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<td>Cheuk, QKY; Lo, TK; Lee, CP; Yeung, APC</td>
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Double balloon catheter for induction of labour in Chinese women with previous caesarean section: one-year experience and literature review

Queenie KY Cheuk *, TK Lo, CP Lee, Anita PC Yeung

**ABSTRACT**

**Objectives:** To evaluate the efficacy and safety of double balloon catheter for induction of labour in Chinese women with one previous caesarean section and unfavourable cervix at term.

**Design:** Retrospective cohort study.

**Setting:** A regional hospital in Hong Kong.

**Patients:** Women with previous caesarean delivery requiring induction of labour at term and with an unfavourable cervix from May 2013 to April 2014.

**Major outcome measures:** Primary outcome was to assess rate of successful vaginal delivery (spontaneous or instrument-assisted) using double balloon catheter. Secondary outcomes were double balloon catheter induction-to-delivery and removal-to-delivery interval; cervical score improvement; oxytocin augmentation; maternal or fetal complications during cervical ripening, intrapartum and postpartum period; and risk factors associated with unsuccessful induction.

**Results:** All 24 Chinese women tolerated double balloon catheter well. After double balloon catheter expulsion or removal, the cervix successfully ripened in 18 (75%) cases. The improvement in Bishop score 3 (interquartile range, 2-4) was statistically significant (P<0.001). Overall, 18 (75%) cases were delivered vaginally. The median insertion-to-delivery and removal-to-delivery intervals were 19 (interquartile range, 4.1-10.8) hours, respectively. Compared with cases without, the interval to delivery was statistically significantly shorter in those with spontaneous balloon expulsion or spontaneous membrane rupture during ripening (7.8 vs 3.0 hours; P=0.025). There were no major maternal or neonatal complications. The only factor significantly associated with failed vaginal birth after caesarean was previous caesarean section for failure to progress (P<0.001).

**Conclusions:** This is the first study using double balloon catheter for induction of labour in Asian Chinese women with previous caesarean section. Using double balloon catheter, we achieved a vaginal birth after caesarean rate of 75% without major complications.

New knowledge added by this study

- This is the first report from Asian Chinese women on the use of double balloon catheter (DBC) for induction of labour in the presence of a caesarean scar. Using DBC, a vaginal birth after caesarean (VBAC) rate of 75% was achieved without major complications.
- During cervical ripening with DBC, cases with spontaneous balloon expulsion or spontaneous membrane rupture had a more favourable outcome with shorter interval to delivery.
- Previous caesarean section for failure to progress was significantly associated with failed VBAC.

Implications for clinical practice or policy

- Our anecdotal experience with DBC was favourable and its application may reduce repeated caesarean section rates. Further research exploring this potential is warranted and large randomised controlled trials are needed to confirm its efficacy.

**Introduction**

There is widespread public and professional concern about the increasing rates of caesarean section (CS). In the UK and North America, around 25% and 32% of births respectively were by CS. In Hong Kong, according to the 2009 territory-wide O&G audit report, CS rate has been around 42.1%. Previous CS has been the most common indication for caesarean...
以雙球囊導管為曾有剖腹產病史的華籍女性進行引產：一年經驗分享及文獻綜述

卓筠卿、盧子健、李之朋、楊寶芝

目的：以雙球囊導管為曾有剖腹產病史和宮頸不成熟的華籍女性進行引產，評估其療效和安全性。

設計：回顧性隊列研究。

安排：香港一所分區醫院。

患者：2013年5月至2014年4月期間曾進行剖腹產並於足月引產前宮頸不成熟的事例。

主要結果測量：主要療效指標為使用雙球囊導管而達至陰道分娩的成功比率（包括自然分娩或使用儀器助產）。次要療效指標為從置入直至分娩時移除雙球囊導管的時間差距、宮頸成熟度評分的改善、催產素的使用、產婦或胎兒在使用雙球囊導管引產以及分娩時和產後所出現的併發症，並引產失敗的風險因素。

結果：全部24名華籍女性對於雙球囊導管的耐受性良好。雙球囊導管自行排出或被取出時，有18例（75%）促宮頸成熟成功。使用雙球囊導管使宮頸成熟度（Bishop）評分改善中位數為3分（四分位距：2-4分）的病例有顯著改善（P<0.001）。總體而言，18例（75%）成功經陰道分娩。置入雙球囊導管至分娩的時間中位數為19小時（四分位距：13.4-23.0小時），取出雙球囊導管至分娩的時間中位數為6.9小時（四分位距：4.1-10.8小時）。與沒有自行排出球囊或胎膜自破的參與者比較，自行排出球囊或胎膜自破的參與者的分娩時間明顯較短：7.8比3.0小時（P=0.025）。使用雙球囊導管並無發生嚴重的產婦或新生兒併發症。唯一與剖腹產後陰道分娩失敗有關的風險因素為曾經因產程進展不良而進行剖腹產（P<0.001）。

結論：這是為曾經進行剖腹產的亞洲婦女使用雙球囊導管催生引產的首項研究。採用雙球囊導管後，有75%成功以陰道分娩而無嚴重併發症。

Methods

This retrospective study was conducted in the obstetrics unit of Pamela Youde Nethersole Eastern Hospital in Hong Kong. The unit provides tertiary care and conducts over 3000 deliveries per year. Prior to the introduction of DBC, the background CS and VBAC rates in our unit was approximately 30% and 1.9%, respectively. The overall success rate of VBAC was more than 80%. In our study, we identified VBAC cases using DBC for IOL between 1 May 2013 and 30 April 2014 through the departmental database. Clinical details were reviewed from the case notes and hospital electronic systems.

Inclusion and exclusion criteria

Inclusion criteria were women with one lower transverse caesarean scar and no contra-indication for VBAC who were given the option of either repeated elective CS or VBAC. Those VBAC cases requiring medically or obstetrically indicated IOL...
were offered DBC if the cervix was unfavourable (modified Bishop score <6) and membranes intact. The exclusion criteria for using DBC were: women with two or more previous CS, classical CS scar, inverted T or J or low vertical incision in previous CS; previous uterine scar for gynaecological conditions, eg myomectomy, hysterotomy; congenital uterine abnormality; twin pregnancy, non-cephalic presentations, intra-uterine death, suspected fetal distress; uterine fibroids which may obstruct labour, placenta praevia, antepartum haemorrhage, leaking, clinical chorioamnionitis, suspected macrosomia (ultrasound estimated fetal weight ≥4000 g), polyhydramnios (amniotic fluid index ≥25 cm or single deepest pocket ≥8 cm), congenital fetal abnormalities; and maternal diseases or maternal infection which would contra-indicate vaginal delivery or warrant prompt delivery. Ethical approval for this study was obtained from the local institutional human research ethics committee.

**Induction-of-labour protocol**

Eligible patients were admitted into hospital in the evening and an initial Bishop score was obtained. Cardiotocogram for 60 minutes, and ultrasound scan to assess estimated fetal weight, liquor volume, fetal wellbeing by umbilical artery Doppler and placental location were performed. After informed consent, the DBC was inserted according to the manufacturer’s instruction. If the DBC insertion failed, women would be offered CS the next day morning. The procedure of DBC insertion in all patients was done by one investigator (KY Cheuk). The uterine and vaginal balloons were inflated in phases to 40-50 mL and 60 mL, respectively using normal saline. After insertion, vaginal examination was performed to confirm correct placement. The catheter was taped to the woman’s inner thigh without tension. Following insertion of catheter, continuous fetal heart monitoring (CFHM) was done for 60 minutes. The catheter was kept for 12 hours if spontaneous expulsion did not occur, or removed earlier if there was spontaneous rupture of membranes, excessive vaginal bleeding, fetal distress, scar tenderness, or patient intolerance. Immediately following balloon expulsion or removal, the Bishop score was reassessed, followed by an attempt to have artificial rupture of membranes (ARM) regardless of Bishop score. To reduce the potential inter-observer bias, the same investigator (KY Cheuk) assessed the Bishop score before DBC insertion and immediately after DBC expulsion or removal. Oxytocin infusion (Syntocinon; Sandoz Pharmaceuticals, East Hanover [NJ], US) was commenced if after ARM the uterine contractions were suboptimal at a rate of 1 mU/min and the infusion rate was doubled every 30 minutes until the uterine contractions were regular at 3 minutes’ interval. The maximum dose was capped at 8 mU/min. Oxytocin was not started without membrane rupture or if the DBC was still in place; CFHM was started after ARM till delivery. Labour was managed by the attending obstetrician and midwives. Assessment of labour progress and administration of analgesia was made according to departmental protocols. Group B streptococcus prophylaxis was given according to departmental protocol. It was commenced after DBC insertion until delivery for group B streptococcus carriers.

**Outcome measures**

The primary outcome was successful vaginal delivery (spontaneous or instrument-assisted). The secondary outcomes were: induction-to-delivery interval; device-removal-to-delivery interval; cervical score improvement; oxytocin augmentation; maternal or fetal complications during cervical

### Table 1. Baseline characteristics of women with previous caesarean section induced with double balloon catheter

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Data*</th>
</tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>35 (32.5-36.3)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>159.0 (154.0-161.0)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>22.6 (20.6-26.4)</td>
</tr>
<tr>
<td>Parity</td>
<td>1 (1-1)</td>
</tr>
<tr>
<td>Obstetric history</td>
<td></td>
</tr>
<tr>
<td>Previous vaginal delivery</td>
<td>4 (16.7)</td>
</tr>
<tr>
<td>Successful VBAC</td>
<td>1 (4.2)</td>
</tr>
<tr>
<td>Indication of previous caesarean section</td>
<td></td>
</tr>
<tr>
<td>Failed to progress</td>
<td>8 (33.3)</td>
</tr>
<tr>
<td>Malpresentation</td>
<td>7 (29.2)</td>
</tr>
<tr>
<td>Placenta praevia</td>
<td>2 (8.4)</td>
</tr>
<tr>
<td>Others†</td>
<td>7 (29.2)</td>
</tr>
<tr>
<td>Current pregnancy</td>
<td></td>
</tr>
<tr>
<td>Duration from last caesarean delivery (years)</td>
<td>5.5 (3.0-7.3)</td>
</tr>
<tr>
<td>Gestation at labour induction (weeks)</td>
<td>39.1 (38.7-39.6)</td>
</tr>
<tr>
<td>Cervical Bishop score before induction</td>
<td>3 (3-4)</td>
</tr>
<tr>
<td>GBS carrier</td>
<td>6 (25)</td>
</tr>
<tr>
<td>Indication for induction</td>
<td></td>
</tr>
<tr>
<td>GDM</td>
<td>8 (33.3)</td>
</tr>
<tr>
<td>Past-term (&lt;40 weeks)</td>
<td>7 (29.2)</td>
</tr>
<tr>
<td>Decreased fetal movement</td>
<td>4 (16.7)</td>
</tr>
<tr>
<td>Oligohydramnios</td>
<td>2 (8.3)</td>
</tr>
<tr>
<td>Bad obstetric history</td>
<td>1 (4.2)</td>
</tr>
</tbody>
</table>

* Data are shown as median (interquartile range), or No. (%)
† One case each for fetal distress, cord round neck, large for gestational age with GDM, large head circumference, prolonged leaking, meconium-stained liquor, and bad obstetric history
ripening, intrapartum and postpartum period, which included failed device insertion, inability to void during insertion, intolerance of device necessitating early removal, uterine hyperstimulation, uterine rupture, fetal distress, abruptio, antepartum haemorrhage, cord prolapse, malpresentation, meconium-stained liquor, intrapartum and postpartum infection, postpartum haemorrhage, readmission in puerperium period, neonate delivery with Apgar score of <7 in 5 minutes, cord blood pH of <7.2, admission to neonatal intensive care unit, neonatal sepsis, respiratory distress syndrome and neonatal death, and risk factors associated with unsuccessful induction.

Uterine hyperstimulation was defined as either the occurrence of five or more contractions in 10 minutes for two consecutive 10-minute period, or a contraction lasting for at least 2 minutes, with or without changes in fetal heart rate pattern. Uterine rupture was defined as disruption of the uterine muscle extending to and involving the uterine serosa or disruption of the uterine muscle with extension to the bladder or broad ligament. Uterine dehiscence was defined as disruption of the uterine muscle with intact uterine serosa. Intrapartum infection was defined by maternal fever of ≥38°C during labour. Failed IOL was defined as failed ARM after catheter removal or cervical dilatation of <3 cm after at least 8 hours of optimal uterine contractions.

Literature review

We also conducted a literature search on PubMed, Ovid Medline, EMBASE, Cochrane library database of systematic reviews and open library using the keywords “double balloon catheter”, “Atad balloon”, “double balloon device”, “Foley catheter”, “induction”, “previous caesarean section”, and “previous scarred uterus”. Bibliographies of all relevant articles identified were searched manually to locate additional studies. We excluded non-English publications, or if the original paper was not available from various sources such as PubMed, local hospital or universities library systems and internet.

Statistical analyses

The statistical analysis was done by PASW Statistics 18, Release Version 18.0.0 (SPSS Inc, 2009, Chicago [IL, US]). Fisher’s exact test was used for categorical data, while independent t test was used if normally distributed, and non-parametric test (ie Mann-Whitney U test) if highly skewed. Univariate analysis was used to assess the risk factors associated with unsuccessful VBAC. To identify the differential effect over time, Wilcoxon signed rank test was used to compare the cervical Bishop scores before and after DBC application. The critical level of statistical significance was set at P<0.05.

Results

Twenty-five cases were identified during the 1-year study period, and one non-Chinese woman’s data were excluded. The remaining 24 cases were included for analysis. Table 1 summarises the baseline characteristics of study patients.

Figure 2 depicts the induction process and outcomes of the 24 cases; DBC was well tolerated in all cases (Table 2). There was no case of failed insertion. After DBC expulsion or removal, the cervix became favourable (Bishop’s score ≥6) in 18 (75%) cases. The improvement in Bishop score 3 (interquartile range [IQR], 2-4) was statistically significant (P<0.001). Artificial rupture of the membranes was successful in all 22 cases with intact membranes, regardless of cervical favourability. Oxytocin augmentation was required in 18 (75%) cases. Overall, 75% of cases were delivered vaginally. Among them, the median insertion-to-delivery and removal-to-delivery intervals were 19 (IQR, 13.4-23.0) hours and 6.9 (IQR, 4.1-10.8) hours, respectively. All the four women with previous vaginal deliveries had successful VBAC. Compared with cases without, the balloon expulsion-to-delivery or removal-to-delivery interval was shorter in those with spontaneous balloon expulsion or early balloon removal due to spontaneous membrane rupture during ripening (7.8 vs 3.0 hours, P=0.025). All the cases had good neonatal outcomes with cord blood pH of >7.25, 5-minute Apgar score of 10, without the need for neonatal intensive care unit admissions (Table 3). One case reported severe scar
pain during oxytocin augmentation. Scar dehiscence was suspected and emergency CS performed. Dehiscence was not substantiated intra-operatively. The baby was born in good condition. Apart from a few cases of maternal complications (e.g., postpartum infection and postpartum haemorrhage), there was no case of uterine rupture or adverse neonatal complications.

To study the risk factors associated with unsuccessful VBAC, univariate analysis was performed using maternal age, height, body mass index, cervical Bishop score, cervical favourability after DBC removal or dislodgement, gender and birth weight of baby, gestational diabetes mellitus, history of vaginal delivery, history of successful VBAC, inter-pregnancy interval, the indication for previous CS, and the indication for IOL in the current pregnancy as variables. Previous CS for failure to progress was the only factor significantly associated with unsuccessful VBAC ($P<0.001$).

**Discussion**

Few studies have investigated the use of DBC for IOL in patients with previous caesarean scars. Table 4 summarises the findings from some of the studies including the current study. Most of the studies showed significant improvement in Bishop score after using the device and a favourable cervix was achieved in 75% to 85% of cases. The overall vaginal delivery rate was 60.2% (71/118). There was one (0.85%) case of symptomatic scar dehiscence, and no adverse neonatal complications. The cervical ripening success rate in our study was comparable to those in other studies, and also our study achieved a higher vaginal delivery rate. One explanation for this would have been due to differences in the IOL protocols. Some authors would offer CS directly if the cervix failed to ripen after the DBC. Our practice was to continue induction with ARM and oxytocin even if the cervix remained unfavourable.
that ethnicity does impact VBAC success rates. A third reason could have
been differences in ethnicity. Studies have shown with successful VBAC. A third reason could have
association with mechanical induction is a concern, the evidence is contradictory. A systematic
review by Heinemann et al on studies using Foley catheter for IOL showed that use of mechanical
devices was associated with significant increase in maternal morbidity due to infectious morbidity
when compared with pharmacological agents. On the other hand, a recent Cochrane review showed no
increase in serious maternal morbidity with the use of the Foley catheter. Further support was provided
from the recent open-label randomised controlled trial PROBAAT, which compared Foley catheter
to vaginal prostaglandin in 824 women without previous CS. The study showed that Foley catheter
had similar CS rates, less uterine hyperstimulation, fewer maternal and fetal morbidities, and no increase
in infectious morbidity. Although Foley catheter was featured in all these studies, DBC potentially
has additional utility for an unripe cervix as it applies pressure on both the external and internal
os, avoiding the need for traction and reduces the associated patient discomfort. Double balloon
catheter has a larger inflated volume compared with Foley catheter (80 mL vs 30 mL) and therefore
IOL with a bigger balloon volume may shorten duration of labour with better cervical dilatation.
Nevertheless, clinical data comparing DBC with Foley catheter in the presence of a caesarean scar are
lacking, while those on intact uterus are scarce and inconclusive.

Table 3 summarises the results of studies using Foley catheter for IOL in the presence of a caesarean
scar. It appears that DBC achieved comparable vaginal delivery rate (60.2% vs 58.0%) and similar
uterine rupture/dehiscence rate (0.85 % vs 0.65%). There was no case report of neonatal death in studies
using DBC while there were two cases reported with Foley catheter. One was due to uterine rupture;
another was due to rupture of vasa praevia which was independent of the method of induction. Further
research to compare the efficiency and safety of the two devices for IOL in women with previous CS is
warranted. Although uterine rupture and infectious morbidity seemed rare with DBC in women with
previous CS, the number of women studied was too small to allow solid conclusion on its safety.

The complication rate for VBAC attempt was highest in those who failed to achieve VBAC in the
end. Knowledge of the factors associated with successful VBAC would therefore enable better
counselling on the choice of mode of delivery. Landon et al in a large cohort of 14 529 women showed that
previous vaginal delivery and previous successful VBAC were the best predictors of successful VBAC;
the success rates were 86.6% and 89.6%, respectively. In our study, all four cases with previous vaginal
delivery (including one with previous VBAC) had successful VBAC. In the study by Landon et al, factors associated with unsuccessful VBAC included
Abbreviations: DBC = double balloon catheter; IOL = induction of labour; NND = neonatal death; PPH = postpartum haemorrhage

* Intrapartum fever: body temperature of ≥37.8°C during labour
† Chorioamnionitis diagnosed by histological analysis of placenta
‡ Blood loss ≥500 mL
§ Included urinary tract infection and gaped wound

Table 4. Analysis of studies using DBC and Foley catheter for IOL in women with previous caesarean section8-11,14,20-24

<table>
<thead>
<tr>
<th></th>
<th>Year</th>
<th>No. of cases</th>
<th>No. of vaginal deliveries</th>
<th>Success rate (%)</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>DBC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Khotaba et al8</td>
<td>2001</td>
<td>37</td>
<td>24</td>
<td>64.9</td>
<td>3 Could not tolerate device</td>
</tr>
<tr>
<td>Miller and Davis9</td>
<td>2005</td>
<td>8</td>
<td>2</td>
<td>25.0</td>
<td>1 Could not tolerate device</td>
</tr>
<tr>
<td>Ferradas et al10</td>
<td>2013</td>
<td>32</td>
<td>18</td>
<td>56.3</td>
<td>1 Uterine scar dehiscence</td>
</tr>
<tr>
<td>Ebeid and Nassif11</td>
<td>2013</td>
<td>17</td>
<td>9</td>
<td>52.9</td>
<td>7 Intrapartum fever* 3 Chorioamnionitis†</td>
</tr>
<tr>
<td>Present study</td>
<td>2015</td>
<td>24</td>
<td>18</td>
<td>75.0</td>
<td>3 PPH‡</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 Postpartum infection§</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td>118</td>
<td>71</td>
<td>60.2</td>
<td></td>
</tr>
</tbody>
</table>

| Foley                    |      |              |                            |                  |                                     |
| Ravasia et al14          | 2000 | 129          | 79                         | 61.2             | 1 Uterine rupture                   |
| Ben-Aroya et al22        | 2002 | 161          | 82                         | 50.9             | 0 Uterine rupture                   |
| Bujold et al21           | 2004 | 255          | 142                        | 55.7             | 4 Uterine rupture                   |
| Ziyauddin et al22        | 2013 | 35           | 25                         | 71.4             | 0 Uterine rupture                   |
| Jozwiak et al23          | 2014 | 208          | 148                        | 71.2             | 1 Uterine rupture 2 NND             |
| Sananès et al24          | 2014 | 135          | 59                         | 43.7             | 0 Uterine rupture                   |
| Overall                  | 2015 | 923          | 535                        | 58.0             | 6 (0.65%) Uterine rupture           |

Conclusions

This is the first report from East Asia on the use of DBC for IOL in the presence of caesarean scar. A success rate of 75% was achieved using VBAC in Chinese women with a caesarean scar and an unfavourable cervix. The procedure of DBC was well tolerated, and no major complications were observed. Our favourable experience with DBC in Asian Chinese women lends support to further research exploring the potential of this promising modality in averting the rising CS rates in this part of the world.

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