Int J Clin Exp Med 2016;9(4):7573-7584
www.ijcem.com /ISSN:1940-5901/IJCEM0018582

Review Article

Foley catheter balloon versus prostaglandins for cervical ripening and labor induction: a systematic review and meta-analysis

Yue Li[1,2*], Zhigang He[1*], Liwen Song[1], Jiawen Zhang[1], Jinbo Wang[1,2], Jiajing Cheng[1,2]

[1]Department of Gynecology and Obstetrics, Shanghai Tenth People's Hospital, Shanghai, China; [2]Department of Gynecology and Obstetrics, Nanjing Medical University, Jiangsu Province, China. [*]Equal contributions.

Received August 19, 2015; Accepted March 9, 2016; Epub April 15, 2016; Published April 30, 2016

Abstract: There are many methods for cervical ripening. At present, FCB and prostaglandins, including PGE2 and PGE1, are the two major methods. We conducted a meta-analysis to compare the efficiency and safety of cervical ripening and labor induction between the two methods. We performed a systematic literature search of Medline, web of science, and Cochrane library. The risk ratio (RR) with a 95% confidence interval (95% CI) was calculated using fixed-effect models or random-effect models. Eighteen randomized controlled trials were included in this meta-analysis with 3,437 patients. 1,711 participants received FCB and 1,726 participants received prostaglandins (PGE2: 1240, PGE1: 486). The FCB group and prostaglandins group had a similar risk of caesarean section, vaginal delivery in 24 h or less, 5 min Apgar score less than 5, and arterial cord pH level less than 7.10. The FCB group had a higher risk of oxytocin augmentation and the prostaglandins group had a higher risk of neonatal ICU admission. In conclusion, FCB may be safer for cervical ripening despite a higher risk of oxytocin augmentation or use.

Keywords: Cervical ripening, foley catheter balloon, labor induction, prostaglandins

Introduction

Labor induction is one of the most common obstetric interventions, occurring in approximately 20% to 30% of all deliveries in developed countries [1]. With an unfavorable cervix, exogenous oxytocin alone leads to a longer induction to delivery [2]. Some women have an unfavorable cervix at the start of induction, and have a higher risk of caesarean section [2]. Therefore, cervical ripening is necessary in these cases. At present, ripening of the cervix is an obbligato part of the induction process for an unfavorable cervix.

An ideal method for cervical ripening is still not known. There are various methods for cervical ripening, including mechanical and pharmacological methods. The mechanical method was the first method used for cervical ripening and labor induction, and is still widely used today [3]. Foley catheter balloon (FCB) is the main mechanical method. FCB is inserted in order to modify the cervical condition by dilating the cervix, but may limit uterine contractions. In 1977, some investigators [4] declared that the FCB had less of a contribution to cervical ripening than the prostaglandins because of its much slower action. The prostaglandins, including prostaglandin E2 (PGE2) such as dinoprostone and prostaglandin E1 (PGE1) such as misoprostol, are the major pharmacologic methods. PGE2 given vaginally and intracervically has been proven to be an effective agent [5]. In addition, PGE1 has also been shown to be an effective agent [6]. At present, various randomized controlled trials have compared the efficacy and safety of FCB with prostaglandins for cervical ripening, but few have attempted to review and summarize them.

Twenty-seven randomized controlled trials (RCTS), which compared prostaglandins with FCB alone or in combination with extra amniotic saline solution infusion (EASI) and/or intravenous oxytocin (IVO), were included in a meta-

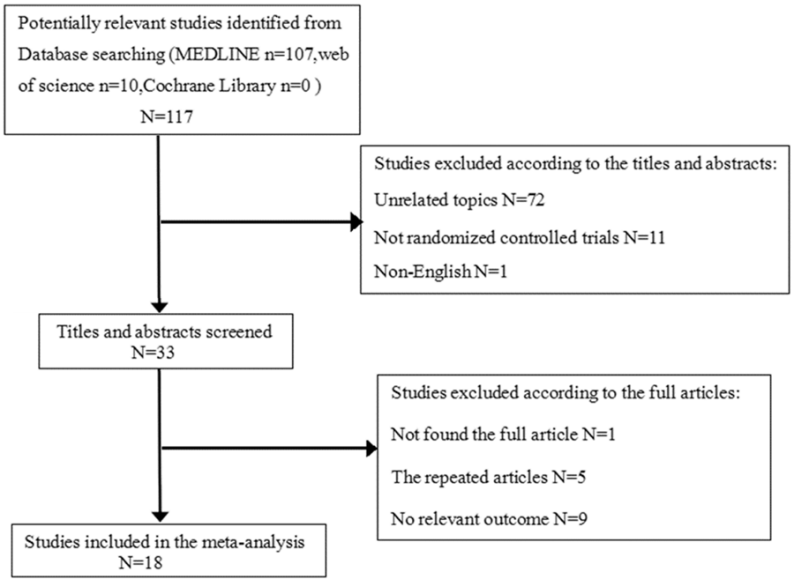

Figure 1. Flow diagram of our method of evidence, the remaining 18 randomized controlled trials were included in this meta-analysis.

analysis in 2010 [7]. The author concluded that FCB and prostaglandins result in similar cesarean delivery rates, FCB has a higher risk of oxytocin use and/or augmentation for labor induction, and prostaglandins carry a higher risk of contraction abnormalities. Since that meta-analysis study was published 5 years ago, there have been more randomized controlled trials published. We undertook the meta-analysis to compare the clinical outcomes between FCB and PGE2 or PGE1 alone.

Materials and methods

Article search

We conducted the previous studies according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. We searched all randomized controlled trials by the following terms: ((((((balloon dilatation [Title/Abstract]) OR catheterization [Title/Abstract]) OR Foley [Title/Abstract]) OR extra-amniotic saline [Title/Abstract])) AND (((Prostaglandins [Title/Abstract]) OR Prostanoids [Title/Abstract]) OR "Prostaglandins" [Mesh])) AND ((random* [Title/Abstract]) OR ("Randomized Controlled Trials as Topic" [Mesh] OR "Randomized Controlled Trial" [Publication Type])). These articles were searched in Medline, web of science, and Cochrane Library electronic databases.

Selection criteria

Only RCTS that appeared in English-language publications that compared FCB alone, and PGE2 or PGE1 on their efficacy and safety in cervical ripening and labor induction were included in this meta-analysis. Studies were excluded if they combined FCB with other methods, if they used other balloon devices, if they had no relevant outcomes, or if they only appeared in abstracts.

Outcomes of interest

The interesting clinical outcomes included maternal outcomes (caesarean section, vaginal delivery in 24 h or less, and oxytocin augmentation or requirement) and neonatal outcomes (ICU admission, 5 min-Apgar score less than 5, and Arterial cord pH level less than 7.10).

Methods of meta-analysis

The meta-analysis was carried out using the Review Manager software package (RevMan, version 5.3; The Nordic Cochrane Center, Copenhagen, Denmark). We analyzed the dichotomous outcomes by calculating the risk ratio (RR) with a 95% confidence interval (95% CI). Pooled estimates were calculated fixed effect models (Mantel-Haenszel) or random effects models (Der Simonian & Laird). Heterogeneity between trials was measured by Q-test. *P* value < 0.1 or $I^2 > 50\%$ indicated significance in the analysis of heterogeneity. The fixed-effect model was used when the Q-test indicated no heterogeneity between the included studies. The random-effect model was used when heterogeneity was presented between RCTS. A Funnel plot and Egger test were performed to test the potential publication bias of the included studies. The criteria used to assess the methodological quality included Random sequence generation, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective reporting and other biases.

Table 1. Baseline characteristics of included trials comparing FCB to PGE2

Study and year	N		FCB	Maternal age (y)		Gestational age (WK)		Cervical situation	Situation of fertility
	F	P	Size/ML	F	P	F	P		
Edwards et al 2014	185	191	16/30 ml	28.0	26.9	39.1	39.2	F: Number of cervical dilation 1 cm or less: 138	F: Nulliparous number: 106
								P: Number of cervical dilation 1 cm or less: 157	P: Nulliparous number: 127
Jozwiak et al 2012	107	119	NR/30 ml	30.5	31.7	39.1	39.8	F: Number of baseline Bishop score 1 or less: 51	F: Nulliparous number: 77
								P: Number of baseline Bishop score 1 or less: 47	P: Nulliparous number: 83
Henry et al 2013	50	51	16/30 ml	32.7	32.9	40.8	40.6	F: Baseline Bishop score: 2.7	F: Nulliparous number: 45
								P: Baseline Bishop score: 2.9	P: Nulliparous number: 46
Jozwiak et al 2011	411	408	16 or 18/30 ml	30.9	30.6	40.1	40.0	F: Number of baseline Bishops score 1 or less: 151	F: Nulliparous number: 268
								P: Number of baseline Bishop score 1 or less: 137	P: Nulliparous number: 263
Cromi et al 2011	132	132	18/50 ml	31.8	31.0	39.9	39.8	F: Baseline Bishop score: 2	F: Nulliparous number: 92
								P: Baseline Bishop score: 2	P: Nulliparous number: 89
CE Pennell et al 2009	107	113	16/30 ml	27	27	40	40	F: Unfavourable cervix	F: Nulliparous number: 107
								P: Unfavorable cervix	P: Nulliparous numeber: 113
M.I. Al-Taani 2004	72	75	18/50 ml	27.7	27.1	39.4	39.5	F: Initial Bishop score: 2.56	F: Number of parity: 7.7
								P: Initial Bishop score: 2.61	P: Number of parity: 7.4
A. Moini et al 2003	35	35	22/30 ml	22.4	23.1	40.6	40.63	F: Baseline Bishop score: 3.9	NR
								P: Baseline Bishop score: 3.29	
S. Nir omanesha et al 2002	45	44	14/30 ml	23.9	24.0	40.7	40.8	All Baseline Bishop score less than 5	F: Number of parity: 0.52
								P: Number of parity: 0.45	
Anthony C. et al 1998	77	72	14/30 ml	26.3	26.3	38.3	38.4	F: Baseline Bishop score: 2.8	F: Number of parity: 0.5
								P: Baseline Bishop score: 2.4	P: Number of parity: 0.4

N = number; y = year; wk = weekend; NR = not reported; *All the patients in both groups; FCB = foley catheter balloon; P = prostaglandins E2.

Table 2. Baseline characteristics of included trials comparing FCB to PGE1

Study and year	Number		FCB	Maternal age (y)		Gestational age (WK)		Cervical situation	The situation of fertility
	F	P	Size/ML	F	P	F	P		
A.T. OWOLABI et al 2005	60	60	18/30 ml	31.1	29.6	40.3	40.7	F: Baseline Bishop score: 3.4	F: Nulliparous number: 13
								P: Baseline Bishop score: 3.4	P: Nulliparous number: 11
ANTHONY C et aL 2001	58	53	16/30 ml	25.1	25.9	NR		F: Baseline Bishop score: 3.0	F: Percentage of nulliparous: 76%
								P: Baseline Bishop score: 2	P: Percentage of nulliparous: 71.10%
E.O. Ugwu et al 2013	45	45	16/30 ml	28.9	27.1	40.7	40.2	F: Baseline Bishop score ≤ 5	F: Nulliparous number: 20
								P: Baseline Bishop score ≤ 5	P: Nulliparous number: 19
Chung et al 2003	54	49	16/30 ml	26.5	26.3	40.0	39.8	F: Number of Baseline Bishop score ≤ 2:13	F: Nulliparous number: 33
								P: Number of Baseline Bishop score ≤ 2:12	P: Nulliparous number: 33
Marta Jozwia et al 2014	56	64	NR/30 ml	31.0	32.3	39.1	39.8	F: Number of Baseline Bishop score ≤ 1:21	F: Nulliparous number: 37
								P: Number of Baseline Bishop score ≤ 1:25	P: Nulliparous number: 41
Greybush et al 2001	71	65	24/50 ml	NR		38.3	38.2	F: Baseline Bishop score ≤ 5	F: Percentage of nulliparous: 63.40%
								P: Baseline Bishop score ≤ 5	P: Percentage of nulliparous: 67.70%
O.Gelisen et al 2005	100	100	18/50 ml	24.4	25.9	41	41	F: Baseline Bishop score: 1.8	F: Nulliparous number: 47
								P: Baseline Bishop score: 1.6	P: Nulliparous number: 46
A. ADENIJI et al 2005	46	50	16/30 ml	30.5	30.2	40.2	39.9	F: Number of Baseline Bishop score ≤ 1:1	F: Nulliparous number: 20
								P: Number of Baseline Bishop score ≤ 1:1	P: Nulliparous number: 26

N = number; y = year; wk = weekend; NR = not reported; *All the patients in both groups; FCB = foley catheter balloon; P = prostaglandins E1.

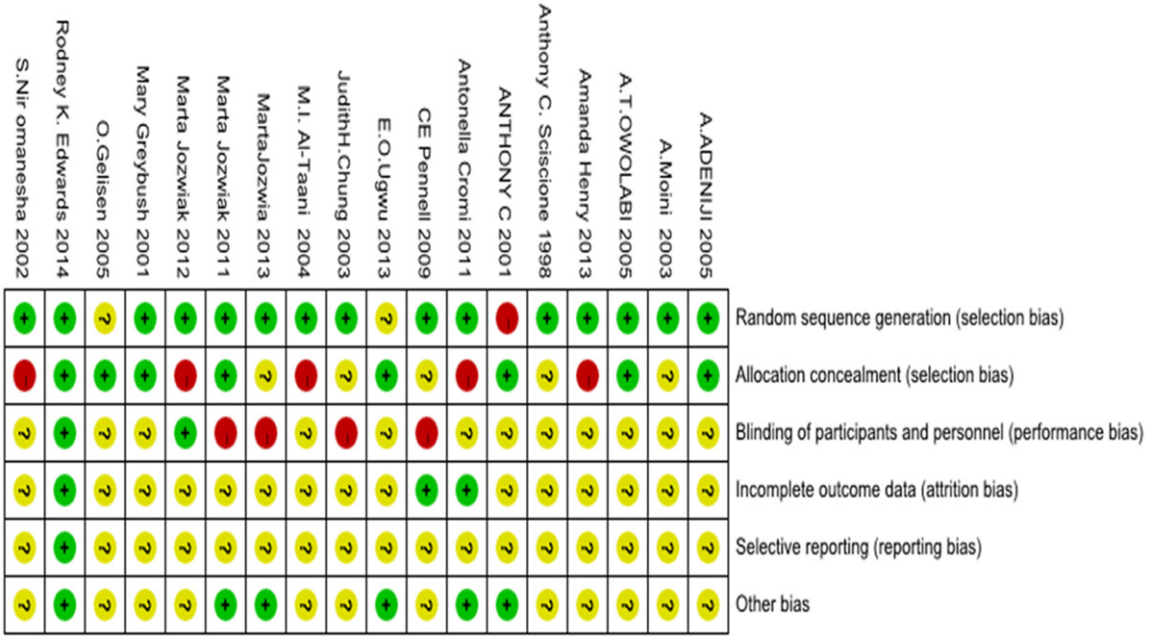

Figure 2. Risk of bias summary: review of authors' judgements about each risk of bias item for each included study.

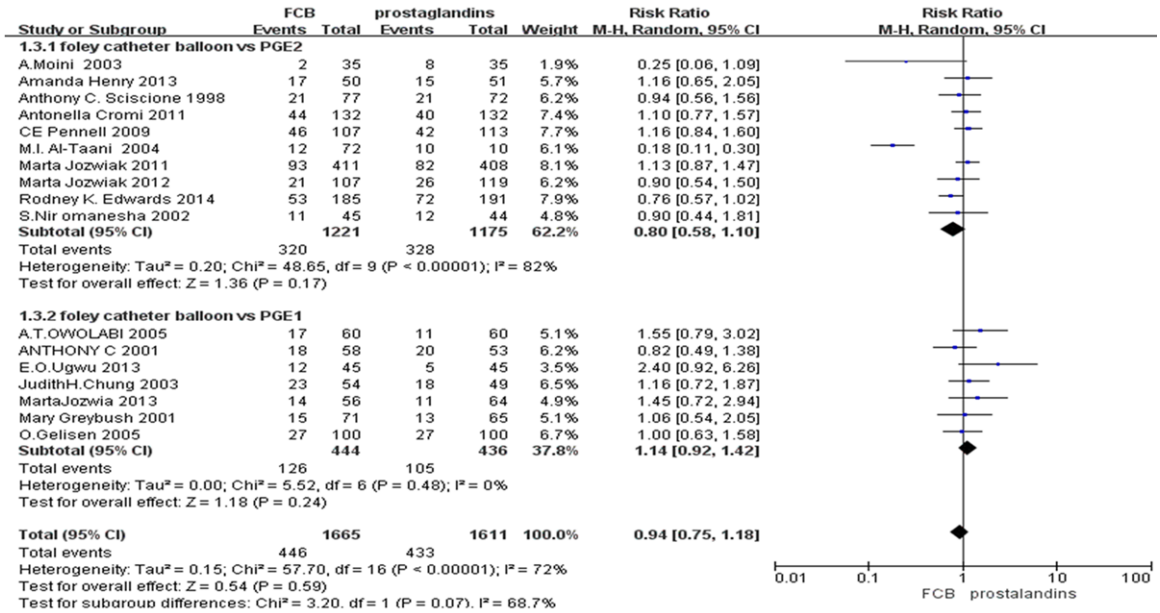

Figure 3. Maternal outcome: Caesarean section, The outcomes of pooled statistical estimation for caesarean section in this analysis were not significantly different between the two groups, and subgroup analysis showed a similar result. M-H, Mantel-Haenszel, CI, Confidence Interval.

Results

Included studies

Of the 117 studies found through the literature search, 84 articles were excluded based on their titles and abstracts. One article was excluded as the full article was not found, five articles were excluded because they were repeats, and nine studies were excluded because they had no relevant outcomes. The remaining 18 randomized controlled trials were included in this meta-analysis (**Figure 1**) [8-25]. These studies included 3,437 patients with an

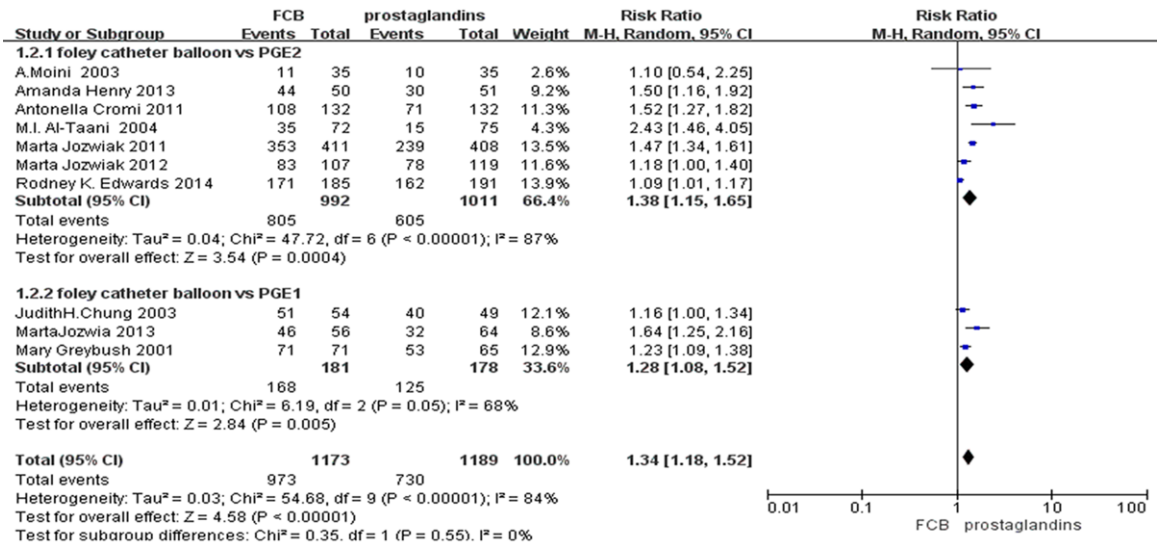

Figure 4. Maternal outcome: Oxytocin augmentation or required, the results exhibited that women who received a Foley catheter balloon had a higher risk of oxytocin augmentation or requirement than women who received prostaglandins. Subgroup analysis revealed a similar statistical outcome. M-H, Mantel-Haenszel, CI, Confidence Interval.

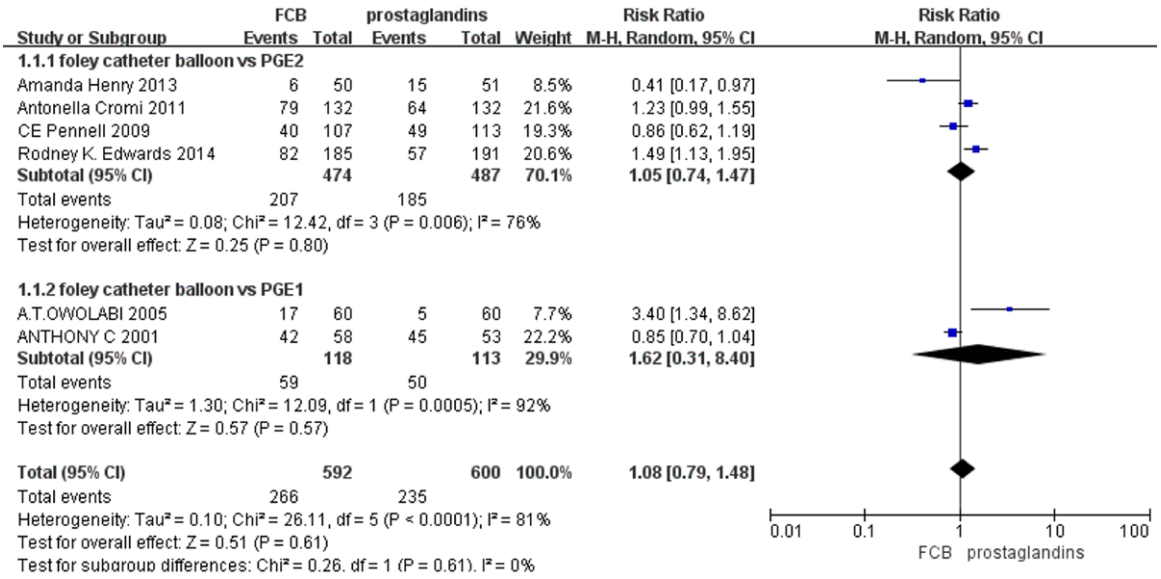

Figure 5. Maternal outcome: Vaginal delivery in 24 h or less, there was no significant difference between women who had a Foley catheter balloon and those who had prostaglandins, and the subgroup analysis showed similar results. M-H, Mantel-Haenszel, CI, Confidence Interval.

FCB group, n=1,711 (49.8%) and prostaglandins group, n=1,726 (50.2%). In the prostaglandins group, there was a PGE2 group, n=1,240 (71.8%) and PGE1 group, n=486 (28.2%). The study and patient characteristics are summarized in **Tables 1** and **2**. The risk of bias in each study included in our meta-analysis is indicated in **Figure 2**.

Maternal outcomes

In the 18 randomized controlled trials, 17 studies reported the number of caesarean sections. A pooled RR and its 95% CI were calculated with a random model because of the high heterogeneity between studies (I^2=72%, *P* heterogeneity < 0.00001). The outcomes of pooled

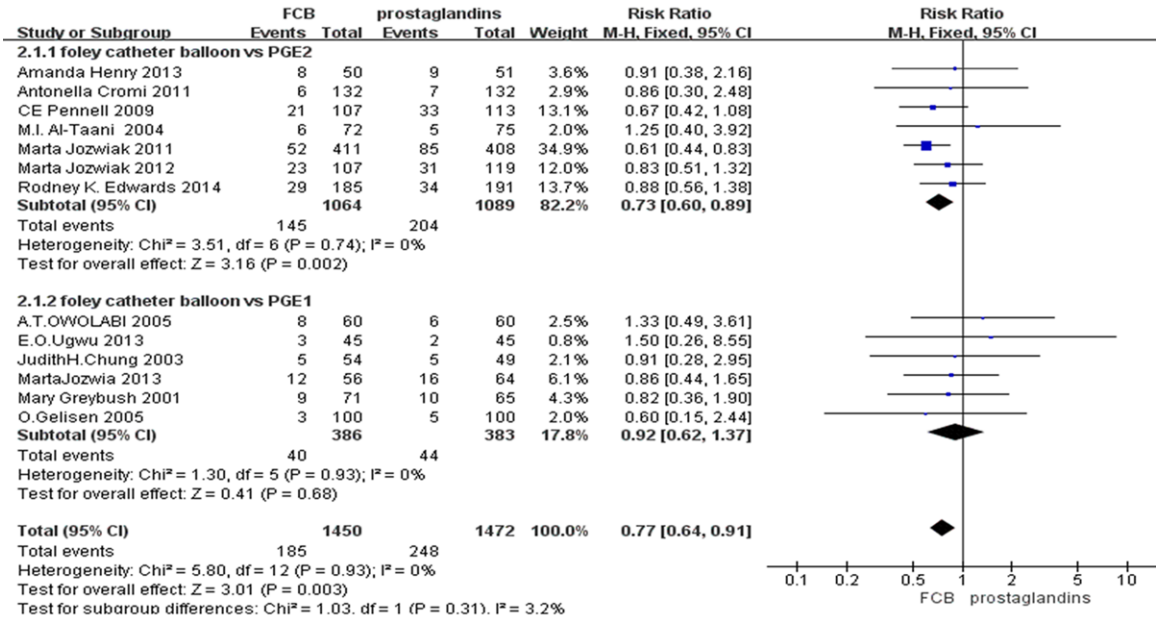

Figure 6. Neonatal outcome: Neonatal ICU admission, the risk of neonates being admitted to ICU was higher in the prostaglandins group than the FCB group. Subgroup analysis also indicated higher risk of neonates admitted to ICU in the PGE2 group than in the FCB group. M-H, Mantel-Haenszel, CI, Confidence Interval.

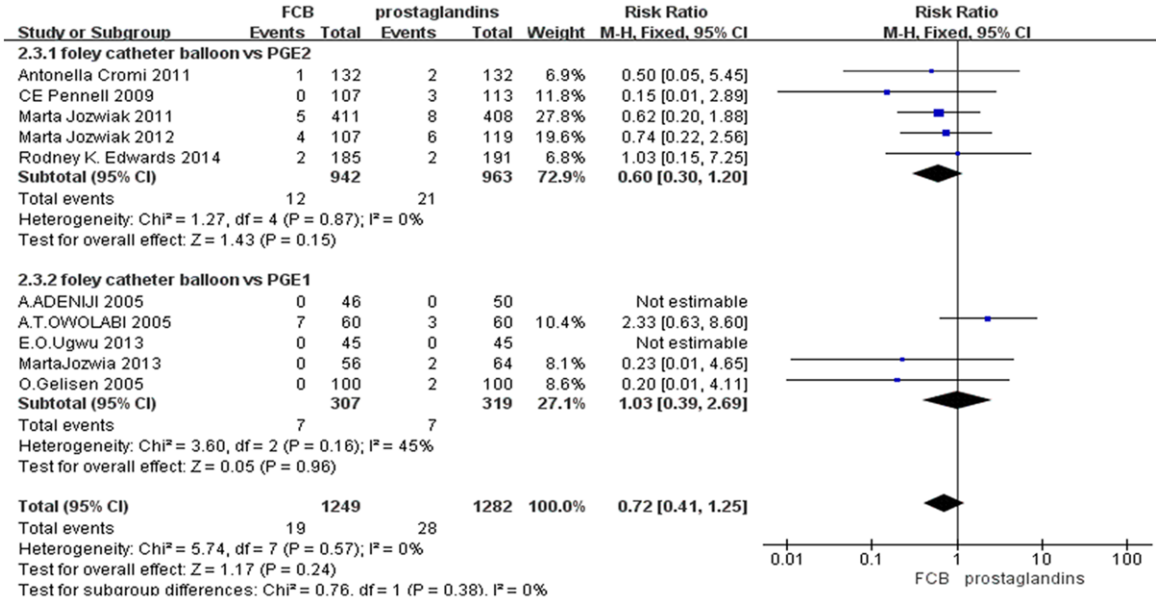

Figure 7. Neonatal outcome: 25 min Apgar score less than 5, there was no significant difference in the proportion of 5 min Apgar score less than 5 between the FCB group and prostaglandins (RR=0.72, 95% CI=0.41 to 1.25, *P*=0.24). Subgroup analysis showed similar outcomes. M-H, Mantel-Haenszel, CI, Confidence Interval.

statistical estimation for caesarean section in this analysis were not significantly different between the two groups (RR=0.94, 95% CI= 0.75 to 1.18, *P*=0.59), and subgroup analysis showed a similar result (**Figure 3**). 10 studies reported the number of oxytocin augmentation or requirement. The results of heterogeneity tests were *P* heterogeneity < 0.00001 and I^2=0.84%. Therefore, a random model was used to calculate the pooled results and the

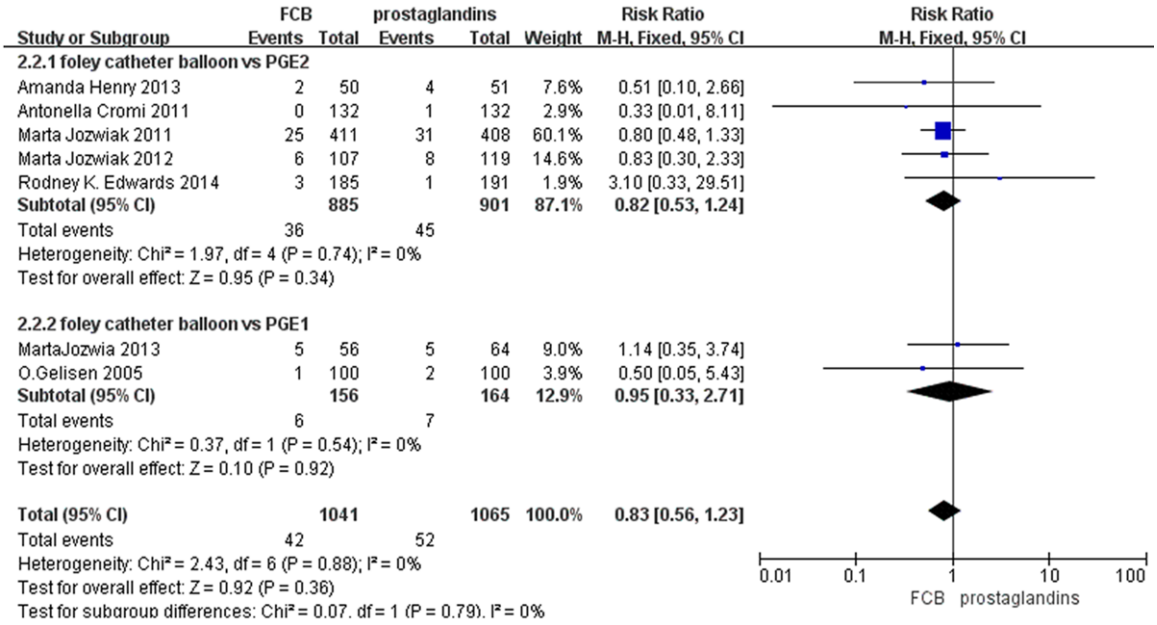

Figure 8. Neonatal outcome: Arterial cord pH level less than 7.10, No significant difference was observed in the proportion of arterial cord pH level less than 7.10 between the FCB group and prostaglandins group. Subgroup analysis also showed no difference between the two groups (M-H, Mantel-Haenszel, CI, Confidence Interval).

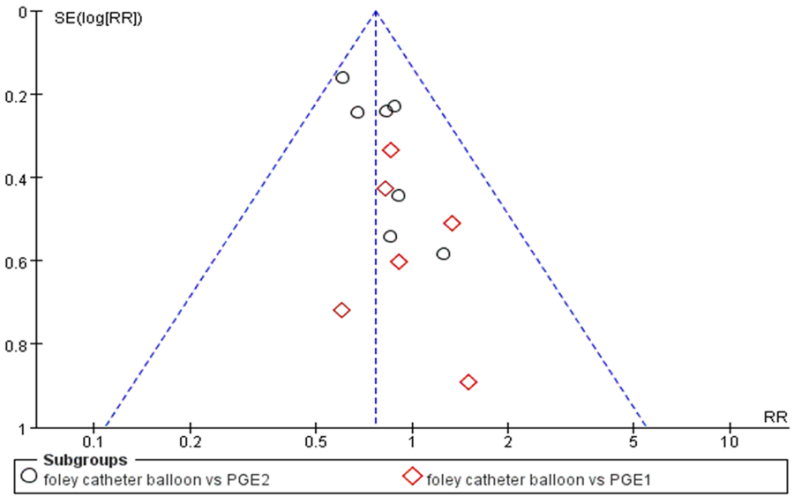

Figure 9. Funnel plots of neonatal ICU admission (RR: Risk ratio; SE (log [RR]): standard error of the natural logarithm of the Risk ratio).

results exhibited that women who received a Foley catheter balloon had a higher risk of oxytocin augmentation or requirement than women who received prostaglandins (RR=1.34, 95% CI=1.18 to 1.52, $P < 0.00001$). Subgroup analysis revealed a similar statistical outcome (**Figure 4**). The number of vaginal deliveries in 24 h or less was reported in only six articles. As the studies have an obvious heterogeneity (I^2=81%, P heterogeneity < 0.0001), we used a random model to analysis the datum and according to the analysis, there was no significant difference between women who had a Foley catheter balloon and those who had prostaglandins (RR=1.08, 95% CI= 0.79 to 1.48, P=0.61), and the subgroup analysis showed similar results (**Figure 5**).

Neonatal outcomes

Thirteen articles mentioned the proportion of neonates admitted to the neonatal intensive care unit. There was no obvious heterogeneity (I^2=0%, P heterogeneity =0.93), so we used a fixed model to analysis the datum. According to the results, the risk of neonates being admitted to ICU was higher in the prostaglandins group than the FCB group (RR=0.77, 95% CI=0.64 to 0.91, P=0.003). Subgroup analysis also indicated higher risk of neonates admitted to ICU in the PGE2 group than in the FCB group (RR=0.73, 95% CI=0.60 to 0.89, P=0.002) (**Figure 6**). The proportion of a 5 min

Apgar score less than 5 was reported in ten studies. The heterogeneity between studies was not significant (I^2=0%, *P* heterogeneity =0.57), so a random model was used to calculate the pooled results. There was no significant difference in the proportion of 5 min Apgar score less than 5 between the FCB group and prostaglandins (RR=0.72, 95% CI=0.41 to 1.25, *P*=0.24). Subgroup analysis showed similar outcomes (**Figure 7**). Seven RCTs compared the proportion of an arterial cord pH level less than 7.10. We used a fixed model to analysis the datum with no significant heterogeneity among the studies (I^2=0%, *P* heterogeneity =0.88). No significant difference was observed in the proportion of arterial cord pH level less than 7.10 between the FCB group and prostaglandins group (RR=0.83, 95% CI=0.56 to 1.23, *P*=0.36). Subgroup analysis also showed no difference between the two groups (**Figure 8**).

Publication bias

We evaluated the possibility of publication bias using a funnel plot. The funnel plot for Arterial cord pH level less than 7.10 did not reveal asymmetry, indicating no evidence of publication bias, but it did reveal asymmetry suggesting that there is publication bias present in terms of neonatal ICU admission and 5 min Apgar score less than 5 (**Figure 9**).

Discussion

In this meta-analysis of randomized controlled trials with 3,437 patients, women who received FCB and prostaglandins had similar efficacy in their caesarean sections and vaginal deliveries in 24 h or less, and there was no difference in the safety indicated by a neonatal 5 min Apgar score less than 5 and an arterial cord pH level less than 7.10. However, women who used FCB had a higher risk in the rate of oxytocin augmentation or requirement than the women who used prostaglandins, and there was an increase in the rate of neonates admitted to ICU with the prostaglandins group compared the FCB group.

Our analysis demonstrated that the proportion of cesarean sections was similar between the two groups, and the subgroup analysis showed the same result between the FCB group and PGE2 or PGE1 groups. Similar to our findings, the previous meta-analysis [7, 26, 27] noted that the risk of cesarean section was similar among the FCB group and PGE2 group. Cesarean section is an effective measure to solve dystocia and save maternal and fetal lives, and it is not a shortcut to delivery. In fact, cesarean delivery is a form of factitious trauma, so it is not unlikely for complications to occur. For parturient, the women who undergo a caesarean delivery have a higher puerperal infection rate and more blood loss than the women who undergo a vaginal delivery. In the process of recovery after caesarean section, intestinal adhesion, intestinal obstruction, pelvic inflammatory disease, and endometriosis are possible. For newborns, the newborns delivered vaginally have a lower risk of wet lung disease than the newborns born via cesarean delivery. According to our results, there is a high rate of cesarean delivery in both the FCB group and prostaglandins group, so control of the rate of cesarean sections is still a challenge for obstetricians.

A recent meta-analysis [7, 27] demonstrated the increased need for oxytocin augmentation or requirement in the FCB group as compared to the PGE2 group, and our meta-analysis and subgroup analysis confirmed the difference. However, Boulvain M and colleagues [27] reported a different result; they found that there was no difference between the FCB group and PGE2 group. When using oxytocin for labor induction, a drug allergy could occur. Ankylosing uterine contractions are likely to occur, which can result in precipitate labor and even hysterorrhexis after using oxytocin. In the process of strengthening contractions, fetal distress, arrested labor and other abnormal situation may occur, and then termination of the pregnancy is urgently required by caesarean section or obstetric forceps. As a consequence, we need to be careful when using oxytocin.

It was reported that there was increased risk in the FCB group as compared to the PGE2 group in terms of vaginal delivery not being achieved in 24 hours or less [26, 27]. However, Zvi Vaknin could not confirm the difference [7], and in our meta-analysis, there was no significant difference between the women who received FCB and prostaglandins in terms of vaginal delivery in 24 hours or less, and the subgroup showed no significant difference between the FCB group and PGE2 or PGE1 groups. The time of

normal delivery is between 4 to 24 hours. If the delivery time is more than 24 hours, it is called prolonged labor. When the production of labor is too long with continuous uterine contractions, the muscle of the uterus will lengthen and become thin after contraction and recovery for a long time, and the risk of hysterorrhexis increases. After a long time of delivery and throe, the puerperal will feel very tired and even become exhausted. After the delivery, it is more likely that uterine atony will occur, which usually results in postpartum hemorrhage. In addition, the puerperal have a high probability of infection, such as intrauterine infections and even more serious infections. Additionally, at the peak period of uterine contractions, the fetal circulation of the blood is interrupted for a short period of time. If the labor time becomes too long, it may result in fetal hypoxia. Moreover, the probability of pneumonia, sepsis and other complications may increase for the newborns. Based on our meta-analysis, in both the FCB group and prostaglandins group, the proportion of vaginal deliveries completed in 24 hours or less is not very satisfactory. Therefore, dealing with prolonged labor times is still a challenge for obstetricians.

There was no significant difference between the two groups in the neonatal outcomes including the proportion of 5 min Apgar score less than 5 and the proportion of arterial cord pH level less than 7.10 in this meta-analysis, which was consistent with the previous comparative study trials [7, 26, 27].

In addition, our analysis indicated the risk of neonatal ICU admission was increased in the prostaglandins group as compared to the FCB group, and the subgroup analysis noted that the PGE2 increased the risk of neonates being admitted to ICU as compared to the use of FCB. In contrast, previous reviews [7, 26, 27] have suggested no difference between the two groups.

Considerable heterogeneity was observed with respect to maternal outcomes, including proportion of caesarean sections, oxytocin augmentation or requirement, and vaginal delivery in 24 h or less. This implied that there was no homogeneity between the two groups, and it was difficult to offer the exact pooled effect data. To solve this problem, we used a random-effect model in which the fixed effect could transform into random effect. Subgroup analysis could also be used to address the issue. Statistical heterogeneity is usually a result of the clinical or methodologic multiformity in the included studies in terms of the researcher, patients, study design and the definitions of outcomes. More specifically, first the researchers had a diversity of judgements in the face of the same condition. Second, the difference in the participant inclusion criteria such as age, gestational age, baseline Bishop Score, body mass index, parity, previous mode of delivery is noted. Some of the included studies reported the body mass index (BMI), but the other studies did not stratify the results based on the BMI, and Rodney K Edwards et al. [8] had attested that a lower BMI was more effective than a higher BMI for labor induction. Fertility was reported in all included studies, but they also did not stratify the results based on parity, which could influence the proportion of cesarean deliveries. Additionally, the previous mode of delivery could influence the proportion of cesarean delivery and vaginal delivery in 24 hours or less. Third, there is a difference between the trials in the FCB sizes and the preparations and dosages of prostaglandins. In the 18 RCTS, 14 studies used a Foley catheter balloon volume of 30 ml and 4 used 50 ml. Levy R and Delaney Shad proved that a higher volume FCB was more effective than one of lower volume [28, 29]. The higher dose prostaglandins are associated with an increased risk of tachysystole, which influence the maternal and neonatal outcomes [30]. Fourth, the definitions of outcome, such as measurement of Bishop Score, are different. Additionally, the management protocols of the delivery rooms and obstetric decisions are diverse among the included trials. Therefore, it is not surprising to observe significant heterogeneity in maternal outcomes.

Our meta-analysis also had certain limitations that could not be ignored. First, there were many other mechanical methods, such as extra-amniotic saline infusion and luminaria, but our analysis did not include any other mechanical methods. Second, we may have failed to search all relevant randomized controlled trials for inclusion in our meta-analysis. Third, it was not possible for all relevant outcomes, such as the change in Bishop Score, which assessed the efficacy of cervical ripen-

ing, and postpartum complications, which assessed the safety of cervical ripening, to be collected for analysis because there were only a few studies that reported outcomes. Fourth, the studies we searched were confined to English-language articles. Fifth, the type of intervention which is masked or blinded in some RCTS include in our meta-analysis is impossible, so the awareness of patients and investigators may bring about inherent bias. Sixth, we did not try to get in touch with the academic leaders of the included trials to verify the quality of RCTS and gain the relevant outcomes which were unpublished, as it has been a long time since the studies were published.

The shapes of the funnel plots for neonatal ICU admission and 5 min Apgar score less than 5 showed evidence of publication bias. The varying quality of the studies may be the potential reason why the studies with lower quality and smaller samples are more rigorous than the high-quality studies in term of outcomes analysis. On the other hand, they are more likely to cause greater intervention and produce false positive results. Additionally, the heterogeneity between the studies, false appearance and opportunity can all give rise to asymmetry. On the other hand, positive results are easier to publish and we only included the published studies. Therefore, some publication bias is inevitable, and we have attempted to search as many studies as possible.

In summary, the findings of the meta-analysis indicated that FCB and prostaglandins for cervical ripening and labor induction had similar risks of cesarean deliveries. The two methods result in a similar proportion of vaginal deliveries in 24 h or less. According to the analysis, the FCB had a high risk of oxytocin augmentation or use, and the subgroup analysis indicated the same result. In terms of neonatal outcomes, the prostaglandins for cervical ripening had a higher risk of neonatal ICU admission, and the subgroup analysis noted that PGE2 was associated with a higher risk of newborns being admitted to ICU compared to FCB. Additionally, FCB and prostaglandins had no difference in risk of 5 min Apgar score less than 5 or arterial cord pH level less than 7.10. Based on the meta-analysis, FCB seemed to be the safer method for cervical ripening despite the higher risk of oxytocin augmentation or use.

Acknowledgements

We thank our colleagues for their helpful advice during the course of this study.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Jiajing Cheng, Department of Gynecology and Obstetrics, The Seventh Floor, Building 1, Gonghe Road 301, Zhabei District, Shanghai, China. Tel: +86 189-176-83156; Fax: +86 021-663-07151; E-mail: chengjiajing0911@163.com

References

[1] Martin JA, Hamilton BE, Ventura SJ, Osterman MJ, Kirmeyer S, Mathews TJ and Wilson EC. Births: final data for 2009. Natl Vital Stat Rep 2011; 60: 1-70.

[2] Alfirevic Z, Kelly AJ and Dowswell T. Intravenous-oxytocin alone for cervical ripening and induction of labour. Cochrane Database Syst Rev 2009; D3246.

[3] Sciscione AC. Methods of cervical ripening and labor induction: mechanical. Clin Obstet Gynecol 2014; 57: 369-376.

[4] Calder AA, Embrey MP and Tait T. Ripening of the cervix with extra-amniotic prostaglandin E2 in viscous gel before induction of labour. Br J Obstet Gynaecol 1977; 84: 264-268.

[5] Kelly AJ, Kavanagh J and Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. Cochrane Database Syst Rev 2003; D3101.

[6] Hofmeyr GJ and Gulmezoglu AM. Vaginal misoprostol for cervical ripening and induction of labour. Cochrane Database Syst Rev 2003; CD000941.

[7] Vaknin Z, Kurzweil Y and Sherman D. Foley catheter balloon vs locally applied prostaglandins for cervical ripening and labor induction: a systematic review and metaanalysis. Am J Obstet Gynecol 2010; 203: 418-429.

[8] Edwards RK, Szychowski JM, Berger JL, Petersen M, Ingersoll M, Bodea-Braescu AV and Lin MG. Foley catheter compared with the controlled-release dinoprostone insert: a randomized controlled trial. Obstet Gynecol 2014; 123: 1280-1287.

[9] Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O and Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012; 3: 297-299.

[10] Henry A, Madan A, Reid R, Tracy SK, Austin K, Welsh A and Challis D. Outpatient Foley catheter versus inpatient prostaglandin E2 gel for

induction of labour: a randomised trial. BMC Pregnancy Childbirth 2013; 13: 25.
[11] Jozwiak M, Oude RK, Benthem M, van Beek E, Dijksterhuis MG, de Graaf IM, van Huizen ME, Oudijk MA, Papatsonis DN, Perquin DA, Porath M, van der Post JA, Rijnders RJ, Scheepers HC, Spaanderman ME, van Pampus MG, de Leeuw JW, Mol BW and Bloemenkamp KW. Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): an open-label, randomised controlled trial. Lancet 2011; 378: 2095-2103.
[12] Cromi A, Ghezzi F, Agosti M, Serati M, Uccella S, Arlant V and Bolis P. Is transcervical Foley catheter actually slower than prostaglandins in ripening the cervix? A randomized study. Am J Obstet Gynecol 2011; 204: 331-338.
[13] Pennell CE, Henderson JJ, O'Neill MJ, McChlery S, Doherty DA and Dickinson JE. Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel. BJOG 2009; 116: 1443-1452.
[14] Al-Taani MI. Comparison of prostaglandin E2 tablets or Foley catheter for labour induction in grand multiparas. East Mediterr Health J 2004; 10: 547-553.
[15] Moini A, Riazi K, Honar H and Hasanzadeh Z. Preinduction cervical ripening with the Foley catheter and saline infusion vs. cervical dinoprostone. Int J Gynaecol Obstet 2003; 83: 211-213.
[16] Niromanesh S, Mosavi-Jarrahi A and Samkhaniani F. Intracervical Foley catheter balloon vs. prostaglandin in preinduction cervical ripening. Int J Gynaecol Obstet 2003; 81: 23-27.
[17] Sciscione AC, McCullough H, Manley JS, Shlossman PA, Pollock M and Colmorgen GH. A prospective, randomized comparison of Foley catheter insertion versus intracervical prostaglandin E2 gel for preinduction cervical ripening. Am J Obstet Gynecol 1999; 180: 55-60.
[18] Owolabi AT, Kuti O and Ogunlola IO. Randomised trial of intravaginal misoprostol and intracervical Foley catheter for cervical ripening and induction of labour. J Obstet Gynaecol 2005; 25: 565-568.
[19] Adeniji OA, Oladokun A, Olayemi O, Adeniji OI, Odukogbe AA, Ogunbode O, Aimakhu CO, Omigbodun AO and Ilesanmi AO. Pre-induction cervical ripening: transcervical foley catheter versus intravaginal misoprostol. J Obstet Gynaecol 2005; 25: 134-139.
[20] Chung JH, Huang WH, Rumney PJ, Garite TJ and Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter, and combination misoprostol-Foley catheter for labor induction. Am J Obstet Gynecol 2003; 189: 1031-1035.
[21] Sciscione AC, Nguyen L, Manley J, Pollock M, Maas B and Colmorgen G. A randomized comparison of transcervical Foley catheter to intravaginal misoprostol for preinduction cervical ripening. Obstet Gynecol 2001; 97: 603-607.
[22] Greybush M, Singleton C, Atlas RO, Balducci J and Rust OA. Preinduction cervical ripening techniques compared. J Reprod Med 2001; 46: 11-17.
[23] Ugwu EO, Onah HE, Obi SN, Dim CC, Okezie OA, Chigbu CO and Okoro OS. Effect of the Foley catheter and synchronous low dose misoprostol administration on cervical ripening: a randomised controlled trial. J Obstet Gynaecol 2013; 33: 572-577.
[24] Jozwiak M, Ten EM, Oude RK, de Groot C, Feitsma H, Spaanderman M, van Pampus M, de Leeuw JW, Mol BW and Bloemenkamp K. Foley catheter versus vaginal misoprostol: randomized controlled trial (PROBAAT-M study) and systematic review and meta-analysis of literature. Am J Perinatol 2014; 31: 145-156.
[25] Gelisen O, Caliskan E, Dilbaz S, Ozdas E, Dilbaz B, Ozdas E and Haberal A. Induction of labor with three different techniques at 41 weeks of gestation or spontaneous follow-up until 42 weeks in women with definitely unfavorable cervical scores. Eur J Obstet Gynecol Reprod Biol 2005; 120: 164-169.
[26] Boulvain M, Kelly A, Lohse C, Stan C and Irion O. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012; 3: 297-299.
[27] Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O and Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012; 3: CD001233.
[28] Delaney S, Shaffer BL, Cheng YW, Vargas J, Sparks TN, Paul K and Caughey AB. Labor induction with a Foley balloon inflated to 30 mL compared with 60 mL: a randomized controlled trial. Obstet Gynecol 2010; 115: 1239-1245.
[29] Levy R, Kanengiser B, Furman B, Ben AA, Brown D and Hagay ZJ. A randomized trial comparing a 30-mL and an 80-mL Foley catheter balloon for preinduction cervical ripening. Am J Obstet Gynecol 2004; 191: 1632-1636.
[30] ACOG Committee on Practice Bulletins-Obstetrics. ACOG Practice Bulletin Number 107. Induction of Labor. Washington DC: American College of Obstetricians and Gynecologists; 2009.