

Effect of super-specialization in External Cephalic Version: A comparative study

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Abstract

Background: The introduction of an experienced dedicated team is not a completely studied fact. Several studies reported a high ECV success rate when the procedure is executed by a single operator or a dedicated team. The aim of this study is to compare the effectiveness and safety of the ECV when the procedure is performed by senior experienced obstetricians or by super-specialized professionals who composed a dedicated team.

Methods: Longitudinal prospective analysis of ECV performed in a tertiary hospital from 1/1st/2018 to 12/31st/2019. During twenty-one consecutive months, ECV were performed by two senior experienced obstetricians who composed the dedicated team for ECV, designed as Group A. For three consecutive months, ECV was performed by two seniors obstetricians, designed as Group B. Ritodrine was administered during 30 minutes just before the procedure. Propofol was used for sedation.

Results: 186 pregnant women were recruited (150 patients in group A and 36 patients in group B). ECV success rate increased from 47.2% (31.7-63.2) in Group B to 74.0% (66.6-80.5) in Group A. The greatest increase in the success rate of ECV was seen in nulliparae, from 38.5% (21.8-57.6) in group B to 69.1% (59.4-77.6). Complications rate decreased from 22.2% (11.1-37.6) in Group B to 9.3% (5.5-14.8) in Group A.

Conclusions: The introduction of an experienced dedicated team improves ECV success rate, especially in primiparas, and it also reduces ECV complications rate.

Introduction

A breech presentation is a frequent reason for cesarean delivery that occurs in 3–4% of all pregnant women at term[1]. Since the publication of the Term Breech Trial in 2000[2] which demonstrated excess neonatal mortality as a consequence of breech vaginal delivery, cesarean delivery rates have risen alarmingly[3].

External cephalic version (ECV) is a procedure for modifying the fetal position and achieving a cephalic presentation. The objective of the ECV is to offer an opportunity for cephalic delivery to occur which is safer than breech delivery or cesarean section. The use of external cephalic version in breech presentation, according to WHO[4], certainly reduces the incidence of cesarean section, which is of special interest in those units where vaginal breech delivery is not a common practice.

The factors associated with a higher ECV success rate have been deeply studied and they include[5–7]: multiparity, a transverse presentation, black race, posterior placenta, and amniotic fluid index higher than 10 cm.

Certain interventions have been related to helping in ECV[8] such as tocolysis, analgesia, empty bladder before procedure[9], or the introduction of a dedicated experienced team[10]. Ritodrine has been reported

as a safe tocolytic agent and the drug that improves the most ECV success rate[8, 11]. Other tocolytic agents studied in ECV are nifedipine[8], atosiban[8], nitroglycerine[12], or others beta-agonist[12].

About analgesia in ECV, some interventions have been analyzed such as systemic opioids or spinal anesthesia. Spinal anesthesia techniques improve the ECV success rate and pain after procedure[13–16]. No differences are reported in ECV success rate when systemic opioids or spinal anesthesia are compared[13].

The introduction of an experienced dedicated team is not a completely studied fact. Several studies reported a high ECV success rate when the procedure is executed by a single operator[17, 18] or a dedicated team[5, 10, 19, 20]. Just one study has compared a dedicated team with non-experienced gynecologists, midwives, and residents[10].

The main objective of this study is to compare ECV results when the procedure is performed by an experienced dedicated team or by seniors obstetricians who are not involved in a dedicated team. As a secondary objective, predictor factors of ECV success are analyzed in both groups. We hypothesized that an experienced dedicated team could have a higher ECV success rate and a lower complication rate.

Methods

From 1st of January of 2018 to 31st of December of 2019 a longitudinal prospective analysis of ECV performed in 'Virgen de la Arrixaca' University Clinical Hospital in Murcia (Spain) was carried out. The confidentiality of the patient information was assured. Written consent was taken from all the patients. No obligation on the patients to participate in the study. Written informed consent was obtained from all participants to publish their data. This study (intern code: 2020-5-6-HCUVA) was approved by the 'Research Ethics Committee' of 'Virgen de la Arrixaca' University Hospital.

The procedure were performed by two of the four senior experienced obstetricians who composed the dedicated team for ECV in the Maternal-Fetal Unit from 1/1st / 2018 to 9/31st /2019. In this study, this group is designed as 'Group A'. The dedicated team for ECV in Maternal-Fetal Unit has more than seven years of experience in ECV.

However, the members of the dedicated team for ECV were absent between 10/1st /2019 and 12/31st /2019, and they were performed by two seniors obstetricians specialized in obstetrical care. These seniors colleagues were not involved in the dedicated team for ECV. In this study, this group is designed as 'Group B'.

Patients were recruited during the third-trimester obstetric evaluation at 36 weeks gestation [21, 22]. Recruitment criteria were the same for Group A and Group B. ECV was offered to every pregnant woman with non-cephalic presentation and no absolute contraindication for vaginal delivery. Women were considered ineligible in cases of recent vaginal bleeding, confirmed rupture of membranes, severe preeclampsia, and when an absolute indication for cesarean section was identified (eg placenta previa).

In the consult, every pregnant were asked about personal and obstetric history. An ultrasound assessment for studying the fetal position, fetal biometry, amniotic fluid, and placental position was performed in the consult [21, 22].

If the patient was eligible and informed consent was obtained, ECV is performed at 37 weeks gestation. All patients were asked to fast for eight hours before the procedure.

Procedure

ECV was performed following the same protocol in Group A and Group B [21, 22]. The procedure was carried out in the obstetric operating room with the presence of an anesthesiologist and a midwife. Before ECV was performed, pregnant women were evaluated by the anesthesiologist. Just before the procedure, 0.2 mg/min of ritodrine was intravenously administered for 30 minutes.

In the operating room, maternal vital signs were monitored (heart rate, EKG, temperature, noninvasive blood pressure, oxygen saturation). The patient was positioned in Trendelenburg (15°) and administered 1-1.5 mg/kg of propofol[22].

Two ECV attempts following the forward roll technique were performed by two experienced obstetricians. Immediately after the procedure, fetal well-being was assessed with continuous cardiotocograph register during the following 4 hours. Anti-D was given to rhesus-negative women. 24 hours after the procedure, fetal well-being was reassessed with continuous monitoring for one hour.

If any complication occurred immediately after the procedure, an urgent cesarean section was performed. ECV is considered successful when a cephalic presentation is achieved.

Outcome variables

ECV is considered successful when a cephalic presentation is achieved. Intraversion cesarean is considered as any cesarean carried out during the ECV or the first 24 hours after the procedure due to any complication secondary to it (i.e., fetal compromise, cord prolapse, vaginal bleeding, ...).

Statistical Analysis

Data were recorded prospectively on all referrals. Data on pregnancy outcomes were collected from hospital obstetric and neonatal records. Continuous variables were assessed for normality with the Shapiro–Wilk test.

The primary outcome variable was the incidence of external cephalic version procedural success. The secondary outcome variable was the incidence of intraversion cesarean section. Obstetric history, anthropometric measurements, estimated fetal weight at 3rd trimester, placental location, and fetal

presentation underwent bivariate analysis using Student's T-test or Pearson's chi-squared test to compare the characteristics of each group. Subsequently, the primary and secondary outcome variables were compared between both groups.

Afterward, taking primary and secondary outcome variables for each group: all variables above mentioned with P-value < 0.2 in bivariate analysis were considered using a multivariable analysis logistic regression model for both groups. In common with all logistic regression analyses, this produced a model applicable to the dataset from which it was generated.

All tests were two-tailed and the level of statistical significance was set at 0.05. Data analysis was performed using SPSS version 25.0 (SPSS Inc., Chicago, Illinois) and RStudio version 1.2.5033: Integrated Development for R (RStudio, Inc., Boston, Massachusetts), and R version 3.6.2 (<https://www.r-project.org/>. Accessed February 29, 2022).

Results

In total, 186 pregnant women underwent an ECV attempt. Of these, 150 (80.6%) were performed by Group A, and 36 (19.4%) were carried out by Group B. 86 women were nulliparas (66.1%) and 36 (33.9%) women were multiparas. Baseline characteristics are depicted in Table 1. Baseline characteristics were comparable for Group A and Group B.

Table 1

Characteristics of pregnant women who underwent external cephalic version (ECV). Data presented as mean or % (number (n)). P-value < 0.05 in bold, when comparing characteristics between Group A and B, T-student test for normally distributed variables, and Chi-squared for categorical variables. BMI: Body Mass Index. ECV: External Cephalic Version. CS: Cesarean Section. EFW: Estimated Fetal Weight.

Characteristics	Total (186)	95% CI	Group A (150)	95% CI	Group B (36)	95% CI
Age, years	32.3	31.5– 33.0	33.5	31.8– 37.2	33.5	31.8– 35.2
Gestational age at ECV, weeks	37.5	37.4– 37.5	37.4	37.2– 37.5	37.4	37.2– 37.5
Gravida	1.9	1.7–2.1	2.0	1.6–2.4	2.0	1.6–2.4
Nulliparous, % (n)	66.1% (123)	59.1– 72.6	72.2% (26)	56.3– 84.7	64.7% (97)	56.8– 72.0
Previous CS, % (n)	3.8% (7)	1.7–7.2	5.6% (2)	1.2–16.6	3.3% (5)	1.3–7.2
BMI, Kg/m ²	27.7	26.9– 28.4	28.7	26.8– 30.5	27.4	26.6– 28.3
BMI < 25, % (n)	31.1% (50)	24.3– 38.5	23.3% (7)	11.1– 40.4	32.8% (43)	25.2– 41.2
BMI 25–30, % (n)	41.6% (67)	34.2– 49.3	40.0% (12)	24.0–57.8	42.0% (55)	33.8– 50.5
BMI 30–35, % (n)	16.1% (26)	11.1– 22.4	20.0% (6)	8.8–36.7	15.3% (20)	9.9–22.2
BMI 35–40, % (n)	9.3% (15)	5.5–14.5	16.7% (5)	6.7–32.7	7.6% (10)	4.0–13.1
BMI > 40, % (n)	1.9% (3)	0.5–4.9	0% (0)		2.3% (3)	0.6–6.0
EFW before ECV, grams	2797	2749– 2845	2806	2698– 2914	2795	2741– 2849
Placental location, % (n)						
Anterior, % (n)	52.2% (96)	45.0–59.3	55.6% (20)	39.4– 70.8	51.4% (76)	43.3– 59.3
Posterior, % (n)	39.1% (72)	32.3– 46.3	38.9% (14)	24.3– 55.2	39.2% (58)	31.6– 47.2
Fundus, % (n)	4.3% (8)	2.1–8.0	0% (0)		5.4% (8)	2.6–9.9
Lateral wall, % (n)	4.3% (8)	2.1–8.0	5.6% (2)	1.2–16.6	4.1% (6)	1.7–8.2
Amniotic fluid pocket, mm	52.1	48.9– 55.2	48.3	43.9– 52.6	53.2	49.3– 57.0

Characteristics	Total (186)	95% CI	Group A (150)	95% CI	Group B (36)	95% CI
Transversal lie, % (n)	7.0% (13)	4.0-11.3	5.6% (2)	1.2–16.6	7.3% (11)	4.0-12.3

The overall ECV success rate was 68.8% (95% CI 61.9–75.1). ECV outcomes and obstetric outcomes by Group are shown in Table 2.

Table 2

External cephalic version (ECV) and obstetric outcome by group. Data presented as mean or % (number (n)). P-value < 0.05 in bold, when comparing characteristics between Group A and B, T-student test for normally distributed variables, and Chi-squared for categorical variables. ECV: External Cephalic Version. GA: Gestational Age. CS: Cesarean Section.

Outcome	Total (186)	95% CI	Group A (150)	95% CI	Group B (36)	95% CI
ECV Success, % (n)	68.8% (128)	61.9–75.1	74.0% (111)	66.6–80.5	47.2% (17)	31.7–63.2
GA at delivery, weeks	39.5	39.3–39.7	39.5	39.2–39.8	39.5	39.0–40.0
Type of labor, % (n)						
Spontaneous, % (n)	35.7% (65)	29.0–42.9	37.8% (56)	30.3–45.8	26.5% (9)	14.0–42.8
Induction, % (n)	31.3% (57)	24.9–38.3	33.8% (50)	26.5–41.7	20.6% (7)	9.7–36.2
CS, % (n)	33.0% (60)	26.4–40.0	28.4% (42)	21.6–36.0	52.9% (18)	36.5–68.9
Mode of delivery, % (n)						
Spontaneous, % (n)	29.7% (54)	23.4–36.6	31.1% (46)	24.0–38.8	23.5% (8)	11.8–39.5
Operative, % (n)	23.6% (43)	17.9–30.2	25.0% (37)	18.6–32.4	17.6% (6)	7.7–32.8
Urgent CS, % (n)	22.0% (30)	16.4–28.4	21.6% (32)	15.6–28.8	23.5% (8)	11.8–39.5
Planned CS, % (n)	24.7% (45)	18.9–31.4	22.3% (33)	16.2–29.5	35.3% (12)	20.9–52.0

The success rate of ECV increased from 47.2% (95% CI 31.7–63.2) in Group B to 74.0% (95% CI 66.6–80.5) in Group A (Fig. 1). The greatest increase in the success rate of ECV was seen in nulliparas, from

38.5% (95% CI 21.8–57.6) in group B to 69.1% (95% CI 59.4–77.6) (Fig. 1).

After successful ECV, 11 pregnant women (5.9%) showed breech presentation at birth and they were planned cesarean section.

The total vaginal delivery rate after ECV increased from 41.2% (95% CI 25.9–57.9) in Group B to 56.1% (95% CI 48.9–63.9) in Group A. Overall, the rate of planned cesarean after ECV decreased from 33.3% (95% CI 19.7–49.5) in Group B to 22.0% (95% CI 15.9–29.1) in Group A.

Multivariable logistic regression analysis showed that amniotic fluid pocket (OR 1.08, CI 95% 1.04–1.13 $P < 0.001$) was associated with the success of ECV. Multiparity (OR 3.16, CI 95% 1.04–9.58 $P < 0.05$) and lower maternal BMI (OR 0.86, 95% CI 0.77–0.95 $P < 0.001$) were associated with the success of ECV (Table 3).

Table 3

Logistic regression analysis to determine predictors of successful external cephalic version (ECV). P-value < 0.05 in bold. ^a Adjusted for multiparity, amniotic fluid pocket, body mass index, previous cesarean section, maternal age, and estimated fetal weight. OR: Odds Ratio. CI: Confidence Interval. AF: Amniotic Fluid. BMI: Body Mass Index.

Factors	Crude OR	95% CI	P-value	Adjusted OR ^a	95% CI	P-value
Multiparity	2.54	1.23–5.25	0.01	3.16	1.04–9.58	0.04
Previous CS	0.17	0.03–0.89	0.03	0.39	0.03–4.66	0.45
BMI, Kg/m ²	0.91	0.85–0.98	0.01	0.86	0.77–0.95	< 0.01
AF Pocket, mm	1.06	1.03–1.09	< 0.01	1.08	1.04–1.13	< 0.01

Over this period, 22 (11.8%) complications occurred, all during the 24 h following the procedure. Complications rate decreased from 22.2% (95% CI 11.1–37.6) in Group B to 9.3% (95% CI 5.5–14.8) in Group A. 13 minor vaginal bleeding, five non-reassuring fetal heart rate pattern, two preterm rupture of membranes, two chord prolapse and a maternal bronchoaspiration during the procedure were reported.

One newborn was admitted to neonatal unit care due to minor respiratory distress. This was a patient with a successful ECV, and afterward, intrauterine growth restriction was diagnosed. Labor was induced with dinoprostone and it was a spontaneous delivery with a cord blood pH = 7.28 and APGAR score at 1st minute of life = 8 and APGAR at 5 minutes of life = 9. The newborn was discharged after two days with no consequences.

One newborn was admitted to neonatal intensive unit care due to major respiratory distress. This was a planned cesarean section two weeks after unsuccessful ECV. It was an extremely difficult fetal extraction during the cesarean section that needed a J-shaped incision for achieving it. Arterial cord blood pH was 6.97, venous cord blood pH was 7.00, APGAR score at 1st minute of life = 1, and APGAR at 5 minutes of

life = 6. After 7 days, the newborn was discharged to neonatal unit care, where she was admitted for 23 days. No complications arose during the following year.

One patient suffered bronchoaspiration. The bronchoaspiration occurred just after ending the ECV. The patient was admitted to the maternal unit care with antibiotic treatment. Although a cephalic presentation was achieved, finally a cesarean section was performed due to the bronchoaspiration after 7 days with treatment. A female was born with APGAR score at 1st minute of life = 9 and Apgar at 5 minutes of life = 10. Arterial cord blood pH was 7.932, venous cord blood pH was 7.28. The patient and her newborn were discharged with no sequelae.

Discussion

The experience is considered crucial in medicine in general, and in obstetrics particularly. Super-specialization in medicine improves the experience acquisition and makes the daily work safer. It seems logical that the introduction of a super-specialized team in ECV, would improve the success rate and would make the procedure safer. National and International Obstetrics organizations should not only support but also lead specific formation and accreditation plans for External Cephalic Version specialization for obstetricians, midwives, and anesthesiologists in light of this and previous results.

In this study, the success rate of ECV increases from 47.2% (95% CI 31.7–63.2) to 74.0% (66.6–80.5%) with the introduction of a dedicated team. The number needed to treat was 6.7, meaning that 6.7 ECVs performed by the experienced dedicated ECV team led to one additional vaginal delivery in comparison with ECVs performed by the non-dedicated team. The creation of a dedicated experienced team of obstetricians to perform ECV led to an increase in the success rate and a significant decrease in the cesarean section rate overall.

If the results are compared in nulliparas, a greater increase is reported from 38.5% (95% CI 21.8–57.6) in group B to 69.1% (95% CI 59.4–77.6).

It is a known fact that analgesia [8, 12–14, 16, 20, 23] and tocolysis [8, 11] improve the ECV success rate. The present study had remarkable procedure characteristics such as, as far as we are concerned, it is the first group in which propofol is used for deep sedation in ECV, and what tocolysis concerned, ritodrine is administered for 30 minutes just before the procedure [21, 22].

Although several prediction models for the success of ECV have been developed, none of them included the experience of the operator as a potential predictor for success [24, 25]. Kim et al. underlined the potential importance of operator experience by developing a learning curve for ECV. To achieve an expected success rate of 50% in nulliparas, approximately 57 ECV attempts are needed, and for a 70% success rate, approximately 130 attempts are needed. In multiparas, only eight to 10 cases would be necessary for an expected success rate of 50% and 70%, respectively [26].

Several studies have analyzed their results in ECV when it is performed by a dedicated team: single-operator[17, 18] or dedicated team[5, 10, 19, 27]. Bogner et al. showed that the ECV success rate depended not only on parity and gestational age but also on performing physician [28].

It should be highlighted that the success rate of ECV in this study continued to increase in the years after the introduction of the dedicated team, without a change in team members. It may indicate the development of a learning curve.

Other studies have focused on the effect of a dedicated team[10, 27]. Hickland et al. replaced their ECV obstetrician with a weekly breech clinic every 15 days and showed an increase in the success rate of ECV from 32.6–41.9% over 3 years [27]. Thissen et al. compared ECV performed by a non-experienced team with their results after the introduction of a dedicated team. They reported an increase in the ECV success rate (39.8–59.66%) with the greatest increase in nulliparas[10].

Previous studies have tried to elucidate fetal and maternal factors that can predict the ECV result [6, 24, 25, 29, 30]. Normal or high amniotic fluid volume, multiparity, BMI < 35 Kg/m², reduced bladder volume, fetal transverse lie, and increased estimated fetal weight are predictive of the success of ECV in several studies[9, 25, 29]. The present study found that normal to high amniotic fluid volume, multiparity, and lower BMI was associated with the success of ECV.

ECV is considered to be a safe procedure for achieving a cephalic presentation. Two studies analyzed ECV complications rate in dedicated team[31, 32]. Beuckens et al. reported 47.2% of ECV success and 2.63% of complications during the 48 hours next to the procedure. Rodgers et al. reported a success rate of 35% for nulliparas and 62% for multiparas and an ECV complication rate of 4.73%. In both studies, ECV was performed without analgesia nor tocolysis. The present study found that an experienced dedicated team decreases ECV complications rate from 22.2% (95% CI 11.1–37.6) to 9.3% (95% CI 5.5–14.8) with the introduction of ECV dedicated team.

Super-specialization in obstetrics is essential for improving results and maintaining safety in procedures. ECV is an effective procedure for reducing the cesarean section rate and offering a chance for a vaginal delivery. When ECV is performed by experienced obstetricians a reduction in complications rate and an increase in success rate are observed[10]. Although how experience influences in ECV have already been analyzed, experienced dedicated team was compared with residents or non-experienced obstetricians[10]. This study has compared the results, in terms of effectiveness and safety, between the dedicated team and experienced senior obstetricians.

The introduction of a dedicated team not only supposes an advantage in comparison with residents or other colleges but also with other experienced obstetricians. Super-specialization in ECV, in the light of this study, should be enhanced by nationals and international obstetrics and gynecology associations.

Some key questions still unanswered, such as, the learning curve needed, the type of anesthetic technique, the type of tocolytic drug, etc. Besides, clinical trials are needed to evaluate definitively the

effectiveness of super-specialization in ECV. without the potential bias that could affect observational studies.

Strengths and Limitations

A strength of this study is the fact that it is the first prospective cohort study to assess the influence of an experienced dedicated team on the success rate of ECV in comparison with senior experienced obstetricians. This is the first study in which propofol is used for sedation in patients who underwent ECV. It should be also highlighted that in the present study ritodrine is administered for 30 minutes just before the procedure. There were no significant differences in patient and obstetric characteristics making selection bias less likely.

This study has some limitations. First, the number of women who underwent ECV in a non-dedicated team is small, which may affect the power of statistical analysis. However, differences observed in the present study, despite the lack of power, are consistent. Due to the differences in complications rate, it should be not ethical to increase patients recruited in a non-dedicated team in this study. Besides, the learning curve cannot be evaluated in this study due to the absence of temporal analysis.

Conclusion

ECV is a safe and effective procedure. The introduction of an experienced dedicated team improves the ECV success rate. Multiparity, lower BMI, and normal or high amniotic fluid volume have been associated with an increase in the ECV success rate. The introduction of an experienced dedicated team reduces the ECV complications rate. ECV super-specialization plan should be led by national and international obstetrics organizations.

Declarations

Ethics approval and consent to participate: This study was approved on the 30th of April of 2020 by the Clinical Research Committee of the 'Virgen de la Arrixaca' University Clinical Hospital (2020-5-6-HCUVA). Written informed consent was obtained from all participants. This study is in compliance with the 2013 Helsinki World Medical Association Declaration.

Consent to publication: Written informed consent was obtained from all participants to publish their data.

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available due ethics reasons but are available from the corresponding author on reasonable request.

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Figures

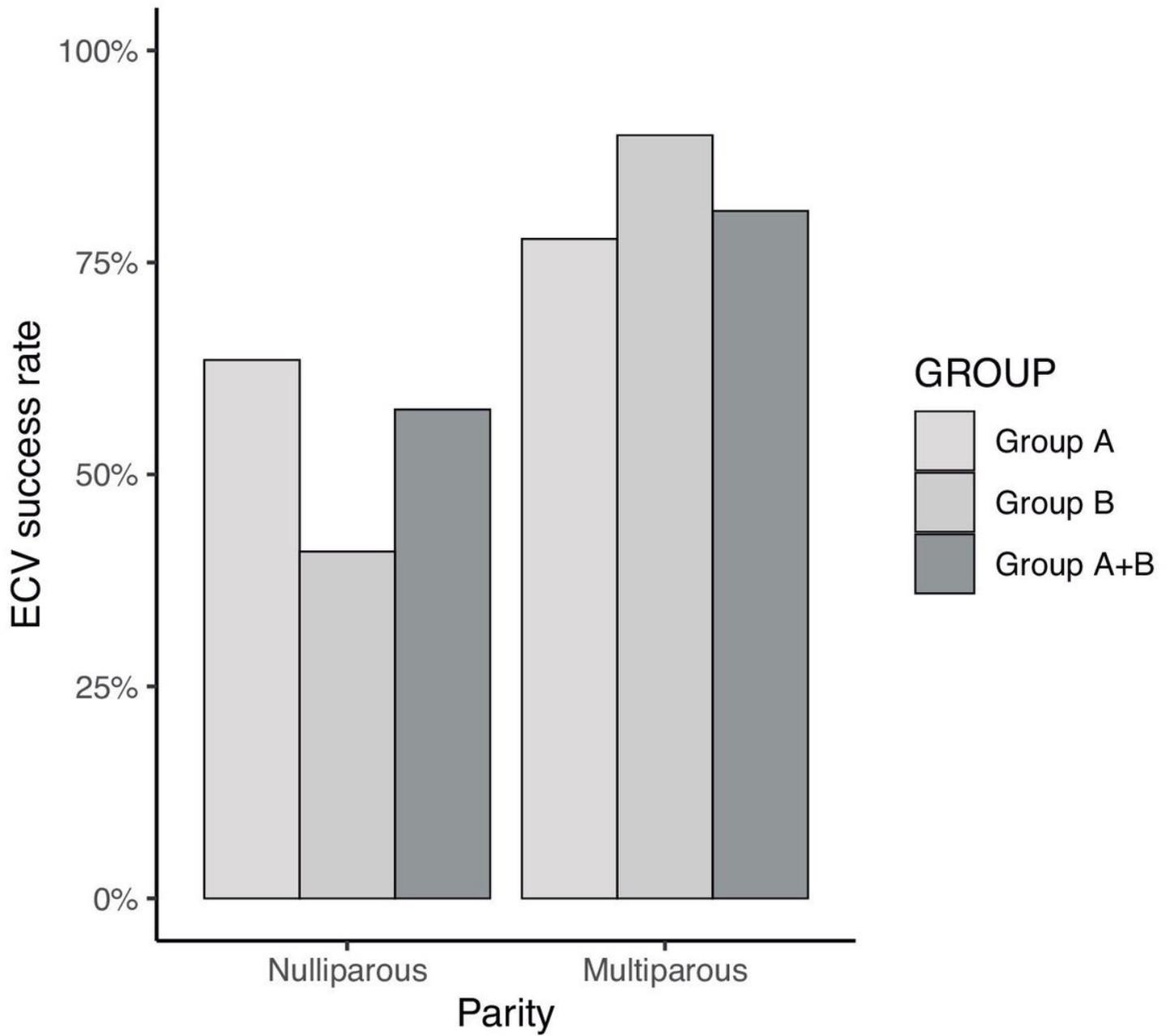


Figure 1

ECV Success rate for nulliparas, multiparas, and total women.