Safety and efficacy of double-balloon catheter for cervical ripening: a Bayesian network meta-analysis of randomized controlled trials

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Abstract

Background: Various methods are used for cervical ripening during the induction of labor. Mechanical and pharmacological methods are commonly used for cervical ripening. A double-balloon catheter was specifically developed to ripen the cervix and induce labor; however, the efficacy of the double-balloon catheter in cervical ripening compared to other methods is unknown.

Methods: We searched five databases and performed a Bayesian network meta-analysis. Six interventions (double-balloon catheter, Foley catheter, oral misoprostol, vaginal misoprostol, dinoprostone, and double-balloon catheter combined with oral misoprostol) were included in the search. The primary outcomes were cesarean delivery rate and time from intervention-to-birth. The secondary outcomes were as follows: Bishop score increment; achieving a vaginal delivery within 24 h; uterine hyperstimulation with fetal heart rate changes; need for oxytocin augmentation; instrumental delivery; meconium staining; chorioamnionitis; postpartum hemorrhage; low Apgar score; neonatal intensive care unit admission; and arterial pH.

Results: Forty-eight randomized controlled trials involving 11,482 pregnant women were identified. The cesarean delivery rates of the cervical ripening with a double-balloon catheter and oral misoprostol, oral misoprostol, and vaginal misoprostol were significantly lower than cervical ripening with a Foley catheter (OR = 0.48, 95% CI: 0.23–0.96; OR = 0.74, 95% CI: 0.58–0.93; and OR = 0.79, 95% CI: 0.64–0.97, respectively; all P < 0.05). The time from intervention-to-birth of vaginal misoprostol was significantly shorter than the other five cervical ripening methods. Vaginal misoprostol and oral misoprostol increased the risk of uterine hyperstimulation with fetal heart rate changes compared to a Foley catheter. A double-balloon catheter with or without oral misoprostol had similar outcomes, including uterine hyperstimulation with fetal heart rate changes compared to a Foley catheter.

Conclusion: Double-balloon catheter did not show superiority when compared with other single method in primary and secondary outcomes of labor induction. The combination of double-balloon catheter with oral misoprostol was significantly reduced the rate of cesarean section compared to Foley catheter without increased risk of uterine hyperstimulation with fetal heart rate changes, which was shown in oral or vaginal misoprostol.

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Introduction
Labor induction is a common obstetric procedure; 20 to 30% of deliveries are induced worldwide [1]. Successful induction of labor depends on the status of the cervix at the time of induction. A poor Bishop score has been shown to be associated with an unacceptably high induction failure rate [2]. Medical interventions are necessary to induce cervical ripening prior to initiation of labor if the Bishop score is ≤ 6 [3–5].

Methods of cervical ripening can be broadly categorized into mechanical and pharmacological methods [4, 6]. Mechanical methods apply pressure from inside the cervical canal to force dilation. The local pressure stimulates the release of prostaglandins (PGs), which facilitate cervical remodeling. Foley catheters and transcervical double-balloon catheters are the two major devices utilized for mechanical dilation [7]. Compared with the unilateral pressure of a single-balloon catheter, the double-balloon catheter offers an improved mechanism of dilation between the internal and external cervical os [8]. There are a variety of pharmaceutical agents available for cervical ripening, including PGs, oxytocin, estrogens, and mifepristone. PGE2 cervical ripening with controlled-release dinoprostone inserts has gained widespread use in clinical practice. Misoprostol, a synthetic structural analog of PGE1, has been shown to be effective in labor induction and is often used as an off-label drug for inducing labor.

To determine if the double-balloon catheter was better than other methods, recent clinical trials have been designed to compare the efficacy and safety with a Foley catheter [9], dinoprostone insert [10], and misoprostol [11]; however, the results have not led to a consensus. We therefore conducted a network meta-analysis (NMA) comparing the double-balloon catheter with four commonly used cervical ripening methods among pregnant women in the third trimester with intact membranes. The purpose of this study was to provide a comprehensive overview of the available evidence involving the use of a double-balloon catheter for cervical ripening in clinical practice.

Methods
The pre-registered protocol was implemented in the PROSPERO database (CRD42022317381). This NMA was reported in accordance with the PRISMA guidelines (Supplemental Table S1).

Search strategy
The PubMed, MEDLINE, Embase, ClinicalTrials.gov, and Cochrane Library databases were searched on March 18, 2022 to identify the relevant studies by two investigators. The keywords in the search strategy were as follows: “cervical ripening” or “labor, induced”; and “double-balloon catheter” or “single-balloon catheter/Foley catheter” or “dinoprostone” or “misoprostol” (Supplemental Table S2). Additionally, we searched the references of articles to further identify literature that met the criteria.

Data extraction and extraction
Original studies were eligible if the following criteria were met: (I) randomized controlled trial (RCT) studies; (II) full text available in English; and (III) the efficacy and safety of different interventions (double-balloon catheter, single balloon catheter/Foley catheter, oral misoprostol, vaginal misoprostol, 10-mg controlled-release dinoprostone vaginal insert, and double-balloon catheter combined with misoprostol/dinoprostone) for cervical ripening in women with an unfavorable cervix and with intact membranes were assessed.

Original studies were ineligible for the following reasons: (I) reviews, observational studies, case control studies, abstracts, letters, or case reports; (II) trials including women whose pregnancies were ≤ 28 weeks gestational age, non-cephalic presentations, multiple pregnancies, or a previous cesarean section(s); (III) other forms of dinoprostone (gel or tablet); or (IV) laboratory animal studies. In the case of several publications from the same study, the study with the greatest number of cases and most relevant information was included.

The first author, year of publication, treatment groups, and number of participants in each group, age (years), nulliparity, gestational age (weeks), balloon volume (mL), misoprostol route and dose, and outcomes were extracted from the eligible studies.

Outcomes
The primary outcomes were cesarean delivery rate and the time from intervention-to-birth. The secondary outcomes included achieving vaginal delivery within 24 h, Bishop score increment, uterine hyperstimulation with fetal heart rate changes, oxytocin augmentation, instrumental delivery, meconium-stained amniotic fluid, maternal adverse events (chorioamnionitis and postpartum hemorrhage), and neonatal adverse events.

Keywords: Cervical ripening, Labor induction, Double-balloon catheter, Foley, Dinoprostone, Misoprostol, Meta-analysis
Statistical analysis
Prior to analysis, the risk of trial bias was assessed for the included studies using the Cochrane Collaboration's tool. The mean difference (MD) and 95% confidence interval (CI) were the time from intervention-to-birth and Bishop score increment. Odds ratios (ORs) were used to report the cesarean delivery rate, achieving vaginal delivery within 24 h, uterine hyperstimulation with fetal heart rate changes, oxytocin augmentation, instrumental delivery, and meconium-stained amniotic fluid. We evaluated the efficacy and safety of different interventions for cervical ripening in women with an unfavorable cervix and intact membranes using an NMA. In this Bayesian NMA, random-effects and consistency models were used to analyze data and carry out the NMA (4 chains, 50,000 iterations, and 20,000 per chain). We assessed inconsistencies using the node-splitting method, and inconsistencies are reported by the Bayesian P values. An overall grading of the quality of evidence was conducted using the GRADE system. To rank the outcomes, we used the surface under the cumulative ranking curve (SUCRA) as an indicator (worst: 0; best: 1) for each intervention. We analyzed the symmetry of a comparison-adjusted funnel plot to evaluate possible small sample effects and used Begg's and Egger's tests to evaluate publication bias in the included studies. A p value < 0.05 was considered statistically significant for asymmetry. All analyses were conducted using the "gemtc" package of R (version 4.0.2; R Foundation, Vienna, Austria) and Stata (version 16.0; StataCorp, College Station, TX, USA).

Results
Baseline characteristics of included studies
Our exhaustive search strategy retrieved 2,981 potentially relevant publications from six databases. After screening and reading the full-text articles, 48 RCTs were included in our final analyses (Fig. 1) [10–57]. These RCTs were conducted between 1997 and 2021 (Table 1) and were carried out in Asia (China, India, Iran, Israel, and}
| Author, year | Country | Groups | Numbers | Age (years) | Nulliparity (%) | Gestational age (weeks) | Balloon volume (mL) | Misoprostol dose | Outcomes |
|--------------|---------|--------|---------|-------------|-----------------|------------------------|---------------------|----------------|----------|
| Wing, 1997 [12] | USA | Dinoprostone | 98 | NR | 42.9 | 39.2 ± 2.3 | - | - | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Vaginal misoprostol | 99 | NR | 48.5 | 39.5 ± 2.4 | - | 25 mcg every 4 h up to 6 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Bennett, 1998 [13] | Canada | Vaginal misoprostol | 102 | 28.7 ± 4.9 | 72.5 | 40.6 ± 1.2 | - | 50 mcg every 4 h up to 5 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Oral misoprostol | 104 | 27.5 ± 5.0 | 66.3 | 40.8 ± 1.1 | - | 50 mcg every 4 h up to 9 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Wing, 1999 [14] | USA | Oral misoprostol | 110 | NR | 48.2 | 39.2 ± 1.7 | - | 50 mcg every 4 h up to 6 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Vaginal misoprostol | 110 | NR | 48.2 | 38.6 ± 2.0 | - | 25 mcg every 4 h up to 6 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Fisher, 2001 [15] | Canada | Vaginal misoprostol | 64 | 27.0 ± 4.5 | 56.2 | 41.0 ± 2.3 | - | 50 mcg every 3 h up to 48 h | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Oral misoprostol | 62 | 27.0 ± 6.0 | 64.5 | 41.0 ± 1.5 | - | 50 mcg every 6 h up to 48 h | [1] [2] [5] [8] [9] [12] [13] [14] |
| Khoury, 2001 [16] | USA | Dinoprostone | 39 | 28.1 ± 7.0 | 59.0 | 39.9 ± 1.4 | - | - | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Vaginal misoprostol | 79 | 29.7 ± 6.3 | 62.0 | 40.0 ± 1.2 | - | 35 mcg every 4.5 h up to 6 doses or 50 mcg every 4.5 h up to 6 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Kwon, 2001 [17] | Canada | Oral misoprostol | 78 | 27.2 ± 5.4 | 56.4 | 40.3 ± 1.8 | - | 50 mcg every 6 h up to 8 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Vaginal misoprostol | 82 | 27.6 ± 5.1 | 52.4 | 40.3 ± 1.7 | - | 50 mcg every 6 h up to 8 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Sciscione, 2001 [18] | USA | Foley catheter | 58 | 25.1 ± 6.9 | 70.6 | > 28 | 30 mL | - | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Vaginal misoprostol | 53 | 25.9 ± 6.9 | 71.7 | > 28 | - | 50 mcg every 4 h up to 6 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Shetty, 2001 [19] | UK | Oral misoprostol | 122 | 28.0 ± 6.8 | 59.8 | 41.0 ± 1.3 | - | 50 mcg every 4 h up to 5 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Vaginal misoprostol | 123 | 28.0 ± 7.8 | 61.8 | 41.0 ± 1.3 | - | 50 mcg every 4 h up to 5 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| le Roux, 2002 [20] | South Africa | Vaginal misoprostol | 120 | 27.9 (mean) | 43.3 | 39 (mean) | - | 50 mcg every 6 h up to 4 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Oral misoprostol | 120 | 28.1 (mean) | 36.0 | 38.3 (mean) | - | 50 mcg every 6 h up to 4 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| Chung, 2003 [21] | USA | Vaginal misoprostol | 49 | 26.3 ± 6.8 | 67.3 | 39.8 ± 2.3 | - | 25 mcg every 3 h up to 6 doses | [1] [2] [5] [8] [9] [12] [13] [14] |
| | | Foley catheter | 54 | 26.5 ± 6.0 | 61.1 | 40.0 ± 2.1 | 30 mL | - | [1] [2] [5] [8] [9] [12] [13] [14] |
| Author, year          | Country | Groups          | Numbers | Age (years) | Nulliparity (%) | Gestational age (weeks) | Balloon volume (mL) | Misoprostol dose                      | Outcomes |
|-----------------------|---------|-----------------|---------|-------------|-----------------|-------------------------|---------------------|---------------------------------------|----------|
| Nopdonrattakoon, 2003 | Thailand | Oral misoprostol | 53      | 24.9 ± 5.5 | NR              | 39.0 ± 1.0             | -                   | 50 mcg every 4 h up to 6 doses        | ①②③④⑤⑥⑦⑧ |
|                       |         | Vaginal misoprostol | 53      | 25.3 ± 5.5 | NR              | 39.1 ± 1.1             | -                   | 50 mcg every 4 h up to 6 doses        |          |
| Ramsey, 2003          | USA     | Dinoprostone    | 38      | 26.7 ± 3.6 | NR              | 39.3 ± 1.3             | -                   | -                                     | ⑧          |
|                       |         | Vaginal misoprostol | 38      | 27.9 ± 4.6 | NR              | 39.3 ± 1.6             | -                   | -                                     | ⑥          |
| Shetty, 2003          | UK      | Oral misoprostol | 51      | 28.6 ± 6.2 | 56.9             | 40.7 ± 1.3             | -                   | 100 mcg every 4 h up to 5 doses       | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Vaginal misoprostol | 50      | 28.0 ± 5.5 | 56.0             | 40.9 ± 1.1             | -                   | 25 mcg every 4 h up to 5 doses        | ⑧          |
| Paungmora, 2004       | Thailand | Oral misoprostol | 75      | 29.1 ± 4.9 | 78.7             | 41.0 ± 1.3             | -                   | 100 mcg every 6 h up to 8 doses       | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Vaginal misoprostol | 76      | 28.2 ± 4.7 | 73.7             | 40.5 ± 1.0             | -                   | 50 mcg every 6 h up to 8 doses        | ①②③④⑤⑥⑦⑧⑬ |
| Rozenberg, 2004       | France  | Vaginal misoprostol | 70      | 29.0 ± 5.2 | 62.9             | 41.3 ± 1.6             | -                   | 50 mcg every 6 h up to 1 dose in the first day and 50 mcg every 4 h up to 3 doses in the second day | ①②③④⑤⑥⑦⑧⑬ |
| Adeniji, 2005         | Nigeria | Dinoprostone    | 70      | 29.0 ± 3.7 | 67.1             | 41.4 ± 2.1             | -                   | 50 mcg every 6 h up to 4 doses        | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Vaginal misoprostol | 50      | 30.2 ± 3.5 | 52.0             | 39.9 ± 1.7             | -                   | 50 mcg every 6 h up to 4 doses        | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Foley catheter  | 46      | 30.5 ± 3.8 | 43.5             | 40.2 ± 1.3             | 30 mL               | -                                     | ①②③④⑤⑥⑦⑧⑬ |
| Afolabi, 2005         | Nigeria | Vaginal misoprostol | 29      | NR          | 44.8             | NR                    | -                   | 100 mcg once                          | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Foley catheter  | 28      | NR          | 46.2             | NR                   | 30 mL               | -                                     | ①②③④⑤⑥⑦⑧⑬ |
| Gelsen, 2005          | Turkey  | Vaginal misoprostol | 100     | 25.9 ± 5.9 | 46.0             | 41.0 (mean)           | -                   | 50 mcg every 6 h up to 4 doses        | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Foley catheter  | 100     | 24.4 ± 4.1 | 47.0             | 41.0 (mean)           | 50 mL               | -                                     | ①②③④⑤⑥⑦⑧⑬ |
| Owolabi, 2005         | Nigeria | Vaginal misoprostol | 60      | 29.6 ± 0.8 | 19.0             | 40.7 ± 0.2             | -                   | 50 mcg every 6 h up to 2 doses        | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Foley catheter  | 60      | 31.1 ± 0.8 | 22.8             | 40.3 ± 0.3             | 30 mL               | -                                     | ①②③④⑤⑥⑦⑧⑬ |
| Ayaz, 2009            | Saudi Arabia | Oral misoprostol | 44      | 34.3 (mean) | NR                | NR                   | -                   | 50 mcg every 4 h up to 4 doses        | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Vaginal misoprostol | 44      | 35.9 (mean) | NR                | NR                   | -                   | 50 mcg every 4 h up to 4 doses        | ①②③④⑤⑥⑦⑧⑬ |
| Ozkan, 2009           | Turkey  | Vaginal misoprostol | 56      | NR          | 51.8             | > 37                  | -                   | 50 mcg every 4 h up to 5 doses        | ①②③④⑤⑥⑦⑧⑬ |
|                       |         | Dinoprostone    | 56      | NR          | 57.1             | > 37                  | -                   | -                                     | ①②③④⑤⑥⑦⑧⑬ |
| Author, year | Country | Groups | Numbers | Age (years) | Nulliparity (%) | Gestational age (weeks) | Balloon volume (mL) | Miso prostol dose | Outcomes |
|-------------|---------|--------|---------|-------------|-----------------|------------------------|---------------------|------------------|----------|
| Pennell, 2009 [33] | Australia | Double-balloon catheter | 107 | 27.0 ± 6.0 | 100.0 | 40.0 ± 1.5 | 80 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪ |
| | | Foley catheter | 110 | 26.0 ± 7.0 | 100.0 | 40.0 ± 1.5 | 30 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪ |
| Cromi, 2011 [34] | Italy | Foley catheter | 265 | 32.1 ± 4.7 | 69.1 | 39.8 ± 1.9 | 50 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Dinoprostone | 132 | 31.0 ± 4.9 | 67.4 | 39.8 ± 2.0 | - | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Roudsari, 2011 [35] | Iran | Vaginal misoprostol | 49 | 24.3 ± 4.0 | NR | 39.8 ± 1.4 | - | 25 mcg every 4 h up to 6 doses | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Foley catheter | 59 | 24.2 ± 5.0 | NR | 40.0 ± 0.9 | 50 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Salim, 2011 [36] | Israel | Foley catheter | 145 | 28.8 ± 6.1 | 53.1 | 39.2 ± 1.4 | 60 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Double-balloon catheter | 148 | 29.2 ± 5.5 | 52.7 | 39.0 ± 1.6 | 80 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Roudsari, 2011 [35] | Iran | Vaginal misoprostol | 49 | 24.3 ± 4.0 | NR | 39.8 ± 1.4 | - | 25 mcg every 4 h up to 6 doses | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Foley catheter | 59 | 24.2 ± 5.0 | NR | 40.0 ± 0.9 | 50 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Jozwiak, 2013 [39] | Netherlands | Foley catheter | 107 | 30.5 ± 4.0 | 72.0 | 39.1 ± 1.9 | 30 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Dinoprostone | 119 | 31.7 ± 5.2 | 70.0 | 39.8 ± 2.1 | - | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Ugwu, 2013 [40] | Nigeria | Foley catheter | 45 | 28.9 ± 4.3 | 44.0 | 40.7 ± 1.5 | 30 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Vaginal misoprostol | 45 | 28.7 ± 4.9 | 42.0 | 40.2 ± 1.7 | - | 25 mcg every 4 h up to 6 doses | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Edwards, 2014 [41] | USA | Foley catheter | 185 | 28.0 ± 6.4 | 57.3 | 39.1 ± 1.4 | 30 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Dinoprostone | 191 | 26.9 ± 5.9 | 66.5 | 39.2 ± 1.5 | - | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Jozwiak, 2014 [42] | Netherlands | Foley catheter | 56 | 31.0 ± 5.0 | 66.1 | 39.1 ± 2.2 | 30 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Vaginal misoprostol | 64 | 32.3 ± 5.2 | 64.1 | 39.8 ± 2.1 | - | 25 mcg every 4 h up to 3 doses | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Suffecool, 2014 [43] | USA | Dinoprostone | 31 | 28.0 ± 7.1 | 100 | 40.2 ± 1.5 | - | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Double-balloon catheter | 31 | 27.5 ± 6.4 | 100 | 40.9 ± 1.1 | 80 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Wang, 2014 [44] | China | Double-balloon catheter | 67 | 27.9 ± 3.9 | 100 | 39.3 ± 2.1 | 80 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Dinoprostone | 59 | 27.8 ± 3.4 | 100 | 39.0 ± 1.3 | - | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Chavakula, 2015 [45] | India | Vaginal misoprostol | 46 | 25.1 ± 4.7 | 69.6 | 37.8 ± 1.2 | - | 25 mcg every 6 h up to 6 doses | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| | | Foley catheter | 54 | 24.3 ± 3.9 | 63.0 | 37.7 ± 1.1 | 30 mL | - | ①②③④⑤⑥⑦⑧⑨⑩⑪⑬ |
| Author, year   | Country   | Groups                                                                 | Numbers | Age (years) | Nulliparity (%) | Gestational age (weeks) | Balloon volume (mL) | Misoprostol dose | Outcomes                                                                 |
|---------------|-----------|------------------------------------------------------------------------|---------|-------------|-----------------|------------------------|---------------------|-----------------|--------------------------------------------------------------------------|
| Du, 2015 [46] | China     | Double-balloon catheter                                                | 76      | 28.5 ± 4.6  | 89.5            | 40.5 ± 0.9             | 80 mL + 80 mL       | -               |                                                                          |
| Ezechukwu, 2015 [47] | Nigeria | Dinoprostone                                                          | 79      | 27.3 ± 3.3  | 91.1            | 40.6 ± 0.8             | -                    | 50 mcg every 6 h up to 4 doses |                                                                          |
|                |           | Oral misoprostol                                                      | 70      | 27.2 ± 4.5  | 62.9            | 40.6 ± 1.5             | -                    | 50 mcg every 6 h up to 4 doses |                                                                          |
|                |           | Vaginal misoprostol                                                   | 70      | 28.2 ± 3.7  | 60.0            | 40.7 ± 1.6             | -                    | 50 mcg every 6 h up to 4 doses |                                                                          |
| Kehl, 2015 [1] | Germany   | Double-balloon catheter with oral misoprostol                         | 162     | 30.0 ± 6.0  | 53.7            | 40.4 ± 1.1             | 80 mL + 80 mL       | 50 mcg orally every 4 h up to 3 doses in the first 24 h then 100 mcg orally every 4 h up to 3 doses in the next 24 h and then 100 mcg vaginally every 4 h up to 3 doses |                                                                          |
|                |           | Oral misoprostol                                                      | 151     | 30.0 ± 6.5  | 60.9            | 40.3 ± 1.1             | -                    | 50 mcg orally every 4 h up to 3 doses in the first 24 h then 100 mcg orally every 4 h up to 3 doses in the next 24 h and then 100 mcg vaginally every 4 h up to 3 doses |                                                                          |
| Noor, 2015 [48] | India    | Vaginal misoprostol                                                   | 60      | 25.1 ± 2.8  | 41.7            | 39.1 ± 1.4             | -                    | 25 mcg every 4 h up to 6 doses |                                                                          |
| Shechter-Maor, 2015 [49] | Israel | Dinoprostone                                                          | 44      | 25.6 ± 4.1  | 31.8            | 39.4 ± 1.2             | 50 mL                | -               |                                                                          |
|                |           | Oral misoprostol                                                      | 26      | 28.5 ± 5.3  | 50.0            | 40.0 ± 1.0             | -                    | 100 mcg orally every 4 h up to 3 doses in the first 24 h then 100 mcg orally every 4 h up to 3 doses in the next 24 h and then 100 mcg vaginally every 4 h up to 3 doses |                                                                          |
|                |           | Oral misoprostol                                                      | 26      | 28.5 ± 5.0  | 50.0            | 40.0 ± 1.3             | NR                   | 100 mcg orally every 4 h up to 3 doses in the first 24 h then 100 mcg orally every 4 h up to 3 doses in the next 24 h and then 100 mcg vaginally every 4 h up to 3 doses |                                                                          |
| Hoppe, 2016 [50] | USA      | Foley catheter                                                       | 48      | 29.9 ± 6.0  | 52.1            | 38.9 ± 2.0             | 30 mL                | -               |                                                                          |
|                |           | Oral misoprostol                                                      | 50      | 30.7 ± 5.2  | 50.0            | 38.9 ± 2.1             | 80 mL + 80 mL       | -               |                                                                          |
| Sayed Ahmed, 2016 [51] | Egypt   | Foley catheter                                                       | 39      | 25.5 ± 5.1  | 100             | 40.4 ± 2.4             | 50 mL                | -               |                                                                          |
|                |           | Oral misoprostol                                                      | 39      | 25.7 ± 4.8  | 100             | 40.6 ± 2.4             | 80 mL + 80 mL       | -               |                                                                          |
| ten Eikelder, 2016 [52] | Netherlands | Foley catheter                                                      | 924     | 31.7 ± 5.2  | 66.0            | 39.5 ± 2.1             | -                    | 50 mcg every 4 h up to 3 doses per day up to 4 days |                                                                          |
|                |           | Foley catheter                                                       | 921     | 31.4 ± 5.9  | 64.7            | 39.6 ± 2.1             | 30 mL                | -               |                                                                          |
| Author, year | Country     | Groups               | Numbers | Age (years) | Nulliparity (%) | Gestational age (weeks) | Balloon volume (mL) | Misoprostol dose                  | Outcomes |
|-------------|-------------|----------------------|---------|-------------|-----------------|------------------------|---------------------|-----------------------------------|----------|
| Yenuberi, 2016 [53] | India       | Vaginal misoprostol  | 380     | 25.0 ± 4.2  | 69.2            | 39.9 ± 1.0            | -                   | 25 mcg every 4 h up to 3 doses     | (①)(②)(③)(⑤)(⑥)(⑧)(⑨)(⑪)(⑬) |
|             |             | Oral misoprostol    | 383     | 25.5 ± 3.8  | 71.0            | 39.7 ± 1.1            | -                   | 50 mcg for the first dose and then 100mcg every 4 h up to 3 doses totally | (①)(②)(③)(⑤)(⑥)(⑧)(⑨)(⑪)(⑬) |
| Somirathne, 2017 [54] | Sri Lanka   | Foley catheter      | 89      | 28.8 ± 4.9  | 49.4            | > 40.9                | 60 mL               | -                                 | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
|             |             | Oral misoprostol    | 91      | 28.6 ± 5.5  | 50.5            | > 40.9                | -                   | 50 mcg every 4 h up to 3 doses     | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
| Leigh, 2018 [55] | India and UK | Foley catheter      | 300     | 24.0 ± 3.5  | 82.3            | 38.2 ± 2.2            | 30 mL               | -                                 | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
|             |             | Oral misoprostol    | 302     | 23.7 ± 3.1  | 78.1            | 38.1 ± 2.1            | -                   | 25 mcg every 2 h up to 12 doses    | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
| Abdī, 2021 [56] | Iran        | Vaginal misoprostol | 60      | 27.4 ± 5.4  | 100             | 42.4 ± 2.1            | -                   | 25 mcg once                        | (①)(②)(③) |
|             |             | Foley catheter      | 60      | 29.5 ± 6.2  | 100             | 42.8 ± 4.7            | 30 mL               | -                                 | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
| Digusto, 2021 [10] | France      | Double-balloon catheter | 607  | 31.1 ± 5.2  | 66.1            | 41.0 - 42.0           | 80 mL + 80 mL       | -                                 | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
|             |             | Dinoprostone        | 609     | 31.3 ± 5.1  | 65.8            | 41.0 - 42.0           | -                   | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |
| Slot, 2021 [57] | Israel      | Foley catheter      | 94      | 27.8 ± 5.1  | 53.2            | 39.8 ± 1.9            | 40 mL               | -                                 | (①)(②)(③)(⑤)(⑦)(⑧)(⑩)(⑬) |

mcg microgram, mL milliliter, PO Per orals, PV Per vagina
① cesarean delivery rate; ② time from intervention-to-birth; ③ achieving vaginal delivery within 24 h; ④ Bishop score increment; ⑤ uterine hyperstimulation with fetal heart rate changes; ⑥ oxytocin augmentation; ⑦ instrumental delivery; ⑧ meconium-stained amniotic fluid; ⑨ Chorioamnionitis; ⑩ postpartum hemorrhage; ⑪ Apgar score < 7 in 5 min; ⑫ Apgar score < 7 in 1 min; ⑬ neonatal intensive care unit admission
Saudi Arabia, Sri Lanka, Thailand, and Turkey), Australia, Europe (France, Germany, Italy, the Netherlands, and the UK), and North America (the USA and Canada). Six types of intervention were assessed, including oral misoprostol, vaginal misoprostol, dinoprostone, Foley catheter, double-balloon catheter, and double-balloon catheter with oral misoprostol. All of the studies were two-arm with 11,482 pregnant women. The balloon volume, misoprostol dose, and outcomes of each study are shown in Table 1. The evaluation of bias risk for all RCTs is presented in Supplemental Figure S1 and S2.

**Primary outcomes**
The cesarean delivery rate in patients who underwent cervical ripening with a double-balloon catheter and oral misoprostol, oral misoprostol, and vaginal misoprostol were significantly lower than a Foley catheter (OR = 0.48, 95% CI: 0.23–0.96; OR = 0.74, 95% CI: 0.58–0.93; and OR = 0.79, 95% CI: 0.64–0.97, respectively; all \( P < 0.05 \); Fig. 2, Supplemental Table S3). The time from intervention-to-birth of vaginal misoprostol was significantly shorter than the other five interventions (Fig. 2, Supplemental Table S4).

**Secondary outcomes**
All of the head-to-head comparisons are shown in Supplemental Table S5–S16. Compared to a Foley catheter, vaginal misoprostol resulted in a higher improvement in the Bishop score (MD = 2.80, 95% CI: 0.55–5.08) and lower rate of oxytocin augmentation (OR = 0.14, 95% CI: 0.094–0.21), but a higher risk of uterine hyperstimulation with fetal heart rate changes (OR = 7.72, 95% CI: 2.44–41.59).

Compared to a Foley catheter, oral misoprostol had a lower rate of oxytocin augmentation (OR = 0.29, 95% CI: 0.18–0.46), but a higher risk of uterine hyperstimulation with fetal heart rate changes (OR = 4.30, 95% CI: 1.08–29.56) and a higher rate of meconium-stained amniotic fluid (OR = 1.73, 95% CI: 1.09–3.32).

Compared to a Foley catheter, a double-balloon catheter with or without oral misoprostol had similar outcomes, including uterine hyperstimulation with fetal heart rate changes (OR = 4.75, 95% CI: 0.26–294.50).

No difference in achieving vaginal delivery within 24 h, instrumental delivery, chorioamnionitis, postpartum hemorrhage, neonatal intensive care unit admission, and arterial pH among these interventions were revealed (Supplemental Tables S5, S9, S11, S12, S15, and S16).

**Network geometry, inconsistency, certainty of evidence, and publication bias**
Network geometry is shown in Supplemental Figure S3. The evaluation of inconsistencies for all outcomes are presented in Supplemental Figures S4-S16. We noted a significance level (\( P > 0.05 \)) for most cases, which indicated that inconsistency was not sufficient to influence the conclusion of this NMA. According to the SUCRA value, ranking of all interventions was done (Fig. 3). Finally, we used the GRADE system to evaluate the certainty of evidence (Table 2). No significant asymmetry was demonstrated in the funnel plot of major primary and secondary outcomes (Supplemental Figures S17 and S18). The results of Begg’s and Egger’s tests are shown in Supplemental Table S17.

**Discussion**
This NMA provides evidence for the relative efficacy and safety of double-balloon catheters for cervical ripening. A large amount of evidence was pooled to allow us to indirectly compare the clinical efficacy and safety profile of a double-balloon catheter with a Foley catheter, misoprostol (oral/vaginal), and a controlled-release dinoprostone insert for cervical ripening and labor induction in women with unfavorable cervixes during the third trimester of pregnancy. These five methods are commonly used for cervical ripening. Our analysis demonstrated that the double-balloon catheter was not superior to other methods with respect to the cesarean section rate, time from intervention-to-birth, and maternal and neonatal adverse events. The combined use of a double-balloon catheter and oral misoprostol significantly reduced the cesarean section rate compared to a Foley catheter without an increased risk of uterine hyperstimulation with fetal heart rate changes, as occurred with oral or vaginal misoprostol alone.

To ripen the cervix, a number of methods are used; however, there is little consensus regarding which method is best [58]. It has been suggested that catheter Balloons were equally effective in cervical ripening as pharmacological methods, with no significant differences in mode of delivery or perinatal outcome [59]. The double-balloon catheter was specifically developed for inducing labor. The mechanism of action by which the double-balloon catheter ripens the cervix is achieved by pressure applied to the external and internal os. The vaginal balloon is used to hold the balloon in the extra-amniotic space during cervix softening and distensibility. As the ripening process continues, the device can spontaneously expel itself early [8].

Previous systematic reviews on the safety and effectiveness of double-balloon catheters have been published; however, these reviews have been limited to pairwise meta-analyses [60–63]. In contrast, NMAs provide an important method of including a large amount of direct and indirect evidence from comparisons of many different interventions. In this NMA, we did not demonstrate...
Fig. 2 Forest plots of network meta-analysis of all trials for primary and secondary outcomes.
an advantage to the double-balloon to other single method in various primary and secondary outcomes of labor induction. When combined with oral misoprostol, the double-balloon catheter was shown to reduce the cesarean delivery rate compared with a Foley catheter. Vaginal misoprostol alone improved the outcomes of labor induction, including the cesarean section rate, time from intervention-to-birth, Bishop score increment, and oxytocin augmentation. Even though vaginal misoprostol alone appeared to be the most effective method in cervical ripening, use of vaginal misoprostol was associated with the highest incidence of uterine hyperstimulation with fetal heart rate changes. Oral misoprostol was shown to have similar efficiency and safety to vaginal misoprostol in our analysis. The resulting uterine hyperstimulation with misoprostol use is consistent with previous studies [52, 64, 65]. Interestingly, uterine hyperstimulation with fetal heart rate changes did not occur with a double-balloon catheter combined with oral misoprostol. This finding may be due to the additional cervical dilation effect of the double-balloon catheter. This effect could reduce the misoprostol dose and the risk of uterine hyperstimulation [66].

Unlike previous studies [60, 63], we did not find any difference in Bishop score improvement between double-balloon and Foley catheters. Chorioamnionitis is a major concern when double-balloon catheters are used. According to our analysis, there were no significant difference in chorioamnionitis between a double-balloon catheter and any other method. Although there was a higher proportion of 5-min Apgar scores < 7 with double-balloon catheter and oral misoprostol use, there were only a few cases and there were no differences in umbilical artery pH, thus this finding was not clinically relevant. Therefore, this NMA indicated that the combination of a double-balloon catheter with oral misoprostol may be a preferable choice in view of the reduction in the cesarean section rate and lack of significant adverse outcomes.

Our analysis evaluated the safety and efficacy of double-balloon catheters. The combined effect of a double-balloon catheter with other cervical ripening methods was also included in our study. However, we did not identify any randomized controlled trial to assess the combined effect of controlled-release dinoprostone and a double-balloon catheter, although this combination may improve the induction outcome much like the combined effect with misoprostol. The high cost of controlled-release dinoprostone and a double-balloon catheter should be the reason. We did not perform an NMA to compare the combined effect of a Foley catheter with other cervical...
| Outcome                                      | Study number | Participants number | Effect estimates (95% CI)                                      | Conclusion                                                                 | GRADE Quality score |
|----------------------------------------------|--------------|---------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------|---------------------|
| Cesarean delivery rate                       | 47           | 11,215              | Double-balloon catheter with oral misoprostol vs. Foley catheter: OR = 0.48, 95% CI: 0.23–0.96; Oral misoprostol vs. Foley catheter: OR = 0.74, 95% CI: 0.58–0.93; Vaginal misoprostol vs. Foley catheter: OR = 0.79, 95% CI: 0.64–0.97 | Double-balloon catheter with oral misoprostol, oral misoprostol, and vaginal misoprostol superior to Foley catheter | Moderatea            |
| Time from intervention-to-birth (min)        | 31           | 7956                | Vaginal misoprostol vs. double-balloon catheter with oral misoprostol: MD = -800.17, 95% CI: -1597.71–-3.01; Vaginal misoprostol vs. double-balloon catheter: MD = 320.31, 95% CI: -568.84–-74.77; Vaginal misoprostol vs. oral misoprostol: MD = -204.68, 95% CI: -414.34–-41.6; Vaginal misoprostol vs. Foley catheter: MD = -243.93, 95% CI: -407.61–-85.42; Vaginal misoprostol vs. dinoprostone: MD = -259.09, 95% CI: -450.10–-74.08 | Vaginal misoprostol superior to double-balloon catheter with oral misoprostol, double-balloon catheter, Foley catheter, and dinoprostone | Moderate3            |
| Achieving vaginal delivery within 24 h       | 22           | 5154                | More details in Supplemental Table S5                           | No difference among these interventions                                   | Lowab               |
| Bishop score increment                       | 8            | 1533                | Vaginal misoprostol vs. Foley catheter: MD = 2.80, 95% CI: 1.35–5.08 | Vaginal misoprostol, oral misoprostol, and dinoprostone inferior to Foley catheter | Moderate3            |
| Uterine hyperstimulation with fetal heart rate changes | 27           | 7673                | Vaginal misoprostol vs. Foley catheter: OR = 7.72, 95% CI: 2.44–41.59; Oral misoprostol vs. Foley catheter: OR = 4.30, 95% CI: 1.08–29.56; Dinoprostone vs. Foley catheter: OR = 5.74, 95% CI: 1.06–50.85 | Vaginal misoprostol, oral misoprostol, and dinoprostone inferior to Foley catheter | Moderate3            |
| Oxytocin augmentation                        | 36           | 9536                | Vaginal misoprostol vs. Foley catheter: OR = 0.14, 95% CI: 0.09–0.21; Oral misoprostol vs. Foley catheter: OR = 0.29, 95% CI: 0.18–0.46; Dinoprostone vs. Foley catheter: OR = 0.33, 95% CI: 0.20–0.54; Vaginal misoprostol vs. double-balloon catheter: OR = 0.09, 95% CI: 0.04–0.18; Oral misoprostol vs. double-balloon catheter: OR = 0.18, 95% CI: 0.08–0.39; Double-balloon catheter with oral misoprostol vs. double-balloon catheter: OR = 0.18, 95% CI: 0.04–0.74; Dinoprostone vs. double-balloon catheter: OR = 0.21, 95% CI: 0.12–0.36; Vaginal misoprostol vs. oral misoprostol: OR = 0.49, 95% CI: 0.34–0.69; Vaginal misoprostol vs. dinoprostone: OR = 0.42, 95% CI: 0.26–0.67 | Vaginal misoprostol, oral misoprostol, and dinoprostone superior to Foley catheter; Vaginal misoprostol, oral misoprostol, double-balloon catheter with oral misoprostol, and dinoprostone superior to double-balloon catheter; Vaginal misoprostol superior to oral misoprostol and dinoprostone | Moderate3            |
| Instrumental delivery                        | 25           | 7140                | More details in Supplemental Table S9                           | No difference among these interventions                                   | Moderatea            |
| Meconium-stained amniotic fluid              | 28           | 6241                | Oral misoprostol vs. Foley catheter: OR = 1.73, 95% CI: 1.09–3.32 | Oral misoprostol inferior to Foley catheter                                | Moderate3            |
| Chorioamnionitis                             | 10           | 2410                | More details in Supplemental Table S11                          | No difference among these interventions                                   | Moderatea            |
Table 2 (continued)

| Outcome                                      | Study number | Participants number | Effect estimates (95% CI)                                                                 | Conclusion                                                                                                                           | GRADE Quality score |
|----------------------------------------------|--------------|---------------------|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Postpartum hemorrhage                        | 14           | 5421                | More details in Supplemental Table S12                                                    | No difference among these interventions                                                                                           | Moderate<sup>a</sup> |
| Apgar score < 7 in 5 min                     | 26           | 8149                | Vaginal misoprostol vs. double-balloon catheter with oral misoprostol: OR = 0.05, 95% CI: 0–0.93; Double-balloon catheter vs. double-balloon catheter with oral misoprostol: OR = 0.02, 95% CI: 0–0.42; Dinoprostone vs double-balloon catheter with oral misoprostol: OR = 0.04, 95% CI: 0–0.80; Foley catheter vs double-balloon catheter with oral misoprostol: OR = 0.04, 95% CI: 0–0.64 | Vaginal misoprostol, double-balloon catheter, dinoprostone, and Foley catheter superior to double-balloon catheter with oral misoprostol | Moderate<sup>b</sup> |
| Apgar score < 7 in 1 min                     | 16           | 4367                | Double-balloon catheter vs. dinoprostone: OR = 0.10, 95% CI: 0–0.85; Double-balloon catheter vs. vaginal misoprostol: OR = 0.08, 95% CI: 0–0.83; Double-balloon catheter vs. oral misoprostol: OR = 0.09, 95% CI: 0–0.92 | Double-balloon catheter superior to dinoprostone, vaginal misoprostol, and oral misoprostol                                                                                           | Moderate<sup>a</sup> |
| Neonatal intensive care unit admission       | 34           | 9351                | More details in Supplemental Table S15                                                    | No difference among these interventions                                                                                           | Moderate<sup>a</sup> |
| Arterial pH                                  | 9            | 1478                | More details in Supplemental Table S16                                                    | No difference among these interventions                                                                                           | Moderate<sup>a</sup> |

CI: Confidence interval, MD: Mean difference, OR: Odds ratio

<sup>a</sup> Rated down for serious imprecision;
<sup>b</sup> Rated down for serious inconsistency
ripening methods in the present study. Because safety and efficacy was similar between double-balloon and Foley catheters, whether a Foley catheter combined with misoprostol has the same effect needs to be confirmed. It should be noted that a Foley catheter is much less expensive than a double-balloon catheter. In fact, use of a Foley catheter is a classic mechanical method for cervical ripening and widely used in low-resource settings [55, 67]. Among developing countries where health-related costs are a major concern, a Foley catheter is recommended as a better option than other cervical ripening methods.

**Strengths**

One of the strengths of our review was the application of an NMA. Our NMA was strictly confined to randomized trials and provided comprehensive comparisons between a double-balloon catheter and five other cervical ripening techniques, which increased the interpretation of the existing evidence. We calculated the probabilities of ranking cervical ripening methods using Bayesian analysis. Furthermore, to minimize potential bias due to the variation in the characteristics of the included women, we applied several restrictions for inclusion in the review. Specifically, we excluded studies that included outpatients or pregnant women who were in the second trimester. Third, only few included trials were of low quality. Moreover, our protocol was registered with PROSPERO before data abstraction commenced.

**Future directions**

First, because a Foley catheter is much less expensive than a double-balloon catheter, trials aimed to compare the efficacy of “the combination of a Foley catheter with misoprostol” and “the combination of a double-balloon catheter with misoprostol” needs to be conducted. Second, compared with inpatient management, women may be able to find better psychological and social support at home. Therefore, the safety of outpatient cervical priming of a double-balloon catheter also needs to be confirmed. Third, only one trial compared a double-balloon catheter with oral misoprostol to oral misoprostol alone [11], thus additional evidence is needed.

**Limitation**

The current meta-analysis had some limitations. First, to decrease the heterogeneity, we only included trials with the dinoprostone formulation that was most often used in the trials compared with a double-balloon catheter. Second, the misoprostol dose and the volume of the double-balloon or Foley catheter were variable, which may affect the credibility of the conclusion. Third, the characteristics of the participants, such as maternal age, parity, gestational age, body mass index, baseline Bishop score, and labor induction, were diverse and underlying confounders. Fourth, some of the involved trials were not double-blinded due to the nature of the intervention.

**Conclusion**

The clinical outcomes were similar between a double-balloon catheter alone and other single methods. For pregnant women with intact membranes after 28 weeks gestation, vaginal misoprostol was shown to be the most effective methods for cervical ripening with respect to the cesarean delivery rate, time from intervention-to-birth, and oxytocin augmentation; however, vaginal misoprostol was associated with higher rates of uterine hyperstimulation with fetal heart rate changes. The combination of a double-balloon catheter with oral misoprostol was the best method to reduce the likelihood of delivery by cesarean section without uterine hyperstimulation with fetal heart rate changes.

**Abbreviations**

CI: Confidence interval; MD: Mean difference; NMA: Network meta-analysis; OR: Odds ratio; RCT: Randomized controlled trial; SUCRA: Surface under the cumulative ranking curve.

**Supplementary Information**

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The authors declare that they have no competing interests.

Not applicable.

Consent for publication

The study was approved by the Institutional Review Board (IRB) of the First Affiliated Hospital of China Medical University (No. 2022035 on February 25, 2022). The IRB waived the need for informed consent because this was a meta-analysis study based on published data.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board (IRB) of the First Affiliated Hospital of China Medical University (NO. 2022035 on February 25, 2022). The IRB waived the need for informed consent because this was a meta-analysis study based on published data.

Consent for publication

Not applicable.

Competing interests

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