Original Investigations

Risk factor analysis in women who underwent trial of labor after cesarean section: a multicenter study in Germany

Gitas et al. Risk factor analysis in women who underwent trial of labor after cesarean section

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Abstract
Introduction: Rising caesarean delivery (CD) rates throughout the world are accompanied with high rates of severe maternal complications. The aim of the present study was to analyze the outcome of trial of labor after caesarean section (TOLAC) in a Western population and identify factors associated with the success of vaginal birth after caesarean section (VBAC).
Materials: A retrospective study was performed at two large obstetric departments in Germany from 2008 to 2018. Women with singleton pregnancies, a history of only one previous caesarean delivery with a low transverse incision, a viable fetus in cephalic presentation, and gestational age > 32 weeks were included in the study. The characteristics and outcome of successful VBAC and failed TOLAC were compared. A subgroup analysis

addressed gestational age, interpregnancy interval, fetal macrosomia, body mass index (BMI), and maternal age.

Results: Of 1546 patients, 62.3 % achieved VBAC while 37.7% had a secondary CD. Independent factors associated with the success of TOLAC were a history of vaginal birth in previous pregnancies ($p<0.001$) and the use of oxytocin ($p<0.001$), whereas preterm birth between gestational week 32 and 37 signified a higher risk of failed TOLAC ($p=0.04$). The success of VBAC did not differ significantly for patients older than 40 years of age, those with a shorter interpregnancy interval than 12 months, and fetal macrosomia with birth weight exceeding 4000 grams. Maternal and neonatal outcomes were poorer in women with failed TOLAC.

Conclusion: Nearly two thirds of women with a history of CD achieve VBAC in Germany. Previous vaginal birth and the augmentation of labor with oxytocin are positively associated with the achievement of VBAC and no major perinatal complications. The decision to have a TOLAC should be encouraged in the majority of patients. Further studies are needed to evaluate the feasibility of TOLAC in preterm delivery.

Keywords: VBAC, TOLAC, predictors, risk factors, maternal outcome, neonatal outcome

Introduction

The frequency of caesarean deliveries (CD) has risen markedly in the last few decades. In Europe, CD rates have increased from 11.2% of all deliveries in 1990 to 25.0% in 2014 (1). The most frequent indication for CD is prior CD, which contributes strongly to the overall increase in CD rates (2). Trial of labor after caesarean section (TOLAC) is a crucial strategy to reduce CD rates. Vaginal birth after caesarean section (VBAC) is achieved in 60% to 83.3% of cases (3, 4). VBAC is a medically safe procedure. The fall in VBAC rates worldwide from 24% to 8% is a matter of public and professional concern (5). The drop in VBAC rates has been accompanied by large numbers of elective repeat caesarean section (ERCS) (6).

CD is known to be associated with severe maternal complications, including a high risk of mortality (7) compared to vaginal deliveries. The numerous benefits of vaginal birth, such as rapid maternal recovery, fewer maternal complications in future pregnancies, lower risk of childhood diseases (allergies, asthma etc.), are also worthy of note (8). A number of studies focusing on the outcome of TOLAC, published in the last few years, have yielded diverse results. However, VBAC was shown to be relatively safe for mother and child compared to ERCS (9). Successful VBACs are also associated with lower overall morbidity rates (10) compared to ERCS. Nevertheless, a failed VBAC increases the risk of perinatal and maternal complications compared to ERCS (11).

Several attempts have been made to identify clinical factors associated with successful TOLAC. One of the aims of these investigations was to create validated risk scores for the likelihood of VBAC (12). Factors such as ethnicity, prior vaginal delivery or VBAC, cervical length, head-perineum distance, maternal age, interdelivery interval, neonatal weight, and body mass index (BMI) were investigated. Risk scores might help physicians and expectant mothers to decide in favor of or against TOLAC, but have not been established so far. In view of the absence of an international consensus concerning VBAC and the frequent modification of guidelines every few years, the outcome of TOLAC must be re-evaluated in the light of recent data.

The purpose of the present study was to assess the possibility of vaginal delivery in women who underwent TOLAC, identify predictors and risk factors that could influence the success of a planned VBAC, and present maternal and neonatal outcomes of successful and failed

TOLAC. Data from two large tertiary care academic hospitals in Germany were analyzed in order to issue recommendations for counseling candidates for TOLAC.

Material and Methods

A retrospective multicenter investigation was conducted at two large departments (the academic teaching hospitals of Klinikum Leverkusen and the University Hospital of Luebeck) of obstetrics with facilities for high-risk pregnancies in Germany from January 2008 to January 2018. Written informed consent *was* obtained from all patients. The study was in compliance with the Helsinki Declaration and was approved by the ethics committee (approval number 19-285A). Inclusion criteria were singleton pregnancy, a history of only one previous caesarean delivery with a low transverse incision, a viable fetus in cephalic presentation, intention to deliver vaginally, and patients >32 weeks of gestation (a vaginal delivery under this gestational age was not favored at these institutions).

A computer-based search yielded 4139 patients with one previous caesarean section in their medical history. All patients have given their consent of attempting TOLAC. Approximately a half of the patients had undergone an elective repeat caesarean section, while the other half wished to attempt TOLAC. In addition to ERCS, exclusion criteria were emergencies before labor, intrauterine growth restriction, fetal anomalies, and multiple gestation. Finally, 1546 patients (607 from Leverkusen and 939 from Luebeck) fulfilled the inclusion criteria (Figure 1).

Patients were divided into a successful VBAC group (Group I) and a failed TOLAC group with secondary CD (Group II). Success rates and risk factors were studied in both groups. Patient characteristics are summarized in Table 1. The period of investigation extended from the start of regular labor pain to birth. Maternal surveillance data such as analgesia for labor, sanguineous or green amniotic fluid, the use of oxytocin, and labor induction with prostaglandin were analyzed.

A subgroup analysis was performed to identify specific risk factors for successful TOLAC. According to the international classification, 'severely obese' is defined as a BMI $\geq$ 35 kg/m^2 (13). The following factors were analyzed in both groups: an interpregnancy interval shorter than 12 months, women older than 40 years of age, BMI higher than 35 kg/m^2, fetal macrosomia with birth weight exceeding 4000 grams, preterm delivery between gestational week 32 and 37, postterm TOLAC beyond 40+0 weeks of gestation, and neonatal pH below 7.10. The BMI limit of 35 kg/m^2 was selected in order to facilitate comparison of our data with the published literature. Maternal and neonatal outcomes were also analyzed (Table 2). Both institutions had the same standards of care.

Statistical analysis

Statistical analysis was performed using statistical software program IBM SPSS Statistics for Windows, version 21.0 (IBM Corp. 2012. Armonk, NY: IBM Corp). Continuous data were reported by mean (SD). The categorical variables were shown as numbers of patients and percentages and the χ2 test or Fisher's exact test was used. Normal distribution of data was assessed using a one–sample Kolmogorov-Smirnov test. Quantitative variables were compared by Student's *t*-test. *P*-values less than or equal to 0.05 were considered to be statistically significant.

Results

Baseline characteristics and maternal surveillance were homogeneous in the two groups (963 women in Group I vs. 583 women in Group II) (Table 1). The success rate of intended and completed VBAC was 62.3% and the rate of secondary CD, 37.7%. Success rates were 60.7% in Luebeck and 64.6% in Leverkusen. Vacuum or forceps extraction accounted for 13.8% (133/963) of vaginal deliveries. Episiotomy was used in about 67% of assisted and 20% of spontaneous deliveries. Nearly 1/3 (n = 477, 30.9%) of the patients had labour induced with prostaglandin.

Prior vaginal birth was a strong independent factor associated with successful TOLAC($p<0.001$). Epidural anesthesia and the induction of labor with prostaglandin or oxytocin were significantly more common in women with successful VBAC than in those who had a repeat CD ($p<0.001$). Failed TOLAC was associated with a history of caesarean section due to obstructed labor. Further parameters are shown in Table 1.

The time period from the beginning of regular labor to parturition was significantly shorter (5.8 ± 3.1 vs. 7.9 ± 5.5 hours; $p<0.001$) in women who had a spontaneous birth prior to cesarean delivery. The time period from the start of regular labor to parturition was also significantly shorter (5.3 ± 3.1 hours vs. 8.0 ± 5.5 hours; $p<0.001$) in women with a previous VBAC. This significance existed in subgroup of patients with a history of fetal distress (6.8 ± 5.0 hours; $p=0.031$) but not in those with a history of obstructed labour (8.8 ± 5.7 hours). Women who delivered before completed 37 weeks of pregnancy had a significantly shorter duration of delivery after the start of regular contractions (4.9 ± 3.3 hours) compared to those with term pregnancies (7.8 ± 5.4 hours; $p<0.001$).

The subgroup analysis (Table 3) yielded no significant difference in the success of VBAC in patients older than 40 years of age, an interpregnancy interval less than 12 months, and fetal macrosomia with birth weight exceeding 4000 grams. Women with a postterm pregnancy exceeding 40 + 0 weeks of gestation had greater chances of a successful VBAC. Failed TOLAC was associated with preterm birth between 32 and 37 weeks of gestation.

Patients with failed TOLAC experienced significantly greater blood loss and had higher uterine rupture rates than those with successful VBAC (Table 2). Only five patients (25%) with uterine rupture were given oxytocin. Neonatal outcomes were significantly poorer in the failed TOLAC group. Analytically, an umbilical cord pH<7.1 was significantly more common in women with failed TOLAC compared to those who had a normal or operative vaginal delivery by VBAC ($p<0.01$). Additionally, significant differences were noted in the rates of 5-minute Apgar scores below 6 ($p<0.02$) or 7 ($p<0.001$), and Apgar score at 10 minutes ($p<0.001$). (Table 2).

Discussion

To our knowledge, the present study is the largest investigation conducted in Germany on outcomes and risk factors for TOLAC. Baseline characteristics and maternal surveillance were similar in the successful VBAC group and the failed TOLAC group. Approximately two thirds of patients who attempted TOLAC (62.3%) achieved VBAC safely. This is in line with the data reported in a large cohort study (6) comprising 143,970 patients from England (63%), but slightly lower than the rates reported in previous studies.

The majority of investigations report successful VBAC in 60% to 83.3% of cases (3, 4). A relatively high success rate of 91.0% was reported in one study (14). These variations are probably due to differences in healthcare systems or selection criteria. At our institutions, a trial of TOLAC was offered to all women with no contraindications in accordance with international standards (15-18). The two institutions involved in the present study did not differ in terms of structure. The difference in success rates between Luebeck (60.7%) and Leverkusen (64.6%) suggests that the management of TOLAC is a multifactorial issue.

In keeping with previous studies (19, 20), our data showed that a previous vaginal birth is a strong predictor of the success of VBAC. Information about previous vaginal births must be included in any consultation of a patient asking for VBAC. The likelihood of successful VBAC is approximately threefold higher in patients with a previous vaginal delivery (21). Moreover, a previous vaginal delivery is associated with a six- to ten-fold greater likelihood of achieving VBAC (22).

We observed an association between the use of epidural anesthesia and the success of VBAC, which is contrary to the data reported in many studies (23, 24). Furthermore, the indication

for previous CD (obstructed, fetal distress history, malpresentation history, etc.) may be an important factor in the success of TOLAC. In our analysis, a history of obstructed labor, rather than a history of malpresentation, was significantly associated with failed TOLAC. The general higher age of motherhood (after 35 years) in recent times has been associated with a rise in pregnancy complications, such as preeclampsia, gestational diabetes, placental anomalies, and caesarean section (25). The role of maternal age as a predictor of the success of TOLAC is controversially discussed (26). Nevertheless, maternal age was regarded as an important parameter in our analysis. In an investigation of 335 women older than 40 years who had never delivered by the vaginal route, Levin et al. (27) registered successful TOLAC in 62.3%. In a subgroup analysis of women who underwent TOLAC, we found no difference between 128 women older than 40 years of age and those younger than 40 years. The success of TOLAC was reported to be impaired by gestational diabetes and a high BMI, resulting in a high risk of fetal distress, labor arrest, and failed induction (26). However, Mei et al. (28) found no difference in TOLAC success rates stratified by obesity classes of BMI 30-34.9, 35-39.9, or more than 40 kg/m^2. Coleman et al. (29) noted that women with gestational diabetes were less likely to have a successful TOLAC than those without diabetes. In an analysis of 423 deliveries complicated by type I gestational diabetes versus 9437 control deliveries, Marchiano et al. (29, 30) observed similar success rates in both groups. We found no association between the success of TOLAC and gestational diabetes or severe obesity (BMI≥35 kg/m^2). Regan et al. compared the success of TOLAC between high-risk pregnancies (maternal BMI>30 or diabetes) versus low-risk patients, and observed similar rates of successful VBAC in the two groups (31).

We suspected that the apparently negative impact of gestational diabetes on the success of TOLAC was not due to the presence of diabetes itself, but due to fetal macrosomia and other differences in baseline characteristics. We examined the success of TOLAC in 156 women with fetal macrosomia (> 4000 grams), and observed no significant difference in the outcome of TOLAC. Oboro et al. (32), on the other hand, reported a fetal weight in excess of 4,000 grams as one of the most important factors underlying the failure of VBAC.

In a subgroup analysis, we found that an interpregnancy interval shorter than 12 months had no negative impact on the success of TOLAC. Similar data were reported in a study (33) on the success of TOLAC in 3176 women with a short interdelivery interval: a shorter interval than 12 months was no risk factor for maternal death, uterine rupture, or other major complications, but the risk of preterm delivery was higher in this group. In a large meta-analysis (26), an interpregnancy interval shorter that 24 months was not related to failed TOLAC. However, it should be noted that the meta-analysis included only one study (34) with an interpregnancy interval shorter that 18 months.

Although the induction or augmentation of labor is not contraindicated in patients undergoing TOLAC, the issue is controversially discussed among clinicians. The likelihood of uterine rupture is believed to be higher when oxytocin is used. A large study comprising 13,523 patients who underwent TOLAC showed an association between uterine rupture and the dose of oxytocin: a high rupture rate (2.07 %) was registered for the highest dose (35). The rate of uterine rupture in our study (1.3 %) was slightly higher than the range reported in the published literature (0.2-0.5 to 0.9%) (10, 21). However, we found that the induction of labor with prostaglandin or the use of oxytocin is positively correlated with the success of TOLAC. We also observed no association between oxytocin and uterine rupture. The induction of labor with prostaglandin in women undergoing TOLAC was associated with higher rates of uterine rupture and perinatal morbidity compared to other types of labor induction (10). Thus, the use of prostaglandin in patients undergoing TOLAC requires further investigation. Palatnik et al. (36) noted that the induction of labor at 39 gestational weeks might increase the chances of VBAC, but also those of uterine rupture, compared to expectant management.

Our analysis revealed that a gestational age of 37-40 weeks is not associated with the success of TOLAC. A postterm pregnancy also did not affect the success of TOLAC, which is in line with a large study published by Ram et al. (37). In a cohort study, Hammoud et al. (38) noted lower rates of success and higher rates of uterine rupture in women who delivered at >41+0 weeks of gestation.

As a gestational age < 37 weeks was an exclusion criterion in the majority of studies, we have a very limited body of published data concerning TOLAC before 37 weeks of gestation (36, 37). We analyzed 186 patients who underwent TOLAC between gestational week 32 and 37, and noted a negative association between preterm deliveries and the success of TOLAC. Large studies will be needed to evaluate the outcome of preterm deliveries in patients undergoing TOLAC.

In our analysis, blood loss und uterine rupture were significantly greater in patients with failed TOLAC than in those with successful VBAC. Failed TOLAC was associated with poorer neonatal outcomes, thus parameters which may be associated to long-term neonatal outcome, such the rates of 5-minute Apgar scores below 6 (0.5% vs 2.9%) or 7 (0.7% vs. 2.9%), were statistical significantly higher in this group and higher than the medial rate reported in the literature (less than 1%) (39). Furthermore, the incidence of postpartum acidosis (pH<7.1) were higher in failed TOLAC group. Similar data were reported in previous studies (14, 32). Neonatal complications, including respiratory distress syndrome, meconium, and retraction, were significantly higher in the failed group than in the successful VBAC group (40).

Study Limitations

The prime limitation of the present study is its retrospective design. Factors such as operator experience or physician preferences were not assessed, and might have accounted for the results. However, it may be very difficult to perform a prospective investigation in a large sample. A Cochrane review in an Australian population of women undergoing VBAC or ERCS highlighted the difficulty of randomization (41). Despite these limitations, we believe that the data obtained in the present study signify a valuable contribution to the current published literature.

Conclusion

In Germany, approximately two thirds of patients undergoing TOLAC are able to achieve a safe VBAC. A history of previous vaginal birth and the augmentation of labor with oxytocin are positively associated with the achievement of VBAC without major perinatal complications. TOLAC should be offered to all eligible women, and should not be discouraged in postterm pregnancies, older, or obese women. The use of data from the early 2000s might have been one reason for the diverse published reports concerning risk factors for TOLAC. Practical guidelines have changed significantly since that time. Further studies will be needed to evaluate the feasibility of TOLAC in preterm deliveries.

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Table 1. Patient characteristics according to birth mode

	N	Group I (n=963)	Group II (n =583)	Total	p[a]
Age (years)	1545	32.29 ± 5.02	32.82 ± 5.03	32.49 ± 5.03	**0.051**
Parity	1546	2.48 ± 0.864	2.23 ± 0.683	2.38 ± 0.809	**< 0.001**
BMI (kg/m^2)	922	25.66 ± 5.84	26.21 ± 5.92	25.66 ± 5.84	**0.003**
Gestational age (weeks)	1546	39.25 ± 1.78	38.70 ± 2.54	39.05 ± 2.11	**0.004**
Gestational diabetes	1544	100 (10.4 %)	71 (12.2 %)	171 (11.1 %)	**0.274**
Hypertension, pregnancy-related disease	1544	48 (5.0 %)	37 (6.4 %)	85 (5.5 %)	**0.253**
Previous vaginal birth	1312	269 (33.3 %)	78 (15.5 %)	347 (26.4 %)	**< 0.001**
Birth weight at prior CD (grams)	524	2969.29 ± 819.95	3202.70 ± 776.44	3052.14 ± 811.76	**< 0.001**
Neonatal weight (grams)	1546	3357.82 ± 529.06	3321.67 ± 670.91	3344.19 ± 586.64	**0.766**
Obstructed labor history	529	47 (13.8 %)	47 (24.9 %)	94 (17.8 %)	**0.008**
Fetal distress history	529	97 (28.5 %)	56 (29.6 %)	153 (28.9 %)	**0.212**
Prostaglandin used	1546	278 (28.9 %)	199 (34.1 %)	477 (30.9 %)	**0.030**
Oxytocin used	1544	397 (41.3 %)	173 (29.7 %)	570 (36.9 %)	**< 0.001**
Epidural anesthesia	1546	393 (25.4)	197 (12.7 %)	590 (38.2 %)	**< 0.001**
Oxytocin and prostaglandin used	1546	115 (11.9%)	63 (10.8%)	178 (11.5%)	**0.498**
Sanguineous or green amniotic fluid	1546	27 (2.8%)	48 (8.2%)	75 (4.9%)	**<0.001**
Cervical opening at admission	603	2.02 ± 2.24	1.15 ± 1.50	1.71 ± 2.05	**<0.001**
Smoking during pregnancy	942	63 (11.0%)	45 (12.2%)	108 (11.5%)	**0.589**

[a] P value was calculated by χ2 test (for qualitative variables) or t-test (for continuous variables) to test the difference between the two groups

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Table 2. Maternal and neonatal outcome

	N	Group I	Group II	Total	p
Blood loss (ml)	940	267.98±363.89	431.49±200.28	332.34±319.98	**< 0.001***
Uterine rupture	1546	3 (0.3%)	17 (2.9%)	20 (1.3%)	**< 0.001****

	N				
Postpartum hysterectomies	1546	2 (0.2 %)	1 (0.2 %)	3 (0.2 %)	**0.893****
Apgar score at 1 minute (mean)	1545	8.68 ± 1.03	8.14±1.67	8.48 ± 1.33	**< 0.001***
Apgar score at 5 minutes (mean)	1545	9.69 ± 0.83	9.25±1.19	9.52 ± 1.00	**< 0.001***
Apgar score at 10 minutes (mean)	941	9.86 ± 0.80	9.59±0.91	9.75 ± 0.85	**< 0.001***
Umbilical cord pH	937	7.29 ± 0.08	7.30 ± 0.10	7.29 ± 0.09	**< 0.001***
pH < 7.10	937	6 (1.1%)	14 (3.8%)	20 (2.1%)	**0.005*****
Transfer to neonatal intensive care unit	607	25 (2.6 %)	17 (2.8 %)	42 (2.6%)	**0.401*****
5-minute Apgar score below 6	1545	5 (0.5 %)	17 (2.9 %)	15 (1.0 %)	**0.020*****
5-minute Apgar score below 7	1545	7 (0.7 %)	17 (2.9 %)	24 (1.6 %)	**0.001*****
*Student's t test, **Fisher's exact test, ***χ2 test					

Table 3. Subgroup analysis					
	N	**Group I (n=963)**	**Group II (n=583)**	**Total**	**p**
Age ≥ 40 years	1546	71 (7.4%)	57 (9.8%)	128 (8.3 %)	0.096***
BMI ≥ 35 kg/m^2	922	54 (9.7%)	28 (8.2%)	82 (9.1 %)	0.428***
Interpregnancy interval less than 12 months	603	24 (2.5 %)	15 (2.7 %)	39 (2.6 %)	0.893***
Fetal macrosomia (birth weight > 4000 g)	1546	91 (9.4 %)	73 (12.5 %)	164 (10.6 %)	0.054***
Postterm pregnancy (> 40 + 0)	1546	205 (33.4 %)	337 (38.5 %)	582 (37.3 %)	< 0.001***
Preterm birth (32-37 weeks of gestation)	1546	83 (8.6 %)	103 (17.7 %)	186 (12.0 %)	<0.001***
*Student's t test, **Fisher's exact test, ***χ2 test					
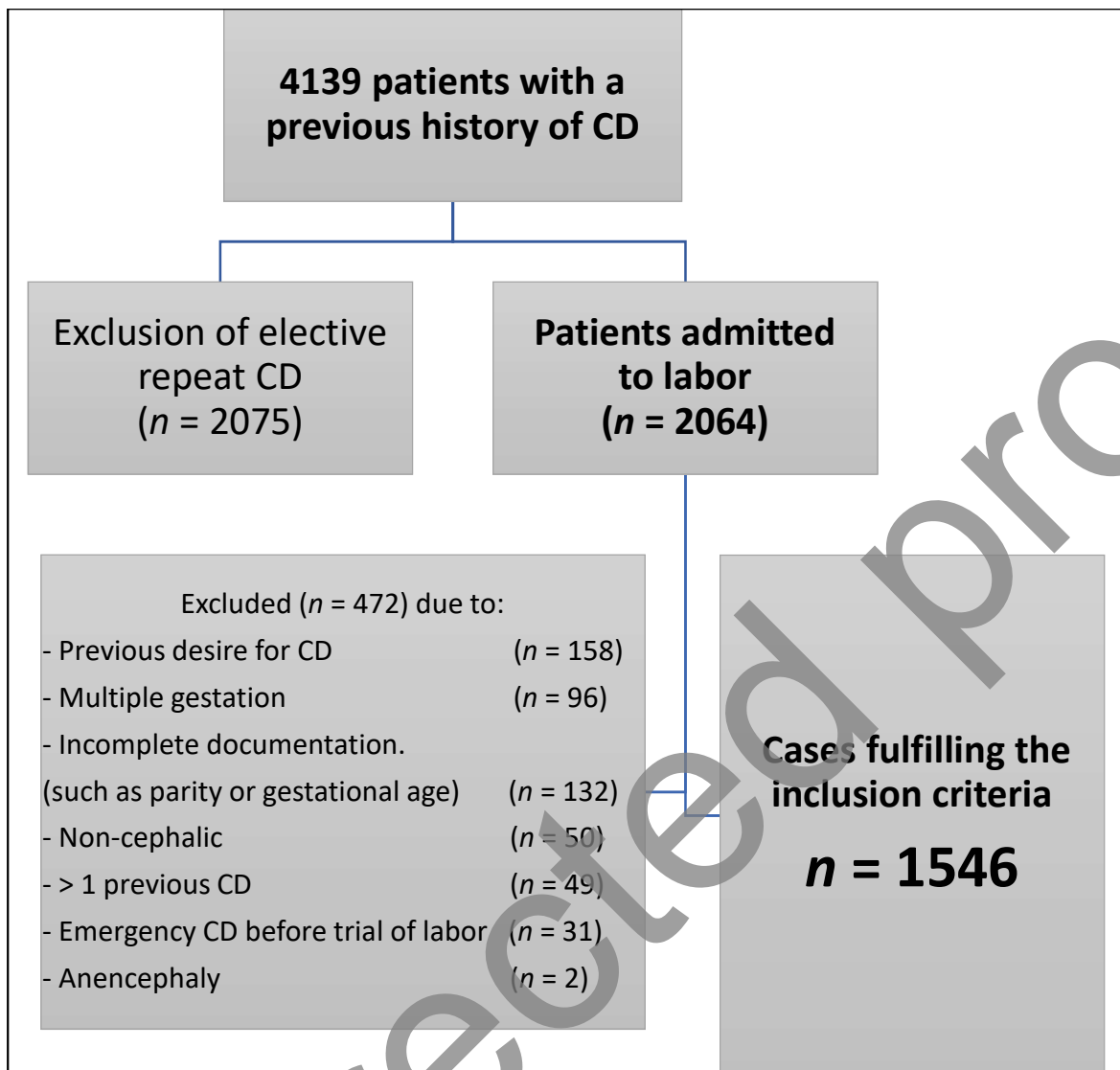
Figure 1. Flowchart throughout the recruitment phase of the study