

Intravenous Nitroglycerin for External Cephalic Version

A Randomized Controlled Trial

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OBJECTIVE: To estimate whether treatment with intravenous nitroglycerin for uterine relaxation increases the chance of successful external cephalic version.

METHODS: Two double-blind, randomized clinical trials were undertaken: one in nulliparous women and a second in multiparous women. Women presenting for external cephalic version at term were eligible to participate. The primary outcome was immediate success of external cephalic version. Other outcomes were presentation at delivery, cesarean delivery rate, and side effects and complications. Sample size calculations were based on a 100% increase in success of external cephalic version with a one-sided analysis and $\alpha=0.05$ (80% power).

RESULT: In total, 126 women were recruited—82 in the nulliparous trial and 44 in the multiparous trial. Seven patients did not have external cephalic version before delivery but were included in the analysis of success of external cephalic version. One patient was lost to follow-up. The external cephalic version success rate for nulliparous patients was 24% (10 of 42) in patients who received nitroglycerin compared with 8% (3 of 40) in those who receive placebo ($P=.04$, one-sided Fisher exact test, odds ratio 3.85, lower bound 1.22). In multiparous patients, the external cephalic version success rate

did not differ significantly between groups: 44% (10 of 23) in the nitroglycerin group compared with 43% (9 of 21) in the placebo group ($P=.60$).

CONCLUSION: Treatment with intravenous nitroglycerin increased the rate of successful external cephalic version in nulliparous, but not in multiparous, women. Treatment with intravenous nitroglycerin appeared to be safe, but our numbers were too small to rule out rare serious adverse effects.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, www.clinicaltrials.gov, NCT00896311 and NCT00901758. (*Obstet Gynecol* 2009;114:560–7)

LEVEL OF EVIDENCE: I

Breech presentation complicates 3–5% of term pregnancies. Since the Term Breech Trial, the majority of fetuses presenting breech now are delivered by cesarean owing to the increased risk of perinatal mortality and morbidity with vaginal breech delivery.¹ External cephalic version has a recognized role in decreasing breech presentation at term and subsequent cesarean delivery rates.^{2,3}

The success rate of external cephalic version at term varies between 20% and 80%. The success rate is higher in multiparous women and with the use of betamimetic agents (such as ritodrine) for tocolysis^{2–10}. Ritodrine is no longer available in Canada, and the current Canadian standard of care is to conduct external cephalic version with no tocolysis. Nitroglycerin has been studied as an alternate uterine relaxant for use during external cephalic version. Sublingual nitroglycerin spray did not significantly improve external cephalic version success rates compared with placebo in women who had failed a previous version attempt or in multiparous women.^{2,11–13} Because intravenous nitroglycerin action (90 seconds) and clearance (2–5 minutes) are faster compared with sublingual nitroglycerin, intravenous nitroglycerin allows

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for titration of dose to desired uterine relaxation.¹¹ Intravenous dosing is recommended over other routes of administration of nitroglycerin for uterine relaxation in obstetrical emergencies such as uterine inversion and uterine hyperstimulation.¹¹ No previous study has compared intravenous nitroglycerin with placebo for tocolysis during external cephalic version.

The IV Nitroglycerin for Versions Trial was a double-blind, randomized controlled trial comparing intravenous nitroglycerin with placebo for uterine relaxation during external cephalic version. The purpose of this study was to estimate whether titration of intravenous nitroglycerin to achieve uterine relaxation would result in more successful external cephalic versions compared with placebo. Because of the documented differences in external cephalic version success rates and effects of tocolysis with parity,² two independent trials were conducted simultaneously—one in nulliparous patients (nulliparous trial) and the other in multiparous patients (multiparous trial). The primary outcome was external cephalic version success rate, and the secondary outcomes were presentation at the time of delivery, caesarean delivery rate, and occurrence of side effects and potential complications of treatment.

MATERIALS AND METHODS

These randomized controlled trials were conducted on labor and delivery units at the three hospitals in Calgary, Alberta, Canada, after obtaining institutional ethics approval (University of Calgary Conjoint Health Research Ethics Board reference #16682). Women presenting for external cephalic version at term were invited to participate by their obstetrician or research nurse. Patients were assessed for eligibility with history, bedside ultrasound scan, and a nonstress test. Inclusion criteria were any noncephalic singleton presentation, gestational age at least 37 weeks, normal amniotic fluid index (more than 5 to less than 20), and reassuring fetal heart rate. Patients were excluded if they were in labor or if they had ruptured membranes, history of third-trimester bleeding, any preexisting uterine scar, pregnancy-induced hypertension or gestational diabetes, oligohydramnios, hydramnios, intrauterine growth restriction, macrosomia, maternal hypotension, or any serious medical condition or inability to comprehend the consent form. The decision to exclude these patients was based on the possibility that these diagnoses might have an effect on the need for caesarean delivery, one of our outcomes of interest. In addition, maternal hypotension may be worsened by nitroglycerin and was therefore considered a safety issue.

Using separate randomization sequences for nulliparous and multiparous women at each hospital site, participants were assigned a study number from sequentially numbered opaque envelopes. The study number was forwarded to the pharmacy, and the allocated treatment was provided based on the corresponding study number from randomization tables kept in the pharmacy. The treatment was prepared as 10 mL of clear fluid in a 10-mL syringe with either 10 mL of 100 micrograms/mL of nitroglycerin for women in the nitroglycerin group or 10 mL of normal saline for women in the placebo group. The syringes for nitroglycerin and placebo were visually indistinguishable. Group of allocation was unknown to the obstetrician, nurse, anesthesiologist, and patient.

With the patient in the supine Trendelenburg position, external cephalic version was attempted with intravenous access and the obstetrician, nurse, and anesthesiologist present. Baseline vital signs were recorded before the anesthesiologist administered 1 mL of trial treatment as a test dose. Vital signs and the occurrence of effects were recorded by the anesthesiologist. After palpation to ensure that the uterus was relaxed adequately, the obstetrician would attempt the external cephalic version according to usual clinical practice. The presenting part was palpated first if engaged suprapubic pressure was applied to disengage the breech; then fundal pressure to the fetal head was applied to induce a forward or backward roll depending on operator preference. If that attempt was unsuccessful or if the uterus was not adequately relaxed, further doses of treatment medication were given at the discretion of the obstetrician. Further doses were specified by the protocol to be given in 1-mL to 3-mL increments up to a recommended maximum of 10 mL. The protocol recommended no more than four external cephalic version attempts. Ultrasonography was used to aid version and visualize the fetal heart. Maternal blood pressure, side effects, discomfort, and uterine relaxation were recorded along with external cephalic version success or failure (the primary outcome) on standardized data-collection forms. The obstetrician attempting the external cephalic version was kept aware of vital signs and side effects so that patient safety could be monitored closely.

The sample size calculations were carried out before the start of the study based on a local chart review of 54 external cephalic versions using no tocolysis, which demonstrated a success rate of 16% for nulliparous patients and 26% for multiparous patients. Based on a 100% increase in success of external cephalic version with a one-sided analysis



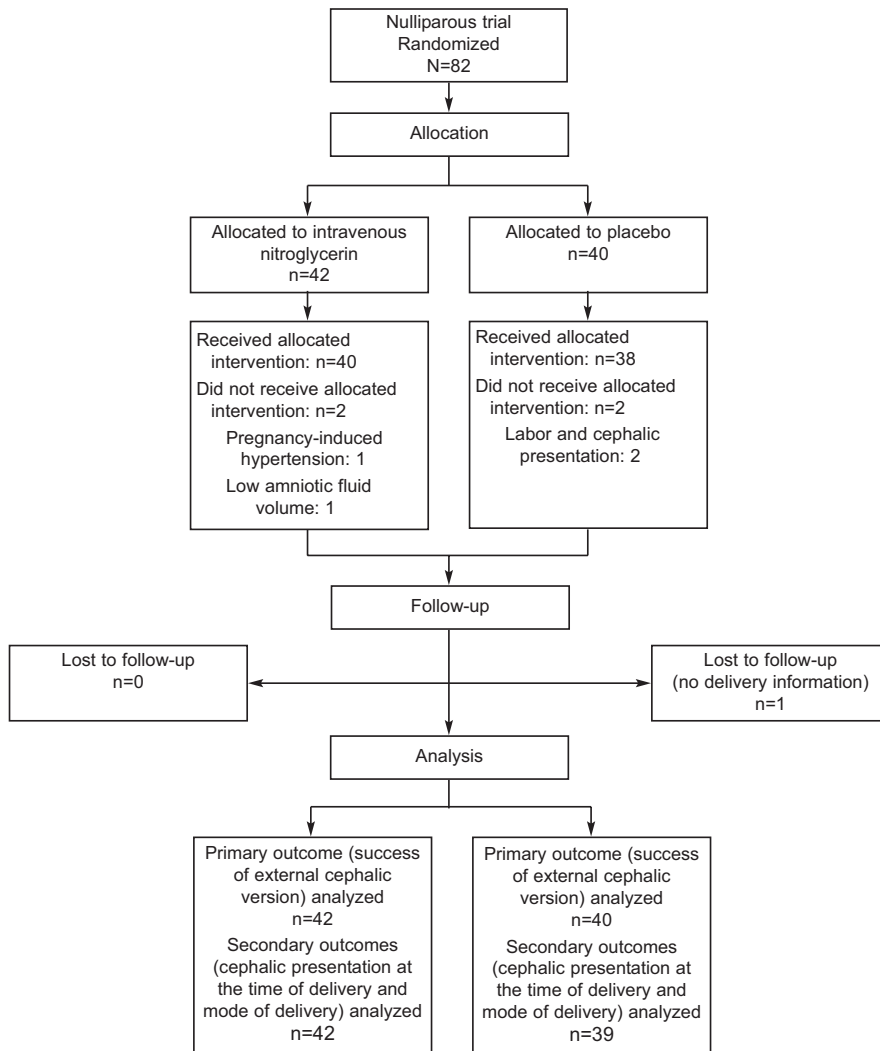


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) diagram of patient flow in the nulliparous trial. Four women in the nulliparous trial did not receive their allocated intervention but were included in the analyses of the primary and secondary outcomes. One woman who was lost to follow-up was included in the analysis of the primary outcome but not in the analysis of the secondary outcomes.

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and $\alpha=0.05$ (80% power), the sample size required was 39 patients per group for the nulliparous trial (total 78) and 20 patients per group for the multiparous trial (total 40). A one-sided analysis was chosen a priori because intravenous nitroglycerin would be introduced into clinical practice only on the basis of benefit over placebo. Recruitment was increased to adjust for some women being randomized but not undergoing an external cephalic version.

Once recruitment was complete, a chart review was performed to determine the final presentation at delivery and the mode of delivery. The treatment groups then were unblinded and data analyzed using SPSS 15.0 (SPSS, Inc., Chicago, IL). Intention-to-treat analysis was planned a priori. Patients who were recruited but did not undergo external cephalic version or treatment are included in the analysis of the primary outcome as unsuccessful external cephalic

versions. The analysis was performed separately for the nulliparous and multiparous trials, except for maternal side effects and complications, where the data were combined for analysis. Odds ratios were calculated with single-sided confidence intervals to describe treatment effect. Statistical significance was assessed with the Mann-Whitney test and Fisher exact test where appropriate.

RESULTS

Between March 2003 and September 2006, a total of 126 patients were recruited—82 in the nulliparous trial (Fig. 1) and 44 in the multiparous trial (Fig. 2). There were seven patients who did not undergo external cephalic version, but their outcomes were included in the analysis. One nulliparous patient in the placebo group was lost to follow-up, and delivery data were not available (Fig. 1).



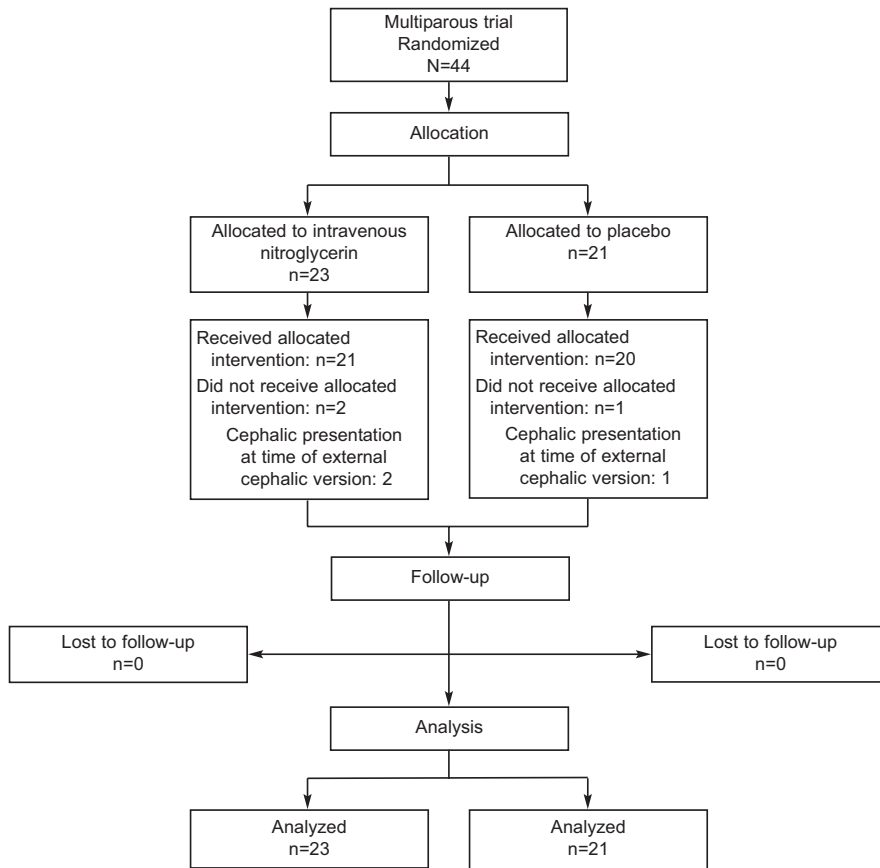


Fig. 2. Consolidated Standards of Reporting Trials (CONSORT) diagram of patient flow in the multiparous trial. Three women in the multiparous trial did not receive their allocated intervention but were included in the analyses of the primary and secondary outcomes.

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Table 1 summarizes the patient characteristics after randomization. Covariates were balanced between the two groups. One fetus presented oblique at the time of external cephalic version. The remainder were breech presentations.

The immediate external cephalic version success rate for nulliparous patients was 10 of 42 (24%) in the nitroglycerin group and 3 of 40 (8%) in the placebo group ($P=.04$, one-sided Fisher exact test, odds ratio 3.85, lower bound 1.22, Table 2). In nulliparous

women at the time of delivery, 12 of 42 (29%) patients who were treated with nitroglycerin had fetuses presenting cephalic and 10 of 42 (24%) went on to deliver vaginally compared with 4 of 39 (10%) and 3 of 39 (8%), respectively, in placebo-treated patients ($P<.05$, one-sided Fisher exact test, Table 2). The number needed to treat with intravenous nitroglycerin during external cephalic version to have one more successful external cephalic version was six (95% confidence interval 3 to 94) in nulliparous patients. Additional data, including number of attempts, amount of treatment given, uterine relaxation, and patient discomfort, are displayed in Table 3. Nulliparous patients in the nitroglycerin group received less treatment, and fewer patients had poor uterine relaxation compared with the placebo group. Nulliparous patients in the nitroglycerin group also had fewer external cephalic version attempts compared with those the placebo group. Maternal discomfort did not differ between the nitroglycerin and placebo groups.

In multiparous patients, the external cephalic version success rate did not differ significantly between the nitroglycerin group and placebo group (10 of 23 [43%] compared with 9 of 21 [43%], $P=.60$,

Table 1. Patient Characteristics

	Nitroglycerin Group	Placebo Group
Nulliparous trial	n=42	n=40
Patient characteristic		
Maternal age (y)	30 (± 5)	29 (± 4)
Gestational age (wk)	37 4/7 (± 5 d)	37 5/7 (± 5 d)
Anterior placenta	17 (41)	13 (33)
Multiparous trial	n=23	n=21
Patient characteristic		
Maternal age (y)	31 (± 5)	32 (± 5)
Gestational age (wk)	37 5/7 (± 5 d)	37 4/7 (± 3 d)
Anterior placenta	5 (22)	5 (24)

Data are mean (\pm standard deviation) or n (%).



Table 2. Outcomes for the Nulliparous Trial

Outcome	Nitroglycerin Group (n=42)	Placebo Group (n=40)	Odds Ratio	Single-Sided	Statistical Significance: One-Sided Fisher Exact Test
ECV success	10/42 (24)	3/40 (8)	3.85	Lower bound 1.22	.04
Cephalic presentation at delivery	12/42 (29)	4/39 (10)*	3.50	Lower bound 1.24	.04
Cesarean delivery rate	32/42 (76)	36/39 (92)*	0.27	Upper bound 0.85	.05

ECV, external cephalic version.

Data are n (%) or 95% confidence interval unless otherwise specified.

* One patient lost to follow-up.

Table 4). In addition, the percentage of patients with fetuses presenting cephalic at delivery and the rate of vaginal delivery did not differ significantly between the nitroglycerin and placebo groups (Table 4). There were fewer external cephalic version attempts and fewer patients with poor uterine relaxation in the nitroglycerin group compared with the placebo group. However, there was no difference between groups in the amount of treatment received (Table 5). In multiparous patients, discomfort during the external cephalic version procedure did not differ significantly between the nitroglycerin and placebo groups (Table 5).

Headache, lightheadedness, and flushing occurred more frequently in the patients treated with nitroglycerin compared with those treated with placebo (Table 6). The incidence of other side effects such as weakness, nausea, palpitations, tachycardia, and bradycardia did not differ between groups. Patients' mean arterial pressures dropped in both the nitroglycerin and placebo groups during the external cephalic version (Table 6). However, the mean difference in mean arterial pressure was greater in the nitroglycerin group (9 mm Hg) compared with the placebo group (4 mm Hg) ($P < .007$). Hypotension requiring resuscitation occurred in eight patients—five in the nitroglycerin group and three in the placebo

group. One patient in the nitroglycerin group required intravenous ephedrine for resuscitation. The remaining patients required an intravenous crystalloid bolus (range 200–1,000 mL). No patient in our study required emergency cesarean delivery for persistent fetal heart rate abnormalities as a result of external cephalic version. However, transient heart rate abnormalities were observed in three patients in the nitroglycerin group and four in the placebo group (Table 6). One patient in the nitroglycerin group started contracting and went into labor after external cephalic version, and one patient in the placebo group had spontaneous rupture of membranes after external cephalic version.

DISCUSSION

No previous placebo-controlled study has examined intravenous nitroglycerin titrated to achieve uterine relaxation during external cephalic version. In our exploratory trial, we found that intravenous nitroglycerin improved external cephalic version success rates in nulliparous patients. Intravenous nitroglycerin use for external cephalic version in nulliparous patients also significantly decreased breech presentations at term and subsequent cesarean delivery rates. In contrast to the results for nulliparous patients, there was

Table 3. Data From External Cephalic Version—Nulliparous Trial

Variable	Nitroglycerin Group (n=40)*	Placebo Group (n=38)*	Statistical Significance
Amount of treatment (mL)	3 (1, 7)	4 (1, 10)	.04 [†]
ECV attempts			<.03 [‡]
2 or fewer	29 (73)	18 (47)	
3 or more	11 (28)	20 (53)	
Patient discomfort			1.00 [‡]
Intolerable discomfort	3 (8)	4 (11)	
None, some, painful	37 (93)	34 (90)	
Uterine relaxation			<.02 [‡]
Excellent	4 (10)	1 (3)	
Poor, reasonable, good	35 (90)	37 (97)	

ECV, external cephalic version.

Data are median (minimum, maximum) or n (%) unless otherwise specified.

* Two patients in each group did not have ECV.

[†] Mann-Whitney test.

[‡] Fisher exact test.



Table 4. Outcomes for the Multiparous Trial

Outcome	Nitroglycerin (n=23)	Placebo (n=21)	Odds Ratio	Single-Sided	Statistical Significance: One-Sided Fisher Exact Test
ECV success	10 (43)	9 (43)	1.03	Lower bound 0.38	.60
Cephalic presentation at delivery	12 (52)	10 (48)	1.20	Lower bound 0.44	.50
Cesarean delivery rate	12 (52)	13 (62)	0.67	Upper bound 1.84	.37

ECV, external cephalic version.

Data are n (%) or 95% confidence interval unless otherwise specified.

no observed improvement in external cephalic version success rates in multiparous patients with intravenous nitroglycerin. In addition, in multiparous patients, there were no significant differences between the nitroglycerin and placebo groups in rates of cephalic presentation at term or cesarean delivery.

The decision to use one-sided statistical tests was made a priori, but we anticipate that some readers will feel that one-sided statistically significant results are not sufficient for them to accept the validity of our findings. We believe that a single, small clinical trial regardless of its results generally should not be enough to change practice; however, our results contribute to the debate about the place of intravenous nitroglycerin in promoting uterine relaxation during external cephalic version.

Two previous randomized controlled trials have examined the use of sublingual nitroglycerin spray compared with placebo for uterine relaxation during external cephalic version, and neither trial showed an improvement in external cephalic version success rates.^{12,13} A trial conducted in patients who failed an initial external cephalic version showed a trend toward improved external cephalic version success rates with sublingual nitroglycerin spray.¹² However, more than 50% of the patients in that study were multiparous, and parity was not considered in the

analysis. A second study compared sublingual nitroglycerin with placebo during external cephalic version in multiparous patients only.¹³ It showed that, in parous women, sublingual nitroglycerin was associated with more side effects and did not improve external cephalic version success rates. These negative results may have been due to inclusion of multiparous patients, mode of delivery of nitroglycerin, lack of titration of nitroglycerin dose, and small sample size.^{12,13}

Intravenous nitroglycerin has advantages over other routes of administration for uterine relaxation during external cephalic version because it has a short duration of action and can be titrated. Our study protocol involved titration of nitroglycerin dose to achieve adequate uterine relaxation and repeat administration in 1-mL to 3-mL increments with unsuccessful external cephalic version attempts. The pharmacokinetics of nitroglycerin contribute to considerable interpatient variability in response, and, therefore, a titration of nitroglycerin to effect may be superior to a standard dose of nitroglycerin. Our data suggest that titration of nitroglycerin is clinically important because the volume of treatment delivered was lower in the nitroglycerin group than in the placebo group and the uterine relaxation was determined to be poor less often in the nitroglycerin group.

Table 5. Data From External Cephalic Version—Multiparous Trial

Variable	Nitroglycerin Group (n=21)*	Placebo Group (n=20)*	Statistical Significance
Amount of treatment (mL)	3 (1, 5)	3 (1, 8)	.26 [†]
ECV attempts			
2 or fewer	18 (86)	12 (60)	<.03 [‡]
3 or more	3 (14)	8 (40)	
Patient discomfort			1.00 [‡]
Intolerable discomfort	0	2 (10)	
None, some, painful	21 (100)	18 (90)	
Uterine relaxation			<.02 [‡]
Excellent	6 (29)	4 (20)	
Poor, reasonable, good	15 (71)	16 (80)	

ECV, external cephalic version.

Data are median (minimum, maximum) or n (%) unless otherwise specified.

* Two patients in the nitroglycerin group and one in the placebo group did not have ECV.

[†] Mann-Whitney test.

[‡] Fisher exact test.



Table 6. Side Effects and Complications—Nulliparous and Multiparous Trials Combined

Side Effect/Complication	Nitroglycerin Group (n=65)	Placebo Group (n=61)	Statistical Significance
Did not have ECV	4	3	
Side effects	n=59*	n=58	
Headache	9 (15)	0	.002†
Weakness	0	2 (3)	.2†
Lightheadedness	12 (20)	4 (7)	.03†
Flushing	12 (20)	4 (7)	.03†
Hypotension	3 (5)	2 (3)	.5†
Tachycardia	4 (7)	0	.06†
Palpitations	1 (2)	2 (3)	.5†
Syncope	0	1 (2)	.5†
Nausea	4 (7)	3 (5)	.5†
Complications	n=61	n=58	
Fetal heart rate abnormality	3 (5)	4 (7)	.5†
Resuscitation	5 (8)	3 (5)	.4†
MAP	n=59‡	n=54‡	
Initial MAP	89 (±10)	90 (±11)	.2§
Lowest MAP	81 (±12)	87 (±12)	.003§
Difference in MAP	9 (±11)	4 (±8)	.007§

ECV, external cephalic version; MAP, mean arterial pressure.

Data are n (%) or mean (±standard deviation) unless otherwise specified.

* Two patients did not have side effects recorded.

† Fisher exact test.

‡ Six patients did not have MAP recorded.

§ Mann-Whitney test.

Other tocolytics such as beta-2 agonists also have been used for external cephalic version. A study evaluating ritodrine did not document an overall increase in successful external cephalic version but found a significant improvement on subgroup analysis of nulliparous patients.⁹

The success rates in our study of 24% and 8% (nitroglycerin compared with placebo) in the nulliparous patients and 44% and 43% in the multiparous patients are lower than published external cephalic version success rates.^{4,6,7,9,12,13} There are several reasons for our lower success rates. Many of the previously published success rates were achieved by preselecting patients for a trial of external cephalic version only if there was mobility of the breech in the pelvis.^{9,12} In our trials, all patients who presented for external cephalic version were considered for eligibility regardless of mobility of the fetus. Prerandomization evaluation of mobility of the breech may have selected out patients who would not tolerate external cephalic version, and this could account for the higher success rates in other studies. In our study, nine women stated the external cephalic version procedure was intolerable, and this may have led to an inadequate trial of external cephalic version. Finally, this study was conducted at three hospitals, and external cephalic versions were performed under 22 different obstetricians with differing levels of experience and skill at performing the procedure. The

heterogeneity of clinicians may have led to a lower success rate than that in trials with dedicated clinicians, but it likely reflects general clinical practice more closely. The success rates in our study were also different from what we expected based on the chart review that provided the bases for our sample-size calculation. This also may reflect the fact that the chart review was from cases of a single obstetrician specializing in external cephalic version.

Although our study was not powered for safety, in our sample, intravenous nitroglycerin titrated to achieve uterine relaxation during external cephalic version produced few adverse events. There were more side effects in the nitroglycerin-treated patients (headache, light-headedness, and flushing), but these were likely short-term and self-limiting because of the short half-life of intravenous nitroglycerin. The incidence of fetal heart rate abnormalities, need for resuscitation, and hypotension episodes did not differ between the nitroglycerin and placebo groups.

We believe that the results of this study are encouraging for the use of intravenous nitroglycerin to improve external cephalic version success rates in nulliparous patients. By decreasing cesarean delivery rates in nulliparous women, it will affect not only the morbidity associated with the first delivery, but also morbidity associated with future pregnancies.



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