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Balloon catheters for induction of labor at term after previous cesarean section: a systematic review

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ABSTRACT

To systematically review the application of balloon catheters for cervical ripening and labor induction at term after previous cesarean section.

All pregnancies at term with previous cesarean section were included when cervical ripening or labor induction was conducted with balloon catheters. MEDLINE, Cochrane database and bibliography of identified articles were searched for English language studies. Reviews and meta-analysis, randomized and non-randomized controlled trials, prospective and retrospective cohort studies as well as case-control studies were considered.

A total of 48 potentially relevant studies were identified. The title and abstract were screened for eligibility and 32 articles were excluded. The remaining 16 publications included 1447 women (single-balloon catheter: $n = 1329$, double-balloon catheter: $n = 118$). There were no randomized controlled trials. Most of the trials were retrospective studies ($n = 10$). The rate of uterine rupture after labor induction was low ($n = 18$, 1.2%). Meta-analysis of studies comparing the risk of uterine rupture between labor induction and spontaneous onset of labor found a higher risk after induction (OR 2.45, 95%CI 1.34–4.47, NNH 186). The average rate of oxytocin application was 68.4%, and vaginal birth was achieved in 56.4%. The risk for cesarean delivery was higher when labor was induced (OR 2.63, 95%CI 2.24–3.10).

Data on balloon catheters for labor induction after previous cesarean section are limited by small sample size and retrospective analyses. The present data show a moderately increased risk for uterine rupture (OR=2.45) compared to spontaneous onset of labor. However, for evidence based recommendations much more well-conducted trials are needed.

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Introduction

With the increasing number of cesarean sections worldwide, the number of women with a scarred uterus who will need induction of labor in a subsequent pregnancy will also rise [1]. It has been estimated that nearly one-quarter of women who were candidates for a trial of labor after cesarean section (TOLAC) requires induction of labor [2]. For all patients, attempting vaginal birth after cesarean section (VBAC), the success rates range from 60 to 85% [3], however, dramatic reduction of TOLAC has been observed after reports of worrying increase in rupture-associated severe perinatal outcome (e.g., hypoxic-ischemic encephalopathy) and also in severe maternal complications (e.g., severe postpartum

hemorrhage, hysterectomy) [4–6]. This increase in short-term morbidity must be balanced by the increase in maternal and neonatal risk associated with multiple repeat cesarean sections [7–11]. It is not clear whether all induction agents have been associated with the same magnitude of increased risk of uterine rupture in the setting of TOLAC [4,12]. Evaluation of the evidence on specific methods of induction reveals that the lowest rate of uterine rupture occurs with oxytocin at 1.1% (95% CI 0.9–1.52%), then dinoprostone at 2% (95% CI 1.1–3.5%) and the highest rate is with misoprostol, 6% (95% CI 0.74–51.4) [4,12–15].

The use of a transcervical Foley catheter for cervical ripening is reported to have similar success rates for induction of labor with intravaginal prostaglandins in women without a history of cesarean section [16–18]. In addition, the use of balloon catheters is a relatively inexpensive method and is associated with fewer abnormalities of contraction pattern, and fewer maternal side-effects when compared to prostaglandins [16–18]. Balloon catheters (single- or double-balloon) have become an attractive

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alternative to prostaglandins for patients with an unfavorable cervix without previous cesarean section. The 'renaissance' of balloon catheters is reflected by a yearly rising number of publications since 2010. However, the use of balloon catheters for cervical ripening and labor induction varies from country to country. It is rarely used in Switzerland [19], and in only 2% of all labor inductions in Germany [20], while the corresponding rate for the Netherlands is 10% [21] and for France nearly 50% [22]. Neither balloon catheters nor dinoprostone are licensed for inducing labor in patients with a scarred uterus, but there is a growing body of evidence, that the use of balloon catheters is an effective and safe method for cervical ripening and labor induction also after previous cesarean section [16]. In the Netherlands, for instance, the use of the Foley catheter for labor induction after prior cesarean section has increased from 49% in 2006 to 72.2% in 2010 [21]. The aim of this article was to review the evidence about efficacy and safety of balloon catheters for cervical ripening and induction of labor in women with a previous cesarean section.

Patients and methods

A criteria list based on the PICOS (population, intervention, comparison, outcomes and study designs) was created to identify all the pertinent manuscripts. All pregnancies at term with previous cesarean section were included (population) when cervical ripening or labor induction was conducted with balloon catheters (e.g., single-balloon, double-balloon, Foley) (intervention). Cervical ripening/labor induction with these mechanical devices was compared with any other methods or spontaneous onset of labor (comparison). There were no restrictions to outcome measures (outcomes). Reviews and meta-analysis, randomized and non-randomized controlled trials, prospective and retrospective cohort studies as well as case-control studies were included (study designs). The relevant articles were identified by using an extensive search string from the MEDLINE and Cochrane databases ("balloon"[Title/Abstract] OR "catheter"[Title/Abstract] OR "Foley"[Title/Abstract]) AND ("induction"[Title/Abstract] OR "ripening"[Title/Abstract]) AND ("previous cesarean"[Title/Abstract] OR "previous cesarean"[Title/Abstract] OR "scarred uterus"[Title/Abstract] OR "prior cesarean"[Title/Abstract] OR "prior cesarean"[-Title/Abstract]). Titles and abstracts between January 1990 and June 2015 identified as a result of the literature search were screened by the authors to select potentially suitable papers for full-text assessment. Manuscripts were excluded in case of intrauterine fetal death, fetal malformation and abnormality. If

they were not published in English but an abstract in English was provided, they were considered for abstract assessment. The bibliography of the articles was searched for further relevant studies. After all, the remaining articles were reviewed to give an update for the use after previous cesarean section.

For the purpose of integrating the findings of individual studies, a statistical meta-analysis has been applied. Study results have been weighted by sample size. In order to compare relative frequencies of two groups, Odds ratio together with 95% confidence interval (95%CI) have been assessed and Chi2 test or Fisher's exact test have been performed, as appropriate. All statistical calculations have been done with SAS software, release 9.3 (SAS Institute Inc., Cary, NC, USA).

Results

A total of 48 potentially relevant studies were identified (Fig. 1). The title and abstract were screened for eligibility and 32 articles were excluded. Finally, 16 publications were assessed by abstract and full-text screening and assigned to the appropriate question (e.g., single- or double-balloon catheter) (Tables 1 and 2). There were 7 studies with single-balloon catheter [23–29], 5 trials with double-balloon catheter [30–34], and 4 manuscripts that were not published in English but provided an English written abstract [35–38].

There were no randomized controlled trials conducted. One investigation was undertaken prospectively [36], and 10 were retrospective studies [23–28,30,34,35,37]. In 5 manuscripts, there was no exact information whether the data were collected prospectively or retrospectively [29,31–33,38]. These 16 investigations included 1447 women with labor induction using balloon catheters. Most of them had induction of labor with single-balloon catheters ($n=1290$), the remaining 157 with double-balloon catheters. There were 9 trials with less than 40 included women and 7 with 129–255 cases.

Rate of uterine rupture

The rate of uterine rupture is depicted in Table 1. Among all women with the balloon catheter ($n=1447$) 18 had uterine rupture (1.2%), while the rate of uterine rupture was 0.7% in women with spontaneous onset of labor (45/6364). Meta-analysis of studies comparing the risk of uterine rupture between labor induction and spontaneous onset of labor [23–25,27,28] found a higher risk after induction (OR 2.45, 95%CI 1.34–4.47, $p=0.0027$). The number

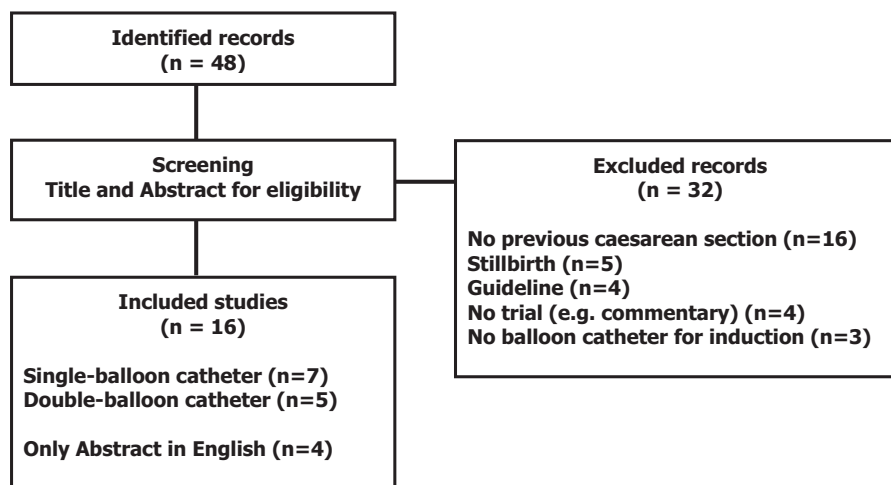


Fig. 1. Trial profile.

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