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Double-balloon catheter and sequential oral misoprostol versus oral misoprostol alone for induction of labour at term: a retrospective cohort study

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ABSTRACT

Objective: To evaluate the efficacy of induction of labour using a double-balloon catheter and, if necessary, sequential oral misoprostol without delay after removal of the catheter, in comparison with oral misoprostol alone.
Study design: This retrospective cohort study included women undergoing induction of labour with oral misoprostol or double-balloon catheter with sequential oral misoprostol in singleton pregnancies at term. The catheter was placed in the evening and removed when there was no onset of labour within 12 h. Then oral misoprostol was started within 3 h. Primary outcome measure was the caesarean section rate.
Results: There were 13,082 deliveries during the study period with 3466 labour inductions out of which 1032 were eligible and analysed. The caesarean section rate was significantly lower in the double-balloon catheter group (26.1% vs. 17.3, $p = 0.021$). Furthermore, in the combination group, the induction-to-delivery interval was shorter (median values 1144 vs. 1365 min, $p = 0.001$) and there were more deliveries within 24 h (51.9 vs. 64.7%, $p = 0.003$) and 48 h (87.4 vs. 95.8%, $p = 0.002$). When stratifying for parity, there were less caesarean sections in the combination group (37.2% vs. 24.2%, $p = 0.015$) in nulliparous women, too. In both, nulliparous and parous women, the induction-to-delivery interval was shorter (1742 vs. 1400 min, 0.005; 1020 vs. 912 min, $p = 0.018$). Especially in parous women, the rates of delivery within 24 h (62.6% vs. 79.0%, $p = 0.007$) and 48 h (88.6% vs. 99.0%, $p = 0.007$) were higher in the combination group.
Conclusion: Double-balloon catheter and sequential oral misoprostol without long delay in absent onset of labour after removal of the catheter resulted in less caesarean section and shorter induction-to-delivery interval in comparison with oral misoprostol alone.

Introduction

Induction of labour, a common obstetric procedure, is nowadays being used more widely than ever before [1].

Mechanical and pharmacological methods are available to promote cervical ripening and the onset of labour. Despite mechanical methods have been replaced by pharmacological methods, single and double-balloon catheters have been used increasingly in the last years [2]. Labour induction with these devices is as effective as prostaglandins [3–5] and well accepted by the women [6,7].

Modes of action involved in the mechanical and pharmacological methods for cervical ripening differ. Investigations evaluating the effect of a combination of the two practices have shown that the simultaneous use is beneficial [3,8–10].

When balloon catheters are used for cervical ripening, there is an onset of labour in 23.5–33% [11,12]. So, further agents are necessary to achieve labour in most cases. Oxytocin was given in most previous trials which explains its higher need [3–5]. Some previous investigations demonstrated good results with sequential prostaglandins [9].

In a recent publication, we could not find a relevant difference between oral misoprostol and the sequential use of a double-balloon

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catheter and oral misoprostol [12]. However, in that trial, the balloon catheter was inserted in the morning, removed after 12 h, and oral misoprostol given the next morning. It could be demonstrated that timing of application of balloon catheter is important. Balloon catheter placed in the evening resulted in a shorter induction to delivery interval for instance [13].

The aim of this study was therefore to evaluate the efficacy of induction of labour using a double-balloon catheter and, if necessary, sequential oral misoprostol without delay after removal of the catheter, in comparison with oral misoprostol alone.

Patients and methods

This historical cohort study was undertaken in two university hospitals, Erlangen and Mannheim (2010–2014), in Germany.

Labour inductions with oral misoprostol or double-balloon catheter with sequential oral misoprostol in singleton pregnancies at term (≥259 days of gestation) were included. The double-balloon catheter (Cook Medical, Cervical Ripening Balloon; Cook OB/GYN, Bloomington, Indiana, USA) was placed in the evening and removed when there was no onset of labour within 12 h. Oral misoprostol was started within 3 h after removal of the balloon catheter. Women were excluded if the sequential use of double-balloon catheter and oral misoprostol was different from the described protocol. Further exclusion criteria were breech presentation, favourable cervix (Bishop score >6), previous caesarean section, premature rupture of the membranes, structural or chromosomal fetal malformation, intrauterine fetal death, placenta praevia, or any other contraindication to vaginal delivery. Gestational age was assessed from the menstrual history and confirmed by measurement of fetal crown–rump length at a first-trimester scan. The Bishop score was assessed before labour induction.

The double-balloon catheter was inserted in accordance with the manufacturer's instructions in the evening. The balloons situated on each side of the cervix were filled with up to 80 ml of saline each. The external end of the mechanical device was taped without traction to the woman's thigh. As reported before, the balloon catheter was removed in cases in which it did not fall out spontaneously within 12 h. Reasons for removing the catheter included the request by the woman but not rupture of the membranes. If labour did not start after mechanical ripening, the women received misoprostol orally within 3 h after removal. Initially, the dosages were 50 μg with repeat doses 4 and 8 h later if the first stage of labour had still not yet begun. A dosage of 100 μg was given up to three times if necessary, 24 h after the start of misoprostol administration. Forty-eight hours following the start of oral misoprostol, misoprostol (100 μg) was administered vaginally every 4 h up to three times per day. When labour was induced by misoprostol alone, the misoprostol regimen described above started from the beginning. Neither artificial rupture of the membranes nor routine oxytocin administration were carried out routinely in the two participating hospitals.

The primary outcome parameter was the caesarean section rate. Secondary outcome measures were the induction-to-delivery interval (from placement of the balloon catheter or application of misoprostol), the rate of vaginal deliveries within 24 and 48 h, failed labour induction (defined as no vaginal delivery within 72 h) as well as neonatal outcome parameters (e.g. arterial umbilical cord pH and base excess [BE], Apgar score after 5 min, postpartum admission to neonatal care unit).

This was a historical cohort study whereas ethical approval by the institutional review board was not necessary. When the women were admitted to the hospitals, they accepted use of their data for analysis.

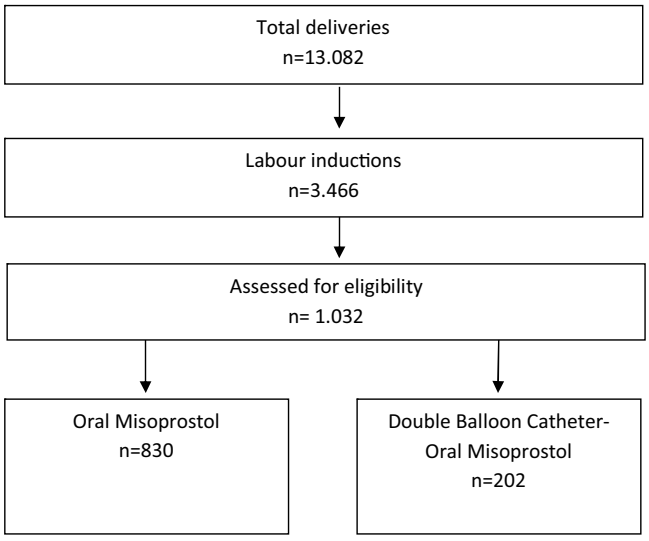

Fig. 1. Trial profile.

Student's *t*-test and the Mann–Whitney *U* test were used to compare two groups of continuous normally and non-normally distributed variables, respectively. The Chi^2 test or Fisher's exact test has been performed to analyse proportions. For these simple tests a significance level of 5% was chosen. Furthermore, we performed multiple logistic regression analysis in order to analyse several variables (i.e. BMI, height and group) on a binary outcome simultaneously to adjust for possible confounders. A multiple linear regression analysis has been done to investigate women's BMI, height and the factor "treatment group" on the quantitative outcome "induction-to-delivery interval". For these multiple tests, a significance level of 10% has been chosen. All statistical calculations have been done with SAS software, release 9.3.

Results

In total, 13,082 women delivered at the participating hospitals during the study period and labour was induced in 3466 (26.5%). There were 1032 cases eligible for analysis (Fig. 1). Labour induction was undertaken in 830 women with oral misoprostol alone and in 202 cervical ripening was started with a double-balloon catheter and continued with oral misoprostol in absent onset of labour after removal of the balloon catheter.

The baseline demographics and pregnancy characteristics were similar across both groups (Table 1). The women in the misoprostol group were somewhat younger (29.8 ± 5.6 vs. 30.8 ± 5.4 years, $p = 0.049$), smaller (166.3 ± 6.6 vs. 167.8 ± 6.9 cm, $p = 0.004$) and less overweight (BMI 28.6 ± 5.9 vs. 27.2 ± 6.3, $p = 0.004$).

The indications for labour induction are given in Table 2. There were more inductions for fetal growth restriction, placental insufficiency or abnormal Doppler ultrasound in the double-balloon catheter group (3.3% vs. 8.0%, $p = 0.003$). The other indications were not significantly different between the two groups.

The pooled outcome parameters are demonstrated in Table 3. The caesarean section rate, the primary outcome measure, was significantly lower in the double-balloon catheter group (26.1 vs. 17.3%, $p = 0.021$). In the combination group, the induction-to-delivery interval was shorter (median values 1365 [205–9001] vs. 1144 [152–7036] min, $p = 0.001$) and there were more women that delivered their baby within 24 h (51.9% vs. 64.7%, $p = 0.003$) and 48 h (87.4% vs. 95.8%, $p = 0.002$).

The total median amount of misoprostol used was 150 μg in both groups, but with a wider range in the oral misoprostol group