

# Induction of labor using double balloon cervical device in women with previous cesarean section: Experience and review\*

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## ABSTRACT

Induction of labor remains one of the most challenging interventions in current obstetrics. Different pharmaceuticals have been used for cervical ripening such as prostaglandins; however they can lead to a number of potential inconvenient risks namely uterine tachysystole and pathological fetal cardiocography (CTG). In cases of women with previous caesarean births, using prostaglandins would pose even higher risks such as uterine rupture and perinatal mortality. A mechanical method of cervical ripening could represent an alternative for these women. We report the use of the extra-amniotic double balloon cervical device (Cook's device) for ripening of unfavourable cervix in seventeen women attempting vaginal birth after cesarean section (VBAC). Using Bishop scoring system to assess cervical dilatation, position, consistency, fetal station and effacement, the unfavourable cervix is the cervix that scores less than 6. We review the relevant literature discussing this method of induction focusing on its effectiveness, simplicity, safety and efficacy, low cost and any associated serious side effects. **Conclusion:** Success was estimated to be over 50% with no serious life threatening maternal or fetal complications. We considered the process satisfactory and practical. We recommend larger studies to assess safety and efficacy of Cook's device in vaginal birth after caesarean section before embarking on routine elective caesarean delivery. **Objectives:** To estimate success rate for vaginal delivery after previous caesarean section using cervical double balloon device (Cook's device). **Design:** Three-year observational study. **Setting:** Maternity unit in district general hospital, UK. **Population:** Women who had one previous lower segment caesarean section and unfavourable cervix identified as

having Bishop Score less than 6. **Methods:** Data were obtained from the birth registry over 3 years from January 2008 until December 2010. **Main outcome:** Measure successful vaginal delivery. **Results:** Out of 25 cases that had induction of labor with history of one previous lower segment caesarean section, 17 patients did fit in the inclusion criteria and were studied. 53% had a successful vaginal delivery while 47% had to have caesarean section either due to failure to progress or pathological cardiocography. 82% required to have syntocinon infusion for augmentation as per local unit protocol. All newborn babies were in good condition and did not require admission to neonatal intensive care unit.

**Keywords:** Labor; Induction; Cervical Balloon; Cook Balloon; Double Balloon; Cesarean Section

## 1. INTRODUCTION

A common dilemma facing the obstetrician is the induction of labor in the presence of unfavourable cervix. Using Bishop scoring system to assess cervical dilatation, position, consistency, fetal station and effacement; the unfavourable cervix is defined as a cervix that scores less than 6. The most common methods used are intravaginal prostaglandins E2 and intravenous Oxytocin, however these agents can cause tachysystole of the uterus with its concomitant sequelae. A trial of labor, whether spontaneous or induced, in women after a previous caesarean delivery is always a major concern because of the increased risk of uterine rupture. Elective repeated caesarean section (ERCS) would be perhaps the most popular option between obstetricians in the UK where spontaneous delivery has not started by 41 weeks gestation and the cervix remained unfavourable. There are no randomised controlled trials comparing planned VBAC with planned ERCS and this may be an unrealistic aspiration [1].

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## 2. MATERIALS AND METHODS

A total of 25 women with an unfavourable cervix, history of previous caesarean section and underwent induction of labor were included in this study starting from January 2008 until December 2010.

The inclusion criteria were patients who had one lower segment caesarean section requesting VBAC at term between 41 + 3 and 42 weeks and had singleton pregnancy, vertex presentation, not in established labor and have intact membranes. The cervicometric assessment using Bishop Score is less than 6.

The exclusion criteria were previous uterine incision apart from lower segment caesarean section such as classic caesarean incision, myomectomy and hysterotomy. We also excluded abnormal placentation; breech presentation; ruptured chorionic membranes; abnormal cardiotocography (CTG) prior to balloon insertion; and active genital herpes infection.

All patients had to have at least thirty minutes of normal CTG according to the National Institute of Health and Clinical Excellence (NICE) guideline before and after balloon insertion. Patients gave verbal consent on admission prior to the start of the process.

In lithotomy position using Cusco's speculum the cervix is cleaned and the device is gently inserted until both balloons have entered the cervical canal. The inner (uterine) balloon was inflated with 40 mls of normal saline using standard 20 ml Luer-Lock syringe through the red Check-Flo valve marked "U" and pulled back until it came in contact with the internal cervical os. Then the outer (vaginal) balloon in turn was inflated with 20 mls normal saline.

Once the balloons were situated on either side of the cervix the speculum was removed and more saline added until each balloon contained 80 mls [2].

Subsequently the women's activity was not restricted and the device was left for a maximum period of twelve hours as per manufacture guidance. In cases where spontaneous rupture of membranes (SROM) occurred then both balloons had to be deflated and the device had to be removed.

Once labor was established, patients were managed according to intrapartum care guideline recommended by NICE [3] and in line with Birth after Previous Caesarean birth Green Top Guideline [4].

## 3. RESULTS

Out of 25 patients, 17 women with a history of a previous caesarean section and who had unfavourable cervix underwent mechanical induction of labor using Cook's Cervical Ripening Balloon. We excluded eight cases at the beginning of the study, as they did not fit in the inclusion criteria. We looked at insertion to delivery time

interval, removal to delivery time interval, success of artificial rupture of membranes, mode of delivery, Apgar score and the associated complications. Also we assessed the patient satisfaction and the practicality of the process perceived by the staff.

All cases had either artificial rupture of membranes or had spontaneous rupture of membranes before reaching the twelve hours limit of the device being in place. Out of seventeen patients 9 (53%) had successfully delivered vaginally while only 8 cases (47%) had to have caesarean delivery for either failure to progress (3 cases) or pathological cardiotocography (5 cases). Only one baby was delivered by assisted vaginal delivery using Kiwi Omnicup. Average insertion to delivery time interval and removal to delivery time interval were 27 hours & 15 hours respectively. The average Bishop Score before and after using the device was 3 & 6 respectively. Fourteen patients (82%) required to be augmented by Syntocinon infusion as per unit protocol. The average Apgar score at 5 minutes was nine out of ten. None of the newborn babies required admission to the neonatal intensive care unit. Apart from one case that had postpartum haemorrhage, which was treated by uterotonics according to the local guideline policy, the rest of the cases had no other postpartum complications reported. No case of puerperal pyrexia, puerperal sepsis or neonatal infections was reported in our study. The process was widely regarded as satisfactory and practical by patients and staff involved.

## 4. DISCUSSION AND REVIEW OF LITERATURE

We conducted a search of Medline from January 1950 to 2011 and Embase between 1980 and 2011 for journal literature related to the topic. Induction of labor when the uterine cervix is unfavourable is associated with frequent maternal complications and high rates of induction failure and caesarean sections. Different techniques have been tried to ripen the unfavourable cervix and enhance the changes necessary for labor [5].

Using prostaglandin for induction in an unscarred uterus is associated with 6/10,000 risk of perinatal death [6].

It can also be associated with significant and potential lethal untoward effects on mother, foetus or newborn [7].

Systematic reviews examining induction and augmentation of labor for women with previous caesarean birth have found Compared with spontaneous labor; induction was more likely to result in caesarean delivery. Of women undergoing spontaneous labor, 20% had a caesarean (range 11% - 35%) compared with 32% receiving oxytocin (range 18% - 44%). In studies of prostaglandins (PGE<sub>2</sub>), spontaneous labor resulted in caesarean delivery in 24% (range 18% - 51%) compared with 48% with PGE<sub>2</sub> (range 28% - 51%) [8].

A decision model analysis compared strategies for VBAC and ERCS in women with previous one caesarean section based on number of desired future pregnancies. Based on probability estimates, ERCS was the preferred strategy for women who desired only one child, but VBAC was preferred for any woman who desired more than one child. Hysterectomy rates were higher in the model based on one additional child with VBAC than with ERCS but the contrary was true in the second model involving more than one additional child [9].

We concluded that careful counselling is crucial taking in consideration patient's future fertility plans. A population based cohort study data analysis from over 20,000 primiparous women who gave birth to live singleton infants by caesarean section, and who have subsequently been induced with prostaglandins revealed rate of uterine rupture of 24.5/1000. However, those who were induced without prostaglandins had rupture rate of 7.7/1000 [10].

In a more recent study of different outcomes associated with trial of labor after caesarean delivery, the risks of uterine rupture/10,000 planned VBAC deliveries were 102, 87 and 36/10,000 for induced, augmented and spontaneous labor groups, respectively [11].

The same study showed the rates of caesarean section in women undergoing planned VBAC to be 33%, 26% and 19% for induced, augmented and spontaneous labor groups, respectively [12].

In an analysis of nationally collected data from Scotland, prostaglandin induction compared with non-prostaglandin induction was associated with a statistically significant higher uterine rupture risk (87/10,000 versus 29/10,000) and a higher risk of perinatal death from uterine rupture (11.2/10,000 versus 4.5/10,000) [13].

Several investigators have reported the use of a single balloon device for mechanical induction such as a Foley catheter; however the traction on the catheter by the women's leg involved a certain degree of discomfort [14].

Balloon ripening was found to be more effective than Oxytocin infusion, resulting in shorter induction-delivery interval [15].

The mean change in cervical score after balloon ripening was significantly higher, with shorter induction delivery interval and fewer side effects when compared with prostaglandins PGE2 or PGF2a [16,17]. The double balloon device introduced by Atad had the advantage of being held in place and two balloons on either side of the cervix thus avoiding traction apply the dilating vector. Moreover a higher increase in Bishop Score resulted from its use and better success rate ensued [18].

In several studies catheter balloon ripening was compared with cervical ripening by other mechanical or pharmacological methods. It was suggested that ripening efficacy by catheter balloon was similar or better than

other methods with no significant difference in the mode of delivery or perinatal outcome. The extra amniotic catheter balloon was also viewed by investigators as simple, low cost and without systemic or serious side effects [19].

A double balloon device was considered a relatively new method of mechanical induction that may be safe and effective to induce labor in women with previous caesarean section [20].

Combined results from two studies showed that the rate of uterine rupture in women with previous caesarean delivery undergoing induction with Transcervical Foley's catheter was similar to that in women attempting vaginal birth and delivered spontaneously: 5 ruptures among 384 women in the former group (1.3%) versus 22 ruptures in 2081 women in the later group (1.1%) [21,22].

In a metaanalysis of 27 RCTs comparing the efficacy and safety of cervical ripening and labor induction by Foley catheter balloon (FCB) vs locally applied prostaglandins (LAPG) in the third trimester of pregnancy concluded that FCB and LAPG result in similar caesarean delivery rates, that FCB bears a higher risk of oxytocin use for labor induction ( $P = 0.0002$ ) and/or augmentation, and that LAPG carries a higher risk of contraction abnormalities  $P \leq 0.0001$  [23].

A recent randomised controlled trial in 12 hospitals in the Netherlands enrolling women with a term singleton pregnancy in cephalic presentation, intact membranes, an unfavourable cervix, an indication for induction of labour, and no prior caesarean section. 824 were randomly allocated to induction of labor with a 30 mL Foley catheter or vaginal prostaglandin E2 gel. A meta-analysis including the trial data confirmed that a Foley catheter did not reduce caesarean section rates. However two serious maternal adverse events recorded, both in the prostaglandin group: one uterine perforation and one uterine rupture. Caesarean section rates were much the same between the two groups (23% vs 20%, risk ratio [RR] 1.13, 95% CI 0.87 - 1.47) [24].

In a small group of parous women, a higher caesarean section rate was demonstrated after balloon ripening comparing it with vaginal PGE2 [25]. This was the only study we found which showed a significant negative impact of this method of induction.

Theoretically, the insertion of a foreign object could increase the risk of intrauterine infection, but limited data from a meta-analysis did not show evidence of an increased risk of infectious morbidity in women who used mechanical methods of cervical ripening [26].

## 5. CONCLUSION

The cervical ripening double balloon (Cook's device) induced significant ripening and dilatation of the un-

favourable cervix and saved at least nine caesarean sections with all their concomitant morbidity and mortality. It is a safe and effective method of inducing labor for women requesting VBAC after term plus ten weeks of gestation with unfavourable cervix.

Our success with VBAC was estimated to be over 50% with no serious life threatening maternal or fetal complications. We considered the process satisfactory and practical.

We recommend larger studies to assess safety and efficacy of Cook's device in VBAC before embarking on routine elective caesarean delivery.

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