

# EFFECTIVENESS OF NIFEDIPINE IN EXTERNAL CEPHALIC VERSION

Bushra Rauf<sup>1</sup>, Sadia Ali<sup>2</sup>

<sup>1,2</sup> Department of Gynaecology & Obstetrics, Hayatabad Medical Complex, Peshawar-Pakistan.

**Address for Correspondence:**  
**Dr. Bushra Rauf**

Associate Professor,  
Department of Gynaecology & Obstetrics, Hayatabad Medical Complex, Peshawar-Pakistan.  
Email: drbushra\_1@hotmail.com

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## ABSTRACT

**Objective:** To find out the effectiveness of oral nifedipine as a tocolytic agent in external cephalic version.

**Methodology:** This was an observational study carried out in the private clinical setting of Peshawar Health Center from Nov 15, 2014 till Nov 15, 2015. It included patients presenting with uncomplicated singleton breech fetuses between 36 to 41 weeks of period of gestation. All the patients were given a 10mg oral tablet of nifedipine, 15 minutes prior to the procedure. A pre-procedure ultrasound was done for assessment of fetal parameters, following which gentle attempt of external cephalic version (ECV) was made. Success of the procedure in terms of persistent cephalic presentation was recorded as the primary outcome. Any fetomaternal complications were noted as the secondary outcomes. A post procedure ultrasound was carried out for fetal reassurance and confirmation of fetal position.

**Results:** A total of 58 patients were recruited in this study. Success rate of oral nifedipine was 77.6%. It was significantly higher (71.1%) in multigravida (p value 0.03) and in patients with flexed breech (84.6%) (p value 0.0001). No significant association was found with gestational age of the fetus and successful outcome.

**Conclusion:** Nifedipine is a good choice as tocolytic agent in ECV, with no maternal or fetal complications and with better outcome in terms of success of ECV.

**Key Words:** Nifedipine, External cephalic version, Tocolytic agent

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## INTRODUCTION

The incidence of breech presentation at term is 3-4%<sup>1</sup>. The well known landmark study in obstetrics "the term breech trial" had shown that planned cesarean section is better than planned vaginal birth for term fetus with breech presentation<sup>2</sup>. The publication of the results of this study led to a marked rise in the rate of cesarean sections done for breech presentations, with resultant increase in the maternal morbidity and mortality associated with cesarean deliveries<sup>3-5</sup>. Need aroused to find an alternative, beneficial to both the mother and the baby, with less complications and better outcome. This has resulted in resurgence of external cephalic version as an effective maneuver, which can result in significant reduction in cesarean section rate<sup>6-7</sup>.

In ECV, the fetus is turned abdominally to cephalic presentation for a trial of vaginal delivery. ECV has a reported success rate of 30-80 % with a commonly quoted figure of 50%<sup>8</sup>. Royal College of Obstetrics and Gynaecologists (RCOG) and American College of Ob-

stetrics and Gynecologists (ACOG) recommend offering ECV to all suitable patients with breech presentation<sup>8-9</sup>. To make the procedure more successful, ECV was coupled with tocolysis. Tocolysis effectively increases the success rate and reduce the incidence of cesarean deliveries<sup>10</sup>. Trials using different groups of tocolytic agents have been conducted in an effort to find an agent with higher efficacy and fewer side effects. Beta sympathomimetics gained popularity in terms of success rate of ECV<sup>11-12</sup>, however these drugs also had associated maternal complications e.g. palpitations, headache, nausea, vomiting, chest pain and hypotension<sup>13</sup>, which resulted in non-acceptance of the procedure in some patients. So the focus shifted to find a tocolytic agent with better side effect profile and comparable efficacy. Nifedipine was already successfully being used in the management of threatened pre-term labor with good results and fewer side effects<sup>14</sup>.

We decided to use nifedipine as a tocolytic agent for ECV in our study with the aim to find an agent with fewer side effects, good efficacy and better patient ac-

ceptability. Basic outcome measures were to observe its effectiveness in terms of successful version to a cephalic position and any fetal or maternal complications secondary to the drug.

## METHODOLOGY

It was an observational study, carried out in the clinical setting of Peshawar Health Center, Peshawar from November 2014 to November 2015. A total of 58 patients with singleton term breech presentation, between 36-41 weeks gestation, who had an otherwise normal antenatal progress and were considered at low risk were included in the study through convenient sampling method. Exclusion criteria were those patients with hypertensive disorders of pregnancy, gestational diabetes, previous cesarean delivery, intra-uterine growth retardation (IUGR), premature rupture of membranes (PROM), any contraindication to vaginal delivery or labor, patient wishes and those who already had gone under an attempt of version somewhere else.

Each parturient was fully explained regarding the procedure, its possible complications and the possibility of emergency cesarean section. An informed consent was taken. All the patients were given a 10mg tablet of nifedipine 15 minutes prior to the scheduled time of ECV. A baseline ultrasound with biophysical profile was done to demonstrate fetal presentation, adequacy of amniotic fluid, placental localization, position of fetal back and flexion of head and absence of congenital abnormalities.

The patients were asked to empty the bladder before the procedure. Intravenous line was maintained and blood was drawn for full blood count, blood type and screen in case she needed emergency caesarean section. Thereafter, a gentle attempt of ECV was made under ultrasound guidance. At the most three attempts were made, during which time fetal heart rate was monitored by ultrasound. The forward roll technique was applied first, followed by a backward roll, if needed. Women who were rhesus negative were given anti-Rh immunoglobulins after the procedure because of the 4.1% risk of the fetomaternal hemorrhage in these patients. A post-procedure biophysical profile was performed for the reassurance of fetal wellbeing.

Clinical parameters including period of gestation, parity, type of breech and fetal biometry were recorded. The occurrence of any complication associated with the procedure like PROM, antepartum hemorrhage (APH) and fetal distress were recorded and patients called for follow up after one week. Data could not be collected regarding mode of delivery and fetal outcome (late outcome of the procedure) as patients were lost to follow up after successful version, only 50% of the patients came for follow up. Reasons to discontinue attempted version included excessive maternal discomfort, repeatedly failed attempts or evidence of fetal compromise on monitoring. All the relevant data was entered in a pre-designed proforma and analyzed using SPSS version 17. The primary outcome measure included success rate of ECV in terms of conversion from breech to cephalic at the end of the procedure confirmed by ultrasound. Chi square test was used and a P value of 0.05 was considered as significant.

## RESULTS

Fifty eight patients were recruited for ECV. With the exception of one patient who had gestational diabetes with mild polyhydramnios, all the rest had unremarkable antenatal record. Overall success rate was 77.6%. Success rate was seen more in multigravida, being 71.1%, in comparison to the primigravida in whom it was 28.9% (p value 0.03, table 1). Another factor contributing to the outcome of procedure in terms of success was the type of breech. A success rate of 82.2% was seen in flexed breech as compared to the extended breech where success rate was only 17.8%, with a p value of 0.0001 as shown in table 2.

Failure rate of our study was 22.4%. The effect of parity on the outcome was observed, as failure was seen in 69.2% of the primipara patients as compared to the multigravida where it was recorded as 30.8%. No significant association was found with other factors like maternal weight, gestational age, and placental localization. No maternal complaints were recorded. Transient fetal bradycardia was observed in 5% of the fetuses for about 35-55 seconds and resolved spontaneously without any intervention. No major fetal or maternal complications e.g. rupture of membranes, placental abruption was observed.

**Table 1: Parity and success of ECV (n=58)**

External Cephalic Version	Primi Gravida	Gravida 2-4	Gravida 5	Total (%)
Successful	13 (28.9%)	16 (35.5%)	16 (35.5%)	45 (77.6%)
Failed	09 (69.2%)	02 (15.4%)	02 (15.4%)	13 (22.45%)
Total	22 (37.9%)	18 (31%)	18 (31%)	58 (100%)

P value: 0.03

**Table 2: Type of breech and success of ECV (n=58)**

External Cephalic Version	Flexed Breech	Extended Breech	Total (%)
Successful	37 (82.2%)	08 (17.8%)	45 (77.6%)
Failed	02 (15.4%)	11 (84.6%)	13 (22.4%)
Total	39 (67.3%)	19 (32.7%)	58 (100%)

P value: 0.0001

**Table 3: Gestational age and success of ECV (n=58)**

External Cephalic Version	36-37 Weeks	38-39 Weeks	40 Weeks	Total
Successful	30 (66.7%)	14 (31.1%)	01 (2.2%)	45 (77.6%)
Failed	07 (53.8%)	05 (38.5%)	01 (2.2%)	13 (22.4%)
Total	37 (63.8%)	19 (32.7%)	02 (3.4%)	58 (100%)

P value: 0.52

## DISCUSSION

External cephalic version has emerged as a valuable tool in the management of breech presentation resulting in significant reduction in cesarean section rate of upto 33%<sup>15</sup>. The average success rate of ECV is low and efforts are being made to improve the success rate, one such effort is complementing the procedure with tocolysis. Studies have shown a positive effect of tocolysis in terms of increasing the success rate of ECV<sup>15-16</sup>. The RCOG has also recommended the use of tocolysis prior to ECV.

In our study we used nifedipine as a tocolytic agent and the success rate was 77.6%. Similar results were seen in a study done in Thailand, where the success rate of tocolysis was observed as 71.4%<sup>16</sup>. The higher success rate observed with tocolysis is attributed to the fact that ECV is least likely to succeed when the uterus is tense<sup>17</sup>. Tocolytics causes relaxation of the maternal uterine muscles and thus less force is needed, this along with the decrease pain experienced by the patient, seem to improve the success rate of ECV. A study in which nitroglycerine was used as tocolytic, showed increase in the overall success rate of ECV in parous women from 50% (without tocolysis) to 71% proving that the use of tocolysis increases the success rate of ECV<sup>18</sup>. Previously the author had conducted a study without using tocolytics and the success rate of ECV observed was 67.5%<sup>19</sup>. Similar results were seen in a study conducted (without tocolytics) at Services Hospital, Lahore with a success rate of 60%<sup>20</sup>. These findings further advocate the use of tocolysis in ECV.

Among successful group 71.1% of the patients were multigravida as compared to 28.9% primigravida, showing that being multigravida is a favorable factor for ECV. Comparable results were reported by other authors with success rates of 80% vs. 30% and 76% vs. 57% (for multigravida versus primigravida) respectively<sup>19,21</sup>. Failure rate of our study was 22.4, mainly attributed to

the type of the breech fetus, as among the failed group 11(84.6%) patients were having extended breech, while only 02(15.4%) patients having flexed breech. Among the successful group 37(82.2%) patients were having flexed breech and 08 (17.8%) patients having extended breech. In a study conducted by Arif et al<sup>20</sup> the success rate was 85% in flexed fetuses and 16% in extended fetuses.

Nifedipine has gained confidence in the management of threatened pre-term labor with good outcome and fewer side effects as compared to the beta-agonists<sup>22,23</sup>. Its role as a tocolytic agent in ECV has also been studied in comparison with ritrodine where the author has reported a success of 54% vs. 50% for nifedipine vs. ritrodine, with fewer side effects observed for nifedipine<sup>24</sup>.

In the present study, we did not record any major or minor maternal complications related to nifedipine with 100% patient acceptability, as patients preferred oral than intravenous route for drug administration. A study showed that 67% of the population preferred oral route for tocolysis compared with an injection<sup>25</sup>. This shows that oral nifedipine can be effectively used prior to ECV. Regarding fetal complications no major side effect were recorded. However transient fetal bradycardia for about 35-55 seconds was seen in 5% of fetuses, which resolved to normal pattern spontaneously. Other studies also show that the most common fetal complication with ECV is the transient abnormal CTG pattern resolving spontaneously; incidence quoted as being 3-5% in some studies<sup>26,27</sup>.

Although in this study we did not encounter any major maternal or fetal complications but Literature review has shown that perinatal and maternal complications do occur with ECV<sup>27</sup>. This is one reason to conduct the procedure in a setting where the facility of cesarean section (C/S) is available. The patients are informed regarding this fact and are kept prepared for C/S in case of any complication.

External cephalic version has a slight (2.4%)<sup>28</sup> risk of silent fetomaternal hemorrhage, so all the rhesus-negative patients should be given anti-D prophylaxis after completion of the procedure; however we didn't have any such patient in our study.

## CONCLUSION

External cephalic version is a valuable tool against the rising cesarean section rate and complementing this procedure by tocolysis can further add up to the success of the procedure. Our study showed that nifedipine has good results in terms of successful immediate outcome & patient acceptability with no major or minor fetomaternal immediate complications.

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#### CONTRIBUTORS

BR conceived the idea, planned the study, and drafted the manuscript. SA helped acquisition of data, did statistical analysis and critically revised the manuscript. All authors contributed significantly to the submitted manuscript.