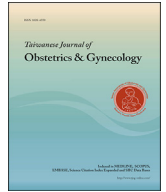




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Original Article

Mechanical induction of labor and ecbolic-less vaginal birth after cesarean section: A cohort study

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ABSTRACT

Objective: During delivery counseling, some women with previous uncomplicated cesarean section (CS) wish mechanical induction of labor (IOL) but they are not accepting the added risk of using ecbolics to induce and/or augment labor. The objective of the study was to assess the safety and efficacy of the isolated use of transcervical Foley's catheter balloon as a mean of mechanical cervical ripening (CR)/IOL and successful ecbolic-less vaginal birth after cesarean section (VBAC).

Materials and methods: A cohort study was conducted in two tertiary care maternity hospitals between October 2013 and July 2016 and recruited women with singleton pregnancy and cephalic presentation who had previous one uncomplicated CS and were scheduled for mechanical CR/IOL at term for routine obstetric indications. No ecbolics were used for induction or augmentation of labor as per patients' request. The primary outcome variable was the rate of successful VBAC.

Results: 108 Women had a completed trial of mechanical CR/IOL without ecbolics till delivery. Active labor started in 94 women (87%), however only 43 women (39.8%) had successful VBAC. No woman in the study cohort had uterine rupture, scar dehiscence, uterine tachysystole, postpartum hemorrhage and/or puerperal sepsis. No cases were admitted to intensive care units and there were no maternal mortalities. Prior successful VBAC and post-expulsion BS were the only independent predictors for successful VBAC and shorter duration of labor after balloon expulsion.

Conclusion: Mechanical IOL with the mere use of transcervical Foley's catheter is a safe and effective method of VBAC in women refusing use of ecbolics.

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Introduction

With the progressive rise in cesarean section (CS) rates, the delivery management of subsequent pregnancies with scarred uterus is challenging [1]. The obstetrician has to maintain the balance between the potential risks of uterine rupture during trial of labor after CS (TOLAC) [2], and the drawbacks of elective repeat CS (ERCS) [3].

Despite being recommended as a reasonable option, the rate of TOLAC shows marked variance between countries [4,5]. The

liability pressures and litigations were found to affect the willingness of obstetricians towards this approach [6].

When labor starts spontaneously in such women, the decision to proceed in TOLAC is easier than when induction of labor (IOL) is indicated [7], as the risk of uterine rupture is increased with the use of prostaglandins [2,7] and oxytocin [2,8]. This made the American Congress of Obstetricians and Gynecologists (ACOG) to advise avoiding the use of prostaglandins for such cases [9].

Previous studies showed transcervical balloon as a safe and successful method for initiation of labor for scarred uterus, however augmentation of labor with oxytocin is still used in good portion of these cases [2,10]. The mechanism by which the balloon induces the cervical ripening (CR) may be incompletely understood. The proposed mechanisms are direct mechanical stretch on

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the cervix and lower uterine segment beside release of some endogenous prostaglandins due to membranes stripping [11].

In the high-parity communities like Saudi Arabia, the healthcare providers have to find a compromise to reduce the risk of complications associated with TOLAC without increasing the rate of ERCS [12]. During delivery counseling, some women with previous uncomplicated cesarean scar wish mechanical IOL but they are not accepting the added risk of eclampsia used to induce and/or augment labor, so in this study, it has been hypothesized that mechanical IOL with the mere use of transcervical Foley's catheter, and without using any oxytocin and/or prostaglandins till delivery, is a safe and effective method of VBAC in this especial group of women.

Patients and methods

This cohort study was conducted in the Obstetrics and Gynecology departments of two tertiary care maternity hospitals in Saudi Arabia (King Faisal military hospital, Khamis Mushait & King Fahad military hospital, Riyadh) between October 2013 and July 2016 after being approved by the ethics and research committee.

The study recruited women with singleton pregnancy and cephalic presentation who had previous one uncomplicated CS and were scheduled for mechanical CR/IOL at term for routine obstetric indications. Presence of multiple uterine scars, multifetal pregnancy, estimated fetal weight >4000 g, ruptured fetal membranes, fetal malpresentations, uterine anomalies, prior uterine rupture, operative report contraindicating trial of scar, and/or permanent contraindication for vaginal delivery (VD) were considered as the study exclusion criteria.

All eligible participants were informed and consented for the procedure. All women were examined abdominally and vaginally for checking the fetal presentation. Pre-induction Bishop score (BS) assessment was done by the attending physician, presence of normal fetal heart rate (FHR) pattern and absence of uterine activity were assured using Cardiotocography (CTG) for at least 60 min (30 min before balloon insertion and 30 min after). After bladder evacuation and under complete aseptic conditions, Foley's catheter 16 gauge was passed through the internal cervical os using sponge forceps under vision. The balloon was inflated by 50 ml sterile water followed by gentle traction making the balloon resting on the internal os. This traction was maintained by fixing the catheter to the medial side of the thigh using plaster tape. The catheter was then checked every 2 h, to exclude balloon expulsion and readjust the traction. Maternal uterine activity, vaginal loss, and vital signs were regularly observed. After 12 h from application, the catheter was removed and the cervix was re-evaluated and if favorable (BS \geq 6) amniotomy was done, otherwise the catheter was reinserted for re-evaluation after another 12 h. Earlier catheter removal was considered when there is a spontaneous rupture of membranes and/or uterine tachysystole. After balloon expulsion, re-evaluation for BS was done and amniotomy was performed if membranes were accessible and labor progress was then observed. No eclampsia were used for CR/IOL or augmentation of labor.

Failure of mechanical IOL was defined as inability to achieve an active labor within 12 h of amniotomy or persistent BS < 6 despite completed 24 h of balloon application. Failure of progress of labor was diagnosed when there was an active phase protraction or arrest. Aside from the aforementioned causes, CS was also performed for the routine obstetric indications emerging during TOLAC.

The primary outcome variable was the rate of successful VBAC. Other study outcome variables included; degree of improvement in BS after balloon expulsion, balloon introduction to expulsion, introduction to delivery and expulsion to delivery times, post-operative hemoglobin deficit, maternal complications (i.e. uterine tachysystole, scar dehiscence, uterine rupture, postpartum

hemorrhage, puerperal pyrexia, maternal intensive care unit (ICU) admission, venous thromboembolic complications and maternal mortality). Fetal outcome variables included Apgar score at 5 min, cord PH, birth asphyxia, meconium stained liquor, neonatal intensive care unit (NICU) admission and perinatal mortality.

Statistical analysis was performed using the following software products: SPSS© version 21 [IBM© Corp., Armonk, NY] and MedCalc© version 11.4 [MedCalc© Software, Ostend, Belgium]. Shapiro–Wilk test was used to examine the numerical data for normality of distribution. Skewed data were presented as median and interquartile range (IQR) and in-between groups differences were calculated non-parametrically using Mann–Whitney U test. Normally distributed data were presented as mean \pm standard deviation (SD) and in-between groups differences were calculated using independent samples t-test. Categorical data were presented as number and percentage (%) and in-between groups differences were calculated using Chi-squared test or Fisher's exact test as appropriate. Multivariable binary logistic regression was used to determine independent predictors for successful VBAC after mechanical IOL. All the potential factors were adjusted for, including: maternal body mass index (BMI), ultrasonographic fetal weight estimation (US-FWE), pre-induction BS, post-expulsion BS, prior VD, prior successful VBAC, the indication for mechanical IOL and the indication of the previous CS. The 'enter' method was used to force all explanatory variables into the model. Receiver-operating characteristic (ROC) curve analysis was then used to examine the value of the generated model to predict successful VBAC after mechanical IOL. A Kaplan–Meier survival analysis was done to detect the probabilities of faster VD after balloon expulsion in women with and without prior successful VBAC and in women with different post-expulsion BS. Comparison of the survival curves was done using the log rank test. Cox regression was then used as a multivariate analysis to detect the independent predictors of faster VD after balloon expulsion in women with successful VBAC. All P values were two-sided and P value < 0.05 was considered statistically significant.

Results

2714 Women with singleton pregnancy and cephalic presentation who had previous one uncomplicated CS were evaluated for the study eligibility criteria, out of them, 108 women had a completed trial of mechanical CR/IOL without eclampsia till delivery (Fig. 1). The main indications for mechanical CR/IOL in the studied cohort were prolonged pregnancy (51.9%) followed by diabetes mellitus (13.9%) and hypertensive disorders (11.1%).

Regarding the indication of the first CS, failed progress of labor was more prevalent in the repeat CS group, while fetal malpresentation was more prevalent in the successful VBAC group. Women in the successful VBAC group also showed significantly higher prevalence of prior VBAC and prior VD. Apart from these variables there were no statistically significant differences between the 2 outcome groups regarding the baseline pre-delivery data (Table 1).

Although, active labor started in 94 women (87%), only 43 women (39.8%) had successful VBAC, and the remaining 65 women (60.2%) had emergency repeat CS due to fetal distress (20.4%), failed progress of labor (26.9%) or failed induction (12.9%).

It was noted that, women in the successful VBAC group had significantly higher pre-induction and post-expulsion BS, shorter balloon introduction/expulsion, introduction/delivery and expulsion/delivery times and lower hemoglobin deficit and percentage deficit (Table 2).

Two women in the successful VBAC group needed instrumental deliveries and one woman in the repeat CS group had puerperal

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