International Journal of Gynecology and Obstetrics 104 (2009) 28–31

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

Intravenous salbutamol for external cephalic version

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ARTICLE INFO

Article history:
Received 1 July 2008
Received in revised form 11 August 2008
Accepted 12 August 2008

Keywords:
Cesarean delivery
Breech
External cephalic version
Salbutamol
Tocolysis

ABSTRACT

Objective: To evaluate the success of external cephalic version (ECV) using an adjusted bolus dose of intravenous salbutamol compared with no tocolysis. *Methods:* An open-label randomized study of 114 women with a term breech fetus randomized to receive either an intravenous bolus dose of 0.1 mg salbutamol with further boluses every 5 minutes, as required, before commencing ECV, or no tocolysis. Primary outcomes were successful ECV and rate of cesarean delivery. *Results:* Salbutamol tocolysis resulted in a higher rate of successful ECV compared with no tocolysis (70.2% [40/57] vs 36.8% [21/57]; RR 1.9, 95% CI 1.3–2.8; $P<0.001$). Cesarean delivery rate was lower in the salbutamol group compared with the control group (31.6% [18/57] vs 63.2% [36/57]; RR 0.5, 95% CI 0.3–0.8; $P=0.001$). Salbutamol dose ranged from 0.1–0.4 mg and outcome was not related to dose. *Conclusion:* Adjusted dose intravenous salbutamol tocolysis prior to ECV increases its success rate and reduces the cesarean delivery rate.

1. Introduction

Breech presentations occur in about 3%–4% of term deliveries [1]. Breech vaginal delivery has long been perceived to be associated with increased risks to the neonate [2], and cesarean deliveries were commonly performed to avoid the complications associated with these breech births [3]. The Term Breech Trial [4] provided strong evidence that planned cesarean birth for fetuses in the term breech position is associated with reduced neonatal morbidity in the immediate postpartum period, and has led to guidance favoring planned cesarean delivery for breech presentation at term [5]. Breech presentation is a common indication for a primary cesarean delivery [6]. External cephalic version (ECV) has been advocated as a safe and effective method to reduce the rate of cesarean delivery for singleton breech fetuses [5,7].

The Cochrane review on interventions that assist in external cephalic version for breech presentation at term demonstrated that tocolysis, particularly with the assistance of beta-agonists, increases the rate of successful cephalic version and reduces cesarean delivery rates [8]. However, the role of the routine use of tocolytics in ECV is still unsettled [7,8]. ECV without tocolysis is considered safe and has been shown to be effective [9,10]. However, although beta-agonists are effective for tocolysis, they are also cardiac stimulants and may cause maternal palpitations and tachycardia [11].

Recent trials and meta-analysis of trials have shown beta-agonists to be beneficial in ECV [8,9,11,12]. The aim of the present study was to evaluate whether bolus dosing of intravenous salbutamol titrated against maternal heart rate is an effective method of tocolysis to achieve ECV.

2. Materials and methods

An open-label, randomized study of dose-adjusted salbutamol tocolysis versus no tocolysis for ECV was performed. The study was carried out between February 2005 and May 2006 at the Maternity Hospital in Penang, Malaysia—a state funded public hospital with approximately 5000 deliveries per year. At the time of the study, ECV was performed with and without tocolysis at the study center depending on providers. The study was approved by the hospital's ethics committee. Informed consent for ECV was obtained from all participants.

Potential participants were identified at the prenatal clinic when they attended for routine care. Inclusion criteria were healthy women carrying a singleton fetus in breech presentation at 37 to 39 weeks of gestation, with intact membranes, no signs of labor, and a clinically estimated fetal weight of 2–4 kg. Ultrasound was performed to confirm breech presentation and to ascertain fetal neck position, amniotic fluid index (AFI) [13], and location of the placenta.

Exclusion criteria were AFI outside the range of 5 to 25, fetal hyperextended neck, placenta previa, and gross fetal anomalies. Women were also excluded if their history included hypertension, gestational diabetes, antepartum hemorrhage, uterine scar (from cesarean, myomectomy, or perforation), uterine malformation, allergy or contraindication to salbutamol, or contraindication to a trial of labor even if in cephalic presentation.

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0020-7292/$ – see front matter
doi:10.1016/j.ijgo.2008.08.014

The study protocol and ECV maneuver were explained to the women who met the inclusion criteria. Women who were willing to participate in the trial were given an appointment for ECV as soon as possible. The participants were instructed to fast from midnight prior to their ECV appointment the following morning because of the small risk of emergency cesarean delivery in the event of fetal distress.

On arrival for ECV a brief ultrasound assessment was performed to reconfirm breech presentation, exclude placenta previa (placental location was categorized as fundal, anterior upper segment, or posterior upper segment), oligohydramnios, or polyhydramnios. Ultrasound assessment also enabled determination of the type of breech. Breech was categorized into: extended (both legs flexed at the hips and extended at the knee); flexed (at least one leg flexed at the knee but the breech presenting below the foot); or footling (at least one leg extended at the knee with the foot presenting below the breech). A cardiotocograph (CTG) was performed to obtain a reassuring trace. Maternal pulse and blood pressure were recorded. An intravenous cannula was set and maternal blood was taken and stored in readiness for an emergency cesarean delivery.

The participants were randomized to receive either salbutamol tocolysis or no tocolysis (control group). Randomization was carried out by opening sealed, numbered opaque envelopes prepared in blocks of 4 with the sequence created by a random number generator.

Women randomized to the control group had their ECV performed without further delay. Women randomized to the tocolysis group received 0.1 mg salbutamol intravenously and pulse rate was checked after 5 minutes. If the maternal pulse was 100 beats per minute or greater, ECV was performed. If the maternal pulse was less than 100 beats per minute, additional 0.1 mg boluses were given and the cycle repeated until the target maternal pulse rate was achieved, after which ECV was performed without further delay.

ECV was performed by trainees under the supervision of an experienced obstetrician (SYL) who intervened in the event of failure. A maximum of 3 attempts were allowed. Each woman was placed in a supine position with her arms extending from the body. ECV was performed without analgesia or anesthesia. According to operator preference and depending on the perceived mobility of the fetal poles, either a forward somersault or a back flip was first attempted to achieve cephalic presentation. The fetal poles were grasped by the operator and rotated as firmly as could be tolerated by the woman to effect the movement of the fetal head to the suprapubic region and the breech to the epigastric area. Each attempt typically lasted no more than 2 minutes. At the end of an attempt, presentation and fetal heart rate were checked by ultrasound. If cephalic presentation was confirmed, a CTG was performed. If the CTG was reassuring, the woman was discharged home after an hour to await spontaneous labor. If fetal bradycardia was detected on ultrasound, CTG was immediately performed with appropriate remedial action taken (including an emergency cesarean delivery). If ECV failed and there was no fetal bradycardia on ultrasound, ECV was attempted again and the above described procedure was repeated up to a maximum of 3 attempts. ECV was abandoned if the woman could not tolerate the discomfort. Maternal pulse and blood pressure were taken 30 minutes after completion of ECV. Maternal tachycardia was defined as a pulse of 120 beats per minute or greater, and hypotension as blood pressure of less than 90/60 mm Hg. Maternal symptoms of palpitations, chest pain, and shortness of breath were assessed prior to discharge.

Women with unsuccessful ECV were usually offered an elective cesarean delivery at 38 weeks of gestation, or as soon as mutually convenient if gestation was already 38 weeks. Pregnancy and neonatal outcome (gestational age at delivery, mode of delivery, presentation at delivery, post ECV antepartum hemorrhage, placental abruption, Apgar score, neonatal admission, neonatal injury and birth weight) were extracted from patients' charts or hospital records.

Sample size calculation was based on a placebo controlled study of beta-agonist tocolysis for ECV [12] that showed a 50% versus 23% ECV success rate in favor of tocolysis. Alpha of 0.05 and power of 0.8 using the Fisher exact test indicated that 56 women were needed in each arm for a suitably powered study.

Data were analyzed using SPSS software (SPSS, Chicago, IL, USA). GraphPad Instat and GraphPad QuickCalc software (GraphPad, La Jolla, CA, USA) were also used. Analysis of available data was performed based on intention to treat. Relative risk (RR) and 95% confidence intervals (CIs) were calculated. $P<0.05$ was considered statistically significant and all tests used 2-sided.

3. Results

A total of 114 women were randomized into 2 groups: 57 to receive salbutamol tocolysis and 57 to the control group (no tocolysis). All participants received their allocated treatment. The characteristics of the participants are shown in Table 1 and were similar for both groups, with the exception that a greater number of anteriorly-sited placentas were found in the control group.

Outcomes after ECV are shown in Table 2. Salbutamol tocolysis resulted in a higher rate of successful ECV compared with no tocolysis (70.2% [40/57] vs 36.8% [21/57]; RR 1.9, 95% CI 1.3–2.8; $P<0.001$). The number needed to treat to benefit was 5 (95% CI, 2.5–17.6). The cesarean delivery rate was lower in the salbutamol group compared with the control group (31.6% [18/57] vs 63.2% [36/57]; RR 0.5, 95% CI 0.3–0.8; $P=0.001$). The number needed to treat to benefit was 4 (95% CI 2.3–9.2). Indications for cesarean delivery were similar for both trial arms. There was no reversal to breech presentation following successful ECV, nor was there any spontaneous cephalic version following unsuccessful ECV. There were only 2 unplanned cesarean deliveries: 1 in a nulliparous woman in the control group following fetal bradycardia after unsuccessful ECV which necessitated an emergency cesarean, and 1 indicated by intrapartum nonreassuring fetal status on CTG following successful ECV in a nulliparous woman in the salbutamol group. There were no vaginal breech births.

Table 1
Characteristics of the study participants[a]

	Salbutamol (n=57)	Control (n=57)	*P* value
Age, y	28.2±4.8	28.7±4.3	0.59
Parity[b]	0 [1.5]	0 [1.5]	0.64
Nulliparas	31 (54.4)	27 (47.4)	0.57
Ethnicity			
Malay	39 (68.4)	39 (68.4)	0.94
Chinese	11 (19.3)	11 (19.3)	
Indian	5 (8.8)	6 (10.5)	
Others	2 (3.5)	1 (1.8)	
Gestational age, wks	38±0.6	38±0.7	0.97
Pre-ECV cardiotocogram			
Fetal heart rate, bpm	137±5.0	138±4.0	0.41
Maternal blood group			
O	21 (36.8)	25 (43.9)	0.50
A	13 (22.8)	14 (24.6)	
B	20 (35.1)	13 (22.8)	
AB	3 (5.3)	5 (8.8)	
Amniotic fluid index			
≤10	28 (49.1)	24 (42.1)	0.57
Placental location			
Fundal	13 (22.8)	5 (8.8)	0.017
Anterior upper segment	19 (33.3)	33 (57.9)	
Posterior upper segment	25 (43.9)	19 (33.3)	
Type of breech			
Extended	29 (50.9)	28 (49.1)	0.39
Flexed	20 (35.1)	25 (43.9)	
Footling	8 (14.0)	4 (7.0)	

[a]Values are given as mean ± SD for continuous data, median [interquartile range] for ordinal data, and number (percentage) for categorical data. Analysis by *t* test for continuous data, Mann-Whitney U test for ordinal data, Fisher exact test for 2×2 categorical datasets, and χ^2 test for larger categorical datasets.
[b]Parity was defined as the number of prior pregnancies of at least 24 weeks of gestation.