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**RESEARCH ARTICLE**

**EVALUATION OF CERVICAL RIPENING BETWEEN TRANSCERVICAL FOLEY CATHETER VERSUS HYGROSCOPIC CEVICAL DILATOR (LAMINARIA TENT) FOR INDUCTION OF LABOUR IN WOMEN WITH PREVIOUS CAESAREAN DELIVERY: PROSPECTIVE RANDOMIZED STUDY**

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**ABSTRACT**

**Objective:** To compare the efficacy and safety between transcervical Foley catheter and hygroscopic mechanical dilator for induction of labour in women agreed for vaginal birth after caesarean section (VBAC) with unfavorable cervix at term.

**Study Design:** This is a prospective randomized controlled trial conducted at a tertiary hospital on 60 women who agreed for trial of vagina delivery after cesarean section and required induction of labour due to various indications. The first group, 30 women underwent induction with 60 ml Foley catheter whereas the second group, 30 women had undergone induction with laminaria tent. The monitoring and induction procedure was standardized between both groups. Outcomes that were measured after 24 hours of induction were the obstetrics outcome of both devices such as Bishop's score changes and successful induction rate in term of vagina delivery. Others outcomes were maternal and fetal complication related to delivery such as post partum hemorrhage, infection and immediate Apgar score for neonate upon delivery. The economic outcome was also compared for both devices in relation to cost of induction and total cost of hospital stay.

**Results:** Among 60 patients, 30 patients were induced with Foley catheter whereas another 30 patients were induced with laminaria tent. All demographic data were comparable between both groups ( $P>0.05$ ). There was no statistical significant increase in the Bishop score for all cases with the mean were 1.57(0.87) for the entire cohort (Foley's: 4.20 to 5.77; Laminaria: 4.10 to 5.26;  $P>0.05$ ). The rate of successful induction was 55% with vaginal birth accounting for 53.3% whereas the rate of caesarean section was 46.7% of all cases (Foley's: SVD: 18 (60%) /CS; 12(40%), Laminaria: SVD: 14(46.7%) / CS; 16(53.3%),  $P>0.05$ ). The incidence of complication such as post partum hemorrhage was recorded in 10 cases (16.7%) (Foley's: 6 (10%); Laminaria: 4 (6.68%);  $P>0.05$ ). and Apgar score less than 9 was observed in 3 cases (5%) (Foley's: 2 (6.7%); Laminaria: 1 (3.3%);  $P>0.05$ ). Higher mean total economic cost (induction and hospitalization) was observed in laminaria group (Foley's: RM 105; Laminaria: RM163) although not statistical significant ( $P>0.05$ ). None of the patients and newborn showed any clinical signs of infection during the study period.

**Implication for practice:** This study concluded that both devices are equally safe and efficacious as induction agent with no increase risk of infection and uterine rupture in women with previous caesarean section. Foley catheter would be an effective and cheaper alternative for induction agent in places where laminaria are not available especially in rural area in Sabah.

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**INTRODUCTION**

Induction of labour is common in obstetric practice whereby the goal is to achieve vaginal delivery when benefit of expeditious delivery outweighs the risk of continuing pregnancy (ACOG, 2004). As there is raising cesarean rate currently, vaginal birth after cesarean (VBAC) has been

actively promoted worldwide (ACOG, 2004; Ade-Ojo IP, 2013). Induction process in this group is considered as high risk due to its possible known complications. The effectiveness and the safety of induction or augmentation in women with a previous lower segment caesarean section using pharmacological and non pharmacological agents have been compared in terms of its outcome such as successful vaginal deliveries, risk of hyperstimulation and incidence of uterine rupture (Calder, 1997).

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Theoretically, mechanical induction showed a lesser risk of uterine pathology but an increase risk of pre-labour infection in various randomized control studies (RCT). In Sabah, the superiority of hygroscopic dilators or Foley catheter for induction of labour is still inconclusive. Therefore, this study is conducted to compare the effectiveness and safety between transcervical Foley catheter and hygroscopic dilator (laminaria) in induction of labour for women with a previous one caesarean section with an unfavourable cervix at term. We hope that this study will help as guide in choosing the most appropriate mechanical induction that will result in more efficient, safe and cost-effective to be used in low resource area especially in district hospitals in Sabah.

## MATERIALS AND METHODS

### Sample and population selection

In the state of Sabah, East Malaysia; The Sabah Women And Child Health Hospital (SWACH) is the only tertiary hospital in west coast of Sabah with O&G facilities. It receives all referral from 9 district included Sipitang, Beaufort, Papar, Tuaran, Kota Belud, Ranau, Pitas, Kota Marudu and Kudat. It covered an area of 150 km away at south Kudat in which also 200 km away to north. Based on local hospital data, there was 16733 vaginal deliveries including VBAC and caesarean rate was 21%. The majority of the population is Dusun while the rest are Malay, Chinese and other Sabahan ethnic groups.

### Research design

This was a prospective randomized controlled trial conducted at the Department of Obstetrics and Gynecology; Sabah Women and Child Health Centre (SWACH) after ethical approval obtained from the National Medical Research Registry (NMRR) Malaysia. Confidentiality and anonymity were assured by the use of a coded system on performa and also during data analysis. This information was only accessible by the researchers. The participants were pregnant women with one prior history of caesarean section that were suitable for trial of vaginal delivery who require induction of labour due to various indications. The inclusion criteria were age at least more than 18 years old, gestational age  $\geq$  37 weeks, a singleton with cephalic presentation, reassuring fetal status and Bishop's Score  $\leq$  6. Those with rupture of membrane, intrauterine death, polyhydramnios (AFI  $\geq$  20), placenta previa, twin pregnancy, other contraindications for induction of labour and those who were unable to provide written consent and to comply with the requirements of the protocol were excluded. All women were counseled prior to the procedure and both informed and written consent were obtained.

In-group A - Transcervical Foley catheter No. 22 F was used in 30 patients. Under aseptic conditions, a 22 French Foley catheter was inserted into the endocervical canal surpassed beyond the internal os. The balloon was inflated with 60 ml of sterile water and the catheter was strapped to the thigh to provide gentle traction. The catheter was confirmed for its position, and traction was monitored at six-hours intervals. If it were expelled spontaneously, it would not be re-inserted. Otherwise, the catheter was removed after 24 hours. The

uterine contraction was monitored 4 hourly from the time of insertion for signs of uterine hyperstimulation. If present, CTG would be applied assess fetal status and appropriate action would be taken accordingly following the local protocol. The cervix was assessed by the primary researcher for Bishop score improvement or presence of spontaneous rupture of the membranes. If membrane was still intact, the Artificial Rupture of the Membranes (ARM) would be done followed by augmentation using intravenous oxytocin infusion of 2.5 units of oxytocin in 500ml of 5% dextrose at 10 drops/minute. The dose will be increased as per labour room protocol until a maximum of 60-drops/ minute, or the desired contractions were achieved.

For group B, hygroscopic mechanical dilator was used in 30 subjects. For each patient, two hygroscopic mechanical dilators were simultaneously placed in the endocervical canal under aseptic conditions. Following that, the contraction will be monitored four hourly from the time of insertion for signs of uterine hyperstimulation. If present, CTG would be applied to assess fetal status and appropriate action would take accordingly following the local protocol. Otherwise the patient was asked in six-hour intervals if the dilators had been expelled spontaneously. If they were expelled spontaneously, they would not be re-inserted.

Otherwise, the dilators were removed after 24 hours and cervical reassessment was done by the primary researcher for any improvement in the Bishop's score or presence of spontaneous rupture of the membranes. If the membrane was still intact, Artificial Rupture of the Membranes (ARM) will be done followed by augmentation using intravenous oxytocin infusion of 2.5 units of oxytocin in 500ml of 5% dextrose at 10 drops/minute. The dose will be increased as per labour room protocol until a maximum of 60-drops/ minute, or till the desired contractions were achieved.

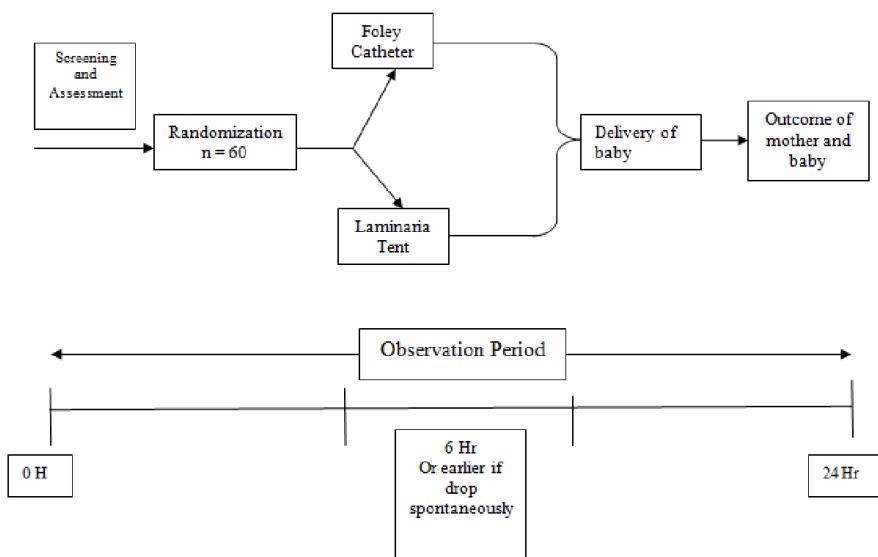
The primary indicators of a successful cervical ripening were the mean of Bishop's score improvement after 24 hours, mode of delivery and the mean duration from induction to delivery interval for both methods. The secondary outcome measures were the maternal and neonatal complications such as uterine tachysystole (hyperstimulation), post partum hemorrhage, post partum pyrexia (infection) and the Apgar score at one minute of life. This study also compared the total cost of induction and hospitalization for both devices.

### Statistical analysis

All the data collected into the performa (CRF) were analyzed with SPSS package version 21.0. The results were considered significant if the p value  $< 0.05$ . Population characteristics were evaluated using mean, frequency, percentage and standard deviations. Categorical variables between both groups were evaluated using Chi-square and Fisher exact test depending on fulfillment of assumption, whereas the continuous variables were analyzed using the t test.

## RESULTS

A total of 60 women who met the inclusion criteria were included in this trial.



**Figure 1. Flow diagram of progress through the phases of the study**

Thirty women were allocated randomly to either group: Foley catheter induction group (A) or laminaria tent induction group (B). All of them had completed their trial as required. The Kadazan formed the majority of entire study population followed by Malay, Brunei, Suluk and Chinese reflecting the demographic distribution of races in Sabah. The other minority races were the ethnic of Sungai, Iranun, and Badjao. Several co-factors that favored successful VBAC were recorded during this study such as age, maternal BMI, estimation fetal weight (EFW) and history of previous VBAC. Overall, the entire study populations had an equal distribution of favourable factors towards successful VBAC and both groups were comparable ( $P>0.05$ ). (Table I). The indication for induction was recorded (Table II) in which the highest was post term pregnancy, and the lowest was IUGR.

The primary study outcomes were the mean Bishop's score at the start and after 24 hours, mean duration from induction to delivery interval and the delivery outcome. The Foley's group showed a higher mean of increment in the Bishop's score after 24 hours compared to the laminaria group (Table III). The delivery outcomes were recorded as successful VBAC or caesarean section. Failed induction of labour was higher in the laminaria group (16 patients) compared to the Foley's group (11 patients) (refer Table IV&V). A total of 28 patients underwent caesarean section due to various indications from both groups, and the highest indication was for fetal distress (Table VI). However, all these outcomes were not statistically significant ( $p>0.05$ ).

**Table 1. Demographic data**

	Foley Catheter (n = 30)	Laminaria (n = 30)	P value
Maternal age (y)	29.67 (7.77)	28.87 (7.18)	0.680*
Gravida	4.80 (2.11)	4.30 (2.37)	0.391*
Prior vaginal delivery	1.33 (0.48)	1.37 (0.49)	0.791*
Estimated Fetal Weight	3.142 (0.39)	2.986 (0.52)	0.196*
Maternal BMI	26.01 (2.91)	26.61 (3.89)	0.493*
Ethnicity			
Kadazan	15 (57.7%)	11 (42.3%)	
Dusun	2 (40.0%)	3 (60.0%)	
Malay	5 (62.5%)	3 (37.5%)	0.440#
Chinese	2 (40.0%)	3 (60.0%)	
Brunei	2 (33.3%)	4 (66.7%)	
Suluk	1 (16.7%)	5 (83.3%)	
Others	3 (75.0%)	1 (25.0%)	

\*Independent t-test, # chi-square test

**Table II. Indications of induction**

Indications	Group A (n=30) (Foley Catheter) (n) (%)	Group B (n=30) (Laminaria Tent) (n) (%)	Total (n=60) (n) (%)
Post Maturity	11(18.3)	12(20.0)	23 (38.3)
IUGR	1(1.66)	4(6.64)	5 (8.30)
Preeclampsia	4(6.67)	5(8.33)	9 (15.0)
GDM/DM	7(11.7)	5(8.33)	12 (20.0)
Others	7(11.7)	4(6.67)	11 (18.3)

**Table III: Induction Outcome in each group (n = 60)**

Parameters	Group A (n=30) (Foley Catheter)	Group B (n=30) (Laminaria Tent)	P Value
	Mean (SD)	Mean (SD)	
Mean Bishop's score at start of induction	4.20 (0.714)	4.10 (0.759)	0.601*
Mean Bishop's score at 24 hours of induction	5.77(1.04)	5.26(1.09)	0.718*
Mean induction to delivery interval (hours)	17.33(4.79)	15.71(5.40)	0.225*

\*Independent t-test

**Table IV: Delivery Outcome**

Delivery Outcome	Group A Foley Catheter (n) (%)	Group B Laminaria Tent (n) (%)	P Value
Failed induction	11 (18.3)	16 (26.7)	0.194*
Delivery between 24-48 hours of induction	2 (3.33)	4 (6.67)	0.67*

\*Chi-square test    †Fisher Exact test

**Table V: Mode of delivery in each group (n = 60)**

Parameters	Group A (n=30) (Foley Catheter) (n) (%)	Group B (n=30) (Laminaria Tent) (n) (%)	P Value
Mode of delivery			
Spontaneous Vaginal Delivery (SVD)	18 (60.0)	14 (46.7)	0.301*
Caesarean section (CS)	12 (40.0)	16 (53.3)	

\*Chi-square test

**Table VI. Indication of caesarean section (CS) in each group (n = 28)**

Indications of CS	Group A (n=12) (Foley Catheter) (n) (%)	Group B (n=16) (Laminaria Tent) (n) (%)	P Value
Failed induction	3 (25)	5 (31.2)	1.00*
Fetal Distress	7 (58.3)	7 (43.8)	0.704*
Poor progress	2 (16.7)	4 (25)	0.501*
Scar Tenderness	-	-	-
Others	-	-	-

\*Chi-square test

**Table VII. Maternal Complications in each group (n = 60)**

Parameters	Group A (n=30) (Foley Catheter) (n) (%)	Group B (n=30) (Laminaria Tent) (n) (%)	P Value
Uterine Rupture	-	-	-
Uterine Tachysystole	-	-	-
Post Partum Hemorrhage	6 (10.0)	4 (6.68%)	0.448*
Puerperal Pyrexia	-	-	-

\*Chi-square test

**Table VIII: Neonatal Complications in each group (n = 60)**

Apgar Score at 5 minutes	Group A (n=30) (Foley Catheter) (n) (%)	Group B (n=30) (Laminaria Tent) (n) (%)	P Value
9-10	28 (93.3)	29 (96.7)	1.00*
7-8	2 (6.7)	1 (3.3)	
4-6	-	-	-

\*Fisher Exact test

**Table IX: Economic Outcomes in each group (n = 60)**

Parameters	Group A (n=30) (Foley Catheter) (Mean) (SD)	Group B (n=30) (Laminaria Tent) (Mean) (SD)	P Value
Mean Hospital Cost	RM 90 (49.8)	RM 103(50.4)	0.359*
Mean Cost of Induction	RM 15 (0)	RM 60 (0)	0.000*
Mean Total Cost	RM 105 (49.8)	RM 163 (50.7)	0.389*
Duration of hospitalization	n (%)	n (%)	
24-48 hours	18 (30)	14 (23.3)	
More than 48 hours	12 (20)	16 (26.7)	0.301 <sup>#</sup>

\*Independent t-test    #chi-square test

Post partum hemorrhage was the only maternal complication observed, and it was higher in the Foley group (6 patients) compared to the laminaria group (4 patients). Fortunately, both groups had no any incidence of uterine tachysystole or rupture, and maternal pyrexia (Table VII). There were three newborns with Apgar score of 7-8 at 5 minutes of life, two From the Foley group and one from the laminaria group. (Table VIII). The pediatric team attended all of them. This outcome did not reach statistical significance ( $p>0.05$ ). Patients from the Foley group had a shorter hospital stay compared to the laminaria. Apart from that, the cost of induction using Foley catheter was significantly cheaper than the laminaria. Hence, the total mean overall cost was lesser for the Foley group compared to the laminaria group (Table IX). However, this outcome was not statistically significant ( $p>0.05$ ).

## DISCUSSION

Induction of labour is a common practice in obstetrics aiming to deliver a healthy baby whilst maintaining maternal good health, at the same fulfilling the overall goal of safe motherhood. The key to successful induction of labour is the state of the cervix prior to initiation of induction. The cervical state assessment is based on the modified Bishop's score introduced by Calder *et al.* in 1974, which consists of score rating from 0 to 13, with a lower score indicating unfavourable cervix (Orhue, 1993).

In this study, the mean of Bishop's score at induction for Sabahan population was 4.20 for the Foley group and 4.10 for the laminaria group. This is considered to be unfavourable based on the modified Bishop's score by Calder *et al.* (1974). Other studies were showed a much lower Bishop's score at induction such as Rajalakhmi *et al.* (2014) with 3.21, Karjaa *et al.* with 3.3, Lewin *et al.* with 3.0 and Farah *et al* with 2.80 (Farah and Sridevi, 2013; Archana *et al.*, 2014; Karjane and Walsh, 2006; Levin *et al.*, 1980). In our study, Foley's catheter is shown to have a shorter duration from induction to delivery with a higher increment of mean Bishop's score at the start of induction (0 hour) and after 24 hours. However, both findings do not reach statistical significance. These findings are similar to a study by Rajalakhmi *et al.* (2014), and they postulated that inflation of the Foley's balloon with 60 ml of sterile water resulted in cytokines release in larger scale compared to laminaria tent, whereby the maximum dilatation is limited by its hydroscopic properties for water absorption.

On the other hand, the maternal and fetal complications also were shown to be as infrequent findings in both groups. The Foley's group revealed a lower failure induction rate (25%) but a higher incidence of post partum hemorrhage (20%) and newborn with APGAR less than 9 (6.7%) in comparison to the laminaria group. However, none of these results were statistically significant. In contrast to the study done by Salva *et al.* (2003), usage of the mechanical dilator, especially Foley's catheter shown a higher association with infection and the study done by Kazzi *et al.* (1982), found 60% of patients developed endometritis and 12% of neonates died of sepsis, which he concluded that both devices will cause higher infection rate to patients and newborn (Salva *et al.*, 2003; Kazzi and Rosen, 1982). This outcome was not seen throughout our study as no puerperal pyrexia was recorded, and it was consistent with the study done by Jozwiak *et al.* (2011). There was no incidence of uterine hyperstimulation or rupture in our study for both the Foley and laminaria groups. This finding was comparable with the study done by Ravasiah *et al.* (2000) where Foley's catheter induction had the lowest uterine hyperstimulation and rupture rate in VBAC group. A study done by Mahvash *et al.* (2014) showed an equivalent outcome with usage of the laminaria (Ravasiah and Polland, 2000; Mashvash *et al.*, 2014). Barbara B Hogg *et al.* (2000) also reported similar outcome and favors Foley's catheter induction due to easier preparation and insertion with more comfort for the patients. They also conclude that both the laminaria and Foley's catheter appear to be appropriate for cervical ripening (Barbara and Hogg, 2001).

The evaluation of financial burden was lower in the Foley's group. This is most probably due to a higher successful induction rate and shorter hospitalization hence a reduction in the overall total cost. However this is not proven to be statistically significant. In addition to that, Foley's catheter is more cost- effective, as it is easily available due to its primary function as an indwelling urinary catheter. It requires simple storage and much cheaper than the laminaria tent, which requires extra budget and could only be used as an induction agent. Therefore, we recommend the Foley's catheter should be implemented in the labour induction protocol due to its similar efficacy, safety and complication to laminaria tent. Jane E Norman *et al.* (2011) concluded that Foley's catheter is a cheaper alternative as a cervical ripening agent in low resource centers, hence in our setup, referring to most district hospitals in Sabah (Jane and Norman, 2011).

## Study limitations

This is a randomization control trial (RCT) study with a sample size of 60 patients. It might not represent a true Sabahan population in which a larger scale study is required to catch all of Sabahan ethnicity to be analyzed. This study is done by only comparing two methods which commonly used and available in Sabah. There are various mechanical methods available worldwide and another study can be done in future to be comparing between them in local Sabah population. The other limitation of this study is both observer and participant is not blinded therefore a blinded RCT is required for more accurate and appropriate result

## Conclusion

In this study, both methods of induction in women with one previous scar were equally safe, simple and effective. The main advantages of cervical ripening by Foley's catheter over laminaria are the lower cost and its availability in district hospitals in Sabah.

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