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Outpatient versus inpatient balloon catheter insertion for labor induction: A systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Objective: To compare between outpatient and inpatient balloon catheter insertion for labor induction.
Methods: We searched in four different databases for the available trials during May 2020. We included randomized controlled trials (RCTs) that compared outpatient to inpatient balloon catheter for induction of labor. We extracted the available data from the included studies and pooled them in meta-analysis using RevMan software. The dichotomous data were pooled as risk ratio (RR) and the continuous data were pooled as mean difference (MD) with the corresponding 95% confidence intervals (CI).Our primary outcome was the rate of cesarean delivery. Our secondary outcomes were the length of hospital stay, Bishop score, and different adverse events including postpartum hemorrhage, Apgar score less than 7 at 5 minutes, and chorioamnionitis.
Results: Eight RCTs with a total number of 740patients were included. The cesarean delivery rate was significantly reduced among outpatient balloon catheter compared to inpatient balloon catheter (RR = 0.63, 95% CI [0.46, 0.86], p = 0.004). Outpatient balloon catheter was associated with shorter hospital stay duration in comparison with inpatient group (MD= -0.38, 95% CI [-0.61, -0.14], p = 0.002). Outpatient group was linked to a more favorable increase in Bishop score (MD = 0.88, 95% CI [0.78, 0.98], p>0.001). There were no significant differences between both groups regarding different adverse events.
Conclusion: Outpatient balloon catheter priming is safe and effective in reducing cesarean delivery rates and shortening the length of hospital stay with a better Bishop score.

Contents

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Introduction

Labor induction is one of the most common obstetric interventions nowadays. From 20 to 25 % of pregnant women undergo induction of labor annually in developed countries [1]. Recent studies have shown that labor induction compared to expectant management results in a reduction in cesarean delivery rate and adverse perinatal outcomes [2].

Cervical ripening is a part of labor induction that leads to cervical relaxation and softening prior to uterine contraction onset [3]. Prostaglandins are commonly used for labor induction as they induce rapid cervical dilatation; however, they require hospital admission and continuous monitoring of side effects, especially tachycardia [4]. Unlike prostaglandins, labor induction using mechanical methods as a balloon catheter does not require monitoring with no significant increase in uterine contraction [5]. Studies have shown that balloon catheter was associated with a comparable cesarean delivery rate and fewer cases of uterine hyperstimulation when compared to prostaglandins in labor induction at term pregnancy [4,6].

With the rising of the medical costs andto achieve patient satisfaction, outpatient labor induction becomes an attractive option [5]. Although prostaglandins are commonly used in inpatient settings for cervical ripening, American College of Obstetricians and Gynecologists (ACOG) did not advocate administrating prostaglandins in the outpatient setting due to their safety concerns [1]. Besides, they suggested that mechanical induction may be convenient in an outpatient site; however, there is not sufficient evidence to support its usage.

A lot of controversies were found regarding outpatient balloon catheter use for labor induction in comparison with inpatient one. Sciscione et al. [7] in their randomized study suggested that outpatient instead of inpatient balloon catheter was applicable for labor induction as it reduced the cesarean delivery incidence with a decline in hospitalization time. A recent randomized controlled trial (RCT)found that outpatient balloon catheter for induction of labor in parous women was not effective in reducing labor duration, hospitalization time, and the rate of cesarean delivery in comparison with inpatient balloon catheter [8].

Thus, we aimed to assess the efficacy and safety of outpatient versus inpatient balloon catheter for labor induction.

Materials and Methods

We performed this systematic review and meta-analysis following the Cochrane Handbook for Systematic Reviews of Interventions [9]. We followed the PRISMA (Preferred Reporting Items for Systematic reviews and meta-analysis) statement guidelines during the preparation of this review [10].

Literature search

We performed a comprehensive electronic literature search in PubMed, Cochrane Library, Scopus, and ISI web of science for the available clinical trials. We used the following search strategy; (Foley catheter OR Foley balloon OR Balloon catheter) AND (Outpatient OR Out-patient OR Clinic OR Ward OR Office) AND (Inpatient OR In-patient OR Hospitalization OR Hospital care) AND (Labor OR Delivery OR Birth) during May 2020. There were no restrictions by the language of the study or the year of publication.Two authors performed the search strategy (A.A & M.F) with no restrictions by the language of the study or the year of publication.

Eligibility criteria

We included the studies according to the following inclusion criteria: (I) **Population**: Women with singleton pregnancies, intact membranes, live fetuses, and unfavourable cervices undergoing cervical ripening and labor induction; (ii) **Intervention**: Any type of balloon catheter administration in an outpatient setting; (iii) **Comparator**:Any type of balloon catheter administration in an inpatient setting; (IV) **Study outcomes**: cesarean delivery rate, length of hospital stay, Bishop score, and maternal and neonatal adverse events;and (V) **Study design**: RCTs. Eligibility screening was conducted in a two step-wise manner (title and abstract screening then full-text screening) by two authors (A.A & M.F). Differences were discussed, and a consensus was reached after discussion.

We excluded studies for the following reasons: (1) in vitro and animal studies, (2) non-randomized trials, and (3) irrelevant studies.

Data extraction

Two authors (A.A & R.A) had extracted the data from included studies on an excel sheet. The following data were collected: the list of authors, year of publication, sample size, and summary of the included studies.Also,our main outcomes were extracted for their entering into the analysis. Our primary outcome was the cesarean delivery rate. Our secondary outcomes were the length of hospital stay, Bishop score, and maternal and neonatal adverse events including postpartum hemorrhage, Apgar score less than 7 recorded at five minutes, and chorioamnionitis.

Bishop score is considered as a cervical scoring system that takes into account the cervical dilation, cervical position, consistency of the cervix, cervical effacement, and fetal station. The length of hospital stay is defined as the duration from hospital admission till discharge. Postpartum hemorrhage is meant by blood loss of more than 500 ml or 1,000 ml after child delivery during the first 24 hours.

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Risk of bias assessment

Two authors (A.A & M.F) evaluated the quality of included studies and the risk of bias using the Cochrane risk of bias assessment tool [11]. The Cochrane risk of bias assessment tool includes the following domains: random sequence generation, allocation concealment, performance bias (blinding of participant and personnel), detection bias (blinding of outcome assessment), attrition bias, reporting bias, and other potential sources of bias. The authors' judgment is categorized as "Low risk," "High risk,"and "Unclear risk" of bias.

Data synthesis

The data analysis was completed independently by two authors (A.A & M.S), and then the results were compared, and any difference was resolved by discussion.The dichotomous data were pooled as risk ratio (RR) and the continuous data were pooled as mean difference (MD)with the corresponding 95% confidence intervals using the Mantel-Haenszel method. All statistical analyses were performed using the Revman software. The statistical heterogeneity was assessed between studies by using I-squared (I^2) statistics and values of $\geq$50% were indicative of high heterogeneity [12].

We used the fixed-effect model when no heterogeneity was reported among the studies.The random-effect model was utilized when heterogeneity was found among the studies. We removed the reported heterogeneity by performing a sensitivity analysis where we excluded one study at a time and assessed the impact of removing each study on the summary results and the heterogeneity.

Publication bias

The assessment of the publication bias using the funnel plot method and Egger's test was unreliable for fewer than ten included studies according to Egger and colleagues. Therefore, we could not assess for the publication bias due to the small number of included studies [13,14].

Results

Results of the literature search

We retrieved 650 studies after searching in different databases. After title and abstract screening, 30 articles were reliable for full-text screening in which 22 of them were excluded, and finally, eight studies matched our inclusion and were included in the final analysis. The PRISMA flow diagram of study selection is shown in Fig. 1.

Characteristics of included studies

Eight RCTs [7,8,15–20] met our inclusion criteria with a total number of 740 patients in which 387 of them were in the outpatient balloon catheter group and 353 patients in the inpatient balloon catheter group. All included studies used Foley balloon catheter for labor induction except one study [20] which used a

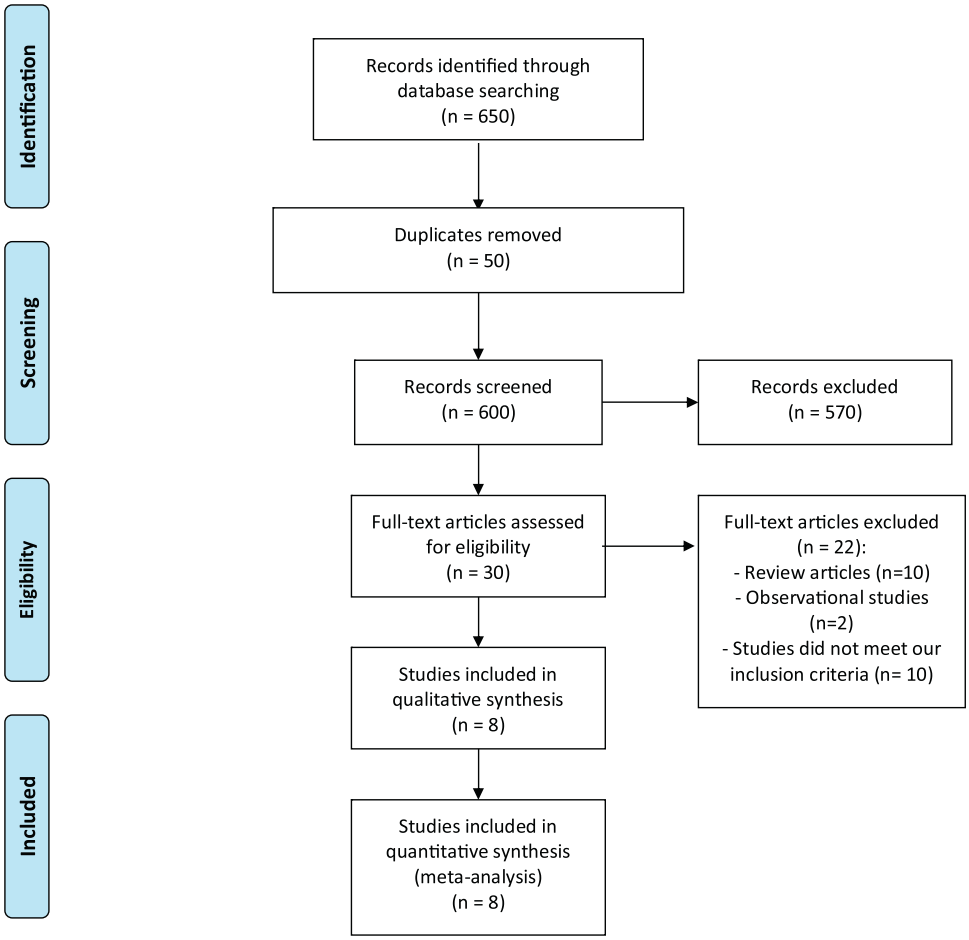

Fig. 1. PRISMA Flow Chart of the study selection process.

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double-balloon catheter. Most of the studies included both nulliparous and multiparous women in their inclusion criteria.

Most of the included studies entered women with low-risk pregnancies in their inclusion criteria except three studies [16,17,20] which included women with high-risk pregnancies. Two of them [16,17] included obese women as they are more likely to suffer from the prolonged first stage of labor. The last study [20] included high-risk pregnancy patients with diabetes mellitus, hypertension, cholestasis, and fetal growth restrictions. The summary of the included studies including the main findings is shown in Table 1.

Risk of bias assessment

The quality of included RCTs was performed based on the Cochrane risk of bias assessment tool. The summary of the risk of bias assessment of RCTs is shown in Fig. 2.

Outcomes

Cesarean delivery

Outpatient balloon catheter was associated with a significant reduction in the rate of cesarean delivery in comparison with inpatient balloon catheter (RR = 0.63, 95% CI [0.46, 0.86], p = 0.004) as shown in Fig. 3. The pooled studies were homogenous (p = 0.65, I^2 = 0%).

Length of hospital stay

Outpatient balloon catheter significantly shortened the length of hospital stay compared to inpatient group (MD= -0.38, 95% CI [-0.61, -0.14], p = 0.002) as shown in Fig. 4. The pooled studies were heterogeneous (p = 0.009, I^2 = 65%). We removed this high heterogeneity by excluding one study [15] (p = 0.13, I^2 = 41%) showing a significant shortening in the duration of hospital stay among the outpatient balloon catheter in comparison with the inpatient group (MD= -0.28, 95% CI [-0.48, -0.09], p = 0.004).

Table 1
Summary of the included studies.

Study ID	Study arms	Sample size	Country	Balloon catheter type	Maternal age (years)	Gestational age (weeks)	Body mass index (BMI)	Main findings
Kuper et al. 2018	Outpatient balloon catheter	65	United States (US)	Foley balloon catheter	26.6 ± 4.3	39.2 ± 0.6	33.9 ± 6.9	Outpatient cervical ripening by balloon catheter in parous women does not shorten the time from labor ward admission until delivery.
	Inpatient balloon catheter	64			25.8 ± 4.2	39.2 ± 0.3	33.2 ± 6.4	
Sciscione et al. 2001	Outpatient balloon catheter	61	United States (US)	Foley balloon catheter	29.8 ± 5.8	40.1 ± 1.3	NA	Foley catheter is effective for pre-induction cervical ripening in the outpatient compared to the inpatient setting.
	Inpatient balloon catheter	50			28.4 ± 6.5	39.8 ± 1.2	NA	
Policiano et al. 2017	Outpatient balloon catheter	65	Portugal	Foley balloon catheter	30.5 ± 6.3	40.3 ± 1.3	24.4 ± 6.2	Outpatient priming by Foley balloon catheter is safe and effective with less cesarean deliveries and shorter hospital stay when compared to inpatient setting.
	Inpatient balloon catheter	65			31.7 ± 5.5	39.8 ± 1.2	25.6 ± 6.4	
Wilkinson et al. 2015	Outpatient balloon catheter	33	Australia	Double balloon catheter	29.1 ± 6.8	40.5 ± 0.1	NA	Outpatient balloon catheter is a safe and effective option for cervical priming in comparison with inpatient balloon catheter.
	Inpatient balloon catheter	15			28.9 ± 4.2	40.4 ± 0.1	NA	
Chen et al. 2019	Outpatient balloon catheter	12	Australia	Foley balloon catheter	33.3 ± 3.7	40.7 ± 1	NA	Outpatient catheter balloon cervical ripening has the potential to reduce the length of hospital stay and facilitate a better birth for the mother.
	Inpatient balloon catheter	16			34.4 ± 4.1	40.3 ± 1.4	NA	
Subramaniam et al. 2019	Outpatient balloon catheter	58	United States (US)	Foley balloon catheter	27.1 ± 3.9	40 ± 0.2	NA	Although outpatient cervical ripening in obese parous women does not shorten the time from admission to delivery, a potential benefit in women with a BMI ≥ 40 should be explored in larger studies.
	Inpatient balloon catheter	50			28.9 ± 4.3	40 ± 0.3	NA	
Ausbeck et al. 2019	Outpatient balloon catheter	63	United States (US)	Foley balloon catheter	29.7 ± 7.8	40.1 ± 0.2	31 ± 6.5	Outpatient cervical ripening with a Foley catheter reduced the time from hospital admission until delivery in nulliparous women.
	Inpatient balloon catheter	63			28.9 ± 7.2	40.2 ± 0.5	34 ± 6.9	
Mohamad et al. 2018	Outpatient balloon catheter	30	Malaysia	Foley balloon catheter	33.2 ± 4.8	40.3 ± 1.3	NA	The outpatient Foley catheter cervical ripening was comparably safe as inpatient settings and it had a better patient satisfaction benefit.
	Inpatient balloon catheter	30			31.8 ± 4.9	38.7 ± 2.7	NA	

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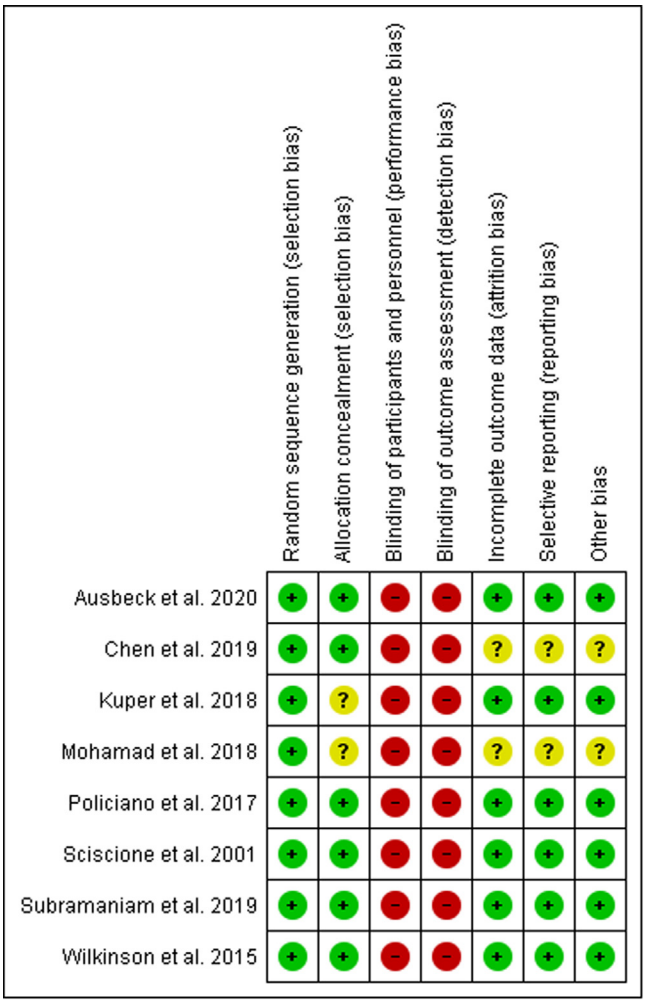

Fig. 2. Risk of bias summary.

Bishop score

Bishop score was significantly improved among outpatient balloon catheter in comparison with inpatient balloon catheter (MD = 0.88, 95% CI [0.78, 0.98], p>0.001) as shown in Fig. 5. The pooled studies were homogeneous (p = 0.10, I^2 = 53%).

Postpartum hemorrhage

There was no significant difference between outpatient and inpatient balloon catheters in postpartum hemorrhage (RR = 0.76, 95% CI [0.29, 1.99], p = 0.58) as shown in Fig. 6**A**. The pooled studies were homogeneous (p = 0.58, I^2 = 0%)

Apgar score less than 7 at 5 min

There was no significant difference between outpatient and inpatient balloon catheter in Apgar score less than 7 at 5 min (RR = 0.90, 95% CI [0.36, 2.22], p = 0.81) as shown in Fig. 6**B**. The pooled studies were homogeneous (p = 0.90, I^2 = 0%).

Chorioamnionitis

There was no significant difference between outpatient and inpatient balloon catheters in the risk of chorioamnionitis (RR = 1.42, 95% CI [0.75, 2.70], p = 0.28) as shown in Fig. 6**C**. The pooled studies were homogeneous (p = 0.72, I^2 = 0%).

Discussion

In this meta-analysis, we found that an outpatient balloon catheter was linked to a significant decline in the cesarean delivery rate and a significant shortening in the hospital stay with a better Bishop score when compared to inpatient balloon catheter. Also, we found no significant differences between outpatient and inpatient balloon catheters regarding maternal and neonatal

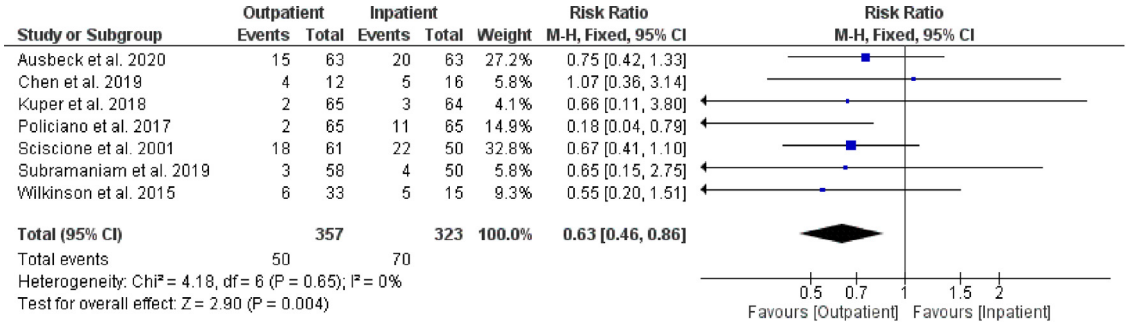

Fig. 3. Forest plot of rate of cesarean delivery.

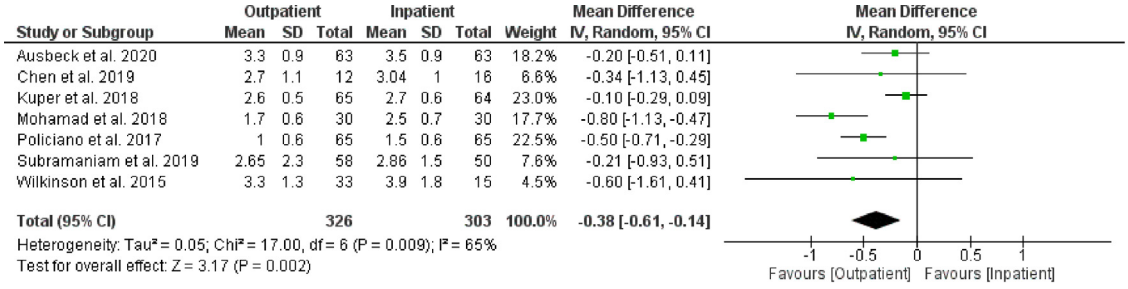

Fig. 4. Forest plot of the length hospital stay.

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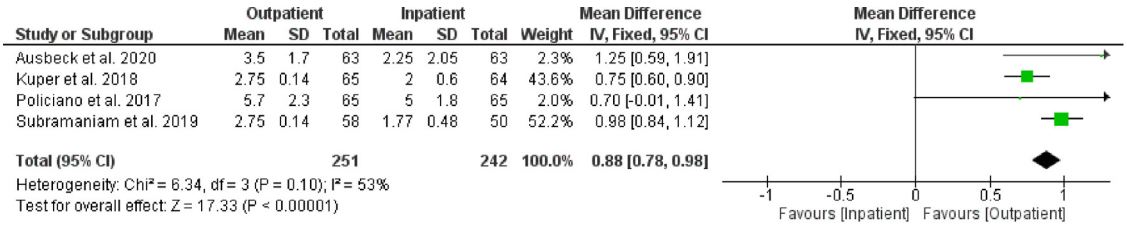
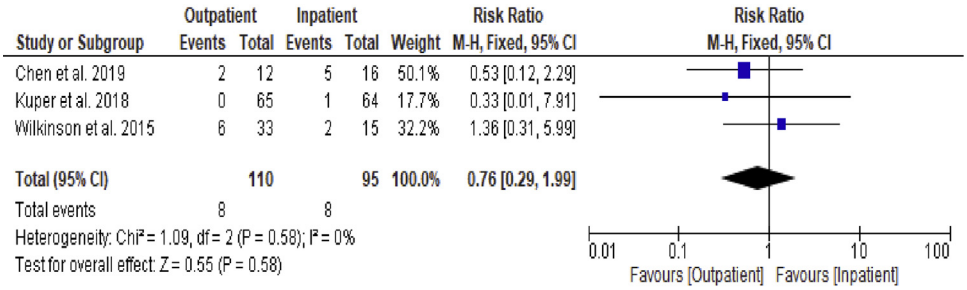
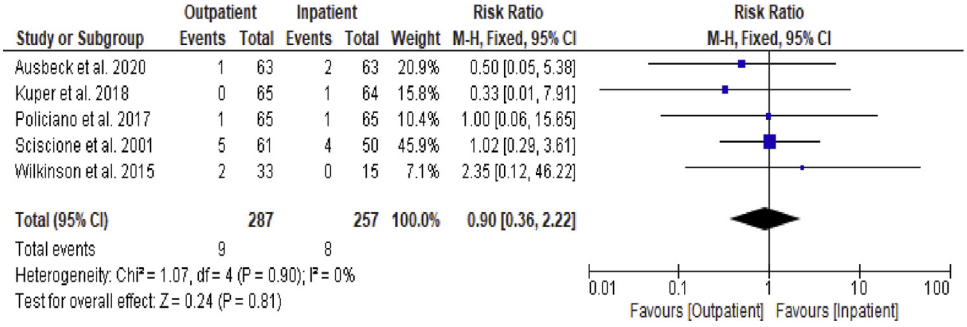


Fig. 5. Forest plot of Bishop score.

Postpartum hemorrhage (Figure 6A)



Apgar score less than 7 at 5 min (Figure 6B)



Chorioamnionitis (Figure 6C)

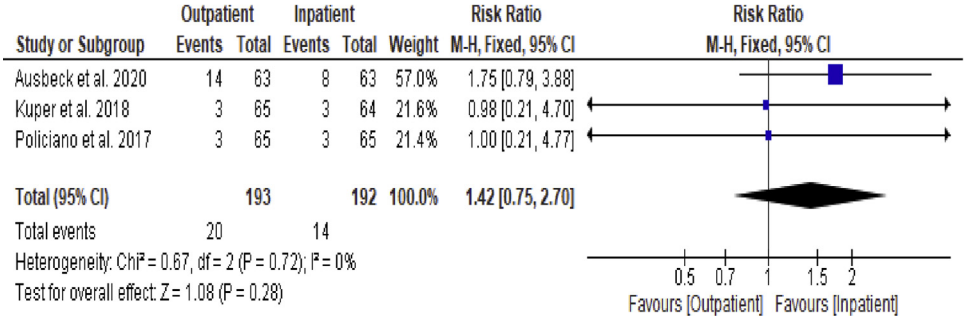


Fig. 6. Forest plots of the safety outcomes.

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adverse events including postpartum hemorrhage, Apgar score, and chorioamnionitis.

Many studies have described several protocols for outpatient induction of labor where they suggested that labor induction in an outpatient setting is acceptable and feasible [21]. The balloon catheter has been introduced for outpatient management as a result of the lower risk of maternal and neonatal adverse events [21]. However, there is insufficient evidence for the administration of balloon catheters for labor induction in an outpatient setting as stated by a recent Cochrane review [22].

Kuper et al. [8] intended to conduct an RCT to assess the benefits of outpatient Foley catheters for labor induction where they included 129 parous women in their study. They found a more favorable Bishop score among outpatient Foley catheters with no increase in maternal and neonatal adverse events when compared to the inpatient group. However, they demonstrated that outpatient trans-cervical Foley catheters did not shorten the total hospital duration with no decline in the cesarean delivery rates [8]. Another observational study by Kruit et al. [23] included 485 women in their observational study and found no differences between outpatient and inpatient Foley catheter for labor induction regarding the rates of cesarean deliveries, and maternal and neonatal adverse events.

Another RCT by Policiano et al. [20] found no significant differences in Bishop score and vaginal delivery rate between outpatient and inpatient Foley catheter insertion. However, they demonstrated a significant decline in the rates of cesarean delivery and a significant shortening in the length of hospital stay among the outpatient Foley catheter [20]. Moreover, another RCT stated that the clinical and perinatal outcomes and satisfaction were similar between outpatient and inpatient double-balloon catheter administrated for labor induction with no differences in maternal and neonatal adverse events [19]. However, the outpatient group required less oxytocin than in the inpatient group [19].

Subramaniam et al. [16] conducted a randomized study to compare outpatient versus inpatient Foley balloon catheter insertion among obese parous women. They found a significant improvement in Bishop score with shorter hospital stay among women with BMI $\geq$ 40 who utilized outpatient Foley catheter for labor induction. However, among women with BMI $\geq$ 30, although they found a better Bishop score among the outpatient group, the length of hospital stay did not differ compared to the inpatient group [16].

A systematic review by Diederen et al. [24] concluded that the risk of side effects between insertion and expulsion of the balloon catheter when used for cervical ripening in an outpatient care was likely to be low. Thus, they suggested that outpatient balloon catheters can be further evaluated and implemented, especially for low-risk pregnancies [24].

Regarding patient satisfaction, Sutton et al. [25] performed a prospective questionnaire form to evaluate the opinions and attitudes among women undergoing outpatient cervical priming in an Australian tertiary hospital. They concluded that outpatient cervical ripening has a great psychological benefit as most patients would like to undergo this procedure in the future [25]. Another study found that most women were greatly satisfied with the outpatient Foley catheter priming for labor induction [23]. However, Wang et al. [26] reported no significant difference in patient satisfaction between outpatient and inpatient Foley catheterization among parous women with low-risk pregnancies.

Christensen et al. [27] performed a cost-effectiveness analysis study between outpatient and inpatient Foley catheter in which they included 760,000 low-risk nulliparous women in their theoretical cohort. They found that the outpatient Foley catheter was the best strategy and a cost-effective option for pre-induction cervical priming as it reduced the rates of cesarean deliveries and failure in labor induction [27]. In addition, Son et al. [28] showed that outpatient trans-cervical balloon catheter was cost-effective compared to inpatient group in which $156.83 would be saved for each patient especially if the time saved on the labor and delivery department was more than 3.5 hours.

Mechanical stretching by balloon catheter results in an augmented release of endogenous prostaglandins, which in sequence induces cervical ripening [4]. Moreover, balloon catheter can induce a local inflammatory effect resulting in elevated levels of interleukin-8 and interleukin-6, nitric oxide synthetase, metalloproteinase-8, and hyaluronic acid on immunohistochemistry of the cervical tissue [29].

Different studies have demonstrated that more active women experienced a lower gestational age at delivery and a more common natural labor than sedentary women. Also, fewer hours of sleep and rest before delivery are considered prognostic factors for extended active labor time [30,31]. Women with outpatient balloon catheter insertion for cervical priming are more dynamic and relaxed and have more hours of good sleep at night in their home atmosphere. Thus, they may ultimately experience a shorter phase of active labor which could also be an explanation for the lower incidence of cesarean deliveries [20].

Although outpatient cervical ripening by balloon catheter is promising, it needs several hours to ensure that cervical ripening is acceptable, to check fetal well-being before and after balloon catheter placement, and to counsel women. In addition,health care workers may challenge the raised number of patient phone calls and early admissions without the advantages of shorter labor or hospital stay [32].

The main strengths of the present meta-analysis are the inclusion of RCTs, the strict adherence to the steps reported in the Cochrane handbook of systematic review for interventions,and the comprehensive eligibility criteria and search methodology. To the best of our knowledge, no previous meta-analysis is performed on this issue.

Our limitations for this meta-analysis include; the limited number of the included studies with the small sample size, non-blinding of our included trials, and different demographic characteristics among the studies. Furthermore, the satisfaction score was not evaluated as one of our main outcomes as satisfaction was reported by a limited number of the studies. We did not perform a subgroup analysis either between nulliparous and multiparous women or between high risk and low-risk pregnancies which adds a further limitation to our meta-analysis.

Further RCTs are needed to confirm our findings with a large sample size. The future trials should evaluate the satisfaction score as one of the main outcomes. More studies are required to assess the safety and efficacy of outpatient balloon catheters among women with high-risk pregnancies. More cost-effectiveness analysis studies are required to assess the advantages of cervical ripening by outpatient balloon catheters in reducing health care costs.

Conclusion

Outpatient balloon catheter priming is safe and effective in reducing cesarean delivery rates and shortening the length of hospital stay with a better Bishop score.

Declaration of Competing Interest

None.

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None.

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