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ORIGINAL ARTICLE

Sonographic cervical length predicts vaginal delivery after previous cesarean section in women with low Bishop score induced with a double-balloon catheter

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ABSTRACT

Objective: To assess the role of cervical length when predicting vaginal delivery after a previous cesarean section (CS) in women with low Bishop score following the use of a double-balloon catheter for induction of labor (IOL).

Methods: A prospective, longitudinal study was conducted at a large teaching hospital in Santiago to recruit pregnant women at term with a previous CS and Bishop score ≤6 for IOL with a double-balloon catheter. The device was maintained for up to 24 h and the patient continued IOL with oxytocin only if the Bishop score was >6. Demographic and clinical variables were recorded and compared against vaginal delivery as the primary outcome. Multivariate logistic regression analysis was used to compare perinatal demographic and clinical variables in women achieving vaginal delivery versus those having a repeat CS.

Results: The final cohort included 40 pregnant women. Women achieving vaginal delivery (n = 17, 42.5%) had statistically significant differences in mean cervical length (24.8 mm versus 33.4 mm, respectively; p = .006), median Bishop score after removing the double-balloon catheter (11 versus 7, respectively; p = .005), and mean interval between double-balloon catheter placement and vaginal delivery or the decision to perform a CS (17.4 h versus 23.6 h, respectively; p = .03). Backward stepwise selection revealed an odds ratio of 0.90 (95% confidence interval = 0.82–0.98) for cervical length and a receiver operating characteristic curve area of 0.73.

Conclusion: Cervical length, as determined by transvaginal sonography, proved to be effective in predicting vaginal delivery in women with a previous CS and low Bishop score following the use of a double-balloon catheter for IOL.

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Cervical length; double-balloon catheter; induction of labor; previous cesarean section; transvaginal ultrasound; vaginal delivery

Introduction

Rates of cesarean section (CS) are increasing worldwide [1]. In Chile, CS rates increased from 27% in 1986 to 38% in 1994 [2], while data published in 2016 reported an overall rate of 45% [3]. One of the strategies to reduce the rate of CS is to promote vaginal delivery after CS. This requires assessment of the CS scar integrity, evaluation of fetal wellbeing, and the ability for proper and timely assistance in a well-equipped hospital in case of any complications [4,5]. With adequate obstetric assistance during labor, the incidence of CS scar dehiscence after a vaginal delivery is around 2%, which is rarely associated with any serious maternal or neonatal complications [4,6]. However, in most cases it is not possible to predict CS scar rupture during pregnancy or labor.

The use of clinical characteristic models has been proposed to determine the probability of vaginal delivery in women with a previous CS [7–10]. Sonographic measurement of cervical length has recently been described as a good predictor of vaginal delivery in women with and without a previous CS [11–18]. In this case, cervical length may be considered an indicator of cervical ripening, with a shorter cervix potentially indicating more favorable conditions for successful induction of labor (IOL) and subsequent vaginal delivery. Several mechanical methods have been described as safe and effective options for IOL in

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women with a previous CS, one of which is the double-balloon catheter [6,19–22]. However, there is limited information for predicting vaginal delivery in women with a previous CS and low Bishop score undergoing IOL with a double-balloon catheter. The aim of this study is therefore to assess the value of measuring cervical length with transvaginal sonography before double-balloon catheter placement for predicting vaginal delivery in women with these conditions.

Subjects and methods

This study was reviewed and approved by the Institutional Review Board at the Luis Tisne Brousse Hospital and the Ethics Committee for the East Metropolitan Health Service, Santiago. It was also conducted in accordance with the Declaration of Helsinki. All women participating in the trial signed a written informed consent before inclusion in the study.

A prospective longitudinal study was designed to include pregnant women with a previous CS interested in achieving a vaginal delivery. They were recruited from the Antenatal Clinic at the Luis Tisne Brousse Hospital, Santiago, between August 2016 and December 2017. This center is a National Health Service tertiary hospital that conducts over 5500 deliveries each year. The CS rate during the recruitment period was 31% and the vaginal delivery rate for women with previous CS was 60%. The inclusion criteria for this study were: (1) pregnant women with 37–41 weeks' gestation; (2) singleton gestation; (3) history of one previous CS; (4) vertex presentation; (5) intact membranes; (6) Bishop score $\leq$6; (7) normal fetal heart rate tracing; and (8) accepted informed consent. Exclusion criteria were: (1) maternal age $<$18 years; (2) declined study participation; (3) previous uterine surgery different from a low-segment CS; (4) unknown type of hysterotomy at the previous CS; (5) more than one previous CS; (6) suspected fetal macrosomia (estimated fetal weight by sonography $\geq$4000 g); and (7) any contraindication for vaginal delivery or maternal-fetal condition that could affect the mode of delivery, including suspected cephalopelvic disproportion, low-lying placenta, fetal demise, or medical conditions such as obesity, diabetes, hypertension, intrauterine growth restriction, or oligohydramnios.

The participants were given information on the use of a double-balloon catheter as a mechanical method of cervical ripening and the risks and benefits of the trial were discussed at length. A pre-induction cardiotocography and sonographic examination were performed upon admission in all cases. Cervical length was measured transvaginally based on well-established sonographic criteria [23] using a Voluson 730 Expert ultrasound equipment (GE Healthcare, Zipf, Austria) with a 5–9 MHz transvaginal probe. Cervical length measurements were recorded and blinded for the attending obstetric team. A cervical digital examination was then performed and the Bishop score was recorded. Patients with a Bishop score $\leq$6 underwent double-balloon catheter placement for cervical ripening, filling both balloons with up to 80 cc of saline solution. Complete filling of the balloons was delayed for some minutes if the patient found the procedure to be painful. Once the device was correctly placed it was strapped to the inner thigh of one leg without traction. No other cervical maturation method was used in these cases. Intermittent fetal heart rate monitoring was performed during the IOL process. The double-balloon catheter was removed after 24 h if spontaneous expulsion had not occurred. Indications for removal before 24 h included persistent maternal discomfort, rupture of membranes, onset of active labor, or non-reassuring fetal heart rate pattern. Once the device was removed the Bishop score was again assessed and recorded. If the Bishop score was $\leq$6 a repeat CS was indicated. If the Bishop score was $>$6 oxytocin was indicated in order to continue IOL. Labor was managed by the attending obstetricians and midwives following the institutional protocols for IOL after a previous CS. Epidural analgesia was administered upon maternal request. Continuous fetal heart rate monitoring was used during oxytocin induction and active labor for all patients.

For the purposes of this study, the following variables were recorded for subsequent analysis: maternal age, gestational age, parity, history of previous vaginal delivery, history of CS with a trial of labor, interpregnancy interval, cervical length and Bishop score before double-balloon catheter placement, time of double-balloon catheter use, Bishop score after removing the double-balloon catheter, need for oxytocin for IOL, mode of delivery (CS or vaginal), birthweight and sex of the newborn infant, maturation/induction/labor time (time elapsed between double-balloon catheter placement and vaginal delivery or decision to perform a CS), and Apgar scores at one and five minutes.

Statistical analysis was performed in a Stata statistical package (Stata/SE 16 for Windows, StataCorp. LLC, College Station, Texas, USA). Descriptive statistics (measures of central tendency and dispersion) considered the measurement scale and the distribution of

the variables. The Shapiro–Wilk test was used to define the null hypothesis with respect to the normal distribution [24]. The mode of delivery was compared for all recorded variables. Pearson's chi-squared test was used to compare frequencies. The Student *t*-test was used to compare average values. In case of absence of normality, the Mann–Whitney test was used to test whether samples originate from the same distribution. A *p*-value $<.05$ was considered statistically significant and all tests were two tailed [24]. The Pearson's correlation was determined for vaginal delivery and the corresponding demographic and clinical variables [24,25].

Multivariate logistic regression was used to predict vaginal delivery [26]. Before constructing the logistic regression model, the continuous quantitative variables were assessed for linearity in the logit using the linear test trend and locally weighted scatterplot smoothing (LOWESS) plot [26]. The variables without linearity in the logit were dichotomized using a cutoff point in order to assure such linearity and be included in the stepwise logistic regression. The logistic regression was conducted using backward stepwise selection. The final logistic regression model was based on explanatory variables whose coefficients were statistically significant on the Wald test, with minor deviance. For the final model, different indicators of goodness of fit (log likelihood (LL); Akaike information criterion (AIC); Bayesian information criterion (BIC)), and their predictions were determined [24–26].

Results

A total of 44 pregnant women were recruited. Three women were subsequently excluded due to incomplete information from the medical records and another one due to rupture of membranes during double-balloon catheter placement. Thus, the final cohort included 40 pregnant women. Maternal age, gestational age, interpregnancy interval, cervical length, birthweight, and maturation/induction/labor time were symmetrically distributed. Overall, the average maternal age was 29.3 ± 4.5 years, gestational age was 275.3 ± 5.8 days, interpregnancy interval was 5.6 ± 3.3 years, cervical length was 29.7 ± 10.1 mm, birthweight was 3481 ± 442 g, and maturation/induction/labor time was 20.9 ± 9.6 h. The parity and double-balloon catheter time use revealed an asymmetrical distribution with a median (interquartile range, IQR) of 2.0 (1.0) pregnancies and 20.1 (11.5) h, respectively. The maturation/induction/labor time fell within a range of 4.6–43.6 h. Cervical length, birthweight, and maturation/induction/labor time revealed evidence of normal distribution ($p > 0.15$, Shapiro–Wilk test). Median (IQR) Bishop score before placement and after removal of the double-balloon catheter was 3 (2) and 8 (4.5), respectively. Median Apgar scores at one and five minutes were 9 (0) and 9 (0), respectively. Oxytocin use during IOL was reported in 31 patients (77.5%; 95% confidence interval (CI): $64.5 - 90.4$). Among the 40 cases, 14 (35%; 95% CI: $20.2 - 49.7$) had a history of at least one previous vaginal delivery and 18 (45%; 95% CI: $29.5 - 61.4$) had a history of a previous CS with trial of labor. The newborn infant was male in 19 cases (47.5%; 95% CI: $32.0 - 62.9$).

Vaginal delivery occurred in 17 cases (42.5%; 95% CI: $27.1 - 57.8$), with four (23.5%; CI 95%: $3.3 - 43.6$) having an instrumentally assisted vaginal delivery. There were no cases of uterine rupture in this cohort. Table 1 shows the differences between women having a vaginal delivery and those having a repeat CS. Women who delivered vaginally showed a statistically significant lower mean cervical length before double-balloon catheter insertion than those who delivered by CS (24.8 mm versus 33.4 mm, respectively; $p = .006$). The Bishop score after removing the double-balloon catheter was significantly greater for women delivering vaginally than those delivering by CS (11 versus 7, respectively; $p = .005$). In addition, women delivering vaginally had a significantly lower mean maturation/induction/labor time than those who delivered by CS (17.4 h versus 23.6 h, respectively; $p = .03$).

Pearson's correlation between vaginal delivery and cervical length showed a value of -0.43 ($p < .01$). Pearson's correlation between vaginal delivery and the following variables were statistically not significant: maternal age (0.12; $p = .46$), gestational age (0.22; $p = .18$), parity (0.10; $p = .53$), history of previous vaginal delivery (–0.01; $p = .97$), history of previous CS with a trial of labor (-0.1; $p = .56$), interpregnancy interval (0.04; $p = .79$), and Bishop score before double-balloon catheter placement >4 (0.05; $p = .76$). The linear trend test and LOWESS plot for cervical length and gestational age revealed adequate linearity in the logit. Maternal age, parity, interpregnancy interval, and Bishop score before double-balloon catheter placement did not reveal linearity in the logit. These variables were therefore dichotomized by selecting a cutoff point based on the linear trend test and LOWESS graph. In this case, the cutoff points were maternal age >27 years, pregnancy number >2, time since last childbirth >5 years, and Bishop score before double-balloon catheter placement >4.

Table 1. Demographic and clinical variables according to mode of delivery in women with a previous cesarean section and induced by a double-balloon catheter for cervical maturation.

Variable	Cesarean section $n = 23$	Vaginal delivery $n = 17$	p-value two tail
Maternal age (years)			
Mean ± SD	28.91 ± 3.81	30.00 ± 5.35	.721[a]
Gestational age (days)			
Mean ± SD	274.30 ± 6.10	276.82 ± 5.28	.179[a]
Parity*			
Median; IQR	2; 1	2; 2	.435[a]
History of previous vaginal delivery			
n (%)	8 (34.78)	6 (35.29)	.973[b]
History of previous CS with a trial of labor			
n (%)	12 (52.17)	8 (47.06)	.749[b]
Interpregnancy interval (years)			
Mean ± SD	5.50 ± 2.79	5.80 ± 4.13	.749[a]
Cervical length (mm)*			
Mean ± SD	33.39 ± 9.80	24.76 ± 8.55	.006[c]
Bishop score before DBC placement			
Median; IQR	3; 1	2; 2	.812[a]
DBC time use (h)			
Median; IQR	21.17; 11.83	17.00; 11.08	.671[a]
Bishop score after removing the DBC			
Median; IQR	7; 5	11; 3	.005[a]
Oxytocin use in induction of labor			
n (%)	18 (78.2)	13 (76.4)	1.00[d]
Birthweight (g)*			
Mean ± SD	3472 ± 456	3493 ± 437	.889[c]
Male newborn			
n (%)	13 (56.5)	6 (35.2)	.184[b]
Apgar score at one min			
Median; IQR	9; 0	9; 1	.269[a]
Apgar score at five min			
Median; IQR	9; 0	9; 0	.390[a]
Maturation/induction/labor time (h)*			
Mean ± SD	23.58 ± 10.81	17.43 ± 6.57	.03[e]

SD: standard deviation; IQR: interquartile range; CS: cesarean section; DBC: double-balloon catheter.
[a]Mann–Whitney test; [b]Pearson's Chi squared test; [c]Student *t*-test assuming equal variance (variance ratio test *p*-value >.05); [d]Fisher's exact test; [e]Student *t*-test assuming unequal variance (variance ratio test *p*-value <.05).
*p-value of the Shapiro–Wilk test was >0.15 for these variables.

The backward stepwise selection approach revealed a final logistic regression model that only included cervical length (odds ratio: 0.899; 95% CI: 0.826 − 0.979). The LL value for this model was −27.27, while AIC was 50.51 and BIC was 53.89. Figure 1 shows the predicted probabilities for the final logistic regression model. The collinearity study for the predictor revealed a conditional number of 6.1, with a variable inflation factor for cervical length of 1. The link test revealed a correct specification for the final logistic regression model. The calibration belt approach [27] revealed an adequate calibration ($p = .64$). For the final logistic regression model, the calibration belt approach revealed an adequate calibration ($p = .84$). The pseudo R-square was 0.15 and the Hosmer and Lemeshow's goodness-of-fit test revealed a p-value of .64. The receiver operating characteristic (ROC) area for the final logistic model was 0.73 (95% CI: 0.57 − 0.88).

Discussion

Pregnant women with a previous CS face a dilemma when it comes to the mode of delivery for their future pregnancies, i.e. attempting a vaginal delivery or having a repeated CS [28]. This dilemma requires the patient to weigh up the risks and benefits. Establishing the *a priori* probability of vaginal delivery in these patients, therefore, becomes increasingly relevant. In this study, we included demographics and clinical variables that are observed and can be easily obtained before and during IOL in order to provide prognostic information to these women. Unlike other studies [9,20], birth weight and duration of the oxytocin induction period were therefore also considered. Our selected sample of term pregnant women with a previous CS were eligible for IOL, with the proportion of vaginal delivery after the use of a double-balloon catheter consistent with results previously reported for this type of device [10,19–21,29–31]. The mean cervical length prior to IOL was significantly lower in women achieving a vaginal delivery. In addition, the significant correlation between vaginal delivery outcome and cervical length prior to IOL suggests that this factor should be considered prognostic for vaginal delivery. The significantly higher median Bishop score

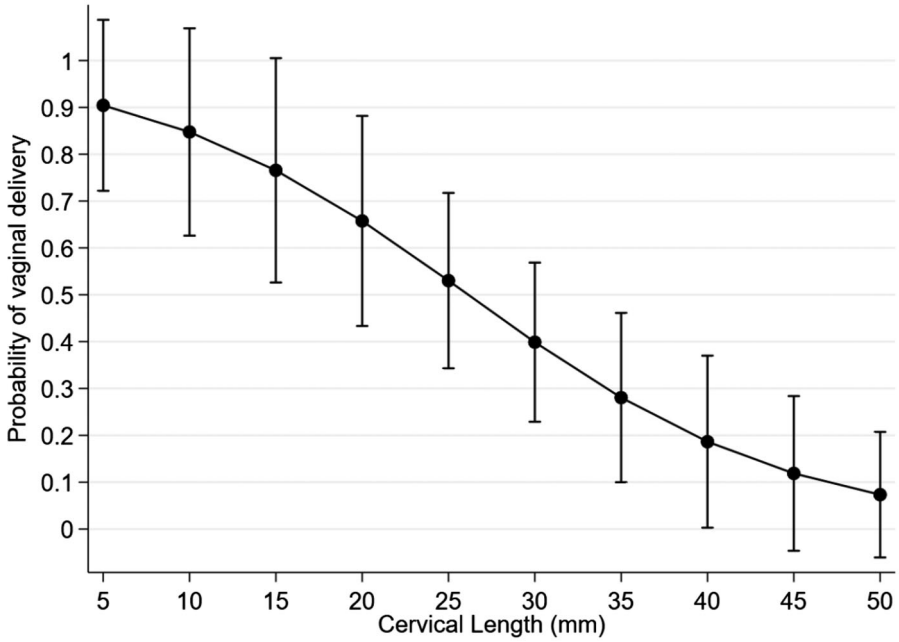

Figure 1. Probabilities predicted by final logistic model using cervical length in 40 pregnant women with a previous CS induced by a double-balloon catheter for cervical maturation.

after removing the double-balloon catheter among women achieving vaginal delivery was due to the fact that this was a criterion for continuing with vaginal delivery.

Stepwise regression led to a final model with a reduced number of predictor variables. The prediction performance of this model was similar to the full models. The stepwise selection method therefore reduced the complexity of the model without compromising its accuracy. The results of this study suggest that the prediction performance of cervical length is similar to the full model, when all other variables are considered. The odds ratio of 0.899 from the stepwise logistic regression model for cervical length shows that an increase of one mm in cervical length decreased the chance of vaginal delivery by 10%.

The ROC curve area is a quantitative measure of diagnostic accuracy. The ROC curve value of 0.73 obtained for this model strongly supports the fact that cervical length was a good discriminatory variable between vaginal delivery and CS. The results reported here are in line with previous studies, where sonographic measurements of cervical length was a predictor of vaginal delivery among term pregnant women with and without previous CS [11–18]. This therefore supports the hypothesis that cervical length may be considered an indicator of cervical ripening. The maturation/induction/labor time was less in women that ended up having a vaginal delivery, highlighting the fact that not only is the occurrence of vaginal delivery important, but also the moment at which this vaginal delivery occurs. This situation is probably the result of multiple factors (trial of labor, fetal dystocia, arrest of descent, etc.) that occur during labor. However, it may indicate that the cervical length could also predict the length of labor in women achieving a vaginal delivery.

Among the limitations of this study, it is worth noting that this was an experimental study without any control group. Current knowledge ethically prevents a pregnant woman with a previous CS scar from being assigned to a placebo group. In our conclusions we therefore determine the effectiveness and not the efficacy [32]. On the other hand, we did not consider certain variables that may have influenced vaginal delivery outcome, such as obesity, diabetes, and hypertensive disorders complicating pregnancy, and ethnicity [7,9]. Nevertheless, because women with these medical conditions were excluded in this study they did not have any impact on our results. With regards to the ethnic composition of the Chilean population, the Chilean National Health Service does not make any ethnic classifications of the population, considering it instead to be an ethnically homogeneous group [33].

In conclusion, cervical length, as determined by transvaginal sonography, may effectively predict vaginal delivery among women with a previous CS and a low Bishop score who underwent double-balloon catheter use for cervical maturation.

Author contributions

AD was responsible for study design, patient care, data collection and interpretation, and writing the manuscript. SA was responsible for study design, statistical analysis, data interpretation, and writing the manuscript. DB, AC, CA, MA, RP, and VP were responsible for patient care and data collection. FG and WS were responsible for data interpretation and writing the manuscript.

Disclosure statement

The authors reported that there were no conflicts of interest, including specific financial interests, relationships and affiliations relevant to the matter or materials discussed in the manuscript (employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties or patents filed, received or pending).

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