Title: Self-traction during mechanical cervical dilatation, acceptability, feasibility and satisfaction of its application: A pilot study

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Running title: Self-traction during mechanical cervical dilatation

Acknowledgements and disclosures

The research team would like to thank all the patients who agreed to take part in the project. We would also like to thank the members of the healthcare staff who contributed to the conduct of this study. Thanks to Audrey Marchand, Interim Chief of Perinatal Hospital Care, CISSSO, who facilitated the project in the care setting. Thanks to Sarah-Hannah O'Reilly, who contributed to data collection. The pedal-like self-traction device was developed by Diane Croteau and Valérie Bohémier. They were involved in drafting the study protocol and writing the article. However,

they were not involved in data analysis. Thanks to the Fondation Santé Gatineau for funding the project. This funding agency played no role in the development, implementation, data analysis, or publication of the project results. All authors have no conflicts of interest to declare.

Abstract

This study aims to measure acceptability, feasibility, and satisfaction with self-traction during mechanical cervical dilatation to induce labour and to explore its effects on pain and the process of labour and delivery. 60 parturients were randomly assigned to self-traction or regular traction. Participants completed questionnaires about sociodemographic characteristics, acceptability, and satisfaction. Self-traction participants reported significantly higher acceptability ($p = 0.026$), and adequacy ($p = 0.018$). They also reported satisfaction with the procedure. A group comparison regarding feasibility, pain, and the process of labour and delivery showed no significant difference. Self-traction is an acceptable and feasible intervention for full-term parturients.

Keywords: Acceptability, Balloon catheter, Feasibility, Labour induction, Maternal well-being, Mechanical cervical dilatation

Introduction

Induction of labour is common in Canada[1] and is indicated when the risks of continuing the pregnancy outweigh the benefits.[2,3] If cervical ripening is not naturally favourable, certain medical interventions, such as pharmaceutical agents or mechanical methods, can be implemented to induce ripening.[4] A recent meta-analysis concluded that mechanical balloon dilatation appears to be as effective and safer than pharmacological dilatation methods.[4]

Mechanical methods include the use of a single-balloon Foley catheter.[3,5] As mentioned in the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the World Health Organization (WHO) recommendations, gentle traction can be applied to promote cervical dilation.[3,5] However, using a balloon catheter for mechanical dilatation can cause pain and discomfort for the parturient when direct traction is applied to the cervix. However, this traction is essential to the dilatation process, as it has been shown that applying tension during mechanical catheter dilatation reduces catheter expulsion time by promoting cervical dilatation.[6]

The use of self-traction for mechanical dilatation to induce labour is an interesting way of enhancing the comfort of the applied traction. The traction exerted by the parturient herself can be adapted to her tolerance, allowing her to feel more comfortable and in control of the pace, enhancing her satisfaction. We found no evidence that self-traction devices have been previously studied. This research project aims to measure the acceptability, feasibility, and satisfaction of the parturient concerning the use of self-traction during mechanical cervical dilatation to induce labour and delivery, and to explore the effects of self-traction on pain, and the process of labour and delivery.

Methods

Design, participants and setting

A pilot randomized controlled trial was conducted. The sample size was 30 participants per group, considering it is a pilot project.[7] To take part in the study, parturients were required to be older than 18 years of age, to speak and read French or English, to be 37 weeks pregnant or more, and to have a Bishop score of less than 6. Parturients were excluded from the study if they had a history of two or more caesarean deliveries, a pharmacological method of cervical dilatation at the same time as mechanical dilatation, a double balloon installed for mechanical dilatation, a multiple pregnancy, a diagnosed in-utero death, or a contraindication to vaginal delivery.

Recruitment for the study took place in the perinatal unit at a Canadian hospital. When the attending physician determined the desired induction method was the mechanical dilatation device, and the participant met the inclusion criteria, a nurse would meet with her and explain the project.

Intervention

After consenting to participate in the research project, participants were assigned to the intervention group or the control group according to a randomization sequence (1:1) previously prepared by a research assistant not involved in the project. The randomization sequence was unknown to everyone involved in the study (numbered sealed envelopes) and was disclosed to each participant following recruitment.

Following the unit's current clinical practice, moreOB (Managing Obstetrical Risk Efficiently)[2] and SOGC guidelines,[3] a balloon catheter (16F) was inserted by the attending

physician for all participants, and it was then filled with 50 ml of sterile water. After balloon inflation, traction was applied according to group assignation.[2]

Participants in the intervention group were exposed to self-traction using a device designed as a pedal. This pedal was attached to the end of the catheter, allowing the parturient to put her foot in a loop to pull on the catheter. Immediately after the insertion of the balloon catheter, the parturient performed maximum traction according to her comfort level, for periods of 10 to 15 seconds at a time, at her own pace. The parturient repeated the exercise until the catheter was expulsed. Nurses received specific training and instructions to install the self-traction device and do the follow-up.

Participants assigned to the control group were exposed to mechanical cervical dilatation with regular traction, achieved by attaching the catheter to the parturient's thigh. Every 15 minutes, the nurse ensured that the traction was still in place by refastening the catheter to the parturient's thigh if necessary (tension in the catheter is reduced as the cervix dilates). This was the usual approach to care in the delivery room where the study took place.[2,3]

Data Collection and Measurement

In the postpartum period, 24 to 48 hours after delivery, participants completed online questionnaires including: a sociodemographic questionnaire, the Treatment Acceptability and Preferences Questionnaire (TAP),[8] and questions about satisfaction. The TAP questionnaire measures four attributes of acceptability (effectiveness, acceptability, convenience, and ease of adherence) on a 5-point scale. Two questions were added for this study (appreciation and adequacy). The original scale has adequate internal consistency ($\alpha > 0.80$)[8], as well as the modified version ($\alpha = 0.89$). A research assistant compiled delivery-related data by consulting

participants' medical records to assess the process of labour and delivery, the feasibility of the intervention (fidelity), parturient pain (visual analog scale), and other medical information.

Data Analysis

Descriptive statistics were conducted for all measured variables. In addition, exploratory statistical analyses (F-tests and chi-square tests) were performed to compare the two groups. Two-tailed significance of 0.05 was adopted for all the statistical tests.

Results

Sociodemographic characteristics

For this pilot project, 60 parturients were enrolled. See Figure 1 for details about the recruitment process. Most participants had a university level of education, worked full-time, and had a household income of (CAD) $50,000 or more. No significant differences were detected for potential confounding variables (multiparity -$p = 0.484$, maternal age - $p = 0.448$, BMI at delivery $p = 0.748$). The administration of oxytocin or epidural was not compared between the two groups as confounding variables since nearly all participants received both treatments during labour. See Table 1 for details about the sociodemographic characteristics.

Acceptability, feasibility, satisfaction and the process of labour and delivery

According to the results of the TAP questionnaire, a higher percentage of participants reported the self-traction as acceptable on all measured elements (effectiveness, acceptability, convenience, and ease of adherence). In addition, more participants reported being satisfied with self-traction, compared with participants assigned to regular traction. See Table 2 for participants' acceptability and satisfaction.

Parturients exposed to self-traction reported significantly higher acceptability and adequacy of the intervention, compared with parturients exposed to regular traction. A comparison of the two groups regarding the feasibility of the intervention (fidelity) shows no significant difference between the groups. In addition, a comparison of the two groups regarding satisfaction with the traction mode applied and the support received from healthcare providers during the traction process reveals no significant difference between the groups. See Table 2 for detailed results. Concerning the process of labour and delivery, there were no significant differences between the two groups in terms of infant well-being (arterial cord pH, APGAR), maternal well-being (postpartum haemorrhage), type of delivery, use of prostaglandins, or duration of traction. See Table 3 for detailed results.

Discussion

This pilot study is innovative because it is the first, to our knowledge, to report the results of the application of self-traction as a method of mechanical cervical dilatation. Participants exposed to self-traction reported that the intervention was appreciated, appropriate, adequate, acceptable, effective, and one they would recommend. In addition, they were satisfied with the intervention and support of the healthcare staff during self-traction. These results are similar to those discussed in a study by Beckmann et al.,[9] which reported that patients appreciated and recommended mechanical balloon catheter dilatation of the cervix. The results of the qualitative study by Coates et al.[10] also support the findings of the present study. The participants mentioned that they appreciated having control over the cervical dilatation process and preferred dilatation with a balloon catheter. In addition, maternal and infant well-being were comparable for both groups, indicating that self-traction as a mechanical dilatation process was just as safe as regular traction for participants in this study. Regular traction is known to be a safe mechanical dilatation

process for mother and baby, as it does not lead to more complications than mechanical dilatation without traction.[9]

Several limitations should be considered when interpreting the results of this study. First, the sample size is small, which may have influenced the results of the statistical tests performed. It is possible that a larger sample would have produced different results. However, the sample size is appropriate for providing information on the acceptability and feasibility of the intervention,[7] which is the primary aim of the study. Future studies should include a larger number of participants and conduct a randomized clinical trial to provide more information concerning the effects of self-traction on the process of labour and delivery (i.e. Time between balloon insertion and balloon fall, delay between balloon insertion and delivery).

Conclusion

In conclusion, self-traction is an acceptable and feasible mechanical cervical dilatation procedure for parturients with full-term pregnancies. By giving patients control over the traction process, this intervention has the potential to improve their experience with cervical dilatation with a balloon catheter. The results of this pilot study support the conduct of a larger randomized clinical trial.

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Figure Legends

Figure 1: Recruitment process

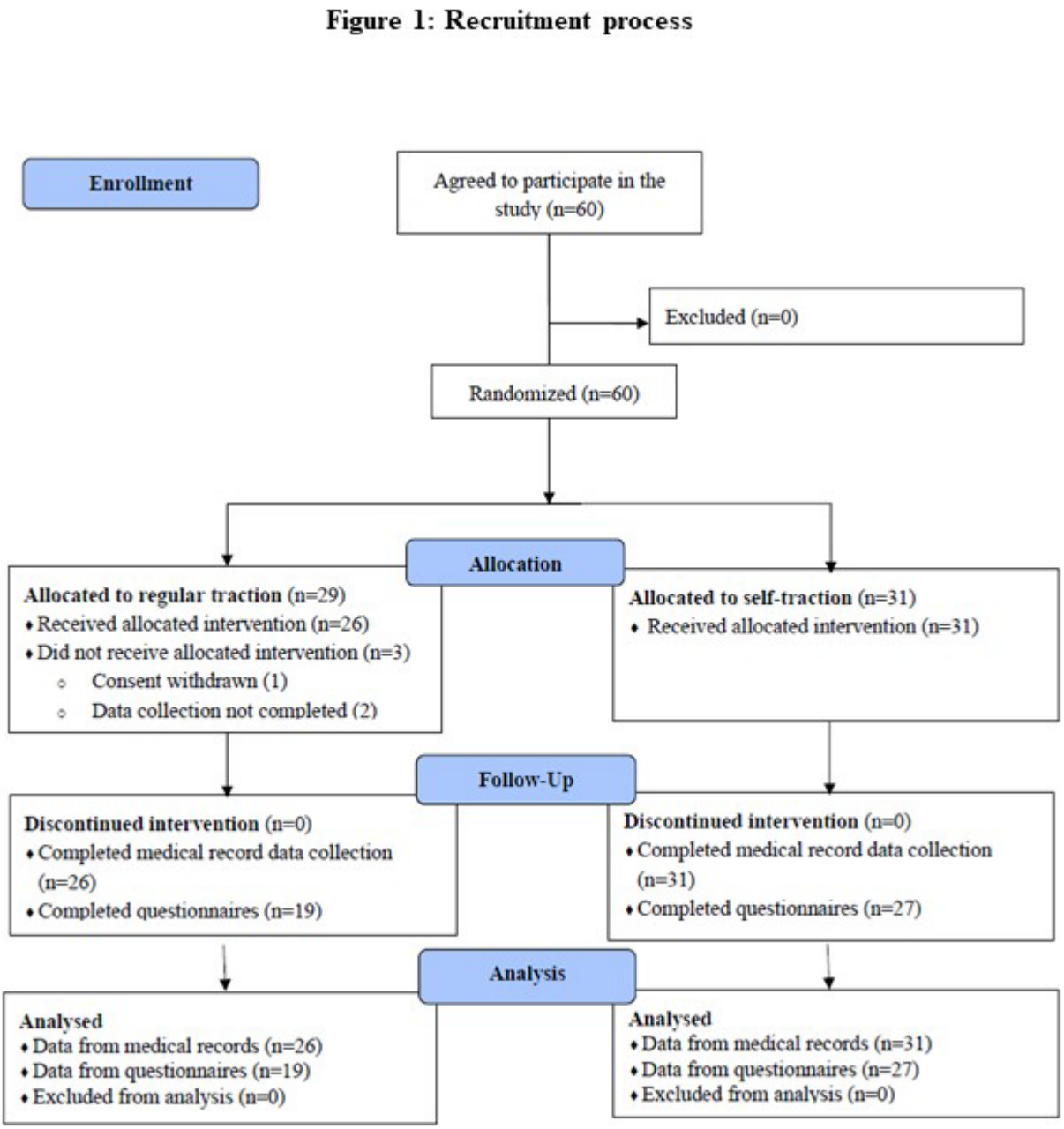

Table 1. Sociodemographic characteristics of participants

	Self-traction group N(%)	Control group N(%)
Education		
High school	6 (22.2%)	2 (10.5%)
Professional degree	2 (7.4%)	0
College	3 (11.1%)	5 (26.3%)
University	16 (59.3%)	12 (63.2%)
Work status		
Full-time	20 (74.1%)	16 (88.9%)
Household income		
Less than $50,000	4 (16.0%)	3 (17.6%)
Between $50,000–$100,000	9 (36.0%)	5 (29.4%)
More than $100,000	12 (48.0%)	9 (52.9%)
Main reason for induction		
Diabetes	6 (19.4%)	4 (15.4%)
IUGR	3 (9.7%)	4 (15.4%)
Hypertension	6 (19.4%)	1 (3.8%)
Oligohydramnios	1 (3.2%)	2 (7.7%)
Polyhydramnios	1 (3.2%)	3 (11.5%)
Post term pregnancy	9 (29%)	8 (30.8%)
BMI above 40	1 (3.2%)	1 (3.8%)
Other	4 (12.9%)	3 (11.5%)
Multiple	8 (25.8%)	8 (30.8%)
Epidural - Yes	29 (96.7%)	26 (89.7%)
Oxytocin - Yes	31 (100%)	26 (89.7%)
Breastfeeding - Yes	23 (85.2%)	14 (73.7%)
Multiparity - Yes	7 (22.6%)	8 (30.8%)

	Self-traction group		Control group	
	Mean (SD)	**Median (Min; Max)**	**Mean (SD)**	**Median (Min; Max)**
Weeks of pregnancy at delivery	39.3 (1.5)	39.0 (37; 41)	39.4 (1.4)	39.5 (37; 41)
Bishop score at insertion	4.1 (1.3)	4.0 (1; 7)	4.1 (1.4)	4.0 (2; 7)
Dilatation at insertion (cm)	1.3 (0.43)	1.5 (0; 2)	1.1 (0.4)	1.0 (0; 2)

Effacement at insertion (%)	53.0 (15.4)	50.0 (0; 90)	45.4 (19.6)	50.0 (0; 80)
Station at insertion	-2.3 (0.5)	-2.0 (-3; -1)	-2.2 (0.6)	-2.0 (-3; -1)
Maternal age (years)	30.3 (5.1)	30.0 (21; 40)	31.4 (3.5)	31.0 (24; 38)
Body Mass Index (at delivery)	33.8 (6.8)	31.7 (24.5; 50.4)	34.5 (8.9)	31.5 (24; 58)

Table 2. Descriptive statistics and group comparison for the TAP questionnaire (acceptability), satisfaction and feasibility

	Self-traction group N (%)/Mean (SD)	Control group N (%)/Mean (SD)	F-test/x^2-test *p*-value (95%CI)
Appreciation			
Did not appreciate at all	1 (3.7%)	0	
Somewhat appreciate	1 (3.7%)	3 (15.8%)	
Appreciate	7 (25.9%)	6 (31.6%)	
Very appreciate	8 (29.6%)	6 (31.6%)	
Very much appreciate	10 (37.0%)	4 (21.1%)	
Appreciation score (Mean ±SD)	2.93 (1.07)	2.58 (1.02)	F(1, 44) = 1.218 *p* = 0.276 (-0.9836; +0.2336)
Convenience/ Appropriateness			
Not convenient at all	0	2 (10.5%)	
Somewhat convenient	2 (7.4%)	1 (5.3%)	
Convenient	7 (25.9%)	4 (21.1%)	
Very convenient	10 (37%)	7 (36.8%)	
Very much convenient	8 (29.6%)	5 (26.3%)	
Convenience score (Mean ±SD)	2.89 (0.93)	2.63 (1.26)	F(1, 44) = 0.636 *p* = 0.429 (-0.9101; +0.3901)
Adequacy			
Somewhat adequate	0	3 (15.8%)	
Adequate	4 (14.8%)	5 (26.3%)	
Very adequate	10 (37%)	6 (31.6%)	
Very much adequate	13 (48.1%)	5 (26.3%)	
Adequacy score (Mean ±SD)	3.33 (0.73)	2.68 (1.06)	F(1, 44) = 6.062 ***p* = 0.018** (-1.1811; -1.1189)
Acceptability			
Somewhat acceptable	1 (3.7%)	5 (26.3%)	
Acceptable	5 (18.5%)	4 (21.1%)	
Very acceptable	10 (37%)	6 (31.6%)	
Very much acceptable	11 (40.7%)	4 (21.1%)	
Acceptability score (Mean ±SD)	3.15 (0.86)	2.47 (1.12)	F(1, 44) = 5.297 ***p* = 0.026** (-1.2683; -0.0917)

Effectiveness			
Not effective at all	1 (3.7%)	1 (5.3%)	
Somewhat effective	0	1 (5.3%)	
Effective	4 (14.8%)	3 (15.8%)	
Very effective	12 (44.4%)	5 (26.3%)	
Very much effective	10 (37.0%)	9 (47.4%)	
Effectiveness score (Mean ±SD)	3.11 (0.93)	3.05 (1.18)	F(1, 44) = 0.035 p = 0.852 (-0.6874; +0.5674)
Adhesion			
Do not agree at all	1 (3.7%)	1 (5.3%)	
Somewhat agree	0	2 (10.5%)	
Agree	1 (3.7%)	3 (15.8%)	
Very agree	14 (51.9%)	8 (42.1%)	
Very much agree	11 (40.7%)	5 (26.3%)	
Adhesion score (Mean ±SD)	3.26 (0.86)	2.74 (1.15)	F(1, 44) = 3.124 p = 0.084 (-1.1168; +0.0768)
Total TAP score (Mean ±SD)	3.11 (0.71)	2.69 (0.93)	F(1, 44) = 2.997 p = 0.090 (-0.9072; +0.0672)
Satisfaction with use of traction			
Not satisfied at all	1 (3.7%)	1 (5.3%)	
Somewhat satisfied	0	3 (15.8%)	
Satisfied	4 (14.8%)	2 (10.5%)	
Very satisfied	12 (44.4%)	6 (31.6%)	
Very much satisfied	10 (37%)	7 (36.8%)	
Satisfaction with use of traction score (Mean ±SD)	3.11 (0.93)	2.79 (1.27)	F(1, 44) = 0.980 p = 0.328 (-0.9730; +0.3330)
Satisfaction with the support			
Not satisfied at all	0	0	
Somewhat satisfied	1 (3.7%)	0	
Satisfied	3 (11.1%)	3 (15.8%)	
Very satisfied	13 (48.1%)	5 (26.3%)	
Very much satisfied	10 (37%)	11 (57.9%)	
Satisfaction with the support score (Mean ±SD)	3.19 (0.79)	3.42 (0.77)	F(1, 44) = 1.022 p = 0.318 (-0.2419; +0.3313)

Feasibility			$\chi^2(1) = 0.072$
Fidelity of intervention - Yes	27 (87.1%)	22 (84.6%)	$p = 0.788$

Bold indicates a statistically significant p-value ($p < 0.05$); CI = Confidence interval.

Table 3. Comparisons between the groups for the process of labour and delivery

	Self-traction group Mean (SD)/N(%)	**Control group Mean (SD)/N(%)**	**F-test/x^2-test, *p*-value**
Pain during traction (0–10)	2.98 (2.96)	4.13 (3.39)	F(1, 50) = 0.207, p = 0.198
Umbilical cord arterial pH	7.21 (0.08)	7.21 (0.08)	F(1, 54) = 0.010, *p* = 0.922
APGAR Score			
1 Minute	7.97 (1.91)	7.92 (1.72)	F(1, 55) = 0.008, *p* = 0.927
5 Minute	8.97 (0.88)	8.77 (1.18)	F(1, 55) = 0.532, *p* = 0.469
10 Minute	9.50 (0.52)	9.40 (1.24)	F(1, 27) = 0.078, *p* = 0.782
Haemorrhage of delivery			
Less than 500 ml	17 (56.7%)	14 (56.0%)	$\chi^2(2) = 0.514$, *p* = 0.773
Between 500 and 1000 ml	11 (36.7%)	8 (32.0%)	
More than 1000 ml	2 (6.7%)	3 (12.0%)	
Type of delivery			
Vaginal	25 (80.6%)	19 (73.1%)	$\chi^2(1) = 0.460$, p = 0.498
Prostaglandins			
Yes	6 (20.0%)	8 (30.8%)	$\chi^2(1) = 0.862$, *p* = 0.353
Active labour - Time between contractions and delivery (mins)	394.74 (211.49)	384.17 (242.40)	F(1, 39) = 0.022, *p* = 0.882
Time between balloon insertion and delivery (mins)	908.21 (296.35)	1033.67 (341.36	F(1, 51) = 2.051, *p* = 0.158
Duration of traction – Time between insertion and balloon expulsion (mins)	91.45 (83.21)	117.32 (75.95)	F(1, 54) = 1.445, *p* = 0.235

Bold indicates a statistically significant *p*-value ($p < 0.05$).