A PROSPECTIVE RANDOMISED CONTROLLED TRIAL OF EXTERNAL CEPHALIC VERSION COMPARING TWO METHODS OF UTERINE TOCOLYSIS WITH A NON-TOCOLYSIS GROUP

G W T Tan, S W Jen, S L Tan, Y M Salmon

ABSTRACT

The use of tocolytic agents to enhance uterine relaxation and facilitate external cephalic version (ECV) has come under recent debate. We studied 90 breech presentations in late pregnancy who did not have contra-indications to ECV. The patients were randomised into 3 groups of 30 patients each: one was administered oral salbutamol 4mg t.d.s.; another had intravenous salbutamol infused until the maternal heart rate rose above 100 bpm for 30 mins; and the last served as a control group. All patients in each group were matched for parity and gestation, and each had an intravenous line, thereby masking the treatment group from the 2 doctors who performed half the number of ECVs each. There was no significant difference in the success of ECV between the treatment and control groups (46.6% vs 50.0% vs 46.6%). The gestational age, the placental site, the attitude of the breech, the abdominal girth, and the maternal weight and fetal birth weights did not seem to influence results. On the other hand, there was a significant difference in successful ECV between nullipara (26%) and multipara (75%) ($p < 0.001$). There were no cases of abruptio placenta or foetal distress, and one patient entered labour one day after the ECV at 39 weeks gestation. There were 2 cases of spontaneous version after failed ECV, and one case of spontaneous reversion to breech after successful ECV. We conclude that the use of salbutamol does not increase the incidence of successful ECV, but multiparity predicts for a successful outcome.

Key Words: External Cephalic Version, Breech, Iocolysis Salbutamol.

SING MED J. 1989; No 30: 155 – 158

INTRODUCTION

It is well established that the delivery of a breech presentation involves a greater risk to the fetus than that of a cephalic presentation. The perinatal mortality rate is higher for vaginal breech deliveries as compared with their cephalic counterparts, and the incidence of mental and motor retardation is also higher amongst the former group. In view of the increased risk to the fetus, prophylactic external cephalic version has been suggested to convert a breech to a less dangerous cephalic presentation before labour commences. This procedure has its origins steeped in history, and Aristotle stated that many midwives in his time were advised when confronted with a breech presentation "to change the figure and place the head so that it may present at birth". However, although many authors favour this procedure, the dispute whether ECV really reduces the incidence of breeches at term and the known complications of ECV like premature labour, abruptio placentae, feto-maternal haemorrhage, cord entanglement and even fetal death (1, 2), have discouraged many from the procedure. In recent years, there has been renewed interest in the procedure when recent studies using tocolysis to relax the uterus in late pregnancy suggest that ECV reduces the incidence of breech presentations at term with few untoward maternal or fetal complications (3, 4, 5). These studies, however, did not have a control group where ECV was performed without tocolysis, and we felt that a study comparing ECV with and without tocolysis was needed in order to clearly establish the advantage of ECV done under tocolysis. We therefore set out to design just such a prospective randomised trial. We limited the number of doctors performing the ECV to two, Prof. Salmon and Dr. Jen to reduce the variability of success, and took measures to ensure that these doctors did not know the treatment groups of the patients in order that such knowledge might prejudice their performance. The use of oral salbutamol was also compared, since its use would be simpler, more convenient to staff and less daunting to the patient.

B Unit
Kandang Kerbau Hospital
Hampshire Road
Singapore 0821

G W T Tan, M Med, MRCOG, Registrar
S W Jen, M Med, MRCOG, Registrar
S L Tan, M Med, MRCOG, Senior Registrar
Y M Salmon, FRCOG, Senior Adviser and Consultant

Correspondence to: Dr G W T Tan

MATERIAL & METHODS

Ninety patients with breech presentations beyond 33 weeks' gestation who were confirmed on ultrasound examination and who did not have contra-indications to ECV (see Table 1) were recruited into the study. The patients were randomised into 3 groups of 30 patients each: Group 1 was administered oral salbutamol 4mg t.d.s. for at least one day; Group 2 had intravenous salbutamol infused until the maternal heart rate rose above 100 bpm for 30 mins; and Group 3 served as the controls. All patients in each group were matched for parity (nullipara vs multipara) and gestation (< weeks of Gestation 'A' vs > = 36 weeks of Gestation 'B') (see Table 2), as it was anticipated that these parameters may influence the success. Based on a preliminary study on the parity and the gestation of breech presentations at diagnosis, it was decided to select 50 nullipara and 40 multipara patients with gestational age divided in a 30% 'A' : 70% 'B' ratio. In practice there were 2 stacks of randomised cards divided according to parity, with each stack further sub-divided by a colour code for either Gestation A or B patients (Table 2).

Groups 1 and 3 were disguised with a dummy intravenous line, thereby masking the treatment group from the 2 doctors who performed the ECVs. Morever, information such as parity, gestational age or fetal attitude were not made known to these doctors. Before the ECV, antenatal cardiotocography was performed to ensure a normal fetal heart rate, informed consent obtained, contra-indications to ECV rechecked and the foot of the bed was elevated to facilitate disengagement of the breech. The ECV was performed in the direction of shorter rotation first, with the other direction attempted if the first failed. No anaesthesia nor tranquilizers were used. The fetal condition was monitored at least once during the procedure by fetal heart auscultation. The manipulation was stopped if fetal distress was suspected or the mother was in pain. After the procedure, the timing was recorded and cardiotocography repeated to ensure fetal well-being. The mother was kept in bed for at least 4 hours after the procedure and only allowed home if there were no complications.

TABLE 1
CONTRA-INDICATIONS TO ECV

Signs of growth retardation
Vaginal bleeding in third trimester
Toxemia of pregnancy
Patient in labour
Polyhydramnios
Placenta praevia
Previous Caesarean scar
Contracted pelvis
Fetal malformation
Uterine malformation

RESULTS

GENERAL DEMOGRAPHIC STATISTICS

The mean age was 26.2 + 8.9 years (range 20 — 36 years). Fifty were nullipara, while 40 were multipara (range 1 — 4/mode 1). The racial mix was 71% Chinese, 20% Malay and 9% Indian, closely corresponding to the racial milieu of our country. 30% of the fetuses were less than 36 gestational weeks, with 70% at 36 weeks or more; all being evenly distributed between the 3 groups. The mean gestation at diagnosis was 34.3 + 3.2 weeks (range 25 — 41 weeks) while the mean gestation at ECV was 36.4 + 1.8 weeks (range 33 — 42 weeks). The mean birth weight was 3122 + 438 gm. The mean maternal weight and abdominal girth at ECV was 60.2 + 8.8 kg and 94.3 + 7.4 cm respectively.

ULTRASOUND FINDINGS

The fetal attitude was extended in 57%, flexed in 40% and footling in 3%. The placenta was evenly distributed between the lateral (26%), anterior (30%) and posterior (22%) locations. Only 22% of the placentas were fundal. There were no abnormalities of the fetus, placenta, liquor or uterus as these would have excluded the patient from the study.

OUTCOME OF ECV

Out of a total of 90 patients, ECV was successful in 43, giving an overall success rate of 47.7%. Comparing the success rate of ECV between the various groups (Table 3), it can be seen that there were no significant differences between the treatment and control groups (47% vs 50% vs 47%).

TABLE 3
OUTCOME OF EXT. LEPHALIC VERSION

	SUCCESS (nullip/multip)	FAILURE (nullip/multip)
Control (N = 30)	14 (4/10) 47%	16 (13/3) 53%
IV Salbutamol (N = 30)	15 (5/10) 50%	15 (12/3) 50%
Oral Salbutamol (N = 30)	14 (4/10) 47%	16 (12/4) 53%

Comparing the success and failure groups (Table 4), it can be seen that the parameter which significantly affected success was parity. ECV was successful in 75% of multipara compared to 26% of nullipara patients. Comparing success with gestational age and fetal attitude, ECV was successful in 63% of gestation < 36 weeks compared to 41% of gestation > = 36 weeks, while there were more flexed breech presentations in the failed ECV group. These results, however, were not statistically significant. The even distribution of success and failure in relation to gestation becomes more obvious in Table 5 where results are divided according to gestation. Characteristics

TABLE 2
DISTRIBUTION OF PATIENTS

	Nullipara	Multipara	Gestation A < 36 weeks	Gestation B > = 36 weeks
Oral Salbutamol (N = 30) Group 1	16	14	9	21
IV Salbutamol (N = 30) Group 2	17	13	9	21
Control (N = 30) Group 3	17	13	9	21
Total (N = 90)	50	40	27	63

like the placental site, abdominal girth, maternal weight and fetal birth weights were evenly distributed in both groups, implying that these factors did not seem to influence results. The mean duration for the ECV was 8.3 + 5.1 mins. When the ECV was a failure, the time taken for ECV was significantly longer (10.5 + 4.9 vs 5.6 + 3.9 mins — $p < 0.001$), and the onset of labour was also significantly earlier (17.6 + 9.8 vs 25.2 + 14.9 days — $0.02 < p < 0.05$), implying that the longer manupilation hastened the onset of labour.

COMPLICATIONS

Premature labour was not found to be a problem, as we only encountered one patient going into labour one day after the ECV at 39 weeks gestation. The average onset of labour after ECV was 21.0 + 12.9 days. There was transient bradycardia in 8 patients (fetal heart rate between 100 — 120 bpm and lasting less than 60 seconds) during the ECV, but which improved spontaneously and bore no apparent relationship to treatment group or fetal outcome. There were no cases of abruptio placenta or foetal distress as evident from the normal cardiotocography after every ECV. There were 17 cases of meconium staining in labour, 14 light, 2 moderate and 1 thick. These were evenly distributed between the groups. The mean Apgar scores were 8.85 + 0.37 at 1 min. and 9.11 + 0.32 at 5 mins.

FINDINGS IN LABOUR

There were 2 cases spontaneous version to head after failed ECV, and conversely, there was one case of spontaneous reversion to breech after successful ECV. At labour, 44 were found to have a cephalic presentation, and of these, only 2 required a Caesarean section (5%); compared to 46 breech presentations in labour, with 29 Caesarean deliveries (63%) and 17 assisted breech deliveries (37%). When the presentation in labour was breech, the 1 min Apgar score was significantly different than when it was cephalic (7.56 + 1.59 vs 8.85 + 0.37 $p < 0.001$).

DISCUSSION

External cephalic version is a procedure performed to minimize the risks of vaginal breech delivery. It is not an entirely innocuous procedure, hence clinicians hold dif-

TABLE 4
COMPARISON OF CHARACTERISTICS BETWEEN SUCCESSFUL AND FAILED ECV GROUPS

	WHOLE GROUP (N = 90)	SUCCESSFUL ECV (N = 43)	FAILED ECV (N = 47)	SIGNIFICANCE
Age	26.2 ± 8.9 yrs	28.3 ± 7.2	25.5 ± 9.8	N.S.
Nullipara	50	13	37	$p < 0.01$
Multipara	40	30	10	$p < 0.01$
Gestation A < 36 weeks	27	17	10	
Gestation B > = 36 weeks	63	26	36	
Maternal weight (kg)	60.2 ± 8.8	60.4 ± 8.3	60.0 ± 9.4	N.S.
Abdominal girth (cm)	94.3 ± 7.4	94.6 ± 6.4	94.0 ± 8.2	N.S.
Maternal height (cm)	153.9 ± 4.9	154.1 ± 4.8	153.7 ± 4.9	N.S.
Birth weight (gm)	3122 ± 438	3196 ± 472	3063 ± 406	N.S.
Gestation at diagnosis (wks)	34.3 ± 3.2	34.0 ± 2.8	34.5 ± 3.5	N.S.
Gestation at ECV (wks)	36.4 ± 1.8	36.1 ± 1.7	36.6 ± 1.9	N.S.
Onset of labour after ECV (days)	21.0 ± 12.9	25.2 ± 14.9	17.6 ± 9.8	0.02
Duration of ECV (mins	8.34 ± 5.10	5.65 ± 3.92	10.45 ± 4.9	$p < 0.01$
Meconium staining in labour	14 LMS 2 MMS 1 TMS	8 LMS 1 MMS	6 LMS 1 MMS 1 TMS	N.S.

TABLE 5
SUCCESS ACCORDING TO GESTATIONAL AGE

GESTATION (weeks)	SUCCESS	FAILURE
33	3	2
34	6	5
35	8	3
36	8	10
37	5	13
38	10	7
39	2	2
40	1	2
> 40	0	2

fering views on the subject. Some do not advocate version at all, believing that if successful, the procedure was unnecessary (6) and that spontaneous version would have taken place. However, between the two British Perinatal Death Surveys (1958 and 1970), when external version was unfashionable, the incidence of breech presentation in Britain increased by 17% (7). Also, a policy of external cephalic version was shown to reduce the incidence of breech presentations by a third (8).

The question of version under anaesthesia is also open to debate. Hay believes that this practice is hazardous (9) whereas Friedman (10) and Bonnar (11), proponents of version under general anaesthesia reported 500 versions under anaesthesia with success in 250 of the patients. However, these authors had a fetal loss due to version of 1.6%. In our study, no anaesthesia was used and there was no fetal loss.

External cephalic version performed at 34 weeks of gestation had the additional hazard of fetal prematurity should complications develop necessitating immediate delivery. That performed later in pregnancy avoided this risk but required tocolysis to offset the effects of an irritable uterus closer to term. Our study showed a 47.7% overall success rate of version with no significant difference between the 3 study groups. However, Fall and Nilsson using terbutaline infusion later in pregnancy reported a 70% success rate (12).

Our study showed that the success rate with external cephalic version was greater in the multiparous patient. This was also reported by White (13) who claimed success rates with external cephalic version of 70 and 88% for primips and multips respectively.

The purpose of this study was to assess objectively the value of tocolysis in the performance of external cephalic version by blinded operators. Uterine relaxation with salbutamol, either oral or intravenous, was not found to be useful for external cephalic version. The procedure was found to be safe, beneficial and successful especially if multiparous patients were involved. There should be careful selection of patients, the factors should be gently "persuaded" around, with no force being used.

ACKNOWLEDGEMENT

We would like to thank Assoc. Prof R.L. Tambyraja and Prof S.S. Ratnam of the U Unit, Kandang Kebau Hospital, for their advice and assistance for this project.

REFERENCES

1. Kasule J, Chimbira TH, Brown IM Controlled trial of external cephalic version. Br J Obstet Gynaecol 1985 Jan; 92 (1): 14-8.
2. Berg D, Kunze U. Critical remarks on external cephalic version under tocolysis. Report on a case of antepartum fetal death. J Perinat Med 1977; 5 (1): 32-8.
3. Van Dorsten JP, Schifrin BS, Wallace RL. Randomized controlled trial of external cephalic version with tocolysis in late pregnancy. Am J Obstet Gynaecol 1981; 141: 417-24.
4. Stine LE et al. Update on external cephalic version performed at term. Obstet Gynaecol 1985 May; 65 (5): 642-6
5. Wallace RL et al. External cephalic version with tocolysis. Observations and continuing experience at the Los Angeles County/University of Southern California Medical Centre. J Reprod Med 1984 Oct; 29 (10): 745-8.
6. Hay D. Observations on breech presentation and delivery. J Obstet Gynaecol Br Emp 1959; 66: 529-47.
7. Myerscough PR. Munro Kerr's Operative Obstetrics. 10th Edition. Balliere Tindall p75.
8. Bock J. The influence of prophylactic external cephalic version on the incidence of breech deliveries. Acta Obstet Gynaecol Scand 1969; 48: 215-21.
9. Hay D. Observations on breech presentations and delivery. J Obstet Gyneacol Br Emp 1959; 66: 529-47.
10. Friedman. The use of general anaesthesia in external cephalic versions. Am J Obstet Gynaecol 1966; 95: 906-16.
11. Bonnar J et al. External cephalic version with anaesthesia. J Am Med Assn 1968; 205: 97-101.
12. Fall O, Nilsson BA. External cephalic version in breech presentation under tocolysis. Obstet Gynaecol 1979; 53: 5.
13. White AJ. Spontaneous cephalic version in later weeks of pregnancy and its significance in the management of breech presentation. J Obstet Gynaecol Br Emp 1956; 63: 706-13.

4. **Fifteen year old Secondary 4 school children** —
The Mantoux Test is done routinely for all in this group of children as for Primary 6 students.

5. **Age 0 to 19 years who are contacts of tuberculosis patients** —
The Mantoux test is done as a routine procedure in this age group as part of our contact examination.

6. **All tuberculosis patients treated in our department** —
A routine Mantoux test was done for all tuberculosis patients registered for treatment in our department between 1983 and 1985. Only those bacteriologically confirmed patients are included in the analysis. The number of confirmed cases below 15 years of age was too small for analysis.

Although a tuberculin reaction of 10 mm is usually considered as a positive reaction, our studies have shown that we have an intermediate group of reactors of 5 mm to 10 mm where the curves for the negative and positive reactors overlap. A reaction size of 8 mm and above was therefore taken as positive.

RESULTS

Tuberculin Reaction among Normal Subjects —
Figure 1 shows the post-vaccination tuberculin reaction in 6-month old babies born in 1979. 42% of the babies were positive reactors of 8 mm and above, and the overall mean reaction size was 5.89 mm. A few other studies done in subsequent years gave very similar results.

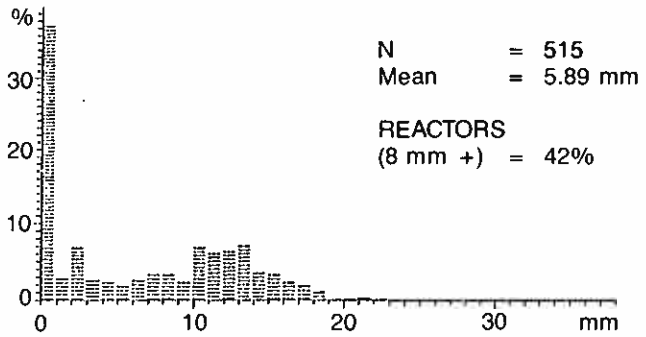

FIGURE 1 — 6 month old babies vaccinated at birth (1979)

Compared to the 6-month old babies, 6-year old children, all of them vaccinated at birth, seem to exhibit very low levels of tuberculin allergy (Figure 2). Only 12% were positive with reactions of 8 mm and above, and the mean size was 2.38 mm. In Sweden where BCG was given extensively at birth, a study using 2 TU of RT23 showed that only 8.4% — 13.7% of 7 year old children had positive reactions of 10 mm and above (3). Karalliedde et al also found significant waning of the tuberculin reaction at age 5 — 7 years in Sri Lanka children who were vaccinated at birth (4).

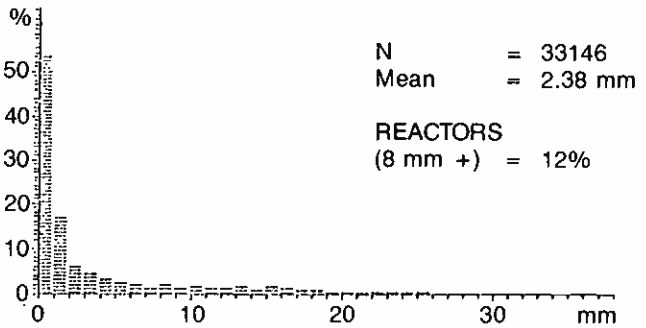

FIGURE 2 — 6 year old school children with BCG scar (1970)

For 11-year old children, 36% were positive reactors and the mean size was 6.27 mm (Figure 3). Several factors could account for this marked difference of the positive rate compared to that in 6-year old children in Primary 1. Firstly, the "booster effect" could be responsible because a proportion of these children examined when they were in Primary 1 and found to have no BCG scar were Mantoux tested. Most of these would have been negative reactors and therefore BCG vaccinated, adding further to the positive pool. Secondly, infection with non-tuberculous mycobacteria which is known to be prevalent in this region is a possibility as the children leave home and become exposed to a wider environment. It is unlikely that much of this high positive rate is due to natural infection with virulent human mycobacteria because the incidence of tuberculosis in the age group 10 — 14 years is very low (below 10 per 100,000) (5).

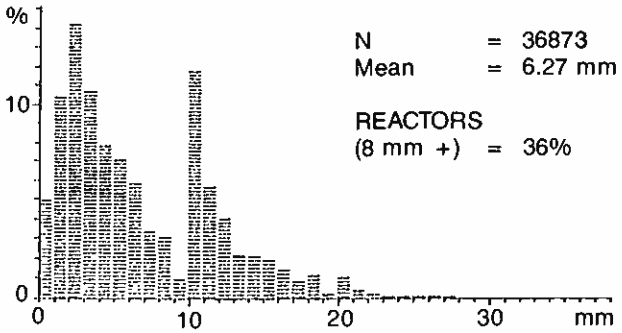

FIGURE 3 — 11 year old school children with BCG scar (1980)

In 15-year old children in Secondary 4 (Figure 4) the positive rate increased to 88% and the mean size to 13.28 mm. This sudden surge of positive rate is mainly due to the accumulation of positive reactors from previous years. Those children who were negative at age 11 years were all re-vaccinated with BCG.

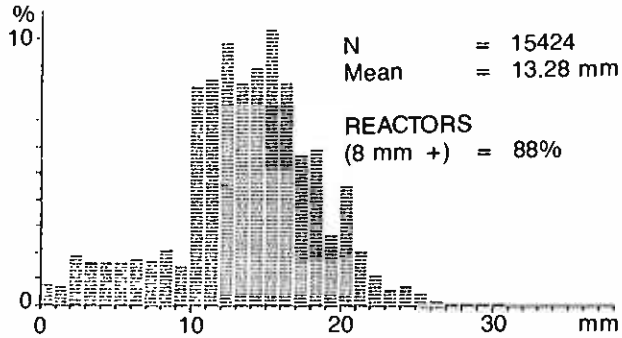

FIGURE 4 — 15 year old school children with BCG scar (1980)

Tuberculin Reaction among Contacts —
The data here have been analysed by age group for comparison with pre-schoolers, primary school and secondary school children.

For the age groups 4 — 8 years (Fig 5), and 9 — 13 years (Fig 6), the positive rate and overall mean reaction size were both higher than those in the corresponding age groups of normal school children, i.e. Pr. 1 and Pr. 6. This is to be expected since contacts are exposed to tuberculosis. The older children 14 — 18 years (Fig 7), gave similar figures as those of Sec. 4 students.