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REVIEW ARTICLE

Meta-analysis of Foley catheter plus misoprostol versus misoprostol alone for cervical ripening

Wenhang Chen [a,b,c,1], Jing Xue [b,c,d,1], Laura Gaudet [b,c], Mark Walker [b,c,e], Shi Wu Wen [b,c,d,e,*]

[a] Department of Obstetrics and Gynecology, The Third Xiangya Hospital of Central South University, Changsha, China
[b] OMNI Research Group, Department of Obstetrics and Gynecology, University of Ottawa, Ottawa, Canada
[c] Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Canada
[d] Department of Epidemiology, School of Public Health, Central South University, Changsha, China
[e] Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, Canada

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ABSTRACT

Background: The effectiveness of Foley catheter plus misoprostol for cervical ripening has not been convincingly shown in trials. *Objectives:* To summarize the evidence comparing Foley catheter plus misoprostol versus misoprostol alone for cervical ripening. *Search strategy:* Embase, Medline, and Cochrane Collaboration databases were searched with the terms "Foley catheter," "misoprostol," "cervical ripening," and "labor induction." *Selection criteria:* Randomized controlled trials comparing the methods of cervical ripening for delivery of a viable fetus were included. *Data collection and analysis:* Study characteristics, quality, and outcomes were recorded. Random-effects models were used to combine data. *Main results:* Eight trials were included, with 1153 patients overall. In a pooled analysis of seven high-quality studies, the combination group had a decreased time to delivery (mean difference −2.36 hours, 95% confidence interval [CI] −4.07 to −0.66; $P = 0.007$). Risk of chorioamnionitis was significantly increased in the combination group (risk ratio [RR] 2.07, 95% CI 1.04–4.13; $P = 0.04$), and that of tachysystole with fetal heart rate changes was decreased (RR 0.58, 95% CI 0.38–0.91; $P = 0.02$). Frequency of cesarean did not differ ($P = 0.77$). *Conclusions:* The combined use of Foley catheter and misoprostol results in a reduced time to delivery, a reduced frequency tachysystole with fetal heart rate changes, and an increased incidence of chorioamnionitis.

1. Introduction

Labor induction is the initiation of labor at a viable pregnancy duration by artificial means, and occurs before the spontaneous onset of labor. It is an increasingly common obstetric intervention—from 1990 to 2012, the rate of labor induction increased from 9.5% to 22.8% in the USA [1]. The goal of labor induction is to achieve a timely and uncomplicated vaginal delivery with minimal adverse effects on the mother or newborn [2].

When the cervix is unfavorable, the success of oxytocin in inducing labor is reduced [3]. Therefore, labor induction often commences with interventions to ripen the cervix. There are generally two categories of cervical ripening: mechanical and pharmacological. The use of an intracervical Foley catheter for cervical ripening was first described in 1967 [4]. It dilates the cervix directly and also acts indirectly by stimulating the secretion of prostaglandin and oxytocin [5]. Misoprostol—a synthetic prostaglandin E1 analog approved for the prevention and treatment of gastrointestinal ulcers and peptic ulcer disease caused by prostaglandin inhibitors [6]—also successfully ripens the cervix during labor induction [7]. It produces cervical softening and effacement mainly through the disintegration and dissolution of extracellular collagen [2]. This drug is relatively inexpensive, is stable at room temperature, and does not require refrigeration [8].

We hypothesized that the combination of Foley catheter and misoprostol used simultaneously would achieve better results because the combined use of cervical ripening agents with differing mechanisms of action might have a synergistic effect. Several studies have compared the combination of Foley catheter and misoprostol with misoprostol alone for cervical ripening [9–12]. However, the results have been inconsistent and some studies were underpowered to detect a difference between the groups. Therefore, the aim of the present study was to systematically review randomized controlled trials (RCTs) comparing the effectiveness of the two interventions (combined [simultaneous] use of Foley catheter with misoprostol versus misoprostol alone) for cervical ripening in women with an unfavorable cervix undergoing induction of labor.

* Corresponding author at: OMNI Research Group, Department of Obstetrics and Gynecology, University of Ottawa, 501 Smyth Road, Box 241, Ottawa, ON K1H 8 L6, Canada. Tel.: +1 613 737 8899x73912; fax: +1 613 739 6266.
E-mail address: swwen@ohri.ca (S.W. Wen).
[1] These authors contributed equally.

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2. Materials and methods

2.1. Data sources and searches

Embase (1947 to May 20, 2014), Medline (1946 to May 20, 2014), and the Cochrane databases (up to May 20, 2014) were searched for RCTs comparing the combined use of Foley catheter and misoprostol with that of misoprostol alone for cervical ripening during labor induction. The search terms used were "Foley catheter," "misoprostol," "cervical ripening," and "labor induction." The reference lists of all relevant eligible articles and recent reviews on the subject were hand-searched for further potential reports. There was no language restriction in the search. A protocol for the review was registered with the Centre for Reviews and Dissemination, University of York, York, UK (registration number CRD 42014007302).

2.2. Study selection

To be included, studies had to have an RCT design, enroll pregnant women undergoing cervical ripening for the purpose of labor induction for delivery of a viable fetus using a combination of Foley catheter and misoprostol, and have a comparison group receiving misoprostol alone for cervical ripening and labor induction.

Reviews, observational studies, case reports, letters, and commentaries were excluded. Studies were also excluded from the present review if participants received induction agents other than Foley catheter and misoprostol concurrently or misoprostol alone, and were undergoing cervical ripening for abortion or intrauterine fetal demise. The use of oxytocin for the augmentation of labor is common during labor induction; trials that used oxytocin for labor augmentation were not excluded.

Two authors (W.C. and J.X.) reviewed the studies to determine if the inclusion criteria were met. Disagreements were resolved by discussion or, if disagreement persisted, by a third author (S.W.W.).

2.3. Data extraction and quality assessment

Data extraction was carried out independently by two authors (W.C. and J.X.). The collected data were abstracted to a structured Excel sheet. Data were collected for: author and year; misoprostol route, dose, and frequency; Foley catheter size and balloon volume; number of patients; pregnancy duration; Bishop score; and outcomes. Any difference in the data extracted by the two reviewers led to reassessment of the validity of the data and resolution by discussion. Attempts were made to contact authors for the full text of conference abstracts and for studies for which information on the predefined outcome measures was missing.

Quality assessment was performed using the Cochrane tool for assessing the risk of bias in RCTs [13]. Because of the distinct differences in the two methods of ripening considered here, the RCTs comparing these two methods could not be blinded. Therefore, the risk of blinding bias was not assessed. The risk of bias was assessed in six domains: random sequence generation, allocation concealment, incomplete outcome data, selective reporting, intention to treat, and other sources of bias. The overall quality of a study was considered to be high if at least four domains—including either random sequence generation or allocation concealment—were rated as low-risk. Any discordance in quality assessment was resolved by the third author (S.W.W.).

2.4. Selection of outcomes

The primary outcomes were the mean time to delivery and the rates of cesarean delivery, chorioamnionitis (maternal temperature > 38 °C during the course of labor induction), and uterine tachysystole with fetal heart rate (FHR) changes. Secondary outcomes included meconium-stained amniotic fluid, oxytocin augmentation, endomyometritis, and admission to the neonatal intensive care unit (NICU). The beginning of induction was defined as the time of the first use of misoprostol or of the Foley catheter placement. All data on tachysystole were included, even though the definition differed slightly between studies. The slight differences were not felt to be clinically significant enough to prevent meta-analysis.

2.5. Statistical analysis

Statistical analyses were performed using RevMan 5.0 (Nordic Cochrane Centre, Copenhagen, Denmark). For continuous data (time to delivery), the overall mean difference and 95% confidence interval (CI) were estimated. For dichotomous data (all outcomes except time to delivery), summary risk ratios (RRs) with 95% CIs were estimated. All data were combined using Mantel–Haenszel random-effects modeling, taking into consideration between-study variances in terms of Bishop score, size or volume of the Foley catheter, and route of misoprostol administration. $P < 0.05$ was considered statistically significant.

Heterogeneity between studies was assessed using the Cochran Q test and the I^2 statistic. The heterogeneity was considered to be significant when $P < 0.10$ in the Q test and $I^2 > 50\%$. A stratified analysis based on the study quality was then conducted to investigate the source of the heterogeneity. Sensitivity analyses were performed by omitting each study to evaluate the stability of the results. When the results for time to delivery in each included study were shown as mean and quartiles, these were converted to mean and standard deviation according to the method described in the Cochrane Handbook [13]. Publication bias was assessed statistically by the Egger test and graphically by funnel plots [14].

3. Results

3.1. Identified studies

In total, 16 studies were identified (Fig. 1). Four [15–18] were excluded because the treatment allocation was not randomized, one [19] was excluded because the full text could not be obtained, two [20,21] were excluded because they involved induction of labor in pregnancies with a nonviable fetus, and one [22] was excluded because misoprostol was not used concurrently with a Foley catheter in the combination treatment group. Therefore, eight eligible studies [9–12,23–26] with a total of 1153 patients were included in the present meta-analysis (Table 1).

Among the included studies, seven [9–12,23–25] had a low risk of random sequence generation and allocation concealment and were judged to be of high quality (Table 2). One study [26] was judged to be of low quality.

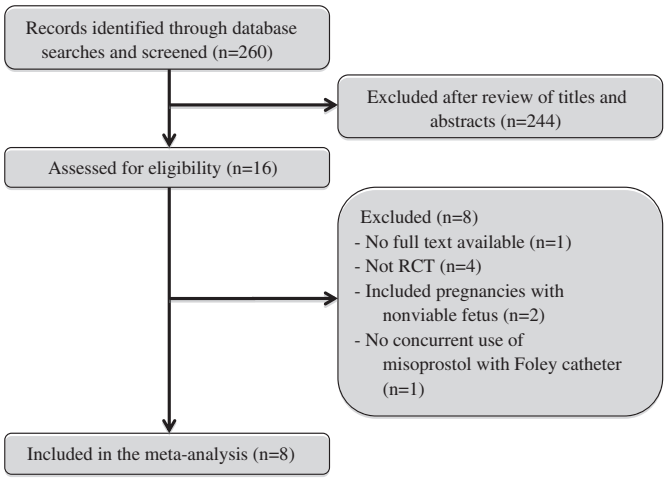

Fig. 1. Flow chart of study selection. Abbreviation: RCT, randomized controlled trial.