

Current Approach for External Cephalic Version in Germany

Aktuelle Praxis der äußeren Wendung in Deutschland



Authors

Fabian Kohls^{1*}, Friederike Gebauer^{2*}, Markus Flentje³, Lars Brodowski², Constantin Sylvius von Kaisenberg², Matthias Jentschke²

Affiliations

- 1 Klinik für Frauenheilkunde und Geburtshilfe, Asklepios Harzlinik Goslar, Goslar, Germany
- 2 Klinik für Frauenheilkunde und Geburtshilfe, Medizinische Hochschule Hannover, Hannover, Germany
- 3 Klinik für Klinik für Anästhesiologie und Intensivmedizin, Medizinische Hochschule Hannover, Hannover, Germany

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Correspondence

PD Dr. Matthias Jentschke
Medizinische Hochschule Hannover,
Klinik für Frauenheilkunde und Geburtshilfe
Carl-Neuberg Straße 1, 30625 Hannover, Germany
Jentschke.Matthias@mh-hannover.de

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ABSTRACT

Introduction Fetal breech presentation at terms occurs in 3–6% of pregnancies. External cephalic version can reduce the number of cesarean sections and vaginal breech deliveries. Different approaches are used to carry out external cephalic version. This study looked at the different approaches used in Germany and compared the approach used with the recommendations given in German and international guidelines.

Material and Methods An anonymized online survey of 234 hospitals in Germany was carried out in 2018. In addition to asking about hospital structures, questions also focused on how external version was carried out in practice (preparations, tocolysis, anesthetics, etc.), on relative and absolute contraindications and on the success rate.

Results 37.2% of the hospitals approached for the survey participated in the study. Of these, 98.8% performed external version procedures. The majority of participating hospitals were university hospitals (26.4%) and maximum care hospitals (35.6%) with an average number of more than 2000 births per year (60.9%). External cephalic version is the preferred (61.7%) obstetrical procedure to deal with breech presentation, rather than vaginal breech birth or primary cesarean section. 45.8% of respondents carry out external version procedures on an outpatient basis, and 42.1% of hospitals perform the procedure as an inpatient intervention, especially from the 37th week of gestation. Prior to performing an external version procedure, 21.6% of surveyed institutions carry out a vaginal examination to evaluate possible fixation of the fetal rump. 95.5% of institutions used fenoterol for tocolytic therapy; the majority using it for continuous tocolysis (70.2%). 1–3 attempts at external version (8.4%) were usually carried out by a specific senior physician. In most cases, no analgesics were administered. The reported rate of emergency cesarean sections was very low. The most common indication for emergency C-section was pathological CTG (56,7%). The assessment of relative and absolute contraindications varied, depending on the surveyed hospital. 67.5% asked patients to empty their bladders before carrying out external version, while 10.8% carried out external version when the bladder

* Shared co-first authorship

was filled. The reported success rate was more than 45%. After successful version, only 14.8% of hospitals arranged for patients to wear an abdominal binder. For 32.4%, the decision to apply an abdominal binder was taken on a case-by-case basis.

Conclusion The approach used in Germany to carry out external cephalic version is based on the (expired) German guideline on breech presentation. Based on the evidence obtained, a number of individual recommendations should be re-evaluated. More recent international guidelines could be useful to update the standard procedure.

ZUSAMMENFASSUNG

Einleitung Die Beckenendlage des Fetus am Geburtstermin tritt mit einer Häufigkeit von 3–6% auf. Mithilfe einer äußeren Wendung lässt sich die Anzahl an Kaiserschnitt- und vaginalen Beckenendlagenentbindungen senken. Bei der Durchführung gibt es unterschiedliche Vorgehensweisen, welche diese Umfrage adressiert und die mit Empfehlungen aus deutschen und internationalen Leitlinien verglichen werden.

Material und Methoden Es erfolgte eine anonymisierte Onlinebefragung von insgesamt 234 Kliniken in Deutschland im Jahr 2018. Neben Fragen zur Struktur der Kliniken wurden Fragen zur praktischen Durchführung der Wendung (Vorbereitung, Tokolyse, Anästhesie etc.), zu relativen und absoluten Kontraindikationen sowie zur Erfolgsrate gestellt.

Ergebnisse 37,2% der Befragten nahmen an der Studie teil. Von diesen führen 98,8% äußere Wendungen durch. Unter den Teilnehmern waren überwiegend Universitätskliniken

(26,4%) und Maximalversorger (35,6%) mit einer durchschnittlichen Geburtenzahl von meist über 2000 Geburten (60,9%) pro Jahr. Im Vergleich zur vaginalen Beckenendlagenentbindung und zur primären Sectio ist die äußere Wendung die bevorzugte geburtshilfliche Intervention (61,7%) bei dieser Lage. 45,8% führen diese ambulant und 42,1% stationär durch, vornehmlich ab der 37. SSW. Vor der Wendung führen 21,6% der Befragten eine vaginale Untersuchung zur Beurteilung einer Fixation des fetalen Steißes durch. 95,5% verwenden Fenoterol zur Tokolyse, größtenteils als Dauertokolyse (70,2%). Zumeist werden 1–3 Wendungsversuche (82,4%) durch eine/n bestimmte/n Oberärztin/-arzt vorgenommen. Eine Analgesie erfolgt mehrheitlich nicht. Die berichtete Notfallkaiserschnitttrate ist sehr gering. Falls erforderlich, ist die häufigste Indikation das pathologische CTG (56,7%). Die Einschätzung zu relativen und absoluten Kontraindikationen variiert zwischen den Kliniken. 67,5% leeren vor der Durchführung der Wendung die Harnblase, wohingegen 10,8% diese bei gefüllter Harnblase durchführen. Die berichtete Erfolgsrate liegt mehrheitlich über 45%. Nach erfolgreicher Wendung legen nur 14,8% einen Stützverband an. Bei 32,4% ist es eine Einzelfallentscheidung.

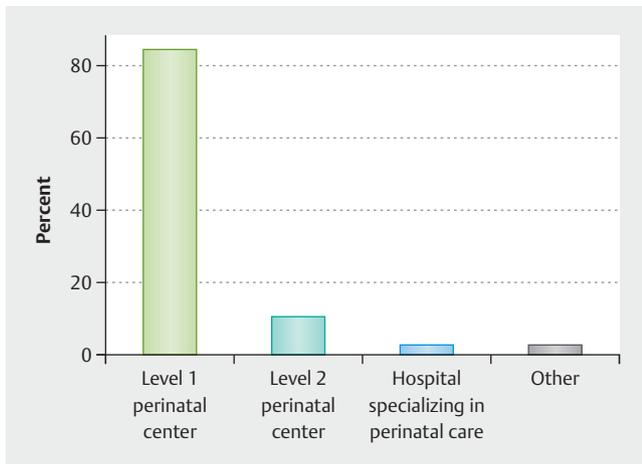
Schlussfolgerung Die Praxis der äußeren Wendung in Deutschland orientiert sich an der (abgelaufenen) deutschen Leitlinie zur Beckenendlage. Einzelne Handlungsempfehlungen sollten aufgrund der vorliegenden Evidenz erneut geprüft werden. Aktuellere internationale Leitlinien können hierbei hilfreich sein.

Introduction

In recent years, the rate of cesarean sections performed in Germany has continually increased [1]. In addition to previous delivery by cesarean section or other prior uterine surgery, breech presentation (BP) is one of the most common indications for elective cesarean section [2]. With an incidence of 3–6% at the end of pregnancy, BP is a very common positional anomaly [3–5]. One of the main reasons for the preference for carrying out primary cesarean section in cases with BP was the publication of the Term Breech Trial (TBT) in 2000, which reported that perinatal infant mortality in BP cases decreased from 1.3 to 0.3% if a planned cesarean section (RR 0–29; 95% CI: 0.10–0.86) was performed [6]. Even though the study was later strongly criticized and follow-up of most of the children after two years found no differences with regard to their neurological development [7], most fetuses in BP are still delivered by cesarean section. However, cesarean section is not always the best form of delivery. Some women categorically wish to have a vaginal birth. Moreover, cesarean section is not just associated with a number of risks during the surgical procedure, it can also have a long-term effect on affected women [8]. The appropriate mode of delivery for BP is now being discussed in a far more differentiated way [9]. Women with BP can now have a vaginal delivery, if they are first informed about the procedure in detail and undergo careful prior examination and the hospital can offer the appropriate obstetrical expertise.

External cephalic version (ECV) is an alternative to cesarean section and to vaginal delivery of BP. The first report of ECV dates from 1807; the procedure was carried out prior to the patient having uterine contractions [10]. A review of preferred modes of delivery over time shows that in the decade between 1950 and 1960, cesarean section was the preferred mode of delivery [11]. At the time, a number of case reports carried warnings about complications associated with ECV [12]. Since then, there have been continual improvements and developments in obstetric medicine. Monitoring improved greatly with the routine introduction of sonography and CTG, and tocolytics such as fenoterol began to be marketed. The new developments reduced the complication rate associated with ECV, and obstetricians became more confident about their manual abilities [11].

Different approaches to carrying out ECV have been described in the literature. The American College of Obstetricians and Gynecologists (ACOG) recommends mentioning the possibility of performing ECV as an alternative procedure and stresses the importance of taking the patient's wishes into account. The obstetrician's experience is important [13]. The Royal College of Obstetricians and Gynaecologists (RCOG) also have recent guidelines, issued in 2017, which describe the procedure used for ECV. The guidelines include detailed information about numerous aspects of ECV and appropriate recommendations [14]. The sister guideline of the RCOG on BP explicitly recommends attempting ECV unless it is absolutely contraindicated, for example in cases with



► **Fig. 1** Breakdown of hospitals according to the level of care offered for preterm infants and neonates.



► **Fig. 2** Time when external cephalic version is carried out, according to the week of gestation (multiple answers possible).

placental abruption, severe pre-eclampsia or pathological Doppler/cardiotocography (CTG) findings [9, 14].

The guideline of the German Society for Gynecology and Obstetrics (*Deutsche Gesellschaft für Gynäkologie und Geburtshilfe*, DGGG) on “Delivery of Breech Presentation” published in 2010 is no longer up-to-date [15]. The appendix merely briefly lists recommended courses of action and outlines the necessary conditions for carrying out external cephalic version as well as specific contraindications such as rupture of membranes, vaginal bleeding of unclear etiology, and placenta previa. A points system such as the Kainer score can be used to estimate the ECV success rate [16].

This study provides an overview of the external cephalic version procedures currently carried out in Germany and compares the collected information with German and international recommendations.

Material and Methods

Study description

A multicenter observation study in the form of an anonymized online survey of 234 hospitals in Germany was carried out. The surveyed hospitals included hospitals from the study group of the Gynecology and Obstetrics Working Group (*Arbeitsgemeinschaft für Gynäkologie und Geburtshilfe*, AGG) together with other hospitals in Germany delivering at least 1000 infants/year which could be identified from the online Milupa list of births (www.hebnews.de) [17]. The aim was to include all large obstetric institutions in the survey. A repeat e-mail was sent three times to the management of the respective maternity hospitals asking them to participate in the survey. As the survey was completely anonymized, it was not possible to send individual reminders to non-respondents.

The survey was web-based (www.surveymonkey.de; SurveyMonkey Europe UC, Dublin, Ireland). The ethics committee of Hannover Medical School approved the study (approval no. 8159_BO_K_2018). Statistical evaluation (descriptive data collection, presentation of data in the form of tables and diagrams) was

performed using Excel version 14 (Microsoft, Redmond, WA, USA).

Questionnaire

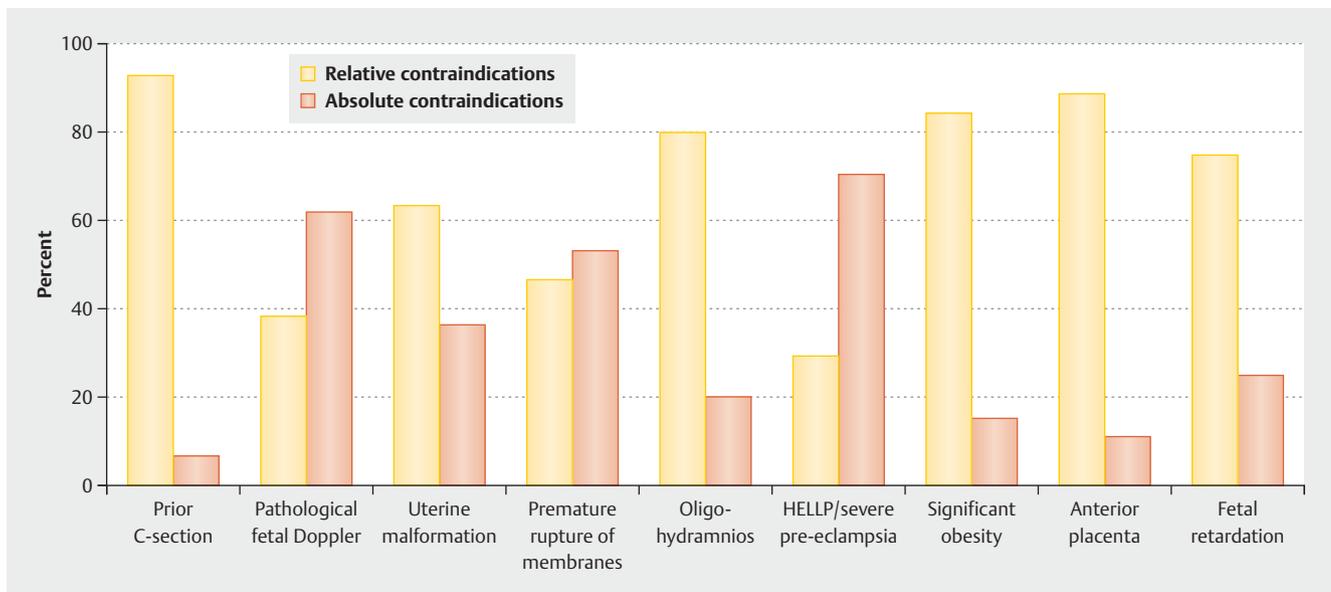
The questionnaire was designed by a local team of experts and based on a review of the literature. The questionnaire consists of 25 items, with respondents given a choice of specific responses for most topics. In some cases, respondents could select multiple answers (e.g. in answer to the question about complications of ECV and contraindications); in some cases, participants also had the option of submitting free-text responses. The questionnaire is shown in the supplement in full. The initial questions at the start of the questionnaire focused on general data about the hospital (size, perinatal center, number of births). Other questions asked how ECV was carried out in practice (preliminary examination, analgesics, tocolysis, etc.) and about the success rate and previous complications.

Results

Participating hospitals

A total of 234 hospitals in Germany were asked to participate in the survey in 2018. 37.2% (n = 87) of the hospitals which were approached participated in the study. Of these hospitals, 98.8% (n = 86) perform ECV. Many of the participating hospitals were university hospitals (26.4%, n = 23) and maximum care hospitals (35.6%, n = 31). 29.8% (n = 26) were secondary care hospitals and 8.1% (n = 7) were primary care hospitals. The average number of births per hospital was more than 2000 deliveries (60.9%, n = 53) per year. The majority of hospitals were level 1 perinatal centers (83.9%, n = 73) ► **Fig. 1**.

When asked about the preferred primary intervention for pregnant women with BP, the majority of respondents said ECV (61.7%, n = 50). Primary cesarean section was the preferred approach for 12.4% (n = 12) of surveyed hospitals, while 25.9% (n = 21) aimed for vaginal BP delivery as the primary treatment.



► Fig. 3 Relative and absolute contraindications for external cephalic version (multiple answers possible).

Time when ECV was performed, contraindications

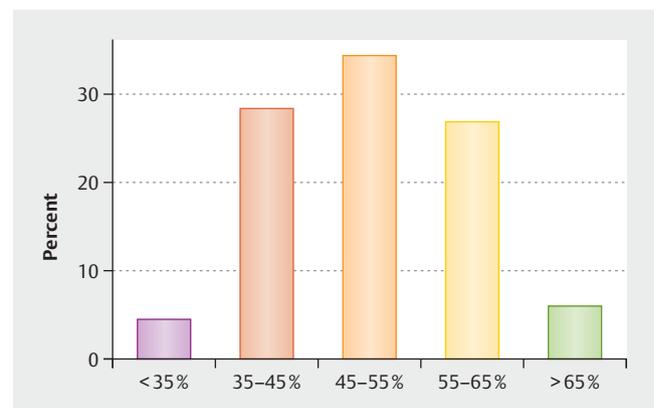
69.1% (n = 56) of the surveyed hospitals stated that they preferred to carry out ECV after the 37th week of gestation (GW). If preterm birth was imminent in week 36 + 0 to week 36 + 6, 63% (n = 51) of hospitals carried out external version procedures (multiple answers possible). Only a few hospitals carried out ECV in the 36th week of gestation (6.2%, n = 5). None of the surveyed hospitals carried out the procedure prior to the 35th GW (► Fig. 2). 45.8% (n = 38) of respondents carried out ECV as an outpatient procedure and 42.1% (n = 35) as an inpatient procedure.

The main relative contraindications include previous cesarean section (93.6%), anterior placenta (89.1%), significant obesity (84.6%) and fetal retardation (75%). Reported absolute contraindications were HELLP/severe preeclampsia (70.8%), pathological fetal Doppler/looped umbilical cord (62%) and premature rupture of membranes (53.4%). An overview of the relative and absolute contraindications is given in ► Fig. 3.

Performing the procedure in practice

Prior to carrying out ECV procedures, 67.5% (n = 50) of hospitals ask patients to empty their bladders. Only 21.6% (n = 16) of surveyed hospitals carried out a vaginal examination to detect possible fixation of the fetal rump.

The majority of participants reported attempting 1–3 external version procedures (82.4%, n = 61). The procedure was usually carried out by a specific person (59.4%, n = 44), usually the senior physician (78.3%, n = 58). In 35.1% (n = 26) of hospitals, two people are involved in carrying out the procedure. Almost all of the hospitals (95.5%, n = 71) use fenoterol as a tocolytic, in the majority of cases for continuous tocolysis (70.2%, n = 52). Nifedipine and atosiban are rarely used. No analgesic is administered in the majority of cases (90.5%, n = 67). If an analgesic is used, it is either nitrous oxide (6.7%, n = 5) or an epidural anesthetic (2.7%, n = 2). When asked about undesirable side effects of ECV, the majority of



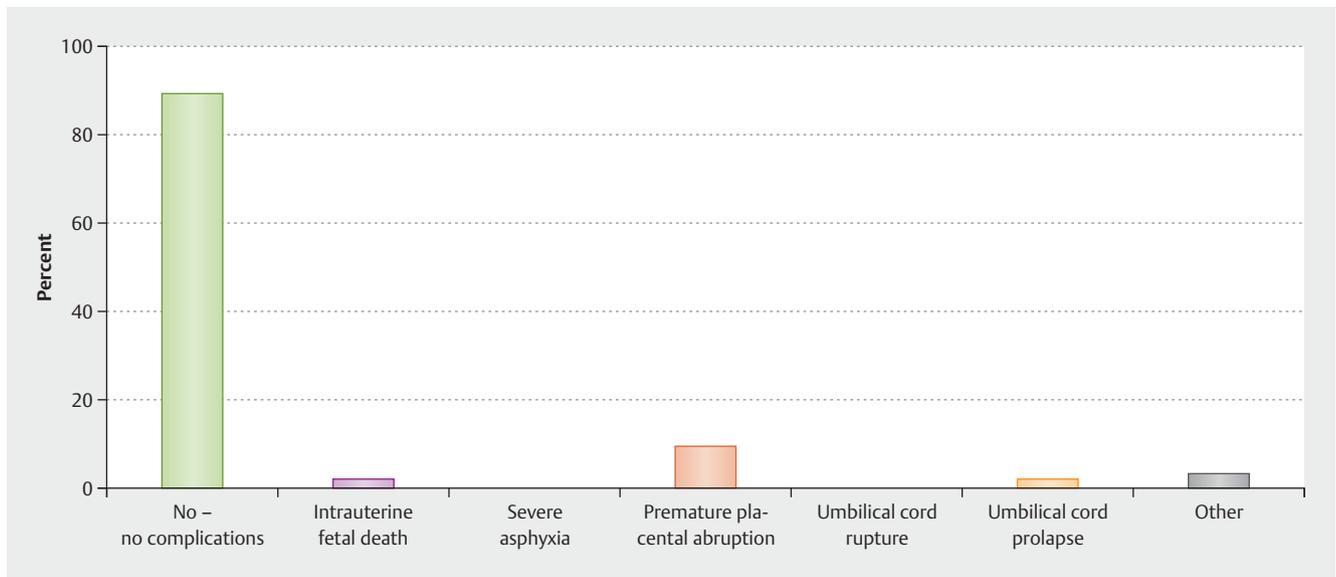
► Fig. 4 Reported success rate for external version procedures.

hospitals (70.2%, n = 52) cited the abdominal pain experienced by the patients. Other reported side effects included tachycardia (22.9%, n = 17), hypotension (12.1%, n = 9) and nausea (10.8%, n = 8).

After successfully performing ECV, 14.8% (n = 11) of surveyed institutions reported that patients were given an abdominal binder to keep the fetus in the new position. By comparison, 32.4% (n = 24) of respondents provided an abdominal binder to patients on a case-by-case basis. In the majority of hospitals, therefore, no measures are taken to secure the fetus in the new position. 25.6% (n = 19) of hospitals use the Kainer score to evaluate the success rate of ECV.

Success rate, complications

34.3% (n = 23) of respondents reported a success rate of ECV of 45–55%, and 26.9% (n = 18) reported a success rate of 55–65% (► Fig. 4).



► **Fig. 5** Reported incidence of serious and very serious complications (multiple answers possible).

The majority (85.1%, $n = 57$) of respondents estimated their emergency cesarean section rate to be $< 1\%$. If an emergency cesarean section nevertheless became necessary, the most commonly reported indication was pathological CTG (56.7%, $n = 38$). When we looked at the overall rate of serious complications, 89.5% ($n = 60$) said that they had no history of complications when attempting a version procedure. 8.9% ($n = 6$) of respondents reported a case of premature placental abruption. Participants were also asked about their complication rate in 2018. Overall, the complication rate was estimated to be very low (► **Fig. 5**). Reported complications included premature placental abruption (0.3%), intrauterine fetal death (0.2%) and umbilical cord prolapse (0.1%).

Discussion

Obstetricians are currently focusing on efforts to lower the rate of cesarean sections and their associated maternal and fetal risks. The development of an evidence-based protocol for ECV is important, as an ECV can reduce the incidence of fetal BP at term and thus also lower the number of C-sections with this indication [18]. Moreover, the majority of women would prefer a vaginal birth and women are very motivated to try an ECV [19]. The results of survey show that ECV is generally available in German hospitals with more than 2000 deliveries per year. Indeed, ECV was the preferred procedure in the majority of participating hospitals (61.7%) when caring for women with BP.

The German guideline on breech presentation deliveries has expired [15]. The expired guideline neither recommended carrying out ECV nor advised against it (“may be carried out”). The earliest timepoint for carrying out ECV was reported to be GW 36 + 0. Anesthesia was not considered to be indicated and tocolysis was not thought to be absolutely necessary; however, sonography to monitor the position of the fetus was considered mandatory. It is

important to ensure that the facilities to carry out an emergency C-section are available; depending on the clinical situation, a CTG may be carried out [15].

Internationally, the ACOG guideline provides clear recommendations for action [20]. Our survey should provide clarity about those aspects of the procedure which are already standardized and where there are divergences in procedures, including in the international literature.

Individual cases excepted, ECV is only performed from week 36 + 0 of gestation, and the overwhelming majority of ECV procedures are only performed after week 37 + 0. This approach is similar to that proposed in the expired German guideline which states: “ECV can be carried out from GW 36 + 0” [15]. Cochrane meta-analyses have shown that performing ECV earlier may reduce the risk of BP at term (RR 0.81; 95% CI: 0.74–0.90) but that the risk of preterm birth rises (RR 1.51; 95% CI: 1.03–2.21) if ECV is carried out before week 37 + 0 of the pregnancy, [21]. There is good evidence that carrying out ECV from GW 37 + 0 reduces the rate of BP at delivery as well as the rate of cesarean sections [22]. It is therefore important to discuss the appropriate time to carry out the procedure with the patient. It is also important to be aware that, in the rare event of complications necessitating an emergency C-section (according to our survey, this occurs in $< 1\%$ of cases), carrying out ECV from GW 37 + 0 means the delivered infant will not be premature. The RCOG also recommends carrying out ECV procedures from GW 37 + 0, in nullipara even from GW 36 + 0 [14].

In principle, the contraindications reported in the survey concur with those given in the literature. Previous cesarean section is a commonly reported relative contraindication. The reason for citing it as a contraindication is the unclear risk of uterine rupture [20]. Two recent observational studies ($n = 100$ and $n = 158$) examined the safety and efficacy of ECV in this specific patient cohort [23,24]. The studies reported no cases of uterine rupture.

However, the success rate for ECV procedures was lower than that of the comparison group without previous cesarean section (OR 0.55; 95% CI: 0.36–0.84; 86.1 vs. 74.1%). Accordingly, the guideline of the RCOG does not consider prior C-section as a contraindication. Rather, pregnant women should be informed that previous C-section does not appear to be associated with increased risks [14].

According to our survey, most participants use a similar approach in practice to carry out ECV procedures: the majority do not consider it necessary to carry out a vaginal examination to determine whether the fetal rump is fixed in position. ECV can be carried out after the patient has emptied her bladder, and 1–3 attempts at external version are performed by an experienced medical professional, usually a specified senior physician. However, some authors also consider a full bladder to be essential for mobilizing the fetal rump [24]. ECV are routinely performed before the patient has had uterine contractions and under continual parenteral tocolysis with fenoterol. This approach is very much evidence-based [18,20]. Parenteral tocolysis with beta mimetic drugs is effective with regard to achieving a head-first position at delivery compared with no tocolytic drugs (RR 1.68; 95% CI: 1.14–2.48) and reduces the rate of cesarean sections (RR 0.77; 95% CI: 0.67–0.88) [18]. Because of the lack of data, no recommendations can be made about other tocolytic drugs.

Our survey also found that in Germany regional anesthesia is not considered to be indicated during version procedures, as was also stated in the German guideline [15]. But according to more recent literature, this standpoint should be reviewed. A meta-analysis has shown that regional anesthesia in addition to tocolysis can increase the success rate (RR 1.58; 95% CI: 1.29–1.93) and, in particular, also further decrease the cesarean section rate (RR 0.83; 95% CI: 0.71–0.97) [25]. Regional anesthesia would reduce the most common side effect of ECV, i.e., abdominal pain, and the patient's fear of experiencing abdominal pain. In a meta-analysis, regional anesthesia was assessed as safe, but the most important limitation of all the data on ECV and interventions is that the evidence is insufficient to be able to comprehensively evaluate the risk profile. The authors of this study are concerned that anesthesia accompanied by hypotension could result in a longer hospital stay [26]. The RCOG only recommends regional anesthesia when a repeat attempt at ECV is carried out after the initial attempt failed due to pain [14].

Our survey has shown that there were considerable differences between participating hospitals with regard to the patient's admission to hospital for the procedure (outpatient versus inpatient procedures). The DGGG guideline and international guidelines recommend carrying out ECV procedures as outpatient procedures.

An important question asked by all patients when they are being informed about the procedure is the question about the success rate in their individual case. Model calculations could help them when making their decision. When we asked about using the Kainer score [16], it became apparent that only some of the hospitals in Germany use it regularly. It is not possible to recommend an alternative model because the evidence is lacking. None of the models have been sufficiently validated [20]. For example, a recent study evaluating higher success rates (65%) identified

body mass index, fetal head diameter and parity as independent determinants [27].

The estimates of the overall success rate also vary quite considerably in Germany (45–65%). Meta-analyses confirm these wide variations (16–100%), with a pooled success rate of 58% and a pooled rate of complications of 6.1% [28].

Overall, it is of course not possible to exclude a certain bias in this study, as is often the case with studies based on surveys. Hospitals which successfully perform ECV procedures were probably more inclined to participate in the study than hospitals where this was not the case. This is also reflected by the response rate of just 37.2% (n = 87). Moreover, large hospitals were overrepresented. Because the survey was completely anonymized, it was not possible to approach hospitals individually and encourage them to participate. The reported figures for success rates, emergency C-section rates and incidence of complications should also be treated with caution as participants were only asked about their personal assessment and no verifiable figures were available. It can certainly be assumed that the perception of these issues was too positive. Nevertheless, the overall picture was relatively homogeneous, and it provides a good cross-section of the predominant approach currently used for ECV in Germany.

Conclusion

The approach used when carrying out external cephalic version in Germany is relatively uniform and is based on the guideline of the DGGG. The estimated rate of complications for ECV is very low. Individual recommendation such as the use of regional anesthesia should be re-examined based on the information collected here. It could be useful to consult more recent international guidelines, such as those of the RCOG, to update current practices.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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