Is Propofol a safe agent for External Cephalic Version?

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March 07, 2024

Abstract

Objective: Analyze ECV results when propofol is used for sedation. Design: Longitudinal prospective analysis Setting: 1st of January of 2018 and 31st of December of 2020. Population: Pregnant women with non-cephalic presentation and no contraindication for vaginal delivery. Methods: Longitudinal prospective analysis of ECV performed in a tertiary hospital between the Just before the procedure, 0.2 mg/min of ritodrine was intravenously administered for 30 minutes. Sedation or neuraxial anesthesia was performed before the ECV. Main Outcome Measures: ECV success rate, Hypotension during procedure, ECV complication rate, cesarean section 24 h after ECV. Results: 242 pregnant women underwent ECV. All data were available for analysis just in 153 cases. ECV success rate was 66.9%. Sedation was performed in 88.8% and neuraxial anesthesia was carried out in 11.2%. For the sedation group, propofol was used in 96.3%. Emergency cesarean section rate during the following 24 hours of ECV was 6.7%. No difference in the emergent cesarean section during the 24 hours following the ECV rate when sedation or neuraxial anesthesia were performed (p=0.53). Conclusions: ECV is a safe and effective procedure. Sedation with propofol is useful for analgesia in ECV. Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

Title Page

Is Propofol a safe agent for External Cephalic Version? An observational study

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Shortened running title: Propofol a safe agent for ECV

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Setting: 1st of January of 2018 and 31st of December of 2020.

Population: Pregnant women with non-cephalic presentation and no contraindication for vaginal delivery.

Methods: Longitudinal prospective analysis of ECV performed in a tertiary hospital between the Just before the procedure, 0.2 mg/min of ritodrine was intravenously administered for 30 minutes. Sedation or neuraxial anesthesia was performed before the ECV.

Main Outcome Measures: ECV success rate, Hypotension during procedure, ECV complication rate, cesarean section 24 h after ECV.

Results: 242 pregnant women underwent ECV. All data were available for analysis just in 153 cases. ECV success rate was 66.9%. Sedation was performed in 88.8% and neuraxial anesthesia was carried out in 11.2%. For the sedation group, propofol was used in 96.3%. Emergency cesarean section rate during the following 24 hours of ECV was 6.7%. No difference in the emergent cesarean section during the 24 hours following the ECV rate when sedation or neuraxial anesthesia were performed (p=0.53).

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Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

Keywords: Sedation, Propofol, ECV, Breech presentation

Tweetable abstract: Propofol does not increase emergent cesarean section nor clinically relevant hypotension in ECV.

Body

Introduction

Breech presentation affects 3–4% of singleton term pregnancies[1,2]. 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, as widely known, is safer than breech or cesarean section. The use of an external cephalic version in breech presentation, according to WHO[2], certainly reduces the incidence of cesarean section, which is of special interest in those units where vaginal breech delivery is not a common practice.

ECV is usually performed before the active labor period begins. Factors associated with a higher ECV success rate include[3–5]: multiparity, a transverse presentation, black race, posterior placenta, amniotic fluid index higher than 10 cm.

Certain interventions have been related to helping in ECV[6] such as tocolysis or analgesia. Ritodrine has been reported as a safe tocolytic agent and the drug that improves the most ECV success rate[6,7]. Other tocolytic agents studied in ECV are nifedipine[6], atosiban[6], nitroglycerine[8], or others β-agonist[8].

Regarding analgesia in ECV, some interventions have been analyzed such as systemic opioids or neuraxial anesthesia. The use of neuraxial anesthesia during ECV has been found to increase the rate of successful ECV by as much as 60%[9–12].

When different types of anesthesia (neuraxial, intravenous, or inhalational) in ECV are compared, neuraxial anesthesia seems to increase ECV success rate the most[13]. No differences are reported in the ECV success rate when systemic opioids, such as remifentanil, or inhalational anesthesia are compared[9]. To the best of

our knowledge, ECV results using propofol as an anesthetic agent have not been previously analyzed, even though propofol is a common agent used for non-obstetric cases.

The main objective of this study is to analyze ECV results when propofol is used. As secondary objectives, it was compared the ECV results when propofol or neuraxial techniques were used. It was also analyzed the predictors of emergency cesarean section during ECV success. We hypothesize that propofol is a safe agent for ECV that does not affect ECV success rate nor severe ECV complications rate.

Methods

It is a longitudinal prospective analysis of ECV performed in 'Virgen de la Arrixaca' University Clinical Hospital in Murcia (Spain) between the 1st of January of 2018 and 31st of December of 2020. This center is the largest maternity department in Spain with approximately 7.000 births per year. This study was approved by the Clinical Research Committee of the 'Virgen de la Arrixaca' University Clinical Hospital. Written informed consent was obtained from all participants. This manuscript adheres to the applicable STROBE guidelines.

Procedure

ECV procedure was performed by the members of an ECV team. Each procedure was performed by two obstetricians of the Maternal-Fetal Unit in the obstetric operating room with the presence of an anesthesiologist and a midwife. Obstetricians, anesthesiologists, and midwives who are members of the ECV team were super-specialized professionals and they had more than 7 years of experience in ECV. Patients were recruited during the third-trimester obstetric evaluation at 36 week's gestation.

ECV was offered to every pregnant woman with non-cephalic presentation and no absolute contraindication for vaginal delivery. Women were deemed ineligible to undergo ECV in cases of severe preeclampsia, recent vaginal bleeding, confirmed rupture of membranes, and when an absolute indication for cesarean section was identified (i.e., placenta previa).

In the consult, all pregnant women 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.

If the patient was eligible and informed consent was obtained, ECV is performed at 37 weeks gestation. All patients were asked to fast for 8 hours before the procedure. Before ECV was performed, pregnant women were evaluated by the anesthesiologist. The patients were asked to empty their bladder. Just before the procedure, 0.2 mg/min of ritodrine was intravenously administered for 30 minutes[14].

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$^{\text{o}}$). The procedure was performed under anesthesia. Anesthesia procedure (sedation or neuraxial anesthesia) was elected by the anesthesiologist.

Two ECV attempts following the forward roll technique were performed by two experienced obstetricians. Immediately after the procedure, fetal well-being was assessed with a 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 1 hour. If any complication occurred immediately after the procedure, an urgent cesarean section was performed.

Outcome variables

ECV is considered successful when a cephalic presentation is achieved. Clinically relevant hypotension was considered if systolic blood pressure (SBP) was below 90 mmHg or the fall of at least 20% of SBP. 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

Clinical data were recorded prospectively on all referrals. Anesthesia data were recorded retrospectively. 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 clinically relevant hypotension. The tertiary outcome variable was the incidence of cesarean section during the following 24 hours. Weight and height at 12 week's gestation were recorded from the computed data records. Taking outcome variables: each obstetric history, anthropometric, 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. All variables with P-value <0.2 in bivariate analysis were considered using a multivariate analysis logistic regression model. In common with all logistic regression analyses, this produced a model applicable to the dataset from which it was generated. Ideally, this model would now be validated in a separate prospective dataset of equal or greater size to ensure that the association shown is robust.

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 4, 2021).

Results

242 patients were recruited between the 1st of January of 2018 and the 31st of December of 2020. Characteristics of pregnant women who underwent are shown in Table 1. Although 242 pregnant women underwent ECV, all data were available for analysis in 153 patients. The mean age was 32.5 years. 62.8% of the patients were nulliparous. Only nine pregnant women (3.7%) had a previous cesarean section. The mean estimated fetal weight at the 3rd trimester was 2784 g. The placenta was located in the anterior wall of the uterus in 52.5% of the patients, posterior in 39.6%, in the fundus in 3.3%, and in the lateral wall in 4.6%. The mean maternal BMI was 28.0 kg/m^2. ECV was performed at 37.4 weeks gestation as an average, and it was indicated because of breech presentation in 93% or transverse lie in 7%.

Characteristics of anesthesia are shown in Table 2. Meanwhile, sedation was performed in 136 patients (88.8%), neuraxial anesthesia was carried out in 17 (11.2%). No differences were found in the characteristics of pregnant women between both groups. For sedation group, propofol was used in 131 (96.3%), remifentanil was used in four (2.9%) and Ketamine was used in one (0.7%). The mean propofol dose was 156.1 mg (SD 6.1). When neuraxial anesthesia was performed, bupivacaine was used in nine (52.9%), prilocaine was used in seven (41.2%), and lidocaine just in one (5.9%).

ECV was successful in 162 pregnant women (66.9%). In nulliparous, a cephalic presentation was achieved after ECV in 93 (61.2%). In multiparous, ECV was successful in 69 (76.7%).

Data of delivery was not available for three pregnant women who gave birth in other hospital. After ECV, the delivery occurred at 38.9 week's gestation as an average. The eutocic delivery rate was 35.6%, operative vaginal delivery rate was 16.3%. Urgent cesarean section was performed on 28 pregnant women (11.7%). And, finally, elective scheduled cesarean section due to non-cephalic presentation underwent in 71 patients (29.7%).

The factors associated with ECV success in the logistic regression multivariant model (Table 3) were sedation (p=0.044; OR=3.44; CI95% 1.03 to 11.46), multiparity (p=0.004; OR=3.53; CI95% 1.48 to 8.38), BMI (p=0.006; OR=0.89; CI95% 0.81 to 0.97) and amniotic fluid pocket (p=0.028; OR=1.03; CI95% 1.01 to 1.06). No statistically significative differences were found in ECV success rate for previous cesarean section (p=0.154; OR=0.17; CI95% 0.01 to 1.96). If BMI was categorized (Table 4), patients with BMI above 30 Kg/m^2 had reduced possibilities of ECV success (p=0.015; OR=0.39; 0.18 to 0.83) when they were compared with those with a BMI below 25 Kg/m^2.

Intraversion complications occurred in 31 (12.8%) pregnant women (Table 5): nine (3.7%) non-reassuring fetal heart rate patterns, seven (2.9%) major vaginal bleeding, five (2.1%) minor vaginal bleeding, four

(1.7%) symptomatic uterine contractions during the following 48 hours, three (1.2%) premature rupture of membranes, two (0.8) cord prolapse and a (0.4%) maternal bronchoaspiration. An urgent cesarean section during the first 24 hours after ECV was required in 16 (6.7%) patients.

Although during ECV clinically relevant hypotension occurred in 29 (20.9%) pregnant women, just in four (2.9%) patients vasoactive drugs were needed. Hypotension was not statistically associated with drug dose ($p>0.05$). Hypotension occurred in 24 (17.8%) pregnant women who underwent sedation and eight (47.1%) patients who underwent neuraxial techniques. These differences reached statistically significance ($p=0.008$; OR=4.11; CI95% 1.44 to 11.74). However, no differences were found in intraversion complications rate nor urgent cesarean section rate during the first 24 hours after ECV when anesthesia techniques ($p=0.538$ and $p=0.516$, respectively) or hypotension ($p=0.411$ and $p=0.289$, respectively) during the procedure were compared.

Two newborns were admitted to neonatal unit care and one was admitted to neonatal ICU. Neither of these three cases was related immediately to ECV. One pregnant had an operative delivery at 38+1 weeks of gestation, two weeks after ECV. During the labor, fetal bradycardia required an operative delivery. The newborn APGAR score was 5/9, the fetal cord pH were 7.11 and 7.21. The newborn was admitted to neonatal unit care. In the second case, an urgent cesarean section was performed for non-reassuring fetal heart rate pattern at 37+6 weeks of gestation (5 days after ECV). The newborn APGAR score was 3/5, the fetal cord were 7.08 and 7.12. The newborn was admitted to the neonatal ICU. The last case was a pregnant with a eutocic delivery at 40+3 weeks of gestation (3 weeks after ECV). A shoulder dystocia occurred during the delivery. The newborn weighed 4120 g, the APGAR score was 5/8, fetal cord pH were 7.05 and 7.12. The newborn was admitted to neonatal unit care.

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 9/10, vein cord pH=7.32. The patient and her newborn were discharged with no sequelae.

Discussion

Main findings

ECV is a safe and effective procedure for achieving a cephalic presentation. ECV success rate in this study is 66.9%, which is higher than those found in the literature (49.0%)[3]. In nulliparous, cephalic presentation in this study is achieved after ECV in 61.2%, which is a higher rate than those found in the bibliography (40%)[3]. Equally, in multiparous, ECV in this study is successful in 76.7% and it is higher than those found in other reports (64%)[3]. This difference may be due to the use of ritodrine, as a tocolytic agent, just before the procedure, the type of analgesia, the gestational age at which ECV is performed, or the obstetrician experience.

Interpretation

Other studies, that have performed spinal techniques for analgesia, have reported lower ECV success rate[9–12]. Nevertheless, two recent studies should be noted since the ECV success rate when neuraxial anesthesia is performed is similar to this[13,15,16]. Although C. Weiniger et al.[15] reported an ECV success rate of 87.1% in pregnant women receiving spinal analgesia, they included the previous cesarean section neither patients with a BMI above 40 kg/m^2. K.S. Khaw et al.[16] reported an ECV success rate of 52.0% in pregnant women receiving spinal analgesia and 40% in pregnant women receiving intravenous remifentanil. In our study, remifentanil was rarely used and it is neither representative nor comparable. Only in 3 patients, remifentanil was administered, and just one resulted successfully.

In this study, the regression logistic model revealed that sedation increases ECV success rate ($p=0.044$; OR=3.44; CI95% 1.03 to 11.46) when it is compared with neuraxial technique. This result shows that sedation in ECV is an effective option that may increase the ECV success rate.

In our study, the most used drug administered intravenously was propofol. To the best of our knowledge, no report using propofol has been published. It should be highlighted that intravenous analgesia with remifentanil[17–19] has reported a lower ECV success rate (56.9%, 51.7%, 49% respectively) than propofol sedation which is used in this report. Burgos et al.[18] advised that although remifentanil did not increase the ECV success rate, the pain related to the procedure was markedly reduced.

No more than two attempts are proposed to perform ECV in the protocol. The National Society of Gynecology and Obstetrics recommends[20] no more than 4 attempts with the objective to avoid abruptio placentae and fetal heart rate disturbance. Due to tocolysis and sedation, obstetricians might be induced to apply greater forces, because of that, attempts in this study are limited to 2 in order to be more cautious with the procedure.

In this study, factors associated with ECV success are sedation (p=0.044; OR=3.44; CI95% 1.03 to 11.46), multiparity (p=0.004; OR=3.53; CI95% 1.48 to 8.38), BMI (p=0.006; OR=0.89; CI95% 0.81 to 0.97) and amniotic fluid pocket (p=0.028; OR=1.03; CI95% 1.01 to 1.06). Besides, multiparity, amniotic fluid pocket, and BMI are recognized as a factor associated with a higher ECV success rate in other reports[3,4,21]. A major effect reducing the ECV success rate is reported in this study when BMI is above 30 Kg/m^2 (OR=0.39, CI95% 0.18 to 0.83) when it is compared with a BMI below 25 Kg/m^2.[21]

ECV complications rate in this study is 12.8%, which is higher than those found in other reports (5.39%)[3]. Other reports have not reported minor complications such as premature rupture of membranes, minor vaginal bleeding, or symptomatic uterine contractions during the following 48 hours. Non-reassuring fetal heart rate patterns occurred in 3.7% of the procedures, this rate is higher than those reported in the literature (0.9%)[3]. When an urgent cesarean section rate during the first 24 hours after ECV is compared in this study (6.7%) with those found in the literature (4.7%)[16], it is slightly higher. These differences may be since tocolysis and sedation might induce the obstetricians to apply greater forces or hypotension caused by anesthesia techniques.

Although hypotension occurred more likely in neuraxial techniques, it did not cause an increase in urgent cesarean section rate during the procedure. The optimal dosage of drugs for neuraxial anesthesia that does not produce clinically relevant hypotension is a difficult goal. Probably, because of that sedation is more used in our hospital.

Even though a bronchoaspiration is reported, it should be highlighted that this is the only severe adverse event that occurred during the 7 years we have ECV records (more than 690 procedures). Notwithstanding that fast are recommended at least during 8 hours before the procedure, delayed gastric emptying can be delayed during pregnancy[22]. Although, this case is rare for a scheduled procedure it is critical to enhancing pre-anesthesia consult for obstetrics procedures.

Strengths and Limitations

Some strengths should be highlighted. This study has a large number of pregnant women recruited. It may be due to the Maternal-Fetal Unit of this hospital is one of the largest in Spain. All the ECV procedures were performed by the same obstetricians, anesthesiologists, and midwives that constitute the ECV working group. This group has more than 7 years of experience in ECV. All the procedures were carried out in the operating room where an urgent cesarean section can be rapidly performed.

An important limitation of our study is the loss of information for an anesthetic procedure. Due to logistic issues, some data for anesthesia techniques were unavailable for 89 patients. No complications arose in any of them, but the type of anesthesia technique, drug dose, blood pressure register, and other relevant information was not available for analysis for those patients. Despite the loss of anesthetic information, ECV results when propofol is used are promising.

Another limitation of our study is that the maternal weight was measured at 12 weeks gestation when the 1st-trimester scan was performed. The weight modifications during pregnancy were not taken into consideration with this measure.

Conclusion

In conclusion, the results of this study showed that the administration of propofol for ECV in pregnant women at term could facilitate a successful ECV.

Contribution to Authorship:

J Sánchez-Romero, J López-Pérez helped to record data, performing an ultrasound scan, and to design the study. AB Flores-Muñoz, MJ Méndez-Martínez, JE Blanco-Carnero, A Nieto-Díaz and ML Sánchez-Ferrer helped to record data and to design the study. F Araico-Rodríguez and D Fuentes-García helped to design the study. L Falcón-Araña helped to record data and to perform anesthesia techniques.

Funding statement:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical statement: This study was approved on the 30thof 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.

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Tables

Table 1 - Characteristics of the pregnant women who underwent ECV.

	Mean±SD/Frequency (count)
Maternal age, years	32.5 ± 0.3
Gestational age at ECV, weeks	37.4 ± 0.1
Previous gestations	1.9 ± 0.1
Parity	
Nulliparity	62.8%(152)
Multiparity	37.2%(90)
Previous cesarean section	3.7%(9)
Maternal BMI, Kg/m^2	28.0 ± 0.3
Estimated Fetal Weight before ECV, g	2 784.2 ± 22.8
Placental position	
Anterior	52.5%(126)
Posterior	39.6%(95)
Fundus	3.3%(8)

	Mean±SD/Frequency (count)
Lateral wall	4.6%(11)
Amniotic fluid Pocket, mm	50.7 ± 1.0
Fetal position	
Breech	93.0%(225)
Transverse lie	7.0%(17)
ECV result	
Success	66.9%(162)
Failed	33.1%(80)
Gestational age at birth, weeks	38.9 ± 0.3
Labor onset	
Spontaneous	33.9%(81)
Induced	30.5%(73)
Elective cesarean section	28.9%(69)
Urgent cesarean section	6.7%(16)
Delivery mode	
Eutocic	35.6%(85)
Operative	16.3%(39)
Urgent cesarean section	11.7%(28)
Elective cesarean section	29.7%(71)
Cesarean section during the following 24 h of ECV	6.7%(16)
Newborn weight, g	3 263.1 ± 28.2
ECV complication	12.8%(31)

Table 2 - Characteristics of the anesthesia techniques performed. Clinically relevant hypotension was considered if systolic blood pressure (SBP) was below 90 mmHg or the fall of at least 20% of SBP.

	Mean±SD/Frequency (count)
Premedication with atropine, midazolam or fentanil	36.2%(55)
Anesthetic procedure	
Sedation	88.8%(136)
Neuraxial	11.2%(17)
Drug used for neuraxial technique	
Bupivacaine	52.9%(9)
Lidocaine	5.9%(1)
Prilocaine	41.2%(7)
Drug used for sedation	
Propofol	96.3%(131)
Ketamine	0.7%(1)
Remifentanil	2.9%(4)
Propofol dosage	156.1 ± 6.1
Ketamine dosage	50.4
Remifentanil dosage	0.6 ± 0.3
Hypotension	20.9%(32)
Vasoactive drugs	2.6%(4)
Antiemetic drugs	9.2%(14)

Table 3 - Regression model for predicting ECV success.

Variable	OR	CI95%	p
Sedation	3.44	(1.03 to 11.46)	0.044
Multiparity	3.53	(1.48 to 8.38)	0.004
Previous cesarean section	0.17	(0.01 to 1.96)	0.154
Maternal BMI, Kg/m^2	0.89	(0.81 to 0.97)	0.006
Amniotic Fluid Pocket, mm	1.03	(1.01 to 1.06)	0.028

Table 4 – Regression model for predicting ECV success: BMI categorized.

Variable	OR	CI95%	p
BMI [?] 25 Kg/m^2	1,00	Reference	0.041
BMI between 25 to 30 Kg/m^2	0.70	(0.33 to 1.48)	0.353
BMI $>$ 30 Kg/m^2	0.39	(0.18 to 0.83)	0.015

Table 5 – ECV complications. FHR: Fetal Heart Rate.

Variable	Frequency	Count
Non-reassuring FHR pattern	3.7%	9
Major vaginal bleeding	2.9%	7
Minor vaginal bleeding	2.1%	5
Uterine contractions	1.7%	4
Premature Rupture of Membranes	1.2%	3
Cord prolapse	0.8%	2
Bronchoaspiration	0.4%	1