

Effect of Early Amniotomy on Delivery Outcome with/without Cervical Ripening: A Systematic Review and Meta-Analysis

Abstract

Background: Although shorter labors are the benefits of Early Amniotomy (EA), it may lead to risks such as non-reassuring fetal testing and cesarean delivery. Also, the effect of cervical ripening to induce labor before amniotomy is unknown. This systematic review and meta-analysis evaluated the effect of EA on the delivery outcome with or without cervical ripening. **Materials and Methods:** Bibliographic search was conducted without time limit until June 2020. PubMed, Scopus SID Magiran, Cochrane Library Science website, and ISI databases were searched with English and Farsi keywords, including amniotomy, delivery, induced, and pregnancy outcome. **Results:** The meta-analysis on ten clinical trials showed that the incidence of cesarean section was lower (0.89% VS 0.94; relative risk, 0.85; 95% confidence interval, 0.55–1.30) compared to the group without cervical ripening, and the time to induce labor was approximately 55 minutes (mean difference, 0.91 hour; 95% confidence interval, -1.43 to -0.33). **Conclusions:** If EA is performed in women after cervical ripening, the incidence of cesarean section will not increase, and the duration of labor will be reduced. A shorter delivery time is associated with perinatal benefits and greater maternal satisfaction. Furthermore, EA with cervical ripening may reduce monitoring time in busy hospitals with limited medical staff.

Keywords: Amniotomy, induction, labor obstetric, pregnancy outcome

Introduction

Early Amniotomy (EA) refers to a selective rupture of embryonic membranes at cervical dilatation ≤ 4 cm.^[1] Amniotomy increases uterine contractions and thus shortens the duration of labor.^[2] Although the exact mechanism of amniotomy is unknown, it has been shown to increase the intensity and frequency of uterine contractions by producing and releasing prostaglandins and oxytocins.^[3,4]

Since childbirth requires several changes in the uterine and cervical functions, the cervix necessarily undergoes more changes before the onset of contractions. Cervical changes principally involve soft tissue changes, called cervical ripening, which is one of the key stages in the onset of labor.^[5] Before Induction of Labor (IOL), cervical ripening is necessary for the success of labor and is one of the widely used measures in the termination of pregnancy,^[6] which is one of the problems of midwifery in cases where the cervix is not suitable for IOL. Because it causes long labor,

increased cesarean section and discomfort of the fetus and increased complications after delivery.^[7] Although it has not been confirmed in previous reports,^[8] cervical ripening also contributes to the successful IOL. Mechanical (Foley catheter) and pharmaceutical methods (prostaglandins, misoprostol, mifepristone, and relaxin) are used for cervical ripening.^[4,9] However, shorter labors are the benefits of EA, and it may lead to risks such as non-reassuring fetal monitoring and cesarean delivery.^[10] Also, the effect of cervical ripening to induce labor before amniotomy is unknown.

A systematic review and meta-analysis evaluated the effectiveness of EA versus Late Amniotomy (LA) or spontaneous rupture of membranes after ripening the cervix. In this study, cesarean rates were similar in women randomized to EA compared to the control group. Also, women with EA had a shorter interval from induction to delivery of about 5 hours. It should be noted that the sample size in this

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study was very small. Only four trials with 1273 women who underwent cervical ripening were included in this study.^[9] Also, we compared delivery outcomes in early and LA without cervical ripening in primiparous women in our previous clinical trial study. The duration of labor was longer in the intervention group.^[11] Similarly, according to the findings of another study, amniotomy does not shorten spontaneous labor, nor does it affect the duration of labor and the rate of cesarean section.^[12] Therefore, according to the findings of these studies and whether EA with cervical ripening has a positive effect on the duration of labor and cesarean section rate compared to the unripened cervix, it was decided to compare delivery outcomes in EA with or without cervical ripening in this systematic review and meta-analysis.

Materials and Methods

The bibliographic search was conducted without a time limit until June 2020. In this systematic review, the databases of Magiran, SID, PubMed, Scopus, Web of Science, ISI, and the Cochrane Library were searched for related articles using the keywords amniotomy; labor, induced; and pregnancy outcome by the AND and OR operators. After a preliminary search with the mentioned keywords to investigate the effect of EA on the labor outcomes, all subsequent steps were followed based on the PRISMA systematic reporting system (the flowchart in Figure 1). Inclusion criteria were all objective-related studies, clinical trial studies, and all Persian and English articles without time limits until June 2020. Exclusion criteria for articles were lack of access to full texts of the articles, irrelevance, and repetition. In the preliminary search, 50 articles were

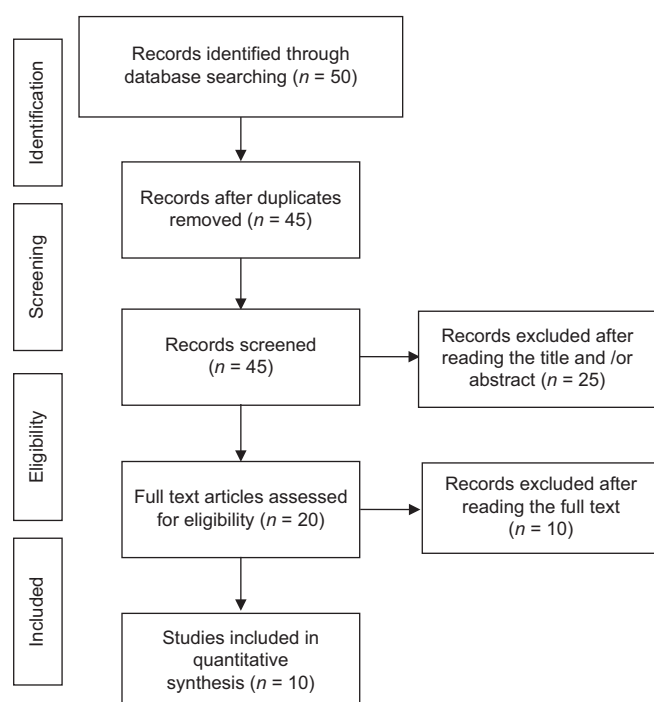


Figure 1: Search plot diagram

collected by the searching method. After systematic review and final evaluation, ten articles were included in the meta-analysis stage. To prevent bias, two project co-authors searched and qualified the articles. A third party's opinion was considered in cases of disagreements. Two co-authors independently extracted data from the full texts of all final papers included in the review process by a pre-prepared checklist consisting of the name of the first author, year of publication, study site, study design, and sample size, as well as information on average labor times and cesarean section incidence. The extracted data were reviewed after data collection.

Each study assessed bias using Cochran's criteria for systematic reviews of interventional studies. Each trial assessed seven domains of bias: random sequence, allocation concealment, blinding participants and medical staff, results of incomplete data, reports of selective outcomes, and other biases. Research bias was classified as low risk, high risk, and unclear risk [Figures 2 and 3]. The results of the homogeneity of studies are presented in Figures 4 and 5.

In this study, the effect of EA on cesarean section rate and duration of labor was compared in two groups of clinical trial studies with or without cervical ripening, and the results were interpreted and analyzed using the effect size. The Cochran test and the I² index evaluated the homogeneity of the studies. The random-effect model was used for heterogeneous studies ($p < 0.05$ and $I^2 > 50\%$). A combination of mean differences, sample size, and significance levels examined the effect of EA on delivery outcomes. Data were analyzed using statistics and data STATA software (version 11). The significance of mean differences was assessed using the Z-value and p value of <0.05 .

Ethical considerations

This manuscript has no plagiarism. The results of the analysis were completely honest. Any data fabrication has been avoided. This article does not contain any studies with human participants performed by any authors. This study was approved by the Ethics Committee of Azad University of Babol with ethics code IR.IAV.BABOL.REC.1397.002.

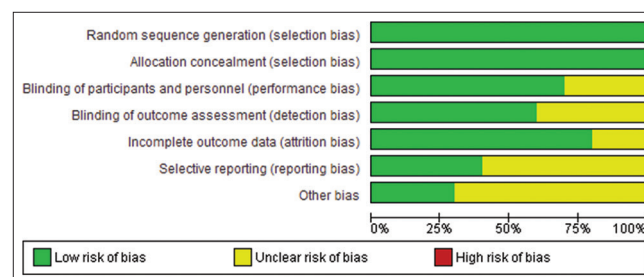


Figure 2: Bias risk; the risk of each bias is shown as a percentage in all studies

Results

In this study, a total of ten studies were reviewed with a sample size of 2,549 individuals. General characteristics and data on the effect of EA on cesarean section incidence and labor duration were investigated for each study [Table 1].

All studies included singleton pregnancies with cephalic presentation and term. Table 2 lists some of the

demographic and fertility characteristics of women. In a group of six studies in which induction was needed in participants for various reasons (e.g., post-term pregnancy, gestational diabetes, preeclampsia, and intrauterine growth restriction), various substances, such as dinoprostone, misoprostol, and Foley catheter, were used before EA to prepare the cervix. In another group of four studies, cervical ripening was not performed for participants with spontaneous labor or required induction.

In the present study, the cesarean section incidence was extracted in the two studies included in the meta-analysis. Then, the cesarean section incidence was compared between the two groups using the odds ratio index, and the results are shown in Figure 4. Accordingly, the odds ratio is 0.85 with a confidence interval of 0.55–1.3, meaning the chance of cesarean section incidence in the cervical ripening group is 0.85 times higher than in the group without cervical ripening. In other words, the chance of cesarean section incidence in the cervical ripening group is 15% lower than in the group without cervical ripening. The heterogeneity index (80.72%) is also statistically significant. No publication bias was observed in these results.

In the two groups, the average duration of labor decreased by 0.91 h using the applied intervention, which was statistically significant. No publication bias was observed in these results [Figure 5].

Discussion

The present systematic review and meta-analysis aimed to investigate the effect of EA on delivery outcomes in the IOLs with/without cervical ripening. The present research results indicated that the cesarean section incidence did not increase in the group with cervical ripening compared to

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bostanci, Evrim	+	+	+	+	+	+	+
Ee, P	+	+	+	?	?	?	?
Gagnon-Gervais, Karine	+	+	?	?	+	?	?
Ghafarzadeh, Masoomeh	+	+	?	?	+	?	?
Macones, George A	+	+	+	+	+	?	?
Makarem, Mohamed H	+	+	+	+	+	?	?
Onah, Livinus N	+	+	+	+	+	?	?
Rasheed, Faris Anwer	+	+	?	?	+	+	?
Vadivelu, Malarvizhi	+	+	+	+	+	+	+
Zare, Ommolbanin	+	+	+	+	?	+	+

Figure 3: Summary of bias risk for each study. The “+” and “?” signs indicate low and unclear bias risks

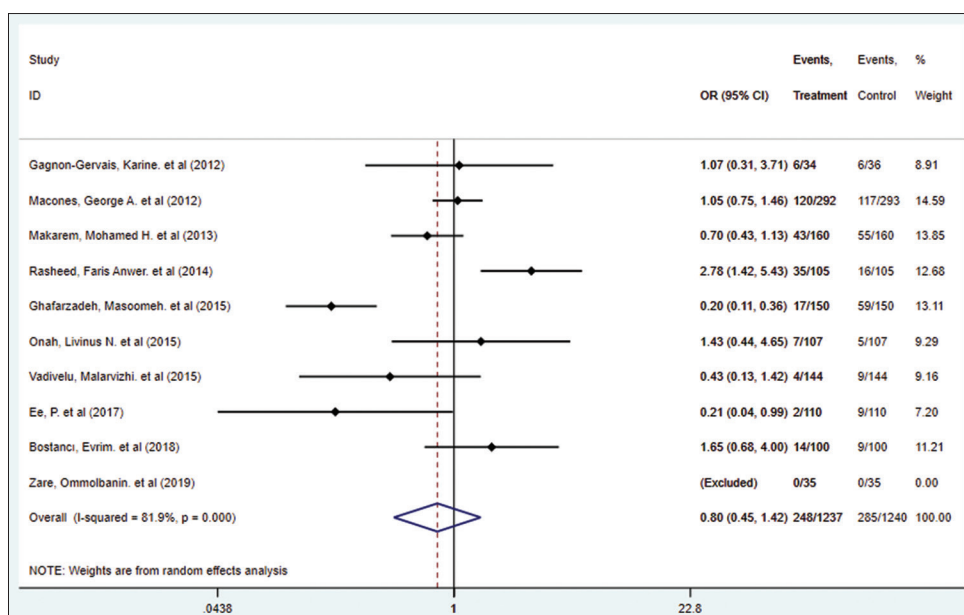


Figure 4: Cesarean section incidence between the two groups with/without cervical ripening

Table 1: The characteristics of studies (2012–2019) included in this systematic review

Authors/Year	Country	Study design	Sample size	Cervical ripening type before intervention	Intervention	Results
Macones <i>et al.</i> (2012) ^[17]	USA	Randomized Clinical Trial (RCT)	EA and standard care groups consisted of 292 and 293 women, respectively.	Misoprostol and Foley catheter	EA was performed at ≤ 4 cm and ≥ 4 cm in EA and standard care groups, respectively.	Average labor times in EA and standard care groups were 19 (9.10) h and 21.30 (10.10) h, respectively ($p=0.04$). Cesarean section rates were 41% and 40% in EA standard care groups, respectively ($p=0.75$).
Gagnon-Gervais <i>et al.</i> (2012) ^[2]	Canada	RCT	The intervention and control groups were 71 and 72 women, respectively.	Foley catheter	Amniotomy in EA and LA groups was performed in the first and the fourth hour of oxytocin administration, respectively.	Average labor times in EA and LA groups were 12.20 (6.70) h and 10.30 (5.50) h, respectively. Cesarean section rates (17% and 18%) were similar and non-significant in EA and control groups.
Bostancı <i>et al.</i> (2018) ^[18]	Turkey	RCT	EA and control groups, each with 100 women	Dinoprostone	In the intervention group, EA was done in 3 cm dilatation, but it was not performed in the control group.	Average labor times in EA and control groups were 13.72 (7.35) h and 22.73 (8.37) h, respectively ($p=0.05$). Cesarean section rates were 14% and 19% in EA and control groups, respectively ($p=0.341$).
Makarem <i>et al.</i> (2013) ^[4]	Egypt	RCT	Intervention group 160 and control group 160 women	Misoprostol	EA was done in the active phase in the intervention group, and the control group received routine care.	Average labor times in EA and control groups were 9.72 (4.61) h and 13.61 (5.61) h, respectively ($p=0.002$). Cesarean section rates were 26.88% and 34.37% in EA and control groups, with no significant differences.
Rasheed <i>et al.</i> (2014) ^[8]	Iraq	Single-blinded RCT	EA group 105 and LA group 105 women	-	Amniotomy was done in ≤ 3 cm and ≥ 4 dilatation in EA and LA groups, respectively.	Average labor times in EA and LA groups were 6.33 (1.65) h and 8.55 (1.30) h, respectively. Cesarean section rates were 33.33% and 15.24% in EA and LA groups ($p=0.002$).
Ghafari-zadeh <i>et al.</i> (2015) ^[19]	Iran	RCT	Intervention group 150 and control group 150 women	-	EA was done in ≥ 4 cm dilatation in the intervention group, and the control group received routine care.	Average labor times in intervention and control groups were 7.50 (0.70) h and 9.90 (1.00) h, respectively ($p=0.001$). Cesarean section rates were 11.30% and 39.30% in intervention and control groups, respectively ($p<0.001$).
Onah <i>et al.</i> (2015) ^[20]	Nigeria	RCT	Intervention group 107 and control group 107 women	-	In the intervention group, EA was done in ≥ 4 -5 cm dilatation, but it was not performed in the control group.	Average labor times in intervention and control groups were 287.10 (66.54) min and 358.60 (60.64) min, respectively ($p=0.001$). Emergency cesarean section rates were 6.50% and 4.70% in intervention and control groups, respectively ($p=0.77$).
Zare <i>et al.</i> (2019) ^[11]	Iran	RCT	EA and LA groups each consisted of 35 women	-	In EA and LA groups, amniotomy was done in ≤ 4 cm and >4 dilatation, respectively.	Average labor times in EA and LA groups were 10.479 (6.904) h and 6.692 (2.308) h, respectively. Cesarean section was not performed in both groups.
Vadivelu <i>et al.</i> (2017) ^[21]	India	RCT	EA and control groups each comprised 144 women	-	In the intervention group, EA was done in 4 cm dilatation, but it was not performed in the control group.	Average labor times in EA and control groups were 235 min and 364 min, respectively ($p<0.001$). Cesarean section rates were 2.80% and 6.20% in EA and control groups, respectively ($p=0.159$).

Contd...

Table 1: Contd...

Authors/Year	Country	Study design	Sample size	Cervical ripening type before intervention	Intervention	Results
Baylas Şahin and Yapar Eyi (2017) ^[3]	Turkey	RCT	EA and control groups, each with 110 women	-	In the intervention group, EA was done in 4 cm dilatation, but it was not performed in the control group.	Average labor times in EA and control groups were 220 (10-1785) min and 189 (10-1238) min, respectively ($p<0.134$). Cesarean section rates were 8.20% and 1.80% in EA and control groups, respectively ($p=0.03$).

those without cervical ripening. In a systematic study and meta-analysis conducted with four clinical trial studies, the EA group with cervical ripening was compared with the LA group, and the cesarean rate did not increase in the intervention group.^[9] In another review and meta-analysis that compared two groups of early and late or spontaneous amniotomy with cervical ripening, there was no difference in the cesarean rate.^[13] According to the findings of the studies mentioned above and the present study, it can be concluded that EA with or without cervical ripening does not increase the rate of cesarean section.

Based on the present study's results, the average labor duration in the amniotomy group with cervical preparation was reduced by 0.91 hours compared to the group without cervical ripening. In the systematic review and meta-analysis, the interval between induction and delivery in EA group was almost 5 hours shorter.^[9] In another review study and meta-analysis, the duration of labor was 3.62 hours shorter in the EA group. When the analysis was performed only on primiparous women, the duration of labor was 5 hours shorter in the EA group compared to the LA group.^[13] Also, another review study observed that with amniotomy, intravenous oxytocin, and vaginal misoprostol, there is the highest probability of vaginal delivery in 24 hours.^[14]

These studies are in line with our study, but there is a difference between the first two studies and our study in terms of the reduction in labor duration, but there is a difference between these two studies in terms of the amount of reduction. This difference may be because in the present study, a comparison was made between two groups of EA with or without cervical ripening. However, in both of the above meta-analyses, a comparison was made between the two groups of EA (intervention) and LA (control) with cervical ripening, so the difference in the duration of labor between the two groups is greater in these studies. In any case, based on the findings of those mentioned above and the present study, it can be concluded that EA with cervical ripening reduces the duration of labor.

In fact, EA has been suggested as a technique to reduce the duration of labor,^[15] but concerns have been raised about the increased risk of cesarean section incidence.^[16] According to our results, performing amniotomy in women with cervical ripening without increasing the incidence of cesarean section reduces the duration of labor.

A strength of our research is that it is the first study to compare the effect of EA on the labor outcome in IOLs with/without cervical ripening. Furthermore, low-risk biases were found in the clinical trial studies reviewed in this meta-analysis. This study's small number of studies with cervical ripening was a limitation. Since no optimal method, mechanical or medication is known for cervical ripening before IOL, further studies must compare

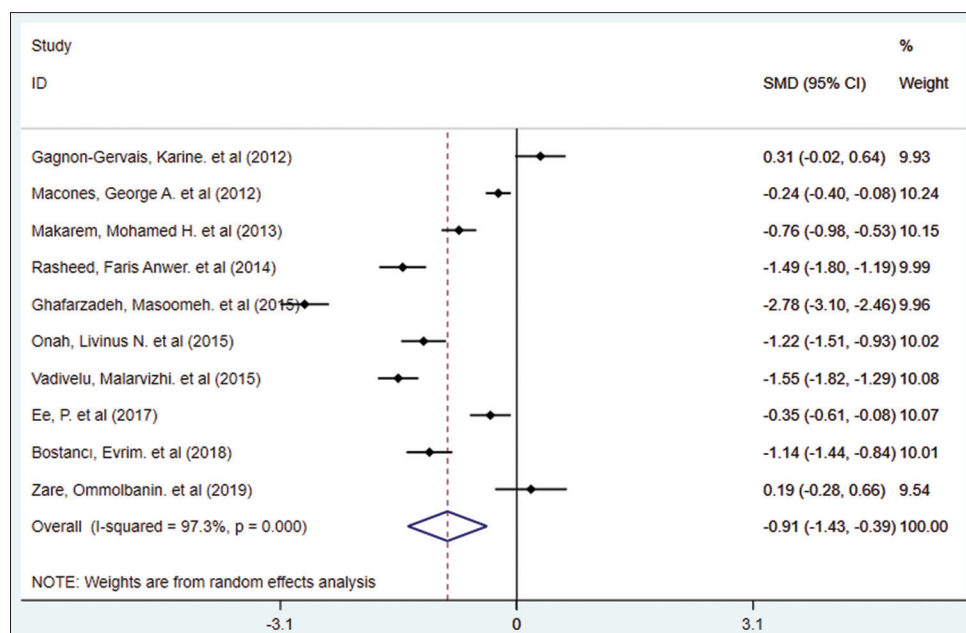


Figure 5: Average duration of labor between the two groups with/without cervical ripening

Table 2: Demographic and fertility characteristics of women in reviewed studies

Authors/Year	Women's age Mean (SD)	Nulliparous Frequency	Multiparous Frequency	Gestational age Mean (SD)
Macones <i>et al.</i> (2012) ^[17]	Intervention 22.7 (5.80) Control 23.3 (6.20)	Intervention 292 Control 293	Intervention 0 Control 0	Intervention 39.70 (1.40) Control 39.50 (1.40)
Gagnon-Gervais <i>et al.</i> (2012) ^[2]	Intervention 22.8 (5.20) Control 30 (5.70)	Intervention 34 Control 36	Intervention 37 Control 36	Intervention 40 (1.30) Control 40 (1.30)
Bostanci <i>et al.</i> (2018) ^[18]	Intervention 28.03 (5.90) Control 27.60 (6.40)	Intervention 57 Control 54	Intervention 43 Control 46	Intervention 39.90 (1.40) Control 39.80 (1.40)
Makarem <i>et al.</i> (2013) ^[4]	Intervention 23.90 (4.20) Control 24.30 (4.20)	Not reported	Not reported	Intervention 40 (4.10) Control 40.70 (4.90)
Rasheed <i>et al.</i> (2014) ^[8]	Intervention 21.01 (4.79) Control 21.89 (4.86)	Intervention 105 Control 105	Intervention 0 Control 0	Intervention 37.46 (2.48) Control 38.01 (2.88)
Ghafarzadeh <i>et al.</i> (2015) ^[19]	Intervention 25.6 (2.60) Control 25.70 (3.30)	Intervention 150 Control 150	Intervention 0 Control 0	Intervention 39.2 (0.70) Control 39.20 (0.70)
Onah <i>et al.</i> (2015) ^[20]	Not reported	Intervention 35 Control 38	Intervention 72 Control 69	Intervention 38.80 (1.26) Control 39.10 (1.38)
Zare <i>et al.</i> (2019) ^[11]	Intervention 24.30 (2.89) Control 23.63 (3.09)	Intervention 35 Control 35	Intervention 0 Control 0	Intervention 38.73 (4.90) Control 38.76 (4.49)
Vadivelu <i>et al.</i> (2017) ^[21]	Intervention 24.90 (3.90) Control 25.40 (4.10)	Intervention 86 Control 88	Intervention 50 Control 49	Intervention 38.70 (0.90) Control 38.80 (0.80)
Baylas Şahin and Yapar Eyi (2017) ^[3]	Intervention 26.44 (5.36) Control 26.84 (6.56)	Intervention 51 Control 35	Intervention 59 Control 75	Intervention 39.14 (1.30) Control 39.12 (1.47)

mechanical or medication methods for cervical ripening in nulliparous and multiparous women.

Conclusion

Performing EA in women after cervical ripening does not increase the incidence of cesarean section and reduces the duration of labor. A shorter delivery time is associated with greater perinatal benefits, increased

maternal satisfaction, and decreased hospital costs. Furthermore, in busy hospitals with limited medical staff, EA with cervical ripening may reduce overall monitoring time.

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Conflicts of interest

Nothing to declare.

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