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Effect of Bionic Airbag Midwifery on the Incidence of Cervical Lacerations in Primipara: A Meta-Analysis

Lifei Xu [1], Feng Luo [2, *], Huiting Zeng [1], Li Ouyang [1], Jingjing Nie [1], Ruohan Li [1], Jiayu Chang [1], Shuang Qiu [1]

[1] School of Nursing, Gannan Medical University, Ganzhou, Jiangxi, 341000, China
[2] Department of Obstetrics, The First Affiliated Hospital of Gannan Medical University, Ganzhou, Jiangxi, 341000, China
[*] **Corresponding author**: Feng Luo (Email: luofengme1980@163.com)

Abstract: OBJECTIVE: This study aimed to investigate bionic airbag midwifery's effect on cervical laceration incidence in primigravida. METHODS: The study searched relevant randomized controlled trials (RCTs) in CNKI, WANGFANG DATA, CQVIP, Sino Med, PubMed, Embase, Web of Science, and Cochrane Library up to February 2024. Four randomized controlled trials with a total of 1029 samples were included in this meta-analysis. RESULTS: Primiparous women who used bionic airbag midwifery did not show a significant difference in the incidence of cervical lacerations compared with controls who did not use bionic airbag midwifery. However, bionic airbag midwifery significantly reduced the duration of all stages of labor and decreased the cesarean section rate. CONCLUSION: Although bionic airbag midwifery did not considerably reduce the incidence of cervical lacerations, it showed potential advantages in shortening the duration of labor and reducing the cesarean section rate, suggesting that this technique can help facilitate the natural birth process.

Keywords: Bionic Airbag Midwifery; Cervical Laceration; Primipara; Vaginal Delivery; Meta-analysis.

1. Introduction

Bionic airbag midwifery is a non-invasive midwifery technique invented by Chinese obstetric researchers in the 1990s [1]. The technique utilizes a silicone inflatable airbag to simulate the fetal head, helping the mother to dilate the soft birth canal during the first stage of labor, accelerating the descent of the fetal head, and shortening the duration of labor. Numerous clinical studies have demonstrated its benefits in assisting vaginal delivery, and the technique is effective in reducing labor injuries, postpartum complications, etc. [2-4]. As a non-invasive assisted labor technique that speeds up the labor process, researchers usually use it in the upper and lower vaginal segments or at the cervix [5, 6], but there is some controversy as to whether it can damage the cervix [7, 8]. Cervical laceration is an important factor in postpartum hemorrhage and is critical to maternal prognosis, and the cervical tissues of primiparous women have not undergone dilatation in labor and lack elasticity, making them more susceptible to tearing during delivery. In addition, the labor process tends to be longer for primiparous women than for transient women, which raises the probability of cervical lacerations. To explore whether this technique may damage the cervix of primipara and increase the incidence of cervical lacerations, this study decided to do so utilizing meta-analysis.

2. Method

2.1. Literature Search Strategy

The literature search was conducted independently by two researchers. The two researchers searched the following databases: CNKI; Wanfang Data; CQVIP; SinoMed; PubMed; Web of Science; Google Scholar; and Cochrane Library. The literature search was conducted by using a combination of subject terms and free words, including specialized vocabulary related to bionic airbag midwifery. The specific search strategy is shown in the supplementary material.

2.2. Literature Inclusion and Exclusion

The language requirement for the literature included in this study was English and Chinese.

Literature inclusion criteria: (1) Study designs included randomized controlled trials (RCTs), crossover RCTs, cluster RCTs, and class experimental studies. (2) PICO characteristics of the study population: p: primigravida; I: birth assisted with bionic airbag midwifery; C: birth assisted without bionic airbag midwifery; O: primary outcome indicator: incidence of cervical laceration, secondary outcome indicators: duration of the first stage of labor, duration of the second stage of labor, duration of the total labor; and type of delivery. Included studies should report all primary outcomes and only one secondary outcome should be reported for inclusion. (3) Literature in English and Chinese.

Literature exclusion criteria:(1) Studies that used combined midwifery interventions (e.g. forceps, fetal suction, guided labor, etc.) other than bionic airbag midwifery. (2) Duplicate publications. (3) Studies in which the subjects had severe pregnancy complications or chronic diseases. (4) Literature rated as high risk after quality assessment by members of the research team. (5) Reviews, meta-analyses, and animal experiments.

Based on the inclusion and exclusion criteria, two researchers independently screened the literature, first selecting the title and abstract, and further reading the full text after excluding irrelevant literature to determine final inclusion. The risk of bias in the included studies was then assessed, and the quality of the included literature was independently assessed by two researchers, in case of disagreement after cross-comparison, the results would be finalized by a third person involved in the discussion. The risk of bias was assessed using Risk of Bias 2 (RoB2) recommended by the Cochrane Collaboration, and in case of

disagreement, a third party was involved in the discussion to resolve the issue.

2.3. Data Extraction

Data extraction included (1) basic information about the included studies, including the title of the study, first author, time of publication, and journal of publication, etc.; (2) key elements required for the risk of bias assessment; (3) basic characteristics of the included studies, including the sample size of the two groups, age, weeks of gestation, duration of labor (including the first stage of labor, the second stage of labor, and the total duration of labor), as well as the prevalence of cervical lacerations, and the mode of delivery, etc.; (4) the interventions specific details of the intervention.

When there is missing data, the researcher will contact the original author. All data collation results will be documented in Excel 2021.

2.4. Data Analysis

Statistical analysis was performed using RevMan 5.4 software. Mean difference (MD) for count data was used as the effect size, and odds ratio (OR) for measure data was used as the effect size. The results were also compared using the corresponding 95% confidence intervals (CI). Heterogeneity among the included results was analyzed using the χ^2 test, and the heterogeneity of the included studies was determined quantitatively with I^2 (I^2< 50% indicates low heterogeneity, using a fixed-effects model; I^2 >= 50% indicates high heterogeneity, using a random-effects model).

3. Results

3.1. Results of Included Literature

As shown in Figure 1, a total of 2,552 literatures were retrieved from eight databases. After the search by two researchers, four articles were finally included in this meta-analysis [9-12]. The remaining articles were excluded due to the following reasons: (1) Duplication of literature (n=1518); (2) Inconsistency with the study topic (n=142); (3) Nature of the literature did not meet the inclusion-exclusion criteria of this study (n=885); and (4) Evaluated as low-quality literature (n=3).

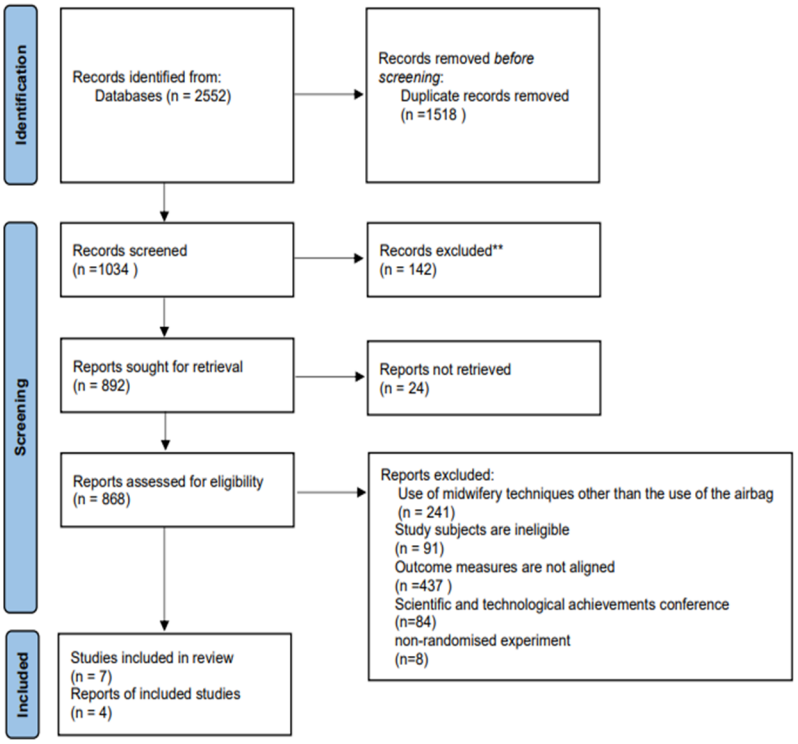

Figure 1. Flowchart of Literature Retrieval

3.2. Characteristics of the Included Literature

The four papers included in this study were randomized controlled trials [9-12], from which the researchers extracted the appropriate information and outcome metrics as originally planned. The specific characteristics of the included literature are shown in Table 1.

The publication dates of the included literature ranged from 2004 to 2019, and all of them were from China, with a total of 1,029 subjects included and sample sizes ranging from 100 to 468. All of the literature reported the results of experimental data needed for this study, but only one literature reported the results in the form of mean ± standard deviation [12], and the fourth literature lacked relevant experimental data for the control group [11].

Table 1. Basic characteristics of the included literature

Number	Author	Nation	Sample size (experimental/control group)	Outcome
1	LianHua Luo 2019	China	100/100	1,2,3,4,5
2	Huiling Wang 2010	China	50/50	1,2,3,4,5
3	ShuZhu Guo 2005	China	234/234	1,2,3,4,5
4	Shen Yin2004	China	Sample size (experimental/control group)	1,2,3,4,5

Note: 1. cervical laceration; 2. duration of the first stage of labor; 3. duration of the second stage of labor; 4. duration of total labor; 5. type of delivery; NA: not mentioned.

3.3. Risk of Bias Assessment Results

Of the four papers finally included in the evaluation, two were low risk [9, 10, 12], and two were moderate risk [9, 11]. The fourth of these papers [11], which lacked control group results in the outcome report, was unanimously rated as medium risk by the study group members. Table 2 and Figure 2 show the results of the risk of bias assessment for the included literature.

Table 2. Results of risk of bias assessment of included literature

Inclusion of literature	D1	D2	D3	D4	D5	final
LianHua Luo 2019	low	low	low	low	low	low
Huiling Wang 2010	low	low	low	low	low	low
ShuZhu Guo 2005	low	low	low	low	low	low
Shen Yin2004	low	low	low	low	medium	medium

Note: D1: bias arising from the randomization process; D2: bias due to deviation from the intended intervention; D3: bias due to missing outcome data; D4: bias in the measurement of the outcome; D5: bias in the selection of the reported outcome.

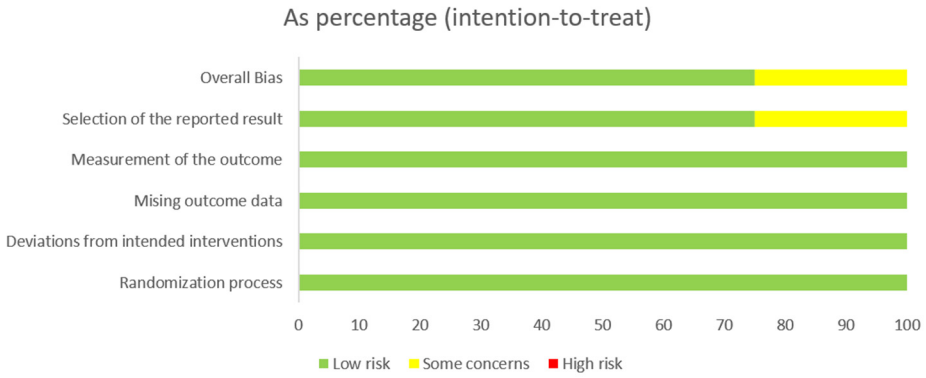

Figure 2. Risk of bias

3.4. Meta-analysis Results

3.4.1. Main Outcome Indicator: Incidence of Cervical Lacerations

The four papers with complete reporting of the primary outcome indicators were included in the analysis, with a total sample size of 1129 cases, including 438 cases in the experimental group and 591 cases in the control group, and the results showed that there was no significant effect of bionic airbag midwifery on the incidence of cervical lacerations compared to the non-bionic airbag midwifery control group (overall effect size of 1.08, 95% CI: [0.61,1.94], P=0.78), with low heterogeneity between studies (I^2=0%) (see Figure 3).

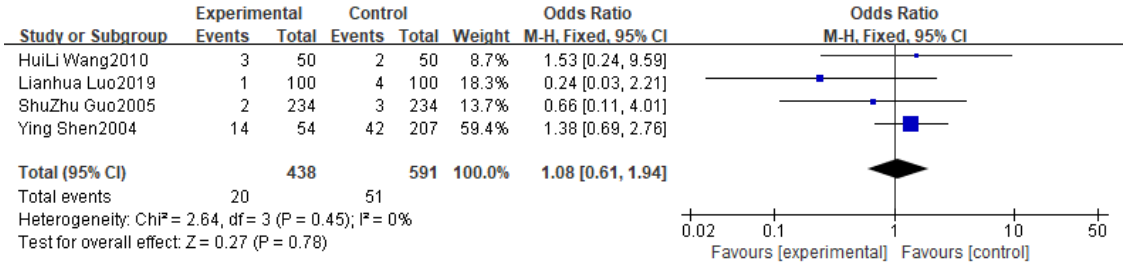

Figure 3. Forest plot of meta-analysis of the incidence of cervical lacerations

3.4.2. Secondary Outcome Indicators: Duration of the First Stage of Labor, Duration of the Second Stage of Labor, Duration of the Total Labor, and Type of Delivery

Due to missing data in the included literature [11], only three studies with complete data were included in the length of labor analysis [9, 10, 12]. In contrast, the included literature all reported the type of labor in full, so the analysis of the type of labor included all studies [9-12], and the results of the analysis are as follows:

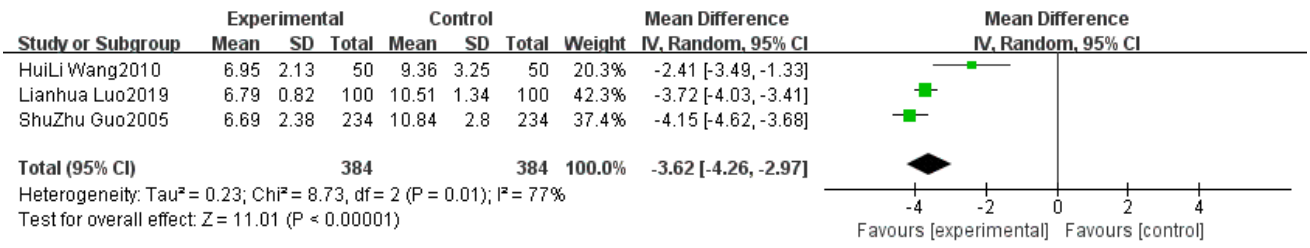

Figure 4. Forest plot of the duration of the first stage of labor

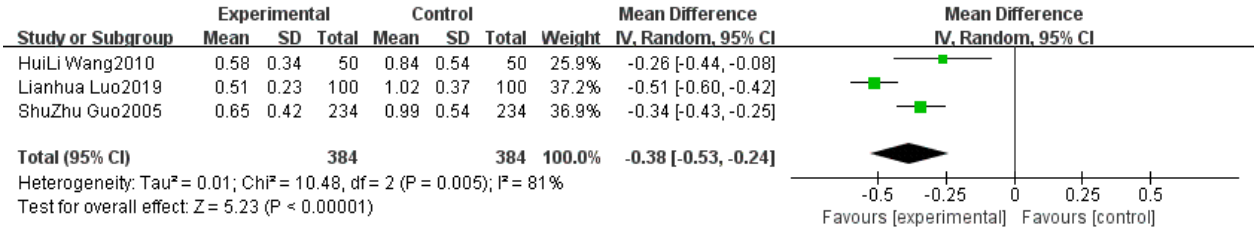

Figure 5. Forest plot of the duration of the second stage of labor

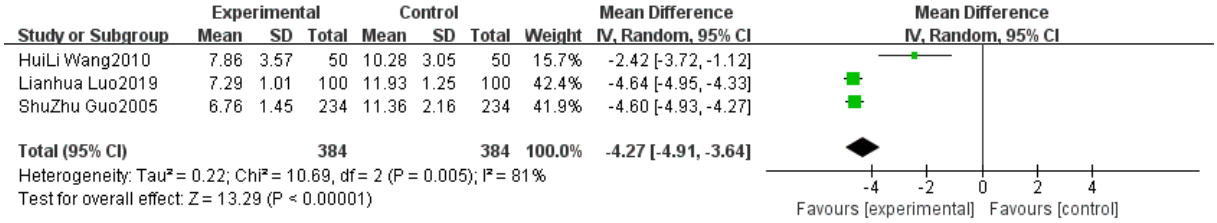

Figure 6. Forest plot of duration of the total labor

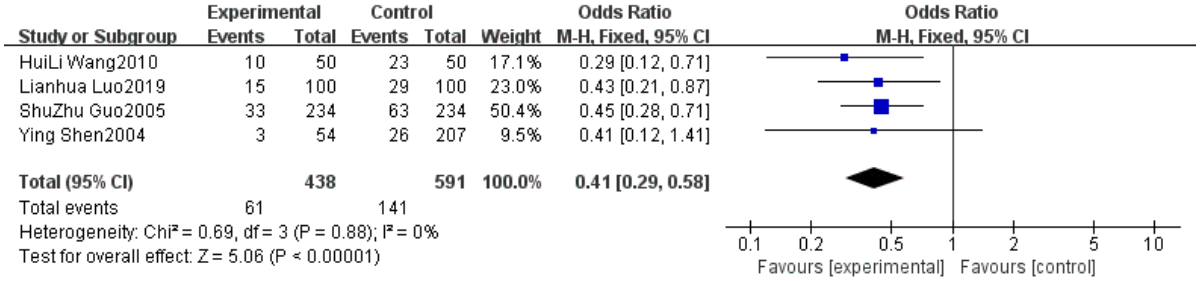

Figure 7. Forest plot of the type of delivery

Since a total sample of 768 cases was included in the three analyses of the length of labor, of which 384 cases were in both the experimental and control groups, and the heterogeneity of the three included studies was >50%, a random-effects model was chosen for the analyses (first stage of labor: overall effect size -3.62, 95% CI: [-4.62,-3.68]), with heterogeneity among studies I^2=77%; the second stage of labor: overall effect size (-0.38, 95% CI: [-0.53,-0.24]), inter-study heterogeneity I^2=81%; total birth: overall effect size -4.27, 95% CI: [-4.91,-3.64], inter-study heterogeneity I^2=81%).

As for the analysis of the type of labor, the total sample of 1129 cases was included in the analysis, of which 438 cases were in the experimental group and 591 cases were in the control group, and the overall heterogeneity of the four studies was <50%, so the fixed effect model was chosen for the analysis, and the overall effect size was 0.41, 95% CI: [0.29,0.58], Z=5.06, and it can be concluded after the results of the study that the bionic airbag midwifery effectively reduced the time of first stage of labor, second stage of labor and total duration of labor and likewise affects the mode of delivery.

4. Conclusion

As a non-invasive assisted delivery technique, the effectiveness of bionic airbag midwifery has been unanimously recognized by most clinicians [13-15]. Many studies have confirmed that this technique is effective in shortening the duration of labor and reducing the incidence of postpartum complications and neonatal asphyxia [16, 17]. However, few studies have examined the effects of bionic airbag midwifery as a soft birth canal-assisted delivery technique on the cervix.

This meta-analysis aimed to study the effect of balloon bionic midwifery on the incidence of cervical lacerations and to provide a basis for the clinical application of balloon bionic midwifery. After searching various databases, only four papers met the criteria [9-12]. By analyzing the included literature, it can be concluded that bionic airbag midwifery does not affect the incidence of cervical laceration, but it can effectively shorten the duration of labor, the latter being consistent with the results of existing studies.

4.1. The Causes of Cervical Lacerations are Complex

It is well known that although the incidence of cervical laceration is only 0.2% [18] when it occurs, it can lead to a range of serious complications [19, 20]. The birth canal is not yet dilated in primiparous women, so the incidence of cervical lacerations is much higher in primiparous women [21]. Some researchers have found that shorter labor may lead to an increase in cervical lacerations in primiparous women [22], which is consistent with the working principle of bionic airbag midwifery. However, there is no single factor for the occurrence of cervical lacerations, besides the specificity of the soft birth canal in primipara, there are also factors of the midwife's maneuver and the fetus [23], and the incidence of cervical lacerations related to the condition of the cervix [24]. In this case, bionic airbag midwifery, as the only variable in this study, may not be a valid condition to influence the incidence of cervical lacerations. The researchers found that midwives assessed the cervical ripeness of the laboring woman to determine if she was a candidate for bionic airbag

midwifery before using bionic airbag midwifery during labor. This may be another reason why the use of bionic airbag midwifery does not lead to more cervical lacerations [25].

4.2. Bionic Airbag Midwifery Investigated in a Single Direction

Only four studies were included in this meta-analysis, not because there are few studies of bionic airbag midwifery, but because many of the outcome indicators are limited to those that are widely validated, such as labor, neonatal asphyxia, and perineal lacerations [26], and fewer studies have focused on cervical lacerations. Although cervical laceration is an important factor in postpartum hemorrhage and interventions affecting the cervix carry the risk of causing cervical injury, minor cervical lacerations tend to go unnoticed and are not easy to observe compared to lacerations of the soft birth canal during labor and delivery, and thus many studies do not report this finding [27]. In addition, unlike soft birth canal lacerations, there is a lack of standardized outcome indicators and definitions for cervical lacerations, leading to possible heterogeneity of outcome indicators in large-scale studies [28]. The current trend in research is to combine bionic airbag midwifery with other methods of guided and assisted labor [29, 30], as an adjunctive technique to explore synergies between various methods of midwifery, rather than just assessing their impact on the woman in labor. This trend stems from the complexity of labor itself, which requires multifaceted interventions to improve the labor experience. Moreover, bionic airbag midwifery, as a noninvasive assisted labor technique, is only used during the cervical dilatation phase of vaginal delivery, and its clinical application and specific conditions of use are limited. Therefore, the typical application scenarios of bionic airbag midwifery are still limited to normal deliveries without complicated complications [31].

4.3. Bionic Airbag Midwifery Applications are Promising

The results of this study show that bionic airbag midwifery can effectively reduce the time of vaginal delivery, which is in line with the results of not some of the existing studies. Vaginal delivery is a physiological process full of risks and pains, and the mother, as the first bearer of the risks of delivery, cares more about whether a midwifery technique reduces the pain and risks of delivery [32], and whether bionic airbag midwifery can precisely satisfy this kind of demand. As a midwifery technique, shorter labor means less time in pain, which can effectively reduce maternal exertion during labor, contraction weakness, and postpartum hemorrhage [33], which can help more women choose to have normal labor and a smooth delivery.

4.4. There is Great Scope for Exploring Airbag Bionic Birth Assistance

Balloon bionic midwifery currently lacks the support of evidence-based medicine, its specific timing of use, the use of techniques, the use of parts of the body, etc. There is no optimal evidence to support, in many cases rely on the experience of the midwife's judgment, which results in the use of the technique has a close relationship with the good of the midwife's skills, and also makes it less effective than the effect of medication to assist labor in general [34]. How to accelerate the spread of this technique in the clinic and make it popular is the next problem that researchers need to solve.

This study is the first to address the effect of bionic airbag midwifery on the incidence of cervical lacerations, and as an assisted labor technique used in the cervical area, it is important to know if it affects the cervix. However, the limitations of this study are obvious, firstly, the small number of included studies resulted in the lack of more detailed sensitivity analysis and subgroup analysis, which makes our experiment limited; secondly, the age of some of the studies resulted in missing data, which prevented us from completing a good overall analysis.

With the change in people's awareness of childbirth and the progress of science and technology, researchers can use more channels and methods to understand and summarize the effect of the use of bionic airbag midwifery, sort out a more comprehensive use of the program, improve the drawbacks of the use of this technology in the clinical use of the technology, such as the lack of training materials, the lack of evidence-based summaries, and so on, to further promote the scope of the use of bionic airbag midwifery, to provide a better birth experience for mothers.

5. Conclusion

This Meta-analysis focuses on the effect of using bionic airbag midwifery on the incidence of cervical lacerations in primipara. The results of this study suggest that bionic airbag midwifery does not affect the incidence of cervical lacerations in primipara. However, considering the positive effects of this technique in shortening the duration of labor and reducing complications, future studies need to adapt and refine the protocols for using this technique to increase its use and effectiveness.

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