groups in terms of total duration of labour induction, rate of deliveries within 24 hours after the beginning of labour induction, delivery route or rate of instrumental deliveries.

In our population, 67.5% chose oral misoprostol versus 21% and 11,5% respectively for PGE2 pessary and Foley catheter. In the misoprostol group, for 73% of these women, the main argument for their choice was the oral administration compared to the other two options that are vaginal. 18.5% mentioned that taking the medication themselves gave them an active role in their labour induction. 21% of patients chose PGE2 pessary. They justified their choice in 51.4% of cases by the intravaginal administration. 22.9% argued that they had been advised by their entourage. Finally, 11,5 % of patients chose to be induced with a Foley catheter, 80% of which said to be attracted by the non-pharmacological character of this device.

Regarding our main outcome, we found no significant difference between the three groups with global satisfaction, rates being quite similar 78,4%, 68,8% and 71,2% ($p=0,091$) for oral misoprostol, PGE2 pessary and Foley catheter respectively (Table 2).

The global satisfaction of labour induction was 72,8%, compared to 36% in the period without offering women the choice of the cervical ripening method ($p<0.001$).

93.4% of the patients reported that the information they received about the several methods of labour induction was sufficient. 95,2% of the patients were satisfied with their final choice and only 3,65% of the women mentioned that having the choice increased their anxiety.

52,3% of the patients in the PGE2 pessary group mentioned that labour induction method was more painful than expected, vs 27.1% and 34.5% in the Foley catheter group and in the misoprostol group respectively ($p<0,001$). We found a significant difference in what method women would choose for a future labour induction: 56,7% of patients in the PGE2 pessary group would make the same choice compared to 77,7% and 72,4% in the misoprostol and the Foley catheter group ($p<0,001$). There was no significant difference in global satisfaction concerning delivery between the chosen method of induction. 97% of the patients felt their choices had been respected during labour induction without significant difference between the three groups.

Finally, we identified that nulliparity (OR = 2.03, 95%CI [1.19 - 3.53]), delivery within 24 hours after the start of induction (OR = 3.46, 95%CI. [2.02 - 6.14]) and adequate information (OR = 4.21,95%CI [1.86 - 9.64]) were significantly associated with greater satisfaction (Table 3).

Factors associated with lower satisfaction were the occurrence of postpartum hemorrhage (OR = 0.51, 95%CI [0.30 - 0.88]) and cesarean section (OR = 0.31, 95%CI [0.17 - 0.54]).

DISCUSSION

Main findings

To our knowledge, this is the first prospective study reporting the direct implication of women's choices in the decision of the method of cervical ripening for labour induction, by comparing three methods. Women were highly satisfied with to be consulted about their preference and to be involved in the labour induction process. However, there was no significant difference in satisfaction rates according to the chosen method. Taking into account the opinion of patients medical decision making is necessary, especially at a time as important as their delivery.

Strengths and limitations

Strengths of this study include the prospective design and the important sample size. The tight management of our study allowed us to have few patients lost to follow up. Finally, we think the innovative and unique character of this study is a real strength.

However, this study also has some limitations. First of all, there might exist a subjective bias due to absence of homogeneity in the way of counseling about the different types of labour induction. All the caregivers in our maternity had agreed to participate. However, we have an imperative in the protocol not to influence the choice of patients. This reflected in the fact that 96 % of patients reported that their choice was respected. Secondly, the monocentric character of the study does not allow for overall generalization of the results.

Although all patients were evaluated at the same interval after the delivery, the short period of time between the delivery and the evaluation of their choice (one-three days postpartum) can be a point of discussion.²¹ Finally, our study was not designed nor powered to compare obstetrical and neonatal outcomes.

Interpretation

Cervical ripening by oral misoprostol was most frequently chosen method (67,5%) which is in line with other studies reporting that oral administration is preferred over vaginal administration in the setting of miscarriage management^{22,23}. In Colon et al. study, 14% percent of women in the vaginal group versus 7.5% in the oral group were dissatisfied with the use of misoprostol²². Moreover, in our study, 18.5% of the included women preferred oral misoprostol because they felt to have an active role in their cervical ripening by taking tablets themselves.

PGE2 pessary is associated with more pain than expected and is the method the less frequently chosen for a next labour induction. In his study, Wang at al. compared Foley catheters to PGE2 pessary and he also found a lower pain score in favor of Foley catheter (4.87 +- 1.01 vs. 5.64 +- 1.03; $P < 0.001$)²⁴.

We found a satisfaction level slightly higher than reported in recent literature, for example in the study of Shetty²⁵, more than one third of patients stated not to be satisfied with the received information against only 7% in our study. Our results emphasize the importance of clear and precise information in the particular situation of labour induction. In our study, the high rate of satisfaction regarding the information received about labour induction is the result of a particular involvement of caregivers as well as the detailed booklet given to each patient. Patient associations were involved in writing the protocol and the information booklet, which may partly contribute to the high level of satisfaction. Similarly, Coates et al. highlights the causality between received information and patient satisfaction¹⁵. Finally, it is important to emphasize that anxiety about the choice of their method was increased in only 3,7% of patients.

Factors associated with patient satisfaction according to our study were concordant with previous studies^{14,26} : primiparity, delivery within 24 hours after start of labour induction and the quality of the received information.

Factors associated with a worse patient satisfaction are caesarian delivery (OR : 0,31 [0,17 – 0,54]) and the occurrence of postpartum hemorrhage [OR 1.3 (95% CI 1.1-1.6)] which is also in agreement with previous studies^{14,26}.

Improving the understanding of women's perceptions of their childbirth experience during the perinatal period has gained interest from researchers and health practitioners in obstetrics¹⁸. A positive experience can lead to a sense of accomplishment and feelings of self-worth and self-confidence. Nowadays, the involvement of women in their own care appears essential, especially considering obstetrical care such as labour induction. We believe it is essential to involve patients in their own care and in medical decision making. Although we had a simplified booklet, the information mode can be further improved, especially for patients with reading difficulties. A video or an illustrated folder might be created in order to better adapt the information to this population.

Also, one of the evolutions of integrating the women's choice in the final decision could be to allow outpatient labour induction in a low risk population as recently described^{27,28,29}. Helmig et al. reported that 72% of patients chose to have cervical ripening at home when possible³⁰. Kruit et al. reported a high rate of satisfaction of 85,3% in patients induced at home³¹.

CONCLUSION

To conclude, it is an innovative study that considers women's opinion about obstetrical management, a challenge in modern obstetrics^{32, 2}. By offering women the choice about the method of cervical ripening for labour induction, we observe an unequal repartition between the three groups with a majority of women choosing oral misoprostol. However, the level of satisfaction is similar between the three considered methods. These results should encourage obstetrical care givers to involve women in the different options of labour induction management.

Disclosure of interests

The authors declare to have no conflict of interest. Full disclosures of interests are available to view online as supporting information.

Contribution to authorship

All authors participated in the editing of this manuscript and approved the final version for publication. ND was involved in the conception and planning of the study, the acquisition and interpretation of data. LL was involved in the analysis and interpretation of the data and provided statistical advice. PLMD was involved in the interpretation of the data and the revision of the article. OP and CV participated in the interpretation of the results and made suggestions for revisions. PG conceived and designed the study, was involved in the analysis and interpretation of data, and the cowriting and critical revision of the article.

Details of ethical approval

The protocol was approved by the French ethics committee for research in obstetrics and gynaecology on 07/01/2019 (CEROG, reference number 2019-OBS-0602).

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Table 1: Maternal demographics and baseline characteristics

	FOLEY CATHETER	ORAL MISOPROSTOL	PGE2 PESSARY	p value
	N = 60 n (11,5%)	N = 351 n (67,5%)	N = 109 n (21%)	
Age (y)	32 [28.75 - 35]	31 [27 - 35]	31 [28 - 35]	0.69
BMI (kg/m2)	22 [20.75 - 25]	25 [20.75 - 25]	24[21 - 28]	0.10
Obesity	6 (10.0)	77 (21.9)	21 (19.3)	0.10
Ethnicity				0.47
Caucasian	46 (76.7)	230 (65.5)	81 (74.3)	
North African	10 (16.7)	84 (23.9)	16 (14.7)	
Subsaharian African	4 (6.7)	24(6.8)	9 (8.2)	

	FOLEY CATHETER	ORAL MISOPROSTOL	PGE2 PESSARY	p value
Asia	0	4 (1.1)	1 (0.9)	
Other	0	9 (2.6)	2 (1.8)	
Comorbidities				
Chronic hypertension	0	9 (2.6)	4 (3.7)	0.34
Pre-existing diabetes	0	14(4)	4(3,7)	0,58
Parity				0.77
Nulliparity	40 (66.7)	217 (61.8)	68 (62.4)	
Pregnancy complications				
Gestational hypertension	3 (5.0)	18 (5.1)	7 (6.4)	0.87
Preeclampsia	0	22 (6.3)	6 (5.5)	0.12
Gestational diabetes	15 (25.0)	114 (32.5)	25 (22.9)	0.11
GA at labour induction	39.7 [38.9 - 41.3]	39.4 [38.9 - 41]	39.4 [38.7 - 41.3]	0.61
Initial Bishop score	1 [0 - 3]	1 [0 - 3]	1 [0 - 3]	0.88
Duration of labour induction	36 [27 - 43.25]	28 [20.5 - 37]	31 [19 - 39]	0.09
Delivery within 24 hours	13 (21.7)	131 (37.3)	37 (34.3)	0.06
Mode of delivery				
Vaginal delivery	48 (80)	271 (77.2)	81 (75)	0.76
Instrumental delivery	5 (8.3)	51 (14.5)	18 (16.7)	0.32
Caesarean section	12 (20)	80 (22.8)	27 (25.0)	0.76

Data are shown as median [interquartile range] or number (%).

BMI, body mass index; GA, Gestational Age

	FOLEY CATHETER	ORAL MISO- PROSTOL	PGE2 PESSARY	Univariate analysis p value	Multivariate analysis * p value
	N = 60 n (11,5%)	N = 351 n (67,5%)	N = 109 n (21%)		
Primary outcome					
Global satisfaction	42 (71.2)	272 (78.4)	75 (68.8)	0.091	0.107
Secondary outcome					
Pain	16 (27.1)	120 (34.5)	57 (52.3)	<0,001	<0,001

	FOLEY CATHETER	ORAL MISO- PROSTOL	PGE2 PESSARY	Univariate analysis p value	Multivariate analysis * p value
Satisfaction of pain management	49 (83.1)	302 (86.8)	89 (81.7)	0.368	0.574
Perception of duration of induction	29 (49.2)	207 (59.3)	62 (56.9)	0.334	0.408
Vaginal exams				0.787	0.634
Too much	1 (1.7)	14 (4.0)	4 (36.7)		
Adapted	49 (83.1)	277 (79.6)	92 (84.4)		
Insufficient	9 (15.3)	57 (16.4)	13 (11.9)		
Same method for a future induction	42 (72.4)	265 (77.7)	60 (56.6)	<0,001	<0,001
Feeling of respect about their wishes	57 (96.6)	336 (97.1)	107 (98.2)	0.794	0.713
Recommended method for relatives	45 (76.3)	294 (85.5)	79 (73.1)	0.008	0.007
Satisfaction delivery	54 (91.5)	324 (93.6)	101 (92.7)	0.686	0.833

Table 2: **Primary and secondary outcomes**

Data are n (%) unless otherwise specified.

*multivariate analysis adjusted on history of labour induction, indication of labour induction, parity and obesity.

Table 3: **Variables associated with satisfaction**

	OR	95% CI
Method of labour induction		
Foley catheter	ref	
Oral misoprostol	1.32	[0.66 - 2.56]
PGE2 pessary	0.78	[0.36 - 1.64]
Indication of labour induction		
Term	ref	
Maternal pathology	1.04	[0.58 - 1.92]
Gestational diabetes or macrosomia	2.17	[1.20 - 4.02]
On-demand	1.16	[1.00 - 1.35]
Placental pathology	0.98	[0.52 - 1.89]
Nulliparity	2.03	[1.19 - 3.53]
Adequate information	4.21	[1.86 - 9.64]
Instrumental delivery	1.08	[0.53 - 2.32]

	OR	95% CI
Caesarean section	0.31	[0.17 - 0.54]
Delivery within 24 hours	3.46	[2.02 - 6.14]
Postpartum hemorrhage	0.51	[0.30 - 0.88]

OR, Odds ratio ; CI, Confidence interval