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CLINICAL ARTICLE

Nifedipine versus terbutaline for tocolysis in external cephalic version

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Abstract

Objective: To study the efficacy of nifedipine compared with terbutaline as a tocolytic agent in external cephalic version (ECV). *Methods:* A prospective, randomized, comparative trial was carried out in a tertiary hospital. Women with singleton term breech pregnancies were randomized for nifedipine (group A) and terbutaline (group B) tocolysis for ECV in an outpatient setting. The efficacy, side effects, and complications were analyzed and compared. *Results:* A total of 86 women were recruited with 43 women in each group. The overall success rate was 48.8% and this reduced the rate of cesarean delivery for breech presentation by 32.5% in our center. ECV was successful in 39.5% of women in group A and 58.1% in group B. Fewer side effects were experienced by the women in group A compared with group B, although this was not significant. *Conclusion:* Nifedipine can be used as an alternative for tocolysis in ECV when there are maternal contraindications to beta-sympathomimetics.

1. Introduction

The Term Breech Trial [1], despite many pitfalls, demonstrated that cesarean delivery is better than vaginal breech delivery in reducing perinatal morbidity and mortality. An alternative management option is to reduce the incidence of breech presentation at term by performing external cephalic version (ECV). ECV lost its popularity [2] among obstetricians and midwives during the 1970s, but there has been a recent surge in the number of ECV attempts. ECV involves manually turning the breech to head first and is not without complications. However, in a good selection of cases it has been proven successful in about 40%–60%, resulting in a vaginal delivery rate of at least 40% in term breech pregnancies [3]. It has also been shown to be a safe procedure with low risk for fetal and maternal complications [4,5]. It has been advocated that all women with an uncomplicated breech presentation at term (37–42 weeks) should be advised to undergo ECV [4].

The factors that influence the success of ECV are parity, gestational age, amount of amniotic fluid, type of breech,

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position of the placenta and, to some extent, the technique used for the procedure [4]. In the past, ECV was performed without tocolysis; however, recent studies have shown better success rates with tocolysis [6,7], where the uterus is more relaxed and the amount of force required is reduced, which allows easier repositioning of the fetus. Tocolysis has also been shown to improve the success rate of ECV when performed by the less experienced and in repeat ECV after a failed first attempt [8].

The present study was conducted to evaluate the efficacy of nifedipine as an alternative to terbutaline in the ECV of term breech pregnancies.

2. Materials and methods

A prospective randomized controlled trial was carried out in a tertiary hospital. All women with a singleton term breech presentation between 37 and 40 weeks of pregnancy were randomized to receive either nifedipine (group A) or terbutaline (group B) for tocolysis prior to ECV in an outpatient setting. Exclusion criteria were women with oligohydramnios (amniotic fluid index less than 10 cm); macrosomia (estimated fetal weight of 4 kg or more); presence of a contraindication for vaginal delivery (e.g. major placenta previa); one previous cesarean delivery; multiple pregnancy; hypertension in pregnancy; rhesus negative mother; previous history of abruptio placentae; lethal fetal anomaly; or contraindication against nifedipine or terbutaline.

The women fasted overnight and their blood was crossmatched in anticipation of complications that might require prompt cesarean delivery. Fetal well-being was assessed by nonstress cardiotocography (CTG) for 20 minutes on arrival at the ECV clinic. An ultrasound scan was carried out for assessment of estimated fetal weight, amniotic fluid index, placental location, and umbilical artery Doppler. Women were excluded at this stage if any criterion was not met. The procedure was explained to the couple and informed written consent was obtained.

A computerized random number generator was used to assign the groups in a sequence of sealed, numbered opaque envelopes. The chosen tocolytic was administered according to the study protocol by a medical officer and a nurse who were not involved in performing the ECV. The women in group A received 20 mg of nifedipine orally, while those in group B received a slow intravenous bolus of 50 μg of terbutaline. Only the doctors attempting the procedure were blinded, not the patients. ECV was attempted 20 minutes after administering the medication and the procedure was carried out within 5 minutes or a maximum of 3 attempts. The forward roll and backward flip techniques were used. The procedure was abandoned if undue force was required, if the woman became distressed, or the maximum number of attempts or the time was exceeded.

An ultrasound scan was repeated at the end of the procedure to confirm the presentation and fetal well-being, including umbilical artery Doppler. A CTG was performed for 20–40 minutes and the woman was then discharged with a fetal kick chart. Each woman was seen again after 1 week and subsequent management was undertaken according to the team responsible for prenatal care. If the ECV was unsuccessful, cesarean delivery was performed on the next operation day. If the fetus reverted to breech position before delivery, an elective cesarean delivery was performed. In cases where CTG was not reactive or suspicious, an emergency cesarean delivery was performed immediately.

The following data were recorded: maternal age, parity, week of pregnancy at ECV, type of breech, position of placenta, amniotic fluid index, umbilical artery Doppler, maternal and fetal complications, mode of delivery, neonatal Apgar score, and admission to the neonatal unit. The success rate and side effects of the drugs in the 2 groups were compared. Discomfort and pain during the procedure were evaluated using visual analogue pain scoring.

With an alpha error of 0.05 and a beta of 0.2, 86 patients were recruited into the study. Categorical variables were analyzed using the χ^2 test, and continuous variables using the t test and the controlled Cochran-Mantel-Haenszel test. $P<0.05$ was considered statistically significant.

3. Results

A total of 86 women were recruited into the study. The characteristics and ultrasound findings were similar in the 2 groups of patients (Table 1). The primary outcome showed an overall ECV success rate of 48.8%, with a differential rate of 39.5% in group A and 58.1% in group B ($P=0.08$). ECV was more successful with terbutaline for any parity when compared to nifedipine, although the difference was not significant ($P=0.66$). In nulliparas the success rate was 36.8% with nifedipine and 63.2% with terbutaline. In multiparas the rates were 43.5% and 56.5%, respectively.

ECV was more successful (although insignificant, $P=0.62$) in complete breech, irrespective of whether nifedipine (64.7%) or terbutaline (36.0%) was used. The overall success rate for ECV was higher, although not statistically significant ($P=0.41$), when the placenta was posterior (terbutaline 56.0%, nifedipine 52.9%).

In terms of side effects, although not statistically significant ($P=0.31$) and transient, there were slightly more women who reported palpitations and abdominal pain (during maneuvering) in group B (Table 2). Among those who had successful ECV, 6 women from group B were lost to follow-up. Of the remaining women, 11 (64.7%) from group A and 14 (73.7%) from group B had vaginal deliveries ($P=0.25$).

Table 1 Demographic characteristics of the study participants

Characteristic	Nifedipine ($n=43$)	Terbutaline ($n=43$)	P value
Maternal age at ECV, years	28.5±4.06	29.9±5.15	0.16
Gestational age at ECV, weeks	37.8±0.8	37.5±0.4	0.06
Amniotic fluid index	12.9±2.70	12.3±2.83	0.28
Nuliparous	18 (41.9)	21 (48.8)	0.52
Type of breech			
Frank	24 (55.8)	24 (55.8)	
Complete	18 (41.9)	17 (39.5)	
Footling	1 (2.3)	2 (4.7)	0.83

Values are given as mean±SD or number (percentage) unless otherwise indicated.