Learning Curve in the Use of Cervical Ripening Balloon for Induction of Labour

Grace Yang Huang NG [1], Toh Lick TAN [1, 2], Sheri Ee-Lin LIM [1], Shephali TAGORE[3], George Seow Heong YEO[3]

ABSTRACT

The aim of this study is to analyze the learning curve in the use of cervical ripening balloon. Although literature has shown that the cervical ripening balloon (CRB) is equally acceptable and efficacious in induction of labour, with lower hyperstimulation risk when compared with prostaglandins, its use is less prevalent and requires training of the staff. In the study, trainees were given a lecture followed by a hands-on session on models in the use of CRB by an experienced trainer. Trainees are supervised for their initial insertion of CRB. A total of 31 CRB insertions by the trainer and trainees were analyzed. The time taken to insert CRB by the trainer was shorter compared to that by the trainees who had experience with two previous insertions. However, trainees who had experience with three or more insertions showed competence by having similar insertion timings and did not require any assistance.

Keywords: Learning curve; Cervical ripening balloon; Labour induction

INTRODUCTION

Induction of labour (IOL) is one of the most common obstetric procedure affecting about a quarter of all term deliveries[1].Prostaglandin E_2 has traditionally been the common method of induction of labour[2]. However there is renewed interest in mechanical IOL in recent years with more studies showing that mechanical devices may be as efficacious in achieving vaginal delivery with lower uterine hyperstimulation risk[1,3]. In the first randomized controlled trial comparing cervical ripening balloon (CRB) to prostaglandin E_2 for induction of labour in Singapore, we also showed that both methods were equally effective in achieving vaginal births, and had similar induction to vaginal delivery times as well as maternal and neonatal outcomes[4].

Mechanical devices like the single-balloon or the double balloon catheters separate the amniotic sac from the cervix and increase the pressure within the cervix. This results in mechanical dilation of the cervix and release of endogenous prostaglandins[3]. The avoidance of exogenous prostaglandins reduces the risk of uterine hyperstimulation. This makes mechanical IOL an attractive alternative in situations where prostaglandins are contraindicated or advised to be used with caution.

Although the evidence supports the use of CRB for IOL, introduction of the device into routine clinical practice may be hampered by unfamiliarity and concerns of its training requirement. When surgical and procedural methods evolve; new skills must be acquired safely and efficiently. As dissemination of new techniques often requires training in new skills, there may be hesitancy at the work place in picking up the new skill. However, learning a new skill usually becomes easier with time, with initial difficulty followed by improvement and plateaued performance. The "learning curve" is often used

[1] *Department of Obstetrics and Gynaecology, KK Women's and Children's Hospital, Singapore*

[2] *Thomson Women's Clinic, Jurong East, Singapore*

[3] *Department of Maternal Fetal Medicine, KK Women's and Children's Hospital, Singapore*

Corresponding Author
Dr Ng Yang Huang Grace
Address: Department of Obstetrics and Gynaecology, KK Women's and Children's Hospital, 100 Bukit Timah Road, Singapore 229899, Singapore.
Telephone: (+65) 6226 5554
Email: grace.ng4@mohh.com.sg

to describe how performance changes with experience over time[5-6].

The resources and training required to train a clinician in the use of CRB has not been previously explored. In proposing to introduce this new procedure in our hospital, we felt that it was useful to assess this. In this study, we aim to ascertain how much training is required to gained proficiency in the use of a CRB.

MATERIALS AND METHODS

We did a broad systems search of clinical databases (MEDLINE, PUBMED and the Cochrane library) from 1985 to February 20, 2015, to identify papers that mention a learning curve on procedures carried out on pregnant women. The search terms used were "cervical ripening balloon" and/or "induction of labour" and/or "learning curve" in pregnant women. We found 181 articles. Two articles were relevant to the antenatal population, but there were no articles on the use of cervical ripening balloon in induction of labour.

Taipale et al.[5] looked at the learning curve of the use of ultrasonography to detect selected major fetal structural defects in early pregnancy over a six year period, during which there was regular training sessions and obstetrician supervision. Sensitivity for major defects rose from 22% in the first year to 79% at the end of the study. They concluded that good results could be obtained with trained midwives, when there were sufficient examinations over a 3-4 year period. The second study by Morris et al.[6] described the learning curve of fetoscopic coagulation for severe twin to twin transfusion while establishing a new service in a fetal medicine centre. Two operators largely did the procedure; and the study concluded that with increasing experience of the procedure by operator there was a significant increase in perinatal survival. For our study, we have defined achievement in competency as when the time taken to insert the CRB successfully and without assistance is similar to that of an experienced clinician.

This study formed part of our trial comparing the use of CRB and prostaglandins for induction of labour[4]. This study included 31 women with term pregnancies at the KK Women's and Children's hospital in Singapore between July 2013 to June 2014. All women participating in the study were provided with written informed consent. The study was approved by the Singhealth Centralised Institutional Review Board with the reference number 2013/553/D. Pregnant women aged 21 – 40 years old with a singleton pregnancy with no major fetal anomaly who were suitable for vaginal delivery and scheduled for a planned IOL at 37^{+0} to 41^{+6} weeks gestation were included into the study.

At the start of the study, trainee doctors were given a mass lecture and attended a hands-on session on models in the use of the CRB by one experienced trainer. Posters showing step-by-step instructions were available on the ward. When the woman had been assigned to the CRB arm of the study, the experienced trainer will be informed. Trainees will observe an actual insertion of the CRB before being supervised for their initial insertion of CRB in the next woman assigned to CRB, thereafter they will insert the CRB independently and seek assistance as necessary.

After cleaning the vulva and vagina with Cetrimide solution, the Cooks Medical's double balloon CRB was inserted into the cervical canal using a plastic Cusco's speculum to visualize the cervix. The uterine and vaginal balloons of the CRB were gradually inflated with normal saline: initially 40 ml and 20 ml respectively, then further increments of 20 ml every hour to obtain 80 ml in each balloons by the third hour. A 20 minutes strip of CTG was taken before and after each inflation. If the woman was not in labour after complete inflation of the balloons, she would be transferred to the antenatal ward for ambulation before removing the CRB 12 hours after insertion in labour ward when possible. The role of the CRB was for the cervix to be sufficiently dilated on its removal for the amniotic membranes to be ruptured.

The time taken for the trainees to insert the balloon and whether help was required during the insertion were recorded. Maternal feedback was recorded after the delivery. The data was collected on a proforma and entered into Microsoft Excel spreadsheet. The data was then analyzed using IBM SPSS Statistics version 19.

RESULTS

In this study, there were a total of 31 patients who had CRB insertions. There was no significant difference in maternal age (31.0 + 6.6 vs 27.2 + 4.5 years, $p = 0.09$), ethnicity, proportion of primigravidae (62.5% vs 60.8%, $p = 0.93$), weight (67.0 + 18.3 vs 63.6 + 13.9 kg; $p = 0.38$), BMI (27.1 + 6.0 vs 24.9 + 4.6 kg m^{-2}; $p = 0.30$) and primary indication for IOL. Gestational age between the two groups was similar.

One CRB insertion was excluded as the CRB extruded

before 12 hours and the cervix was not dilated sufficiently to proceed with rupture of membranes. 30 CRB insertions were analysed. Of these, 8 were done by the trainer and 22 insertions by trainees (Figure 1). Of the 22 trainees' insertions, 10 of them have no previous experience with insertion. Trainees with previous experience did the remainder 12 insertions. This number is too small to construct a learning curve. Therefore, we analysed the data by dividing the trainees into groups according to the number of insertions they have done and comparing them to the trainer (Table 2) using the Wilcoxon test. We divided the trainees into groups by experience that ranges from 2 to 8. The time required in group 2 is significantly different from that of the trainer (p = 0.03947), whereas the time required by groups 3 and 4 were not significantly different from that of the trainer. We conclude that competence is achieved after the third insertion. Only two insertions required additional help. Ten trainees who had no previous experience were able to complete the insertion under supervision.

DISCUSSION

To best of our knowledge, this is the first study published on the training needs for the use of cervical ripening balloon.

Our study showed that competency can be achieved rapidly when the training is supported by lecture, simulation, and supervision. Surprisingly, 10 trainees with no previous experience inserted the CRB in 5.18 + 2.09 min, faster than trainees who had 1 or 2 previous experiences. We believe that the direct supervision at their first CRB insertion provided additional assistance in the form of prompting of the steps and/or help in administrating the saline inflation. Trainees who were inserting the CRB independently during the second or third insertion may have to rely on memory as well as refer to the posters in the wards to aid insertion. These may be the reasons which prolong the time required for insertion of the CRB.

A limitation of the study is the small sample size. However, it was sufficient to demonstrate statistical significance in the time required by the different groups.

Both CRB and prostaglandins are efficacious and complementary methods for IOL. Their availability in an obstetric unit will enable the women and clinician a choice in their method of IOL, and potentially allow IOL in women where prostaglandins are contraindication. A structured training in the use of CRB can enable clinicians to pick up the necessary skill rapidly. Unfamiliarity in the use of CRB can be overcome without undue resource requirement, and need not hinder the implementation of CRB as a complementary method for IOL in an obstetric unit.

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DECLARATION OF INTEREST STATEMENT

No financial interest or benefit has arisen from the direct applications of this research.

Figure 1. Boxplot of the Duration of CRB insertion and Experience

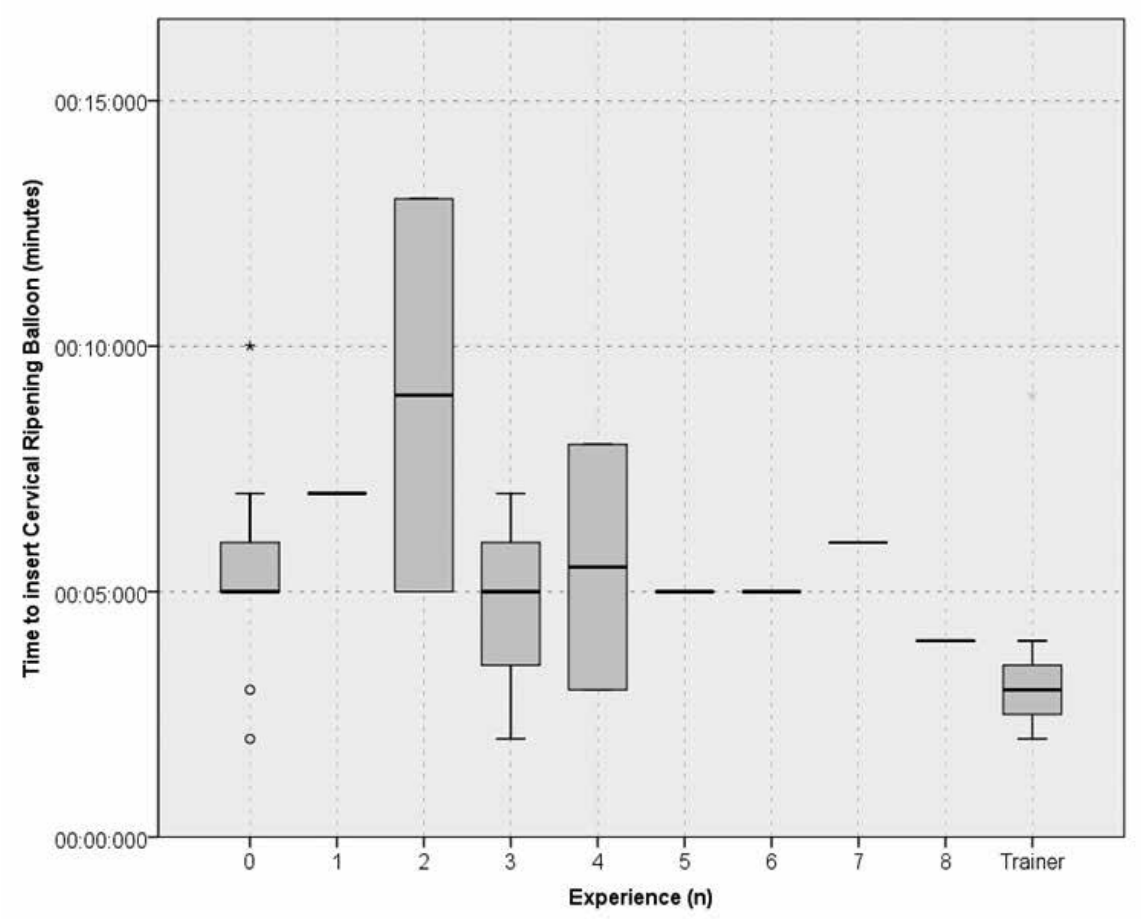

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Table 1. Demographics of participants

	Trainer (8)	Trainee (23)	p-value
Maternal age[1]	31.0+6.6	27.2+4.5	0.09
Ethnicity[2]			0.16
-Chinese	12.5% (1)	43.5% (10)	
-Malay	12.5% (1)	52.1% (12)	
-Indian	62.5% (5)	0% (0)	
-Others	12.5% (1)	4.3% (1)	
Primagravidae[2]	62.5% (5)	60.8% (14)	0.93
Weight, kg[1]	67.0+18.3	63.6+13.9	0.38
BMI, kg m-2[1]	27.1+6.0	24.9+4.6	0.30
Pre delivery Hb, g dl-1[1]	12.0+1.6	11.4+1.8	0.42
GBS positive[2]	37.5% (3)	17.4% (4)	0.21
Cervical dilatation, cm[1]	1.0+0.7	0.93+0.7	0.95
Primary indication for IOL[2]			0.27
-Postdates[3]	62.5% (5)	52.2% (12)	
-Gestational diabetes[3]	25% (2)	13.0% (3)	
-IUGR[3]	0% (0)	4.3% (1)	
-Low amniotic fluid index[3]	0% (0)	26.1% (6)	
-Maternal request[3]	0% (0)	4.3% (1)	
-Preeclampsia[3]	12.5%(1)	0% (0)	

[1] Values are mean ± SD, p calculated with Student t-test
[2] Values are percentage (n), p calculated with Pearson chi-square test
[3] Values are percentage (n), p calculated with Fisher's exact test

Table 2. Learning experience

Group vs Trainer	Mean time (min)	P-value
Group 1 (10)	5.30	0.025
Group 2 (2)	9.00	0.03947
Group 3 (3)	4.67	0.299
Group 4 (2)	5.50	0.2423
Group 5 (2)	5.00	0.06793
Group 6 (3)	5.00	0.04653
Trainer (8)	3.37	-

Group 1 include trainees with no previous experience
Group 2 include trainees with 2 previous experience
Group 3 include trainees with 3 previous experience
Group 4 include trainees with 4 previous experience
Group 5 include trainees with 5 previous experience
Group 6 include trainees with more than 5 previous experience