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Induction of labour with sequential double-balloon catheter and oral misoprostol versus oral misoprostol alone in obese women

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ABSTRACT

Objective: To evaluate the efficacy of induction of labour in obese women using sequential double-balloon catheter and oral misoprostol in comparison with oral misoprostol alone.
Study design: In this cohort study, 400 pregnant women with BMI higher than 35 kg/m2 undergoing labour induction at term were included. Induction of labour with a double-balloon catheter and, if necessary, sequential oral misoprostol (n = 216) was compared to oral misoprostol alone (n = 184). The primary outcome measure was the caesarean section rate. Secondary outcome parameters were, among others, the induction-to-delivery-interval, the rate of vaginal delivery within 24 and 48 h as well as fetal outcome parameters.
Results: The caesarean section rate was significantly lower in the group with sequential use of double-balloon catheter and oral misoprostol (27.6% versus 37.5%, p = 0.0345). After stratification for parity this reduction was seen especially in nulliparous (38.6% versus 56.9%, p = 0.0039). The rate of abnormal CTG was significantly lower as well (19.9% versus 30.4%, p = 0.0150), particularly in nulliparous (25.9% versus 40.4%, p = 0.0138). Uni- and multivariable analyzes showed that the caesarean section rate was significantly influenced by the method of induction of labour (p = 0.0026), parity (p < 0.0001) and Bishop score (p = 0.0425).
Conclusion: In obese women, induction of labour with sequential use of double-balloon catheter and oral misoprostol is associated with significantly more normal vaginal deliveries and less caesarean sections.

Introduction

Induction of labour, being used more widely than ever before, is nowadays a common obstetric procedure [1]. In cases of immature cervix findings, oxytocin is inferior to prostaglandins and should not be used as a sole method [2]. Prostaglandins are available in different forms: as prostaglandin E2 (dinoprostone) or as a synthetic prostaglandin E1 analogue (misoprostol) for vaginal or oral administration. Misoprostol appears to be the most effective drug and should preferably be administered orally [3,4]. Despite mechanical methods have been replaced by pharmacological methods, single and double-balloon catheters have been used increasingly in the last years [5,6]. Labour induction with these devices is as effective as prostaglandins [7–9] and well accepted by the women [10,11]. Investigations evaluating the effect of a combination of the two practices have shown that the simultaneous use [7,12,13] as well as the sequential use [14,15] are beneficial.

Maternal obesity provides a major challenge to obstetric practice [16]. Intrapartum and postpartum complications are higher in obese women. Caesarean section, shoulder dystocia, failed instrumental delivery, postpartum haemorrhage and neonatal problems are more common in obese women [17–19]. Higher maternal BMI at booking is associated with an increased risk of prolonged pregnancy and increased rate of labour induction [20]. Induction of labour in obese women was reported to be more likely to be prolonged, leading to the requirements for higher doses of oxytocin and increased risks of operative deliveries and morbidity [18,21–23].

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

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Patients and methods

This historical cohort study was conducted at two university hospitals in Germany, and included labour inductions in women with BMI higher than 35 kg/m^2 with singleton pregnancy at term in a four-years period in Erlangen (2011–2014) and Mannheim (2010–2013). Cases with multiple pregnancy, breech presentation, favourable cervix (Bishop score > 6), previous caesarean section, prelabour rupture of the membranes, structural or chromosomal fetal malformation, intrauterine fetal death, placenta praevia, or any other contraindication to vaginal delivery were excluded. The maternal weight at the end of the pregnancy before inducing labour was used to calculate the BMI. 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.

Induction of labour was conducted either by oral misoprostol alone or by double-balloon catheter with sequential oral misoprostol. The double-balloon catheter (Cook Medical, Cervical Ripening Balloon; Cook OB/GYN, Bloomington, Indiana, USA) was placed in accordance with the manufacturer's instructions in the evening and 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. 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 mg with repeat doses 4 and 8 h later if the first stage of labour had still not yet begun. A dosage of 100 mg 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 mg) was administered vaginally every 4 h up to three times per day. Women were excluded if the sequential use of double-balloon catheter and oral misoprostol was different from the described protocol.

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. Induction of labour was continued until labour started without cessation.

The primary outcome measure was the caesarean section rate. Secondary outcome parameters were the induction-to-delivery-interval, the rate of vaginal delivery 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).

In the departments in which the study was conducted, all data in case of labour induction were collected routinely and were completely anonymized. Ethical approval was given by the institutional review board (Ethik-Kommission der FAU, 247_17 Bc, 15.08.2017).

All statistical calculations have been done with SAS, release 9.4 (SAS institute Inc., Cary, North Carolina, USA. For quantitative variables which are approximately normally distributed mean value and standard deviation have been calculated. For skewed data, ordinal or quantitative discrete data median value together with minimum and maximum are given. Qualitative factors are presented by relative and absolute frequencies. Two mean values have been compared with a 2 sample *t*-test For data which is not normally distributed Mann Whitney U test has been used instead. For qualitative factors Chi2-test or Fisher's exact test has been performed, as appropriate. Furthermore univariable and multiple logistic regression analyses have been performed for the binary outcome "caesarean section".

Furthermore we performed uni- and multivariable linear regression analysis for the primary outcome measure "caesarean section rate" in order to analyse several variables simultaneously using the "forward selection" method. In general, the result of a statistical test has been considered as significant if the p value is less than 0.05.

Results

In total, 15,164 women delivered at the participating hospitals during the study period and labour was induced in 3868 (24.8%). There were 400 cases which met the inclusion and exclusion criteria (Fig. 1). Labour induction was undertaken in 184 women with oral misoprostol alone and in 216 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 are demonstrated in Table 1. The women in the misoprostol group were lighter (108.6 ± 15.7 vs. 113.0 0 ± 16.6, p = 0.0067) and had a slightly lower body mass index (39.6 ± 4.1 vs. 40.4 ± 4.8, p = 0.0641).

The indications for labour induction are given in Table 2. There were more inductions for abnormal CTG in the misoprostol group (8 (4.3%) vs 2 (0.9%), p = 0.0490). The other indications were not different.

The pooled outcome parameters are demonstrated in Table 3. The caesarean section rate, the primary outcome measure, was

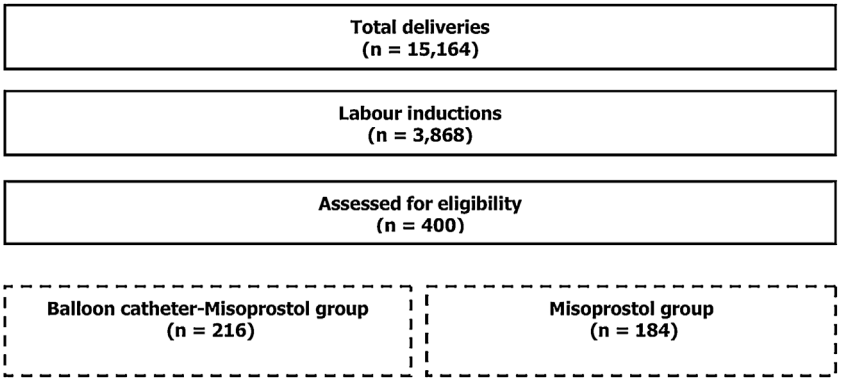

Fig. 1. Trial profile.

Table 1
Baseline demographics and pregnancy characteristics.

Characteristics	BC-OM group (n = 216)	OM group (n = 184)	*P* value
Age (years)	29.9 ± 5.3	29.3 ± 5.6	0.2889
Height (cm)	167.2 ± 7.0	166.0 ± 6.8	0.0939
Weight (kg)	113.0 ± 16.6	108.6 ± 15.7	0.0067
Body mass index	40.4 ± 4.8	39.6 ± 4.1	0.0641
Pregnancy	1 (1 – 9)	2 (1 – 7)	0.5508
Parity	0 (0 – 5)	0 (0 – 4)	0.0541
Gestational age (days)	281.7 ± 8.6	281.9 ± 7.7	0.8018
Birth weight (grams)	3539.3 ± 497.1	3579.8 ± 512.2	0.4257
Bishop score	2 (0 – 5)	2 (0 – 5)	0.1785
Hypertensive disorder (HES; n, %)	53 (24.5%)	33 (17.9%)	0.1092
Fetal growth restriction	7 (3.2%)	5 (2.7%)	0.7597
Placental insufficiency, abnormal doppler (n, %)	9 (4.2%)	11 (6.0%)	0.4074
Gestational diabetes (n, %)	58 (26.9%)	41 (22.3%)	0.2913
Intrahepatic cholestasis of pregnancy (n, %)	1 (0.5%)	3 (1.6%)	0.3379

Quantiative data are presented by median (range) or mean with standard deviation. For qualitative factors, absolute and relative frequencies are given. $P < 0.05$ was considered significant.
BC, balloon catheter; OM, oral misoprostol.

Table 2
Indications for inducing labour.

Indications	BC-OM group (n = 216)	OM group (n = 184)	*P* value
Pregnancy at or beyond 41 weeks	90 (41.7%)	80 (43.5%)	0.7149
Gestational diabetes	32 (14.8%)	22 (12.0%)	0.4044
On request	28 (13.0%)	19 (10.3%)	0.4144
Anhydramnios, oligohydramnios	15 (6.9%)	9 (4.9%)	0.3888
Suspected fetal macrosomia	5 (2.3%)	9 (4.9%)	0.1623
Reduced fetal movements	1 (0.5%)	2 (1.1%)	0.5964
Fetal growth restriction, placental insufficiency, abnormal doppler	7 (3.2%)	7 (3.8%)	0.7598
Preeclampsia, hypertensive disorders, HELLP syndrome	34 (15.7%)	22 (12.0%)	0.2770
Abnormal CTG	2 (0.9%)	8 (4.3%)	0.0490
Intrahepatic cholestasis of pregnancy	1 (0.5%)	3 (1.6%)	0.3379
Other	1 (0.5%)	3 (1.6%)	0.3379

CTG, cardiotocography.
Data are presented as absolute and relative frequencies. $P < 0.05$ was considered significant.

Table 3
Outcome parameters.

Outcome parameters	BC-OM group (n = 216)	OM group (n = 184)	*P* value
Mode of delivery (n, %)			
Normal vaginal delivery	140 (65.4%)	98 (53.3%)	0.0136
Surgical vaginal delivery	15 (7.0%)	17 (9.2%)	0.4147
Caesarean section	59 (27.6%)	69 (37.5%)	0.0345
Induction-Delivery-Interval (min)[a]	1804 (152 – 7624)	1777 (233 – 13,975)	0.1165
Vaginal delivery within 24 h (n, %)[b]	39 (25.2%)	45 (39.1%)	0.0142
Vaginal delivery within 48 h (n, %)[b]	120 (77.4%)	93 (80.9%)	0.4921
Failed induction (no delivery within 72 h; n, %)[b]	12 (7.7%)	9 (7.8%)	0.9796
Arterial umbilical pH	7.27 ± 0.07	7.26 ± 0.08	0.1633
Arterial umbilical pH < 7.05 (n, %)	0	2 (1.1%)	0.2110
Arterial umbilical pH < 7.10 (n, %)	1 (0.5%)	5 (2.7%)	0.0987
BE < −12 (n, %)	2 (0.9%)	1 (0.6%)	1.0000
Apgar score at 5 min < 7 (n, %)	3 (1.4%)	2 (1.1%)	1.0000
BE < −12 and Apgar score at 5 min < 7 (n, %)	0	0	n.c.
Abnormal CTG (n, %)	43 (19.9%)	56 (30.4%)	0.0150
Fetal blood analysis (n, %)	1 (0.5%)	0	1.0000
Epidural anaesthesia (n, %)	91 (42.1%)	62 (34.1%)	0.0995
Oxytocin (n, %)	81 (37.7%)	88 (41.8%)	0.3955
Meconium-stained amniotic liquor (n, %)	49 (22.7%)	39 (21.2%)	0.7200
Chorioamnionitis (n, %)	3 (1.4%)	0	0.2529
Postpartum transfer to neonatal care unit, total (n, %)	35 (16.2%)	30 (16.3%)	0.9783
Infection of the newborn (n, %)	11 (5.1%)	3 (1.6%)	0.0604

BE, base excess; h, hours.
[a] Cesarean sections and failed induction of labor are excluded.
[b] Cesarean sections are excluded.

significantly lower in the sequential group (27.6% vs. 37.5, p = 0.0345). There were less vaginal deliveries within 24 h (39.1% vs. 25.2%, p = 0.0142), too. In 34 cases (15.7%) labour started after balloon catheter only. There was no relevant difference in the induction-delivery-interval (median values 1804 [152-7624] vs. 1777 [233–13975] min, p = 0.1165) and in the rate of failed induction between the two groups (7.7% vs 7.8%, p = 0.9796). There was onset of labour in 15.7% after balloon catheter. Regarding the fetal outcome parameter there were significantly more abnormal CTG (suspicious or pathological according FIGO Consensus Guideline) in the misoprostol group (30.4% vs 19.9%, p = 0.0150). There was no significant difference in the rate of meconium-stained amniotic liquor, chorioamniotitis and infection of the newborn between sequential and misoprostol group (22.7% vs 21.2%, p = 0.7200; 1.4% vs. 0%, p = 0.2529; 5.1% vs 1.6%, p = 0.0604).

After stratifying for parity, the benefit of the combination of double-balloon catheter and misoprostol regarding the rate of caesarean section and abnormal CTG could only be seen in nulliparous women (38.6% vs. 56.9%, p = 0.0039; 25.9% vs. 40.4%, p = 0.0138; Table 4).

Univariable and multiple logistic regression analysis of the primary outcome measure caesarean section rate is demonstrated in Table 5. According the univariable models high body mass index (OR 1.048, p = 0.0428) and hypertensive disorders including preeclampsia (OR 1.656, p = 0.0460) are associated with a higher risk for caesarean section rate. On the other hand it turned out that sequential balloon catheter and misoprostol (OR 0.634, p = 0.0350), high parity (OR 0.171, p < 0.0001) as well as high Bishop score (OR 0.770, p = 0.0006) significantly reduced the probability of a caesarean section.

As this was not a randomized clinical study multiple logistic regression analysis seemed to be reasonable in order to adjust for possible confounders i. e. as body mass index or parity. Applying forward selection technique, method of induction of labour (OR 0.469, p = 0.0026), parity (OR 0.170, p < 0.0001) and Bishop score (OR 0.770, p = 0.0425) remained in the final model. This confirms the treatment influence on the binary outcome “caesarean section”.

Discussion

This is the first study evaluating the combination of cervical ripening with double-balloon catheter and oral misoprostol with oral misoprostol alone in obese women. It could be demonstrated that in obese women the rate of normal vaginal deliveries is significantly higher and the rate of cesarean section significantly lower, when induction of labour was undertaken by sequential double-balloon catheter and oral misoprostol. This benefit was found especially in nulliparous women. The multivariable analysis showed that, besides method of induction of labour (balloon catheter and sequential use of misoprostol versus misoprostol alone) and Bishop score, parity had a significant impact on the caesarean section rate.

Induction of labour in obese women is associated with multiple complications such as an increased risk of operative deliveries [18,21–23]. The main finding of this study was the lower caesarean section rate when labour was induced with sequential balloon catheter and misoprostol. Similar results were found in previous studies evaluating the whole population with obese and non-obese women [15,24]. The difference in the cesarean section rate of 18% (38,6% versus 56,9%) is similar to the 13% in the mixed collective 24]. Ande et al. could even show a reduced caesarean section rate by 20% [14].

In this study, the use of double-balloon catheter resulted in labour in only 16%, what is noticeably less than in previous studies [25]. This might be explained by the more difficult condition of obese women which resulted in higher induction to delivery intervals in previous studies [18,21–23].

The rate of abnormal CTG was significantly lower in the sequence group, what might be explained by smaller total amount of prostaglandins. This could also be found in previous investigations [24,25].

Balloon catheters for labour induction in maternal obesity are effective. Indeed, it was stated that obese women receiving the same dose of misoprostol as non-obese ones have higher rates of failure to achieve active labour, an effect not seen with mechanical

Table 4
Outcome parameters in nulliparous and parous women.

Outcome parameters	Nulliparous			Parous		
	BC-OM group (n = 147)	OM group (n = 109)	*P* value	BC-OM group (n = 44)	OM group (n = 44)	*P* value
Mode of delivery (n, %)						
Normal vaginal deliveryNormal vaginal delivery	75 (51.7%)	35 (32.1%)	0.0018	40 (91%)	38 (86%)	0.5017
Surgical vaginal deliverySurgical vaginal delivery	14 (9.7%)	12 (11.0%)	0.7246	1 (2%)	2 (5%)	1.0000
Caesarean sectionCaesarean section	56 (38.6%)	62 (56.9%)	0.0039	3 (7%)	4 (9%)	1.0000
Induction-Delivery-Interval (min)[a]	2043 (412 – 7374)	2157 (356 – 9001)	0.3163	1490 (152 – 3954)	1659.5 (233 – 13975)	0.4699
Vaginal delivery within 24 h (n, %)[b]	15 (16.9%)	11 (23.4%)	0.3556	17 (41%)	18 (42%)	0.9247
Vaginal delivery within 48 h (n, %)[b]	60 (67.4%)	37 (78.7%)	0.1655	39 (95%)	32 (80%)	0.0480
Failed induction (no delivery within 72 h; n, %)[b]	10 (11.2%)	4 (8.5%)	0.7706	0	3 (7.5%)	0.1158
Arterial umbilical pH	7.26 ± 0.07	7.27 ± 0.08	0.7554	7.27 ± 0.07	7.27 ± 0.08	0.7399
Arterial umbilical pH < 7.05 (n, %)	0	1 (0.9%)	0.4258	0	0	n.c.
Arterial umbilical pH < 7.10 (n, %)	0	3 (2.8%)	0.0760	1 (2%)	0	1.0000
BE < −12 (n, %)	1 (0.7%)	0	1.0000	1 (2%)	0	1.0000
Apgar score at 5 min < 7 (n, %)	3 (2.0%)	1 (0.9%)	0.6396	0	0	n.c.
BE < −12 and Apgar score at 5 min < 7 (n, %)	0	0	n.c.	0	0	n.c.
Abnormal CTG (n, %)	38 (25.9%)	44 (40.4%)	0.0138	4 (9%)	5 (11%)	1.0000
Fetal blood analysis (n, %)	1 (0.7%)	0	1.0000	0	0	n.c.
Epidural anaesthesia (n, %)	83 (56.5%)	49 (45.8%)	0.0929	6 (14%)	7 (16%)	0.7639
Oxytocin (n, %)	73 (50.0%)	62 (56.9%)	0.2761	5 (11%)	7 (16%)	0.5344
Meconium-stained amniotic liquor (n, %)	42 (28.6%)	31 (28.4%)	0.9817	5 (11%)	5 (11%)	1.0000
Chorioamnionitis (n, %)	3 (2.0%)	0	0.2636	0	0	n.c.
Postpartum transfer to neonatal care unit, total (n, %)	31 (21.1%)	21 (19.3%)	0.7201	2 (5%)	4 (9%)	0.6763
Infection of the newborn (n, %)	10 (6.8%)	2 (1.8%)	0.0630	1 (2%)	1 (2%)	1.0000

P < 0.05 was considered significant.
n.c. = not calculable.
[a] Caesarean sections and failed induction of labor are excluded.
[b] Caesarean sections are excluded.

Table 5
Univariable and multiple Logistic regression analysis of the primary outcome measure caesarean section rate.

	Univariable analysis Odds ratio	Univariable p value (p value)	Multiple Analysis Odds Ratio	Multiple Analysis significant p value
Induction of labour Balloon catheter-misoprostol versus misoprostol alone	0.634	0.0350	0.469	0.0026
Body mass index (kg/m^2)	1.048	0.0428		
Age (years)	0.980	0.3362		
Parity	0.171	< 0.0001	0.170	< 0.0001
Gestational age (days)	0.994	0.6171		
Birth weight (kilograms)	0.959	0.8445		
Bishop score	0.770	0.0006	0.841	0.0425
(Gestational) diabetes	0.928	0.7650		
Preeclampsia, hypertensive disorders	1.656	0.0460		
Fetal growth restriction	1.057	0.9290		
Indication for induction of labour				
Pregnancy at or beyond 41 weeks	0.801	0.3110		
Gestational diabetes	0.786	0.4591		
On request	0.551	0.1117		
Anhydramnios/Oligohydramnios	0.689	0.4409		
Suspected fetal macrosomia	2.933	0.0509		
Less fetal movements	1.056	0.9649		
Fetal growth restriction; placental insufficiency; abnormal Doppler	0.839	0.7700		
Preeclampsia, hypertensive disorders	1.942	0.0246		
Abnormal CTG	3.270	0.0703		
Intrahepatic cholestasis in pregnancy	0.701	0.7592		
Other	2.127	0.4531		

ripening [26]. Moreover, Grange et al. showed that induction of labour with a double-balloon catheter was more effective compared with vaginal dinoprostone in obese women at term [27]. There are conflicting results whether maternal BMI influences the efficacy of labour with balloon catheters. While Saylawala et al. stated that the caesarean section rate was significantly higher in obese women compared with non-obese women (54.9% compared with 37.9%, p = 0.001) [28], others found no statistical differences in any maternal or fetal outcome parameters except the maternal satisfaction with the induction process of mechanical cervical ripening [29].

A limitation of the present study is the retrospective design regarding data collection. This is why further prospective trials (ideally randomized clinical trials) are necessary. Strengths of this study are its high number of included cases and the stratification for parity which is often missing in other trials. Cases with prelabour rupture of membranes were excluded since it influences the outcome of labour induction [30].

Conflict of interest

The authors have no conflicts of interest to declare.

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