10 YEARS REVIEW OF SUCCESSFUL EXTERNAL CEPHALIC VERSION (ECV) AT HOSPITAL RAJA PEREMPUAN ZAINAB II (HRPZII)

DR NURUL AIN SAH BINTI MAKHTAR

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1.1 PRELIMINARIES

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LIST OF ABBREVIATIONS

ECV – External cephalic version

ACOG – American College of Obstetrician and Gynaecologist

AFI – Amniotic Fluid Index

BMI – Body Mass Index

EFW – Estimated Fetal Weight

HRPZ II – Hospital Raja Perempuan Zainab II

HREC – Human Research and Ethics Committee of HUSM

NMRR – National Medical Research Register

SPP – Sistem Pengurusan Pesakit

AUC – Area Under Curve

ROC – Receiver Operating Characterisctics

TBT – Term Breech Trial

CS – Caesarean Section

RCOG – Royal College of Obstetricians and Gynaecologists

BPD – Biparietal diameter

HC – Head circumference

AC – Abdominal circumeference

FL – Femur length

AUS – Anterior Upper Segment

PUS – Posterior Upper Segment

ABSTRAK (VERSI BAHASA MELAYU)

Objektif: Untuk mengenalpasti kadar pesakit dengan bayi songsang yg berjaya dengan proses External Cephalic Version (ECV), mengenalpasti faktor- faktor yang membawa kepada proses ECV yang berjaya and seterusnya mencipta alat peramal bagi membantu dalam proses kaunselling kepada pesakit sebelum proses ECV dijalankan.

Rekabentuk kajian: Ini adalah kajian retrospektif berdasarkan rekod klinikal yang dijalankan di Hospital Raja Perempuan Zainab II (HRPZ II). Rekod perubatan 479 wanita yang mengandung secara singleton, dengan kewujudan bayi berkeadaan songsang pada usia kandungan matang, yang telah melalui proses ECV dalam lingkungan Januari 2010 sehingga Disember 2019.Data berkenaan pembolehubah yang berkemungkinan memberi kesan kepada proses ECV yang berjaya dikumpulkan. Pembolehubah yang dikenalpasti adalah minggu kehamilan, pariti, indeks jisim badan, jenis songsang, parameter fetus, kemasukan punggung bayi ke dalam pelvis, kepala fetus yang melentur dengan baik, dan indeks air ketuban (AFI). Perhubungan semua pembolehubah dengan kejayaan ECV dinilai menggunakan regresi logistik multivariate and alat peramal dicipta berdasarkan analisis tersebut.

Keputusan: Secara keseluruhan, 479 rekod klinikal pesakit telah dinilai and kadar berjaya bagi proses ECV adalah 56%. Jenis songsang, pariti,kemasukan punggung bayi ke dalam pelvis, ukurlilit kepala bayi and indeks air ketuban merupakan faktor faktor yang menentukan sama ada sesuatu ECV itu berjaya atau sebaliknya.

Kesimpulan: Keseluruhan kadar kejayaan ECV di Hospital Raja Perempuan Zainab II dalam tempoh sepuluh tahun yang lepas adalah setanding dengan kajian yang dilakukan

di pusat pusat lain. Justeru itu, proses ECV seharusnya ditawarkan kepada ibu- ibu yang mengalami bayi songsang pada kandungan matang. Faktor ibu dan faktor bayi yang dikenalpasti akan meningkatkan kadar kejayaan proses sesuatu ECV itu dapat membantu untuk menilai peluang untuk kejayaan ECV dan seterusnya alat peramal yang dicipta mampu untuk menjangkakan sama ada proses ECV itu akan berjaya ataupun tidak.

ABSTRACT (ENGLISH VERSION)

Objectives: To determine the proportion of patients with successful ECV in breech pregnancy from 36-40 weeks of gestation, the predictors for successful ECV and to create a predictor tool to assist in term of counseling of patients before ECV.

Study design: This single center retrospective based on clinical records reviewed 479 medical records with singleton pregnancies and breech presentations that experienced ECV attempt at Hospital Raja Perempuan Zainab II from January 2010 to December 2019 between 36 to 40 weeks of gestation. Variables with a possible effect on ECV success were collected. These variables include gestation, parity, body mass index (BMI), types of breech, fetal parameters, engagement of buttock, well flexed fetal head, and amniotic fluid index (AFI). Variables' association with ECV success was assessed using a multivariate logistic regression and predictor tool was created.

Results: Overall, 479 clinical records of women underwent ECV being reviewed and success rate of the ECV was 54.7%. Flexed breech (p= 0.007), multiparity (p= 0.000), unengaged of fetal buttock (p=0.000), smaller head circumference (p= 0.017) and higher amniotic fluid index (AFI) (p=0.002) were the independent factors of the version success, while other variables had no statistically significant effect on the success rate. Preoperative predictive score had been created which consist of parity, types of breech, body mass index (BMI), amniotic fluid index (AFI) and engagement of buttock with the minimum score of 8 and maximum score of 13. The favourable predictor score is 9 and above.

Conclusion: The overall successful rate for ECV performed in HRPZ II is analogous to

other studies and ECV should be offered as an option for the mother. Recognized fetal and maternal factors can help to estimate the chances of success and prediction tool enables accurate prediction of successful ECV and in which when the score is more than 8, it is high chance that the ECV will be successful.

1.0 INTRODUCTION

Breech presentation, thought it occurs in only 3.8% of all term pregnancies, accounted for 17% of these primary caesarean deliveries. Among the popular topics of concern and controversy in obstetrics practise is the management of breech presentation at term. Following the publication of the Term Breech Trial in 2000 there was a significant decrease in the number of women going for vaginal breech birth. The Term Breech Trial (TBT) Collaborative Group concluded that a composite variable combining perinatal and neonatal mortality or serious neonatal morbidity was significantly lower in the planned caesarean section (CS) group than in the planned vaginal birth group, which marked an apparent turning point in this controversy[1]. Publication of the international Randomized Term Breech Trial in 2000 appeared to confirm the presumption that primary caesarean section would reduce morbidity and mortality among children in breech presentation at term. The Term Breech Trial had major impact on the attitude of obstetricians towards vaginal breech delivery as the number of caesarean sections for breech presentation at term increased over the years and still on the rise. Based on the short-term outcomes presented in the TBT study, the Royal College of Obstetricians and Gynaecologists (RCOG) and the American College of Obstetricians and Gynecologists (ACOG) recommended over the next few years that all women with persistent singleton breech presentation at term should undergo a

planned CS delivery. In Netherlands, the rate of primary caesarean sections because of breech increased from 57.4% in 2000 to 80.85% in 2001.[3] However, caesarean births itself carries maternal and foetal risks. Therefore, external cephalic version (ECV) is a good option that can be used to reduce the likelihood of caesarean birth among women with breech presentation late in gestation, as well as to reduce the risk of foetal morbidity and mortality among their infants. In 2006, the American College of Obstetricians and Gynaecologists (ACOG) published recommendations reaffirming existing guidelines that obstetricians should offer and perform ECV whenever possible.[2] Considering the global rise in caesarean deliveries in the last decade from approximately 23-34% of which malpresentation is the third indication, ECV is recommended to all women with an uncomplicated breech pregnancy near term. Gottval and Ginstman demonstrate that the use of ECV decreases the risks associated with a breech vaginal delivery and the risks associated with a caesarean section, such as transient tachypnoea of the new-born, increased risk of haemorrhage, and increased risk of deep vein thrombosis following the procedure[3]. Therefore, it is important to know the factors that can predict successful ECV to prevent the complications and increase the success rate of ECV. Therefore, we sought to determine the rate of successful ECV and to identify the predictors that can lead to successful ECV and at the same time create a predictor model and tool to assist in counsel of patients before going for ECV.

2.0 LITERATURE REVIEW

2.1 EXTERNAL CEPHALIC VERSION

External cephalic version (ECV) is a procedure in which the foetus is rotated from the breech to the cephalic presentation manually through manipulation of the mother's abdomen. This procedure is generally performed at or near term to improve the mother's chances of having a vaginal cephalic birth. External version is a simple and effective procedure that can reduce the caesarean delivery rate. However, ECV is associated with various complications, such as placental abruption, fetal-maternal haemorrhage, fracture of fetal femur, prolonged fetal tachycardia, and sinusoidal pattern of the fetal heart rate. Hence, identifying factors associated with successful ECV offers the chance to improve the decision-making process by providing women with an accurate expectation of success.

2.2 SUCCESS RATE OF ECV

Successful rate of ECV vary widely among so many studies ranging from 40-

60%. This variability may be attributable to studies having been conducted in a variety of geographic settings and having employed different study designs. From the study by Brig SK et al (2012), the success rate of ECV was 61% with failure rate of 39%. Success rate was 54.8 % in nulliparous, 71.4% in primiparous and 100% in multiparous group[4]. Jun Yi Lee et al (2020) had 52% of successful ECV and the study showed that the area under curve of height of the elevated fetal buttock was greater than that of parity and amniotic fluid index (AFI)[5]. LY Cho et al (2012), showed success rate of ECV 63% (75% for multiparous and 53% for nulliparous women) and showed that multiparity, non- engagement of the fetal buttock, higher amniotic fluid index (≥ 10cm), low uterine tone, easily palpable head and thin maternal abdomen were associated with successful ECV[6]. Meghana Limaye et al (2019) has overall success rate of ECV 55% and the showed that among women with fetal malpresentation at term, those without a prior vaginal delivery were significantly less likely to undergo attempted ECV[7]. Natalie Kew et al (2017) have an ECV success rate of approximately 37% and of the patients undergoing ECV, 29% proceeded to normal vaginal delivery[8]. Rocio Lopez Perez et al (2020) showed that the overall success rate was 72% and the variables most related to success rate were parity, placental location, amniotic fluid volume, fetal sex, fetal head palpation and descent of the presenting part.[9]

2.3 FACTORS ASSOCIATED WITH SUCCESSFUL ECV

In the millennium era, women should be provided unbiased nondirective information on the advantages, disadvantages, and expected risks and outcomes of an ECV. Numerous studies have addressed the prediction of success in ECVs with conflicting results. Multiple predictive factors were proposed in these studies, including a clinical history and findings of physical and ultrasound examinations. The known factors associated with successful ECV are maternal height, weight, body mass index (BMI), parity, placental location, estimated fetal weight (EFW), and amniotic fluid index (AFI). Additionally, some clinical factors are associated with successful ECV, such as the surgeon's experience and dexterity with the procedure. Burgos et al found that parity, placental location, AFI, and the type of breech presentation were associated with successful ECV.[11] Kok et al (2009) found placental location as a significant factor.[11] Mowat and Gardener (2014) noted that multiparity and AFI were predictable factors for successful ECV, whereas lower AFI and nulliparity reduced the success rate of ECV.[12] One systematic review evaluated the role of the AFI in success of an ECV attempt and found that an AFI below 10 cm may correlate with lower success rate, although the association was not statistically significant. Florian Ebner et al (2016) showed successful rate of ECV of 28% and multivariate binary logistic regression analysis revealed that an increased Amniotic Fluid Index, at least one prior vaginal delivery and high estimated fetal weight were significant independent predictors for a successful ECV.[13]

2.3.1 TYPES OF BREECH

H. Zandstra et al (2013) showed that the type of breech was found to be a significant association with successful ECV. Complete breech had higher rate of successful ECV compared to frank breech.[14] However, the results of effect of types of breech into the outcome of ECV are conflicting and various studies found different fetal presentations to be associated with successful ECV. For example, Burgos et al. (2011) found the double footling breech, Salzer et al. (2015) found that franks breech to be a positive predictor. Ebner et al (2016) stated that this indicates that fetal position is one of many variables that may contribute towards the success rate, but that predictive value of certain fetal position might depend on or interact with other fetal and/or maternal parameters.[13]

2.3.2 PARITY

Many studies showed multiparity is a significant predictor factor for successful ECV. LY Cho et al (2012) showed that multiparity is one of the predictors for successful ECV after univariate and multivariate analysis.[6] Rita Mendes Silva et al (2018) also showed that multiparity is one of the predictive factors for successful ECV[15]. Conversely, Liat Salzer et al (2015) showed nulliparity was associated with 60% decrease likelihood of successful ECV.[16] Natalie Kew et al (2017) found that multiparity is also the factor for successful ECV and the only predictor of cephalic vaginal delivery following ECV.[8]

2.3.3. BODY MASS INDEX (BMI)

One study suggested that a higher BMI was associated with unsuccessful ECV.[19] BMI less than 32.7 defined the most predictive clinical groups in multiparous women.[18] Studies have found that women with a higher BMI were less likely to have a cephalic vaginal delivery following an ECV. Low BMI also was found to be predictor of a successful ECV. [9] LY Cho et al (2012) also showed that thin abdominal wall was associated with successful ECV.[6]

2.3.4 ENGAGEMENT OF FETAL BUTTOCK

For both nulliparous and multiparous women, the most important clinical determinant of ECV success was unengaged presenting part, which is perhaps not surprising. The first manoeuvre of an ECV procedure is to lift the breech from the maternal pelvis so that the fetus can turn freely in the uterus. A Cochrane review of timing of ECV found that beginning ECV early, after 34 weeks and before 37 weeks compared to beginning ECV after 37 weeks result in significantly fewer non- cephalic presentations at birth and a higher likelihood of achieving a vaginal cephalic birth.[18] The hypothesis in those studies was that beginning ECV earlier in pregnancy would potentially allow the fetus to be turned prior to engagement, while the amniotic fluid volumes were maximal and with increased space for the fetus to turn. LY Cho et al (2012) also found that unengaged presenting part (95% of total sample size with mostly

at 37 weeks of gestational age at ECV) is associated with successful ECV in univariate and multivariate analysis.[6] K. Hutton et al also suggests assessing for dipping of the sacrum into the pelvis beginning around 35 weeks' gestation so that ECV can be plan prior to engagement of the buttock.[17]

2.3.5 AMNIOTIC FLUID INDEX

Polyhydramnios was the strongest factor associated with successful ECV.[17] Rita Mendes et al(2018) also showed that a higher amniotic fluid index (mean = 13.9) was also a relevant predictive factor.[15] H. Zandstra et al (2013) found that patients with more amniotic fluid index were more likely to have a successful ECV.[14] Erin R Morgan et al (2018) showed that oligohydramnios was associated with lower version success.[19] Besides that, Natalie Kew et al (2017) found that AFI more than 16cm associated with successful ECV and low AFI (less than 10cm) was associated with ECV failure and furthermore low AFI was found to be a statistically significant negative predictor of cephalic vaginal delivery following ECV.[8]

2.3.6 PLACENTA LOCATION

Burgos et al (2011) and Kok et al (2009) found that placenta location (posteriorly located placenta) was associated with successful ECV.[10, 11.] However, in H. Zandstra et al (2013) found that placental location not a significant associated factor.[14] This is possibly due most of the samples have anteriorly located placenta. Rita Mendes Silva et al (2018) that developed Newman –Peacock Prognostic System that posterior

placental location has been most mentioned as effective predictive factors for successful ECV[15]. Some possible explanations refer to the smaller obstacle on posterior placenta might pose; hence it is easier to rotate the baby. Liat Salzer et al (2015) also showed that posteriorly located placenta had successful ECV more compared with women in the failed ECV group.[16]

3.0 JUSTIFICATION OF STUDY

Some studies have reported complications associated with the ECV procedure. One study observed an increase in foetal heart rate in 10% of ECVs, while a meta-analysis found abnormal foetal cardiotocography in 6% of the procedures. Thirty five percent of women who have undergone ECV procedures have reported them to be painful, and, though rare, the procedure is associated with preterm labour. The procedures also have emotional consequences for women. Many women express anxiety before an ECV. Qualitative data collected after an ECV has also suggested that some women who were not successful felt guilty about having caused unnecessary stress to their baby. Collectively, this study suggests that there are advantages to identify women who are more likely to have a successful ECV. Hence, the ability to predict of successful ECV and use of predictor tool may improve the rates of patient consent and prevent the unpleasant procedure with low chance of success.

4.1 OBJECTIVES

4.2 GENERAL OBJECTIVE

General objective is to evaluate the predictors for successful ECV at HRPZ II.

4.3 SPECIFIC OBJECTIVES

- To determine the proportion of patients with successful ECV in term breech pregnancy.
- To determine the predictors for successful ECV.
- To create a predictor tool for successful ECV to assist in term of counselling of patients before ECV.

5.1 METHODOLOGY

5.2 STUDY DESIGN, SETTING AND DURATION

5.1.1 Study design

Single centre retrospective study using clinical records review.

5.1.2 Study area

This study was conducted in HRPZ II. The relevant information of the patients was collected at Medical Record Unit, HRPZ II.

5.1.3 Study population

Data of pregnant women with singleton pregnancies and breech presentations at 36 to 40 weeks of gestation who undergo ECV from January 2010 to December 2019 at Hospital Raja Perempuan Zainab with the usage of intravenous terbutaline 0.5 mg in 1-pint normal saline as tocolytic agent.

5.2 INCLUSION AND EXCLUSION CRITERIA

5.2.1 Inclusion area

Data of healthy singleton pregnant women at 36-40 weeks of gestation with breech presentation who underwent ECV at HRPZ II from January 2010 to December 2019 with the usage of intravenous terbutaline 0.5 mg in 1-pint normal saline as tocolytic agent.

5.2.2 Exclusion criteria

Data of Healthy singleton pregnant women at 36-40 weeks of gestation with breech presentation who undergo ECV from January 2010 to December 2019, but the data do not complete or available and not fulfilled the requirement for external cephalic version like oligohydramnios less than 6 cm, intrauterine growth restriction (IUGR) baby, macrosomia baby more than 4 kg, placenta praevia, uterine abnormality and also maternal conditions like heart disease in pregnancy and severe preeclampsia.

5.3 SAMPLE SIZE CALCULATION

Sample size (n), using single population proportion formula

Calculation by using confident interval (CI) 95% and 5% precision

$$n = n_1 \quad (1 - \quad)$$

p = expected proportion of individuals in the sample with the characteristics of interest at the determined 100 (1-α) % confidence interval. It can be obtained from literature or a pilot study or preliminary work

Δ = precision

n = n 1 . (– .) = 358, sample size with dropout 10% :394

Based on LY Cho et al study, the prevalence of successful ECV is 63%.[1]

Multiparity

Sample size (n), using single population proportion formula

Calculation by using confident interval (CI) 95% and 5% precision

$$n = n\frac{1}{1} \quad (1 - \quad)\_$$

p = expected proportion of individuals in the sample with the characteristics of interest at the determined 100 (1-α) % confidence interval. It can be obtained from literature or a pilot study or preliminary work

Δ = precision

$$n = n\frac{}{1} \quad 0.35(1 - 0.35) = 350, \text{ sample size with dropout } 10\% \ : 385$$

Based on LY Cho et al study, the prevalence of successful ECV in multiparous is 35%.

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Types of breech

Sample size (n), using single population proportion formula

Calculation by using confident interval (CI) 95% and 5% precision

$$n = n\_1 \quad (1 - \ )\_$$

p = expected proportion of individuals in the sample with the characteristics of interest at the determined 100 (1-α) % confidence interval. It can be obtained from literature or a pilot study or preliminary work

Δ = precision

$n = n^{\text{nil}}\_1$ $0.64(1 - 0.64) = 354$, sample size with dropout 10% : 389

Based on LY Cho et al study, the prevalence of extended breech in ECV is 64 %

Placenta location

Sample size (n), using single population proportion formula

Calculation by using confident interval (CI) 95% and 5% precision

$$n = n\_1 \quad (1 - \ )\_$$

p = expected proportion of individuals in the sample with the characteristics of interest at the determined 100 (1-α) % confidence interval. It can be obtained from literature or a pilot study or preliminary work