ORIGINAL ARTICLE

EARLY VERSUS LATE ECV IN PRIMIGRAVIDAE WITH BREECH PRESENTATION: A PILOT STUDY

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ABSTRACT

This was a pilot study comparing the success between early versus late external cephalic version (ECV) involving primigravidae with singleton breech pregnancy. They were randomised into early (34-36 weeks) and late (37-40 weeks) ECV groups. A total of 44 women were initially randomised into 22 women for each group. The overall ECV success rate was acceptable in both groups although insignificantly higher in the late ECV group (55.6% versus 46.7%, p= 0.732.) Caesarean section in the early ECV group was higher (80% versus 72.2%). Early ECV group had women with higher BMI (29.5 versus 26.8 kg/m^2, p=0.107), anterior placentation (60% versus 38.9%) and extended breech presentation (55.6% versus 44.4%; p= 0.296). In conclusion, early ECV in primigravidae showed no better success rate than late ECV. Maternal obesity, anterior placentation and extended breech presentation should alert to failure risk.

***Key words**: Tocolysis, breech, external cephalic version.*

INTRODUCTION

The planned Caesarean section (CS) rate for singleton breech presentation at term has increased[1,2] since recommendation by the Term Breech Trial in the year 2000[3] in an effort to reduce the risk of perinatal mortality and morbidity (1.6% in planned CS versus 5.0% in vaginal breech delivery: RR 0.33, 95% CI 0.19-0:56). Since then ECV as the alternative for Caesarean section has been strongly advocated[4] in the attempt to reduce problems with uterine scar. Caesarean section is not without risks in which studies[5,6] had shown increased mortality and morbidity risks compared to vaginal delivery. The RCOG guidelines[7] had recommended ECV and it is to be offered to all women with breech presentation at term.

Although studies[8] had proven that successful ECV at term reduces the incidence of non cephalic presentation at birth and reduces the Caesarean section rate for breech presentation, this procedure in not always successful. Many adjustment and modification have been made to the basic procedure in order to make ECV successful. The use of routine tocolytics has been proven to increase the likelihood of the success[8,9]. Other measures like volume expansion and the use of analgesia may be of value in reducing the failure rate[8].

Factors that could also possibly contribute to failure of ECV were studied, among those including nulliparity. However, it is also observed that spontaneous version rates for these women after 36 weeks is as low as 8%[10]. This is explained by the reduced intrauterine space with minimal laxity of the uterus and earlier fetal engagement. In view of this finding, the timing of ECV had been revised to before term in order to make the procedure more successful. The rate of non-cephalic presentation at birth and Caesarean section were seen to be reduced in studies[11,12] among women of all parities where ECVs were done before term. The aim of this current study was to determine the success rate of early compared to late ECV. In order to reduce confounding factors, the study focused only on primigravidae.

MATERIALS AND METHODS

This was a prospective randomised controlled trial conducted over a period of 12 months from August 2009 to July 2010. All primigravidae attending the antenatal clinic with live singleton fetus in breech presentation were invited to join the study. Ultrasound scans were performed to provide information on fetal presentation, identification of type of breech, location of placenta, an estimated fetal weight and estimated of amniotic fluid volume and identification of any fetal anomalies. Women with oligohydromnios (AFI less than 10),

macrosomia (EFW 3.8 kg or more), presence of contraindication for vaginal delivery (for example placenta praevia), severe hypertension in pregnancy, fetal anomaly and contraindication to tocolysis were excluded from the study. Eligible and consenting women were provided with an explanation regarding the study. Randomisation to either early or late ECV by using computer generated numbered sealed opaque envelopes was done at 34 weeks. The women were asked to take one number generated by computer randomisation which in one sealed envelope revealed either early or late ECV instruction. Neither the doctors nor the patients were 'blinded' to the ECV group instruction as they needed to know at what gestation the procedure was going to be performed.

In the early ECV group, the ECV was performed between 34 weeks to 36 weeks and 6 days of gestation. On the other hand, the late ECV group had ECV performed after 37 weeks gestation. A written consent, blood investigations for full blood count and blood group and Rhesus were taken earlier. The patient was fasted overnight prior to the appointment. The external cephalic version was performed as an outpatient clinic procedure. Immediately prior to ECV, the women were reassessed to ensure eligibility for the ECV. The fetal presentation was reconfirmed by ultrasound scan and fetal well being was assessed by continuous fetal heart rate cardiotocograph monitoring for 20 minutes. Tocolysis with Terbutaline Sulphate (®Bricanyl, LBS lab, Thailand) was given as a slow intravenous bolus of 50 µg prior to the maneuver according to the departmental protocol.

External cephalic version was attempted 20 minutes after medication was given and it was carried out within five minutes to a maximum of three attempts. The ECV would be abandoned if undue force was required, the maximum attempts or time had exceeded, or the women became distressed. The backward flip and forward roll techniques were the method of choice. After the procedure, an ultrasound scan was repeated to confirm the presentation and CTG was performed for a further 20 minutes. Women who were Rhesus negative were given anti-D immunoglobulin after the ECV. Those with pathological or suspicious CTG would have an emergency caesarean section (CS).

In the early ECV group, provided fetal heart monitoring was normal, whether the ECV was successful or not, the patient would be given an appointment in one week's time to reassess fetal presentation. The patient was then managed by her own team until delivery. In the late ECV group, those who had successful ECV were given appointments to return in one week's time for re-assessment of presentation. Those with unsuccessful ECV were given dates for elective CS in the team's next operation list. Those who wished for vaginal breech delivery had further assessment of suitability for vaginal breech delivery would be done by the managing team.

All data including maternal demography (maternal age, parity,), gestation at ECV, ultrasound assessments of type of breech, position of placenta, amniotic fluid index, fetal parameters together with maternal, fetal and neonatal outcomes were collected in an electronic database and analyzed using SPSS Version 12.0. The success rates between the groups were compared. With an alpha error of 0.05 and a beta of 0.2, 44 patients were recruited. Fisher exact test was used for categorical data. The Mann-Whitney U test was used for continuous variables that were not normally distributed. A p value < 0.05 is considered to be statistically significant. This study was approved by the Institutional Ethics and Research Board.

RESULTS

A total of 44 primigravidae were recruited into the study and 22 women were randomised into each group. In the early ECV group only 15 women actually had the ECV performed. Four women were lost to follow up, two had spontaneous version to cephalic presentation and one patient was in labour when the ECV was to be performed. Similarly from the late ECV group, 2 patients had spontaneous version and another two women were lost to follow up, leaving 18 patients who finally had ECV procedure done (Figure 1). The maternal demographic data in both groups were similarly with no statistically significant features. Maternal weight was heavier in the early ECV group compared to the late ECV group but was not statistically significant (Table 1). Therefore the early ECV group women had higher Body Mass Index (BMI) compared to the women in late ECV group (29.5 in early group versus 26.8 in late group ($p=0.107$).

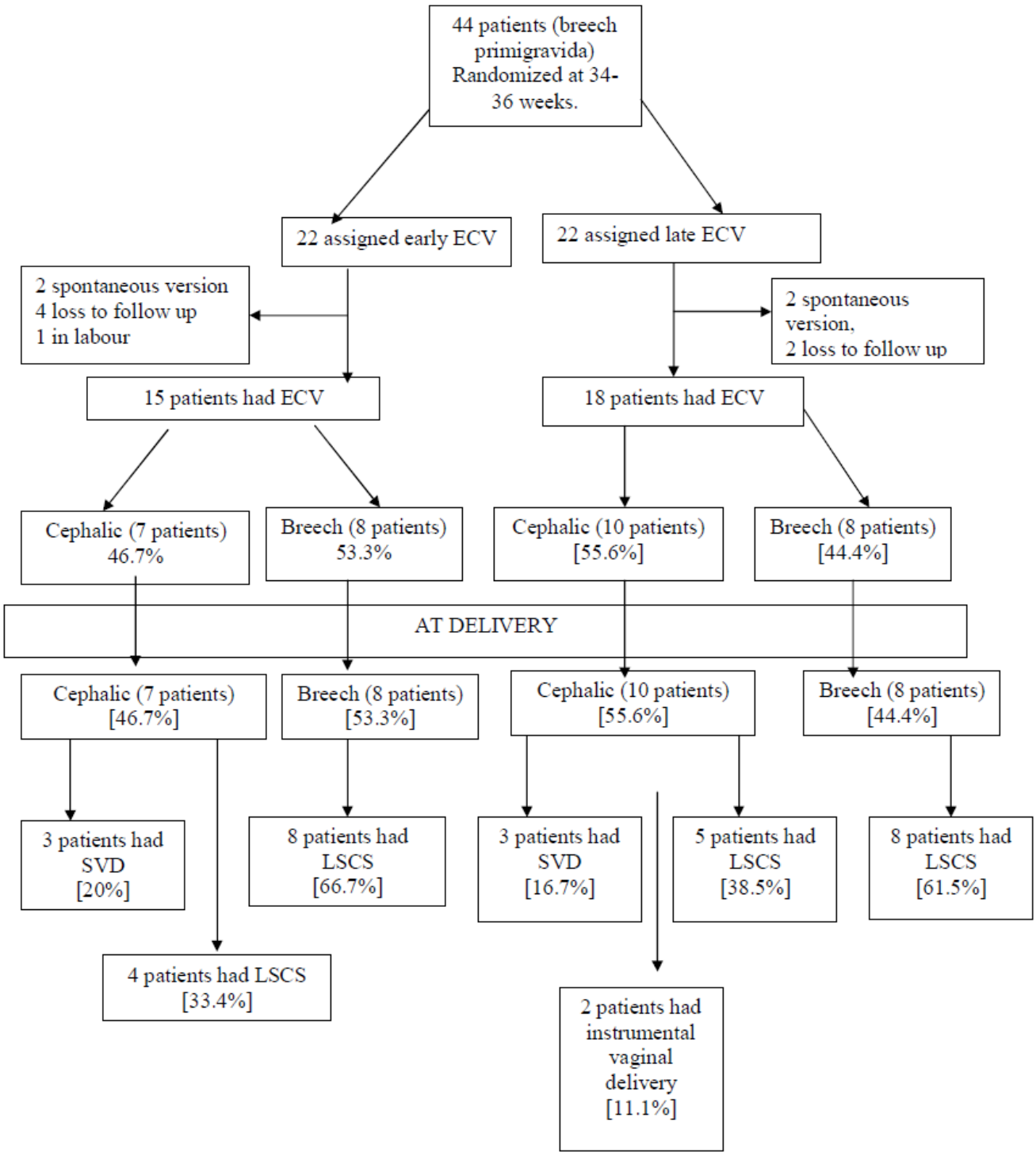

Figure 1. Overall study outcomes

Table 1. Baseline characteristics of women in early and late ECV groups

Characteristics	Early ECV n = 15 (%) median (IQR)	Late ECV n = 18 (%) median (IQR)	p -value*
Maternal age	28 (26,30)	28.5 (19.9, 29.3)	0.985
Maternal height m	1.61 (1.52,1.63)	1.57 (1.49,1.61)	0.638
Maternal weight kg	74 (67.5,82)	66.7 (61,75.6)	0.07
BMI kg/m^2	29.5 (26.8,31.2)	26.8 (24.7,29.5)	0.107

* Mann-Whitney U test.

In the analysis of ECV process and fetal characteristics, early ECV was performed at median gestational age of 36.2 weeks whilst late ECV was performed at 37.6 weeks. More unfavorable features contributing towards failure of ECV were seen in the early ECV group compared to the late ECV group albeit statistically insignificant. These include the preponderance of extended breeches (55.6% versus 44.4%), anterior placentation (60.0% versus 38.9%) and maternal discomfort (3 mothers versus 1 mother) in the early ECV group compared to the late ECV group. On the other hand the late ECV group had more favorable features for ECV success, such as flexed breech (66.7% late group versus 33.3% in early ECV) and posterior placentation (61.1% in late group versus 40.0% in the early group.) Favorable features that were seen more predominant in the early group were higher amniotic fluid index and non-engaged breeches as compared to the late ECV group (Table 2) however they were statistically not significant.

Table 2. Description of ECV procedure and characteristics of women and fetuses at the time of ECV

ECV procedures description		Early ECV n =15 (%) median (IQR)	Late ECV n =18 (%) median (IQR)	p-value*
Gestational age at ECV		36.2 (35.9, 36.5)	37.6 (37,38.3)	0.00001
Types of breech	Flexed	5 (33.3)	10(66.7)	0.296
	Extended	10 (55.6)	8 (44.4)	
	Footling	0 (0)	0(0)	
Placenta location	Anterior	9 (60)	7 (38.9)	
	Posterior	6 (40)	11(61.1)	
	Fundal	0	0	
Amniotic fluid index cm		15 (13,15.3)	13 (12.2,15)	0.224
Station of presenting	Floating	9 (60)	5 (27.7)	0.085
part at the time of ECV	Engaged	6 (40)	13 (72.3)	
Estimated fetal weight (gram)		2597 (2440, 3100)	2964 (2640, 3143)	0.278
Reasons for prematurely discontinuing ECV procedure	Maternal discomfort	3	1	
	Non-reassuring fetal heart	0	0	
Presentation fetus after ECV procedure	Cephalic	7 (46.7)	10 (55.6)	0.732
	Breech	8 (53.3)	8 (44.4)	

The overall success of ECV in both groups was acceptable with the late ECV group showed higher ECV success rate, although the difference was statistically not significant (55.6% versus 46.7% in early ECV; p=0.732). All the fetuses remained in the same presentation after successful ECV and at birth with no spontaneous version or reversion in both groups. There was no significant neonatal finding (Table 3). One baby from the late ECV group was admitted to NICU for observation of hypothermia. No maternal complications (spontaneous rupture of membranes, preterm contractions or placental abruption) and no fetal complications (fetal heart rate abnormality or death) either were seen in the study.

Table 3. Neonatal outcomes

Outcome	Early ECV n = 15 (%)	Late ECV n = 18 (%)	p value
Birth weight	2.93 (2.87, 3.5)	3.08 (2.86,3.25)	0.842
Cord pH	7.312 (7.23,7.34)	7.271 (7.180, 7.324)	0.06
Sex of the baby			
Boy	7 (46.7)	10 (55.6)	0.732
Girl	8 (53.3)	8 (44.4)	
Apgar score at 5 minutes < 7	0	0	
Admission to NICU	0	1	
Serious fetal complications	0	0	

The early group had younger gestational age at delivery, with more (53.3% versus 44.4%) non cephalic presentation at birth. It was also seen that relatively more Caesarean section in the early group (80.0% versus 72.2%) and only 3/7 (42.9%) women who had successful ECV in early group compared to 5/10 (50%) in the late group had successful vaginal delivery (Table 4). Overall assessment of features that favor successful ECV showed significantly less anterior placentation (25% in successful versus 75% in unsuccessful; p=0.05), less engagement of breech (p=0.013) and smaller fetuses (p=0.017) (see Table 5) in the group.

Table 4. Characteristics and outcomes of pregnancy and birth

Characteristics or outcomes		Early ECV median (IQR)	Late ECV median (IQR)	P value
Gestational age of delivery		38 (37.8, 40)	39.5 (38, 40.6)	0.057
Presentation at delivery	Cephalic	7 (46.7%)	10 (55.6)	0.732
	Breech	8 (53.3%)	8 (44.4)	
		12 (80%)	13 (72.2%)	
Reasons for LSCS	Prelabour C-section	8 (66.7%	8 (61.5%)	
	Failure to progress	4 (33.4%)	3 (23.1%)	
	Fetal distress	0	2 (15.4%)	
Vaginal birth	Cephalic spontaneous vaginal birth	3 (20%)	3 (16.7%)	
	Cephalic operative vaginal birth	0	2 (11.1%)	
	Breech delivery	0	0	

Table 5. Factors that influenced the successful of ECV

Variable		Successful	Unsuccessful	Z score	p-value
Maternal age		29 (26.5,30.5)	28 (24.2, 29)	-1.018	0.309
Race	Malay	10 (45.5%)	12 (54.5%)		0.465
	Others	7 (63.6%)	4 (36.4%)		
Maternal height m		1.58(1.55, 1.62)	1.58 (1.51,1.62)	-0.560	0.576
Maternal weight		72 (64,80.5)	70 (64, 80.5)	-0.342	0.732
BMI kg/m^2		27.7 (25.1, 30.6)	27.9 (24.8,31)	-0.090	0.928
Types of breech	Flexed	10 (66.7%)	5 (33.3%)		0.166
	Extended	7 (38.9%)	11 (61.1%)		
Placenta location	Anterior	4(25%)	12(75%)		0.05
	Posterior	13(76.5%)	4 (23.5%)		
Amniotic fluid index cm		15 (13,15.6)	13.1(11.4, 15)	- 1.9	0.057
Station of presenting part at the time of ECV	Floating	11 (78.6%)	3 (21.4%)		0.013
	Engaged	6 (31.65)	13 (68.4)		
Birth weight		3.25 (2.88,3.52)	2.87 (2.83,3.13)	- 2.38	0.017
Sex of the baby	Boy	9 (52.9%)	8 (47.1%)		1.00
	Girl	8 (50%)	8 (50%)		

DISCUSSION

The factors favoring success of ECV have been identified by various studies[13,14]. Among these are multiparae, non-engagement of the presenting part and a more spacious uterus for the breech to be turned into cephalic presentation. In this study the primigravid status probably worked towards detriment of the success as a result of earlier engagement of the presentation part and less laxity of the uterus compared to the multiparae. Thus, the current study only focused on primigravidae.

The rationale for ECV to be performed at term[15,16] has been the fact that less spontaneous version or reversion would happen during later gestation (at term) and a mature fetus can be delivered should any complications arise during ECV which requires emergency delivery. However to minimize these concerns, in this study the ECV was performed at of 34 weeks POA the earliest, when lung maturity is reasonable and survival rate is more than 95% should emergency delivery be required .

It was postulated that ECV success would be more likely in the early group as the presenting part was less likely to be engaged and it was easier for the breech to be dislodged during the procedure. The fetus also would have more space to be turned into cephalic presentation. However, in actual fact this was not seen to be the result of this current study. The success rate of ECV in the early group was lower than the late group which was in contrast to the outcome of previous studies[17,18]. Several factors may have contributed to this unexpected outcome. It is interesting to note that women in the early ECV group had higher BMI[19] (Table 1), more anterior placentation and more fetuses in extended breech presentation compared to the late ECV group (Table 2). These differences although not statistically significant between the two groups, may have contributed to the similar success rates. These factors were identified in previous studies[13,14] to increase the likelihood of ECV failure.

In this study women with non-cephalic presentation at birth were the same as after the ECV was

performed as there was no spontaneous reversion or conversion even in the early ECV group, which is in contrast to other studies[17,18]. This is probably explained by relatively reduced uterine laxity as all these women were primigravidae. Although the non engagement and relatively higher AFI were seen in the early ECV group, these did not seem to help secure ECV success. This was also true albeit non-engagement was statistically significant factor for ECV success as seen in overall success group (Table 5), and was also described by other studies[13,14] .The gender of the offsprings did not influence the success of ECV (Table 3), as was also previously[12,18] seen.

Similarly this study also showed that there was no reduction in the rate of CS (Table 4) as previously shown by larger sample size studies[18,20.] Tendencies of smaller babies in the early ECV group at delivery probably has no association to the failure of ECV as other studies had not shown any significant finding of the success with the babies weight[18]. The overall limitation to this current study is however related to its small sample size that could not eliminate possible biases as the number of women were not enough to equate each possible factor in each group like weight or placental site as it was difficult to recruit just primigravidae with breech presentation as they were not many, thus this pilot study warrant a future larger scale looking at ECV done only in the primigravidae.

CONCLUSION

ECV in primigravidae performed at 34 to 36 weeks did not result in a better success rate compared to those performed after 36 weeks. Maternal obesity, anterior placental location and extended breech presentation were all recognised contributory factors to the failure of ECV.

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