ORIGINAL ARTICLE

Cervical Ripening Balloon for Induction of Labour in High Risk Pregnancies

Hian Yan Voon, MRCOG, Angeline TY Wong, MB BCh BAO, Moi Ling Ting, MD, Haris Njoo Suharjono, FRCOG

Department of Obstetrics and Gynaecology, Sarawak General Hospital, Kuching

ABSTRACT

Background: The Cervical Ripening Balloon (CRB) is a novel mechanical method for induction of labour (IOL), reducing the risks of hyperstimulation associated with pharmacological methods. However, there remains a paucity of literature on its application in high risk mothers, who have an elevated risk of uterine rupture, namely those with previous scars and grandmultiparity.

Methodology: A retrospective study on IOL using the CRB in women with previous caesarean section or grandmultiparity between January 2014 and March 2015. All cases were identified from the Sarawak General Hospital CRB request registry. Individual admission notes were traced and data extracted using a standardised proforma.

Results: The overall success rate of vaginal delivery after IOL was 50%, although this increases to about two-thirds when sub analysis was performed in women with previous tested scars and the unscarred, grandmultiparous woman. There was a significant change in Bishop score prior to insertion and after removal of the CRB. The Bishop score increased by a score of 3.2 (95% CI 2.8-3.6), which was statistically significant (p<0.01) and occurred across both subgroups, not limited to the grandmultipara. There were no cases of hyperstimulation but one case of intrapartum fever and scar dehiscence each (1.4%). Notably, there were two cases of change in lie/presentation after CRB insertion.

Conclusion: CRB adds to the obstetricians' armamentarium and appears to provide a reasonable alternative for the IOL in women at high risk of uterine rupture. Rates of hyperstimulation, maternal infection and scar dehiscence are low and hence appeals to the user.

KEY WORDS:
Cervical ripening balloon, double balloon catheter, mechanical, induction of labour, previous scar, grandmultiparity

INTRODUCTION

One in every five babies are delivered after induction of labour (IOL) at term.[1] Traditionally, oxytocin and vaginal prostaglandins have been used, the latter with greater success rates in patients with unfavourable cervix.

However, the use of prostaglandins have been associated with a two- to three-fold increase risk of scar rupture in women with previous caesarean section. To add to the complexity of this problem, grandmultiparous women still contribute a significant proportion of deliveries in our community.

With rising caesarean section rates, obstetricians continue to strive for a safer method of induction of labour, including mechanical methods. The Cook™ cervical ripening balloon (CRB) is one such novel method, although there appears to be a lack of uniformity on recommendations of its use. The World Health Organization (WHO) guidelines for induction of labour proposes the use of balloon catheters for the induction of labour based on the results of a systematic review and adds that it may be preferred in women with a scarred uterus. On the other hand, the National Institute of Clinical Excellence and Health (NICE) states that mechanical methods should not be routinely used. The Society of Obstetricians and Gynaecologists of Canada (SOGC) recommends the use of double lumen catheter, such as the CRB, as a second line alternative.[2,3,4]

The reported advantage of the CRB is a reduction in the risk of hyperstimulation without increasing caesarean section rates. In an randomised controlled trial involving 330 nulliparous women with unfavourable cervix, Pennell *et al.* did not find a statistically significant increment in caesarean section rates when comparing induction of labour with double balloon catheters, Foley's or Prostaglandin E2. Risk of maternal chorioamnionitis, endometritis and neonatal infection were not found to be increased.[4,5]

Whilst there are increasingly supportive data on the use of CRB in primigravidas, there remains a paucity of evidence in literature on the use of Cook™ CRB in high risk mothers. Notably, it is in this group of women, namely those with previous scars and grandmultiparity, who may benefit most due to a lower risk of hyperstimulation.

This descriptive study will add to our knowledge of the efficacy and safety of the CRB in high risk women.

MATERIALS AND METHODS

This is a retrospective study on IOL using the CookTM CRB for mothers with previous caesarean section or/and grandmultiparity in our hospital. All cases of IOL between January 2014 and March 2015 using the Cook™ CRB in our centre were identified from the Sarawak General Hospital CRB request registry. Individual admission notes were traced and data were extracted by using a standardised proforma.

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Corresponding Author: Voon Hian Yan, Sarawak General Hospital, Jalan Hospital 93586 Kuching, Sarawak
Email: vhaxyn@gmail.com

Inclusion criteria were singleton, pregnancies beyond 36 completed weeks with unfavourable modified Bishop score (<7) and vertex presentation. The modified Bishop score has a minimum score of zero and maximum score of 13 (see Appendix I). For simplicity, the term "Bishop score" is used in this paper. All patients had either one previous lower segment caesarean section and/or grandmultiparity. Women who were both grandmultiparous and had a previous caesarean section would be analysed under the "previous caesarean section" subgroup. In this paper, grandmultipara refers to women who have a parity of four and above. Tested scar refers to women who have had one or more successful vaginal birth after caesarean (VBAC)

Multiple pregnancies, patients with favourable Bishop scores, more than one previous scar, previous LLETZ (Large Loop Excision of Transformation Zone) and maternal fever of any source were excluded. Patients with any contraindication for vaginal delivery were excluded. Women with favourable Bishop score were offered amniotomy and oxytocin for IOL instead.

Gestational age was determined by patient's last menstrual period or by using ultrasound if there were discrepancies between her dates and ultrasound examination. A discrepancy of 5 days or less, 7 days or less, 10 days or less were permitted at gestations less than 10 weeks, 10-14 weeks and more than 14 weeks respectively.

Patients were counselled on the methods of IOL available including the use of vaginal prostaglandins on admission. All decisions for induction in our unit are decided by a specialist or a consultant. Patients who have agreed for IOL are first seen by a registrar in the patient admission centre and indication, risks and methods for IOL were discussed. If decision for IOL was only made as an inpatient, the setting of this discussion would be in the labour suite or antenatal ward. Patients are subsequently allowed to deliberate on their decision and re-counseled by an obstetrician. Contents of discussion and their final decision were documented in the case notes. Prior to insertion of the Cook™ CRB, foetal heart tracing was recorded via cardiotocography and vaginal examination was performed to confirm the Bishop score. A sterile speculum was then introduced to visualise the cervix,Cook™ CRB guided into the os with the use of a pair of forceps until the clinician was satisfied that the whole uterine balloon is above the internal os. 40-80 ml of normal saline was used to inflate the uterine balloon, followed by an equal amount in the vaginal balloon. Once satisfied with the placement, the speculum was removed and the distal end of the Cook™ CRB plastered to patient's thigh. The patients were allowed to ambulate and resume normal activity in the ward.

Patient's were asked to inform the clinician if they had significant discomfort, developed fever, leaking liqour or if the catheter dislodged. If the Cook™ CRB dislodged, the Bishop score reassessed and aimed for amniotomy once bed was available in the labour ward. On the other hand, if the Cook™ CRB remained in-situ, it was removed 12-24 hours later and aimed for amniotomy.

Amniotomy was performed once patient was transferred to labour ward and oxytocin started 0-4 hours later if contractions were inadequate, defined as less than 3 in 10 contractions of moderate strength (40-60 seconds).

Failure of induction was diagnosed if patients did not enter active phase of labour despite at least 6-8 hours of adequate contractions defined above. Poor progress was diagnosed if cervical dilatation was <1cm/hour despite 6-8 hours of moderate contractions (lasting 40-60 seconds) of at least 3 in 10 minutes, especially after of the use of oxytocin. Hyperstimulation was defined as contractions > 5 in 10 minutes or lasting more than 120seconds.

Statistical analysis was performed using SPSS version 19 and significance testing involved the use of Chi Square and Paired T-test. $p<0.05$ was deemed significant. Sub analysis on the success rate of vaginal delivery was performed in patients with a tested scar and grandmultiparity.

Ethical approval was obtained from Medical Research and Ethics Committee (MREC) NMRR ID 15-108-24113

RESULTS

A total of 77 patients were identified from patient registry between January 2014 and March 2015. Three patients were excluded as they did not fulfil the criteria for high risk inductions. Of the remaining 74 women, four were both grandmultiparous and had a previous caesarean section.

The patient demographics are as illustrated in Table I, with a mean gestation of 38.9 (Standard Deviation (SD) 1.3) weeks (range 36-41.4). The overall success rate of vaginal delivery after IOL was 50%, although it slightly lower at 44.8% in women with previous caesarean section. However, the success rate increases to 66.7%, when sub analysis was performed in women with previous tested scars. This was comparable to the success rate in unscarred, grandmultiparous women (68.7%). There were no cases of hyperstimulation but one case of intrapartum fever and scar dehiscence each (1.4%).

There was a significant change in Bishop score prior to insertion and after removal of the Cook™ CRB. Mean Bishop score improved from 3.8 (SD 1.8) to 7.0 (SD 1.9). A paired T-test was performed, which found this positive change in Bishop score of 3.2 (95% CI 2.8-3.6) to be statistically significant ($p<0.01$). Of note, the increase in favourability of Bishop score occurred across both subgroups and was not limited to grandmultiparous women.

Although the Cook™ CRB was planned for insertion between 12-24 hours, more than a third had premature expulsion of the CRB. Interestingly, women with premature expulsion of CookTM CRB were no more likely to deliver vaginally than via caesarean (58.6% vs 41.3%; $p>0.05$).

Failure to progress/IOL was the main indication for caesarean section (54.1%) although two patients had a caesarean section for abnormal lie or presentation after Cook ™ CRB insertion.

Table I: Demographics and Primary Outcomes, Including Subgroup Analysis

	All patients n=74	Previous Caesarean n=58	Grandmultiparous n=16
Age (years) (SD, range)	32.0 (5.0, 22.0-45.0)	30.6 (4.1, 22.0-44.0)	38.8 (3.0, 34.0-45.0)
Parity (n) (SD, range)	2.6 (2.1, 1.0-8.0)	1.6 (0.9, 1.0-4.0)	6.0 (1.3, 4.0-8.0)
Gestational age (weeks) (SD, range)	38.9 (1.3, 36.0-41.4)	39.2 (1.2, 36.7-41.4)	38.0 (1.4, 36.0-40.1)
BMI (kg/m^2) (SD, range)	28.5 (6.1, 19.4-48.7)	28.2 (6.2, 19.4-48.7)	29.8 (5.2, 19.7-37.4)
Mode of delivery			
Vaginal, incl. instrumental	37 (50%)	26 (44.8%)	11 (68.8%
Caesarean	37 (50%)	32 (55.2%)	5 (31.2%)
Complications			
Maternal fever	1 (1.4%)	0	1
Hyperstimulation	0	0	0
Scar dehiscence	1 (1.4%)	1	0
Bishop score			
At insertion (SD, range)	3.8 (1.8, 0.0-8.0)	4.0 (1.8, 0.0-8.0)	3.1 (1.7, 0.0-6.0)
At removal (SD, range)	7.0 (1.9, 2.0-12.0)	7.0 (1.8, 2.0-12.0)	6.7 (1.8, 3.0-11.0)
Mean change in Bishop score (95% CI)	3.2 (2.8-3.6)*	3.1 (2.7-3.6)*	3.5 (2.5-4.5)*
Duration of CRB use (hours) (SD, range)	12.2 (5.4, 3.0-26.0)		
Premature expulsion of CRB	29 (39.2%)		
Interval insertion-delivery (hours) (SD, range)	27.8 (12.6, 6.5-81.0)		
Birthweight (kg) (SD, range)	2.95 (0.41, 1.89-3.90)		

SD - Standard Deviation, BMI - Body Mass Index, CI - Confidence Interval, CRB - Cervical Ripening Balloon.
* p-value < 0.01

Table II: Selected outcomes in women who delivered vaginally

Selected outcomes	Mean/Percentage
Previous caesarean section	n=58
Tested scar	6/9 (66.7%)
Untested scar	20/49 (40.8%)
Grandmultipara	11/16 (68.7%)
Duration: insertion-delivery (hours) (SD, range)	25.6 (13.9,10.0-81.0)
Duration: amniotomy-delivery (hours) (SD, range)	5.2 (3.2, 0.3-13.0)
Duration of augmentation (hours) (SD, range)	3.3 (3.0, 0.0-12.5)

SD- Standard deviation

Table III: Indication for caesarean section

Indication	n (%)
Poor progress/Failed IOL	20 (54.1%)
AFD	13 (35.1%)
Suspected scar dehiscence	2 (5.4%)
Abnormal lie or presentation	2 (5.4%)
Total	37

IOL - Induction of labour, AFD - Acute fetal distress/Presumed fetal compromise

DISCUSSION

To date, there is only one small observational study in the English literature, involving 17 non-Asian patients, looking at the use of CRB specifically, in women with previous scars.[6] We believe our study will add to the available information on this method of induction of labour.

The success rate of IOL using the CRB was 44.8% in women with previous scars, consistent with lower rates reported in the literature when compared with women who present in spontaneous labour.[7,8] The success rate however, increases significantly to 66-68% in women with previous tested scar and in grandmultipara.

In addition, the average duration from induction to delivery and from amniotomy to delivery, obtained in this study, will aid in counselling of patients and provide some form of reassurance.

One patient developed intrapartum fever and was treated as chorioamnionitis. There was no association with prolonged use of CRB, leaking prior to amniotomy, maternal sepsis or poor Apgar at birth. There were two caesarean sections performed for suspected scar dehiscence but intraoperatively, both lower uterine scars were intact. The single case of scar dehiscence in our series only presented more than 24 hours after delivery, when the patient became increasingly tachycardic and anaemic. She was successfully managed conservatively with blood transfusion and there was no foetal morbidity. The overall risk of scar rupture in this study was 1.4%, lower than reported rates of 2.4% with the use of prostaglandins.[9]

A particular concern was the change in foetal lie or presentation after insertion of the CRB. This has not been widely reported previously and occurred in 2.7% of the patients induced. Surprisingly, none of the patients were grandmultiparous and both had normal BMI. Both patients had an unengaged presenting part but foetal presentation was confirmed on admission sonographically and clinically at the point of insertion of the CRB. One patient had a compound presentation (vertex-hand) in early active phase. The second patient had her CRB expulsed at an os of 3cm but the presenting part was vertex at that point. While for the availability of a room in the labour suite, she developed contractions and a repeat vaginal examination found a breech presentation. In both patients, the presenting part remained vertex after removal or expulsion of the balloon. There were no cases of cord prolapse.

There are several limitations to the study, mainly because of its observational design, which does not permit the direct comparison with other methods such as prostaglandin or Foley's catheter. Other factors which may affect the success rate of IOL in women with previous scars were not readily available, ex. indication of previous caesarean section. In addition, there was a variable interval between removal of CRB and subsequent amniotomy, occasionally protracted due to the demands of a busy unit.

Although the CRB has been shown to be equally efficacious for induction of labour compared to the use of vaginal prostaglandins, its cost remains a limiting factor. Currently, a single tablet of Prostin™ costs about a third of a Cook™ CRB. The Foley's catheter is another increasingly popular and cost effective mechanical method of induction. It costs about a tenth of a Cook™ CRB. However, its application here is off label and may be less user-friendly. An increasingly litigious environment for the obstetrician means that the use of an off label product may result in distasteful medicolegal exposure, despite the obstetrician's best intentions. Furthermore, evidence is still lacking on the optimal volume to be placed into a Foley's. In contrast, the Cook™ CRB is a device specifically created for the purpose of IOL and has received FDA clearance. Selective usage of CRB in high risk pregnancies such as women with previous caesarean section and grandmultipara represents a reasonable compromise, due to lower reported rates of uterine rupture where prostaglandins are avoided.

CONCLUSION

Overall, the CRB adds to the obstetricians' armamentarium and appears to provide a reasonable alternative for the IOL in women at high risk of uterine rupture. Rates of hyperstimulation, maternal infection and scar dehiscence are low and appealing to the user. However, more data is needed to determine the significance of a change in foetal lie or presentation after CRB insertion. A high quality, randomised control trial directly comparing prostaglandins, Foley's catheter and CRB in a high risk population would provide much needed evidence to guide future clinical practice.

DISCLOSURE OF INTEREST

None of authors have received any sponsorship, grants, commissions from or have financial interest in the manufacturer of the Cook™ Cervical Ripening Balloon (Cook™ Medical, Bloomington, Indiana) or its local agents.

CONTRIBUTION TO AUTHORSHIP

VHY conceived and designed the study, analysed the data and drafted the manuscript.

AWTY was involved in literature review, drafting of the initial manuscript and acquisition of the data.

TML acquired, analysed and interpreted the data.

HS edited, critically revised the manuscript and provided approval for the final manuscript.

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CONFLICT OF INTEREST

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