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Effect of early amniotomy on dystocia risk and cesarean delivery in nulliparous women: a randomized clinical trial

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Abstract
Purpose Artificial rupture of amniotic membranes (amniotomy) which induces or accelerates labor is the most common obstetrical procedure. There is controversy about the effect of early amniotomy on dystocia and cesarean delivery. The study aim was to determine the effect of early amniotomy on the risk of dystocia and cesarean delivery in nulliparous women.
Methods This randomized controlled clinical trial was conducted on 300 nulliparous women. They were randomly assigned into the experimental (early amniotomy; artificial amniotomy at cervical dilation $\leq$4 cm) and control (routine management) groups (each 150 women). Length of labor, dystocia, cesarean delivery, placental abruption, and umbilical cord prolapse were compared between the groups.
Results Early amniotomy shortened labor duration significantly in experimental group (7.5 $\pm$ 0.7 h) compared to control group (9.9 $\pm$ 1.0 h) ($P < 0.001$). Dystocia (6.7 vs. 25.3 %, $P < 0.0001$), cesarean delivery (11.3 vs. 39.3 %, $P < 0.001$), and placental abruption (4.7 vs. 13.3 %, $P = 0.009$) were significantly lower in experimental group compared to the control group. Multiple logistic regression showed that early amniotomy decreased the odds of dystocia 80.6 % (95 % CI 58.6–90.1 %) and the odds of cesarean section 81.7 % (95 % CI 66.2–90.1 %).
Conclusion Early amniotomy was associated with lower rate of dystocia and cesarean delivery as well as shorter duration of labor.

Keywords Early amniotomy · Dystocia · Nulliparous · Cesarean · Labor

Introduction

Induction of labor is a common obstetric practice, which is performed in one of four pregnant women [1]. In fact, induction of labor has grown over the past decade [2]. The three common forms of labor induction include oxytocin, prostaglandins, and amniotomy. Usually amniotomy is done with simultaneous administration of oxytocin. It has been shown that combination of amniotomy and oxytocin yields better labor augmentation compared to any of these alone [3].

Artificial rupture of amniotic membranes (amniotic sac) or amniotomy is a common obstetric intervention for indication or acceleration of labor progression. It was introduced to obstetrics more than 50 years ago. Amniotomy is considered as an integral part of active management of labor and has reduced the rate of cesarean section [4].

However, this method has been associated with advantages and disadvantages. For example, it was reported that elective amniotomy raised the likelihood of compression on the umbilical cord in the active phase of labor with consequent higher rate of mild and moderate variable decelerations, but without severe changes in fetal heart rate. On the other hand, artificial amniotomy shortened the active phase of labor and decreased the need for oxytocin

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augmentation [5]. Benefits of amniotomy include more rapid delivery, sooner diagnosis of meconium in amniotic fluid, the possibility of attaching electrode to the fetus, and the like [6]. In former studies, early amniotomy was associated with higher risk for cesarean section [7, 8].

Dystocia (difficult labor) is a major concern during delivery. It is characterized by prolonged or slowly progressing labor. It is more common in nulliparous women than in multiparous ones. Dystocia increases the rate of cesarean delivery and is associated with multiple complications. It has been reported that dystocia is the responsible factor for half of cesarean delivery cases [9]. Considering the importance of dystocia as a factor leading to cesarean delivery, the management of dystocia has always been the focus of researchers. Different managements are available for managing dystocia. One of them is amniotomy. However, there is controversy about the effect of amniotomy on dystocia and cesarean delivery rate. Some studies report early amniotomy as not beneficial regarding cesarean delivery rate, and in fact it increased cesarean rate [10, 11], but some other studies report early amniotomy as a safe method which can decrease dystocia [12].

This study aimed to determine the rate of dystocia after early amniotomy in nulliparous women. Findings of this study will aid obstetricians and midwifery staff to judge clinically about the benefits versus disadvantages of early amniotomy.

Materials and methods

This randomized controlled clinical trial (IRCT 2013080114123N1) was done in our tertiary care center in 2013. Study population consisted of all pregnant women who presented to Asali Hospital, Khoramabad, Iran, due to the onset of labor pain during the year 2013.

Nulliparous women with singleton and term pregnancy (37–42 weeks gestational age), blood pressure <140/90 mmHg, spontaneous onset of labor, cephalic presentation of fetus, intact amniotic sac, and normal fetal heart rate were included in the study. Pregnant women with multifetal pregnancy, non-cephalic presentation of fetus, preeclampsia, intrauterine growth retardation, diabetes or other medical conditions, and cervical dilation of 5 cm or more were excluded from the study.

Three hundred consecutive patients were selected by convenient sampling. They were randomly (using stratified block randomization method) assigned into two experimental and control groups (each 150 women). The two groups were matched for age, weight, gestational age, fetal birth weight, and cervical effacement.

For experimental group (150 cases), early amniotomy was done at dilatation of ≤4 cm. In control group, amniotomy was not performed unless there was obstetric indication (e.g., cervical dilation arrest for at least 2 h, failure of labor progression, or fetal distress). Vaginal exam was done every hour and fetal heart rate was recorded every 15 min and after uterine contractions. All other cares provided were similar in two groups. Administration of oxytocin for labor augmentation was allowed in both groups. The variables of interest were length of labor (onset of uterine contractions until 1 h after expulsion of placenta), dystocia, cesarean section, umbilical cord prolapse, and placental abruption. In case of dystocia or other obstetric indications, cesarean section was done. Otherwise, natural vaginal delivery was allowed. The cases were observed in the hospital for 24 h in case of natural delivery and 48 h in case of cesarean section.

Ethics

The study protocol was approved by the Ethics Committee of our university. All patients were informed about the study details and written informed consent was obtained prior to enrollment.

Statistical analysis

Descriptive data are presented as frequency and percentage for categorical data and as mean and standard deviation (±SD) for continuous numerical data. To compare categorical and continuous variables between experimental and control groups, the Chi-squared test or *t* test/Mann–Whitney were used, respectively. The analysis of covariance (ANCOVA) and multiple logistic regression model were used to control the effects of confounding factors. Significance level was set at 0.05. All analyses were done using the SPSS software for Windows (ver. 19.0).

Results

Table 1 presents and compares general characteristics between experimental and control groups. As shown, no statistically significant difference was observed between the two groups regarding maternal age, gestational age, body mass index (BMI), neonate birth weight, cervical dilation as well as cervical effacement upon admission. In Table 2, mean (±SD) length of labor and cervical dilation and effacement at the time of amniotic sac rupture are listed. All three variables were significantly lower in the experimental group than in the control group.

Dystocia occurred in 10 cases of experimental group (6.7 %) which was significantly lower compared to dystocia frequency in the control group (38 cases, 25.3 %). Table 3 compares frequency of dystocia, umbilical cord

Table 1 Comparison of baseline characteristics between experimental (early amniotomy) and control (no early amniotomy) groups

	Experimental (150 cases) mean (±SD)	Control (150 cases) mean (±SD)	*P* value
Maternal age, year	25.6 (±2.6)	25.7 (±3.3)	0.848
Gestational age, week	39.2 (±0.7)	39.2 (±0.7)	0.782
Body mass index, kg/m^2	25.3 (±2.6)	25.1 (±2.6)	0.996
Neonatal weight, g	3,315.6 (±396.6)	3,321.2 (±425.2)	0.844
Initial cervical dilation, cm	1 (±0.2)	1 (±0.2)	0.525
Initial cervical effacement, %	0.3 (±1.8)	0.4 (±1.9)	0.759

Table 2 Comparison of length of labor, cervical dilation and effacement at the duration of amniotic sac rupture between experimental and control groups

	Experimental mean (±SD)	Control mean (±SD)	*P* value
Length of labor, h	7.5 (±0.7)	9.9 (±1.0)	<0.001
Cervical dilation upon amniotic sac rupture, cm	4 (±0.1)	9.5 (±0.47)	<0.001
Cervical effacement upon amniotic sac rupture, %	53.9 (±4.9)	98 (±3.2)	<0.001

Data are presented as mean (±standard deviation)

Table 3 Comparison of dystocia, umbilical cord prolapse, cesarean section, and placental abruption between experimental and control groups

	Experimental	Control	*P* value
Dystocia, *n* (%)	10 (6.7 %)	38 (25.3 %)	<0.001
Umbilical cord prolapsed, *n*	1	0	–
Cesarean section, *n* (%)	17 (11.3 %)	59 (39.3 %)	<0.001
Placental abruption, *n* (%)	7 (4.7 %)	20 (13.3 %)	0.009

prolapse, cesarean section, and placental abruption between experimental and control groups.

Table 4 presents data of ANCOVA test regarding the effects of different variables on mean length of labor, cervical dilation, and cervical effacement. As observed, with controlling of confounding variables, early amniotomy was effective on labor duration, cervical dilation, and cervical effacement.

Table 5 presents logistic regression results that determined factors affective on dystocia and cesarean section. According to the analysis, early amniotomy decreased the likelihood of dystocia 80.6 % (95 % CI 58.6–90.1 %). Early amniotomy also decreased the chance of cesarean section 81.7 % (95 % CI 66.2–90.1 %).

Discussion

According to our findings, early amniotomy in nulliparous women was a safe method which significantly decreased labor duration, cesarean rate, placental abruption, and dystocia. We matched both groups regarding other variables, which could potentially affect dystocia and cesarean delivery rate. In both groups, administration of oxytocin was allowed. After controlling the confounding effects, it was observed that early amniotomy decreased the likelihood of both dystocia and cesarean delivery.

Table 4 Analysis of variance (ANCOVA) results showing the effect of different variables on labor duration, cervical dilation, and cervical effacement

	Length of labor			Cervical dilation			Cervical effacement		
	df	*F*	Sig.	*df*	*F*	Sig.	*df*	*F*	Sig.
Maternal age	1	1.75	0.186	1	1.8	0.176	1	0.06	0.7
Initial cervical dilation	1	0.864	0.353	1	1.1	0.287	1	2.1	0.1
Gestational age	1	0.058	0.810	1	4.1	0.04	1	1.1	0.2
Neonatal weight	1	0.623	0.431	1	1.0	0.3	1	0.03	0.8
Initial cervical effacement	1	0.765	0.383	1	1.3	0.2	1	1.8	0.1
BMI	1	0.395	0.530	1	0.8	0.3	1	3.9	0.04
Early amniotomy	1	487.5	<0.001		18,668.0	0.001	1	8,442.1	0.001

Sig. significance, *df* degree of freedom, *BMI* body mass index

Table 5 Logistic regression results showing the effective variables on dystocia and cesarean section

	P value	Odds ratio	95 % CI
Dystocia			
Early amniotomy	0.001	0.1	0.091–0.4
Maternal age	0.2	0.9	0.8–1.0
Gestational age	0.4	0.8	0.5–1.3
Neonatal weight	0.5	1	0.9–1.0
BMI	0.6	1	0.9–1.1
Initial cervical dilation	0.2	0.3	0–2.5
Initial cervical effacement	0.3	1	0.8–1.3
Cesarean section			
Early amniotomy	0.001	0.183	0.099–0.338
Maternal age	0.1	0.933	0.85–1.02
Gestational age	0.5	1.1	0.75–1.65
Neonatal weight	0.6	1.0	0.99–1.0
BMI	0.8	1.0	0.905–1.12
Initial cervical dilation	0.2	0.305	0.046–2.03
Initial cervical effacement	0.5	0.934	0.73–1.18

BMI body mass index

The obtained results are in part in contrast to findings of Fraser et al. [12] study. They studied 925 nulliparous women in labor dividing them using a cutoff of 3 cm of cervical dilation and randomly assigned them to early amniotomy or control groups. Similar to our results, they also found a much lower rate of dystocia in amniotomy group as well as shorter labor time, however cesarean delivery frequency was similar in both groups. They concluded that early amniotomy was successful in achieving shorter labor time and less frequent dystocia, but not cesarean delivery.

In another study, the authors assessed the role of active management in cesarean delivery. They divided nulliparous women into active management or control groups. In active management, amniotomy was done in the first hour of labor onset and oxytocin was started in cervical dilation of less than one cm. They observed that cesarean delivery was less frequent in those received active management (10.5 %) in comparison to those received traditional management (14.1 %). A similar pattern was also recorded in dystocia as about 25 % reduction in the cesarean section rate was primarily due to a decrease in dystocia [13].

Only one patient in amniotomy group and none in control group developed cord prolapse. There is evidence that amniotomy increases the risk of cord prolapse [14]. The rate of cord prolapse has been reported 0.3 % after amniotomy and it varies between 0 and 0.7 % [15]. Since we observed only one case of cord prolapse, we are not able to comment on this issue and may need a meta-analysis of the relevant studies to conclude about the exact effect of amniotomy on cord prolapse.

Placental abruption was also significantly less frequent in experimental group. Macones et al. [16] in their study compared early amniotomy versus standard management amongst about 600 nulliparous women at term. According to their findings, placental abruption was not significantly higher in amniotomy group (0.4 %) than in the control group (0.6 %), a finding that contradicts ours. Likewise, no case of cord prolapse was seen in the control group while in the amniotomy group 0.7 % developed this complication. The only significant finding of that study compatible with ours was shorter duration of labor. Cesarean delivery was also comparable in amniotomy (41 %) and control group (40 %) [16].

Conclusion

Early amniotomy was associated with shorter length of labor and lower rate of cesarean delivery, cord prolapsed and dystocia. Since, there is controversy about these findings in the literature, we recommend meta-analysis of studies to pool data for a more explicit conclusion.

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