## Beyond the short term effects of caesarean delivery and gynaecological surgery

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# Chapter 5

## Elective repeat caesarean delivery compared with trial of labor after a prior caesarean delivery: a propensity score analysis

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ABSTRACT

**Objective**
To determine neonatal and short term maternal outcomes according to intentional mode of delivery following a caesarean delivery (CD)

**Study design**
Women pregnant after CD between January 2000 and December 2007 were categorized according to whether they had an elective CD (ERCD) or a Trial of Labour (TOL). Prognostically equal ERCD and TOL groups were created using the propensity score matching technique. Conditional logistic regression was performed to asses differences in neonatal and maternal outcomes.

**Population**
Women in their second ongoing pregnancy with a history of CD

**Results**
After ERCD the rates of low 5 minutes Apgar score (OR 0.3, 95%CI 0.2-0.5, p<0.001), meconium aspiration (OR 0.0, 95%CI 0-0.7, p=0.02) and birth trauma (OR 0.08, 95%CI 0.002-0.5, p<0.001) were lower compared to TOL. The rate of infant respiratory distress syndrome appears higher in the ERCD group (OR 1.7, 95%CI 1.0-2.8 p=0.04). Uterine rupture (OR 0.1, 95%CI 0.003-0.8 p=0.02) and hemorrhage (OR 0.6, 95% CI 0.5-0.8 p<0.001) occurred less in the ERCD group.

**Conclusion**
Neonatal and short term maternal morbidity appears to be lower after ERCD than after TOL. Only infant respiratory distress syndrome was seen more often after ERCD.

**Key words**
elective repeat caesarean delivery (ERCD);
vaginal birth after caesarean delivery (VBAC);
trial of labor( TOL);
propensity score matching;
adverse neonatal outcomes

## INTRODUCTION

The increase of caesarean delivery (CD) worldwide has initiated researchers to analyze the safety of trial of labor after CD (TOL). An international multi-centered randomized controlled trial comparing VBAC with elective repeat CD (ERCD) would be the optimal strategy for minimizing the research gap concerning safety of trial of labor after CD (TOL). In 2012 Crowther et al performed a small nested randomized trial to compare benefits and risks of a planned ERCD with planned TOL. Women were assigned by patient preference or randomization Only 22 women (1% of the total cohort 2 323 women) were willing to be randomized. The authors concluded that planned ERCD was associated with a lower risk of fetal and infant death or serious infant outcome, without increase of major maternal complications. Furthermore they concluded that performing a randomized trial to compare ERCD with TOL is difficult due to the need of large sample size for adequate powering and the reluctance of pregnant women to be randomized for mode of delivery. (1) In the absence of randomized trials, analyzing observational data on TOL compared to ERCD has become the substitute "gold standard" in this field of interest. We used the propensity score matching technique to generate comparable ERCD and TOL groups. Thereby minimizing potential bias by balancing covariates. The Netherlands, a small but densely populated developed country in Europe, has a relatively low CD rate (15%: 6,7% elective CS and 8.3% emergency CS) and a high rate of TOL, approximately 73% with an overall success rate of 77%, an ideal setting for conducting a large cohort study on the safety of TOL. (2,3) The Netherlands Perinatal Registry (PRN) provided us with a large database to examine the safety of TOL.

In this study we want to examine adverse maternal and neonatal outcomes of the matched cohort stratified by approach to delivery. We want to provide insight on the safety of TOL in the Netherlands and verify the robustness and clinical importance of previous findings on the safety of TOL.



## METHODS

### Study design

We conducted a prospective cohort study of women with a history of first birth CD that delivered their first and second infant between January 2000 and December 2007. We divided our cohort in two groups, ERCD or TOL, according to intention of delivery in the second pregnancy. Subsequently, we created prognostically similar groups by propensity score matching and analyzed maternal and neonatal outcomes of these two matched groups. Propensity score matching is used to analyze observational data and was first described by Rosenbaum and Rubin. Propensity score methodology can estimate the effect of a binary exposure on an outcome in the presence of confounding by indication. (4,5)

**Inclusion and exclusion criteria**
Our analysis included women with a live, term singleton with cephalic presentation that had an ERCD or a spontaneous TOL after a term CD. Term was defined as beyond 36 weeks 6 days of gestation. An ERCD was defined as a scheduled CD beyond 39 weeks of gestation without signs of labor. Pregnancies complicated by congenital abnormalities, CD prior to 39 weeks of gestation and women having induction of labor were not included in our analysis to ensure that women undergoing ERCD or TOL had no additional obstetrical indication for the intended mode of delivery. By excluding these women we lowered the chance of misclassification and we ensured our cohort being a low risk cohort. Furthermore labor induction has been associated with a lower probability of success and a higher probability of uterine rupture. (6)

**Data collection**
We collected our data from a prospective population-based cohort. Data were collected in a database by the Netherlands Perinatal Registry (PRN), containing information on pregnancies, deliveries and neonatal (re-)admissions until 28 days after birth. The PRN database is a national database that contains linked maternal and neonatal data entered by midwives,obstetric care givers and pediatricians. The coverage of the PRN registry is about 96% of all deliveries in the Netherlands. The records included in the PRN registry are entered at the child's level. There is no unique maternal identifier available in the registry to follow-up on outcomes of subsequent pregnancies of the same mother. Therefore a longitudinal probabilistic linkage procedure in which we linked records of children of the same mother was performed in order to create a mother identifier. (7) Permission for use of registry data was given by the Netherlands Perinatal Registry, (registration number 12.02). For a more elaborate description of the methods used for this longitudinal linkage, we refer to the article of Schaaf et al 2011. (8)

**Outcome measures**
Adverse neonatal outcomes were low Apgar score (<7 after 5 minutes), birth trauma (intracerebral bleeding, cephalic hematoma, brachial plexus lesions or facial nerve lesions), meconium aspiration, infant respiratory distress syndrome (IRDS) and perinatal death within 28 days after birth and a composite of these adverse outcomes.

Adverse maternal outcomes were defined as maternal death, hemorrhage more than 1000 ml, blood transfusion, uterine rupture defined as uterine muscle separation or tear of the uterine muscle with involvement of adjacent structures or placental abruption. Composite maternal outcome was defined as a composite of the above mentioned adverse outcomes. The emergency CD rate in the TOL group was assessed separately.

**Analysis**

Propensity score matched pairs analysis was used to create maximally balanced groups. This statistical method was introduced by Rosenbaum and Rubin and is extensively described in numerous articles and textbooks. (3)(4) The essential method consists of a single variable: the propensity score, representing the probability of a woman to be treated (in this article to undergo ERCD) on the condition of individual baseline covariates. The propensity score variable is thereafter used to match patients in the ERCD group with patients in the TOL group that have similar probability of being treated (to undergo ERCD). The propensity scores were generated by logistic regression, based on all available and relevant baseline covariates that were known from the 1st pregnancy and those that existed before delivery in the 2nd pregnancy, these are listed in table 1. Propensity scores were based on the ERCD group to ensure as many matches as possible since the number of patients in this group was less than that in the TOL group. All covariates were included in the logistic regression without a stepwise procedure. Since propensity scores cannot be calculated if one of the variables is missing, cases with missing data were excluded. One-to-one nearest neighbor matching without replacement was conducted. After matching on propensity scores, the standardized difference was used to assess the balance of the covariates after matching because it is a property of the sample and does not depend on the size of the sample. Significance testing is inappropriate since apparent improvement may be due to the reduced ample size and reduced statistical power. An arbitrary 10% difference was considered indicative for insufficient matching. (9)

For the matched cohort, outcomes were compared with the use of the Mc Nemar's test, and odds ratios and 95% CIs were generated with the use of conditional logistic regression. Statistical analysis was conducted with SPSS version 21 for Macintosh. Propensity score calculation and matching were performed in R for Windows and for Macintosh (R version 3.1.2 (2014-10-31) Copyright (C) 2014, The R Foundation for Statistical Computing; Vienna, Austria) and the R Matching library (http://www.r-project.org/). (10) A 2-tailed nominal probability value of < .05 was considered to indicate statistical significance..



RESULTS

From the linked cohort based on the PRN registry, 35,342 women with a live, singleton, term and vertex gestation that had an ERCD or a spontaneous TOL after a term CD. were available. (Figure 1) Of these, 1,221 women with pregnancies complicated by aneuploidy or congenital malformations were excluded. An additional 3,751 women had an ERCD before 39 weeks of gestation and 10,803 women underwent induction of labor. Finally, we included 15,358 women in the TOL group and 4,209 women in the ERCD group. To generate the propensity scores for the probability of having an ERCD, the 20 patient variables (Table 1) were used. This resulted in 19,545 women (55% of the original cohort) available for further analysis because those with missing data for any variable were excluded from the logistic regression. Eventually, the ERCD group consisted of 4,203 women and the TOL group consisted of women 15,342.

In the unmatched TOL cohort n=11 403 women (74% of 15 342) had a successful VBAC. Table 1 shows the baseline characteristics and the standardized difference for all 20 variables. These variables are unequally distributed among the two groups, reflected by an absolute standardized difference of 10 or more percent in one third of the baseline variables. We assessed the 20 patient variables of the groups and calculated propensity scores for the probability of women receiving an ERCD.

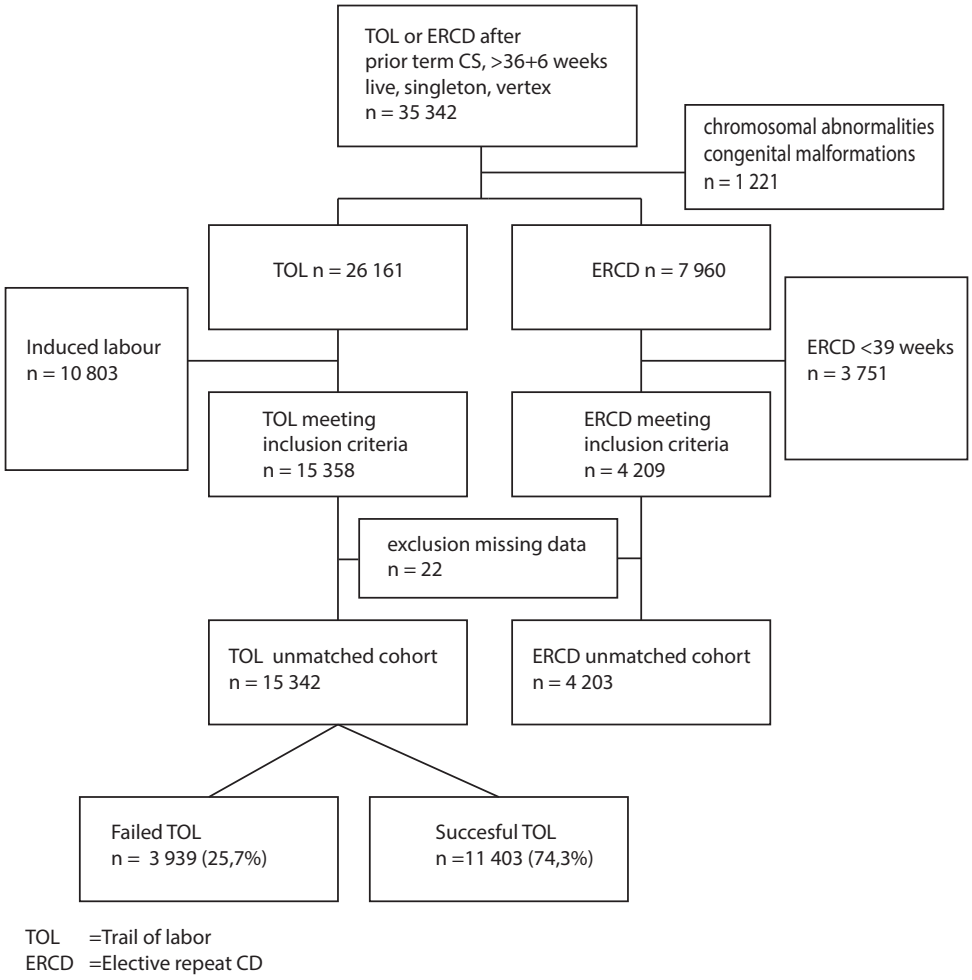


***Figure 1.*** *Flowdiagram*

***Table 1.*** *Baseline characteristics of the unmatched cohort*

| | **ERCD n=4203 (%)** | **TOL n=15342 (%)** | **Standardized difference (%) Before matching** |
|---|---|---|---|
| **Caucasian** | 3661 (87.1) | 13671(89.1) | 6.0 [a] |
| **Low Social economic status (SES)** | 905 (21.5) | 3 413 (22.2) | -1.7 |
| | | | |
| *1st Pregnancy* | | | |
| **In Vitro Fertilisation** | 46 (1.1) | 139 (0.9) | 1.4 |
| ****Age** | 29.7 (4.2) | 29.3 (3.9) | 9.6 [a] |
| **Non gestational diabetes** | 22 (0.5) | 20 (0.1) | 5.4 [a] |
| **Preexisting hypertensive disorders** | 31 (0.7) | 63 (0.4) | 3.8 [a] |
| **Pregnancy induced hypertensive disorder** | 802 (19.1) | 2 443 (15.9) | 8.0 [a] |
| **Spontaneous labor** | 870 (20.7) | 4745 (30.9) | 6.5[a] |
| **Malpresentation** | 470 (11.2) | 6 122 (39.9) | 91.1[a] |
| **Elective CS** | 745 (17.7) | 4 178 (27.2) | 24.9[a] |
| ****Gestational age** | 40.2 (1.4) | 39.5 (1.4) | 53.8[a] |
| ****Birthweight (gr)** | 3729 (562.2) | 3471 (535.5) | 45.9[a] |
| ***Apgar 5 min)** | 10 (9-10) | 10(9-10) | -10[a] |
| **Male gender** | 2 353 (56) | 8 305 (54.1) | 3.7 |
| **Hemorrhage > 1000ml** | 153 (3.6) | 435 (2.8) | 4.3 |
| **Transfusion** | 39 (0.9) | 86 (0.6) | 3.8 |
| | | | |
| *2nd Pregnancy* | | | |
| **Pregnancy interval less than 15 months** | 125 (3.0) | 497 (3.2) | -1.5 |
| **In Vitro fertilisation** | 28 (0.7) | 94 (0.6) | -18[a] |
| ****Age (years)** | 32.4(4.1) | 31.8 (3.9) | 12.1[a] |
| ****Gestational age (weeks)** | 39.8(1.0) | 39.6(1.1) | 13.2[a] |

* median and IQR
** mean and SD
[a] P<0.0001

Figure 2 plots the distribution of the propensity scores in the 2 groups. Overall, as a function of baseline characteristics, the ERCD group (solid line) had a higher probability of receiving an ERCD (dashed line), as indicated by a median propensity score of 0.31 (Min 0.01 IQR 0.22 -0.40, Max. 0.88) compared to a median propensity score of 0.17 (Min 0.0 IQR 0.07-0.29 Max 0.82; p<0.001) (Mann Whitney U test)

To be able to find matches between patients of the two groups, overlap in propensity scores is compulsory. Figure 2 demonstrates the differences in distribution in propensity scores between the two groups, but also the overlap, indicating that one on one matching without replacement is possible. This matching process resulted in the creation of 4109 matched pairs of ERCD and TOL patients. Figure 3 displays the distributions of the 2 matched groups' propensity scores and reveals a high degree of similarity of shape between the 2 groups, in contrast to the distributions illustrated in Figure 2.

The resulting improved covariate balance in the PS-matched cohorts is reflected in the small standardized differences of the baseline characteristics, all below 10 percent. (Table 2).

In the matched TOL cohort n=1,415 (34.4% of 4109) had an emergency CS. The 65.6% of successful TOL in the matched cohort is lower than the 74% successful TOL in the unmatched cohort.

We found hemorrhage more than 1000 ml to occur less often in the ERCD group compared to the TOL group (3.4% vs 5.3, OR 0.6; 95% CI 0.5-0.7, P<0.0001). Uterine rupture occurred in one case (0,02%) of the ERCD group compared to nine cases (0,2%) of the TOL group (OR 0.11; 95% CI 0.0-0.8, P=0.02). Composite adverse maternal outcome occurred in n=140 (3.4%) of the ERCD group compared to n=225 (5.5%) of the TOL group. Maternal blood transfusion and placental abruption were not significantly different between the groups. Maternal deaths did not occur in either two groups.

Five minutes Apgar score below 7 occurred less often in the ERCD group compared to the TOL group (0.8% vs 2.5, OR 0.3; 95% CI 0.2-0.5, p<0.001). The absolute number of reported birth trauma (n=14) and meconium aspiration (n=7) was low, but these adverse outcomes occurred significantly less in the ERCD group compared to the TOL group (0.02% vs 0.3% OR 0.08; 95% CI 0.0-0.5, P=0.002 and 0.0% vs 0.2% OR 0.0 95% CI 0.0-0.7, P=0.02 respectively). IRDS occurred in n=45 (1.1%) in the ERCD group compared to n=27 (0.7%) in the TOL group (OR 1.7; 95% CI 1.0-2.8, P=0.04). Infection rates (0.2%) were not significantly different between the two groups. Composite adverse outcome occurred in n=87 (2.1%) of the ERCD group compared to n=141 (3.4%) of the neonates of the TOL group (OR 0.6; 95% CI 0.5-0.8, p<0.001).

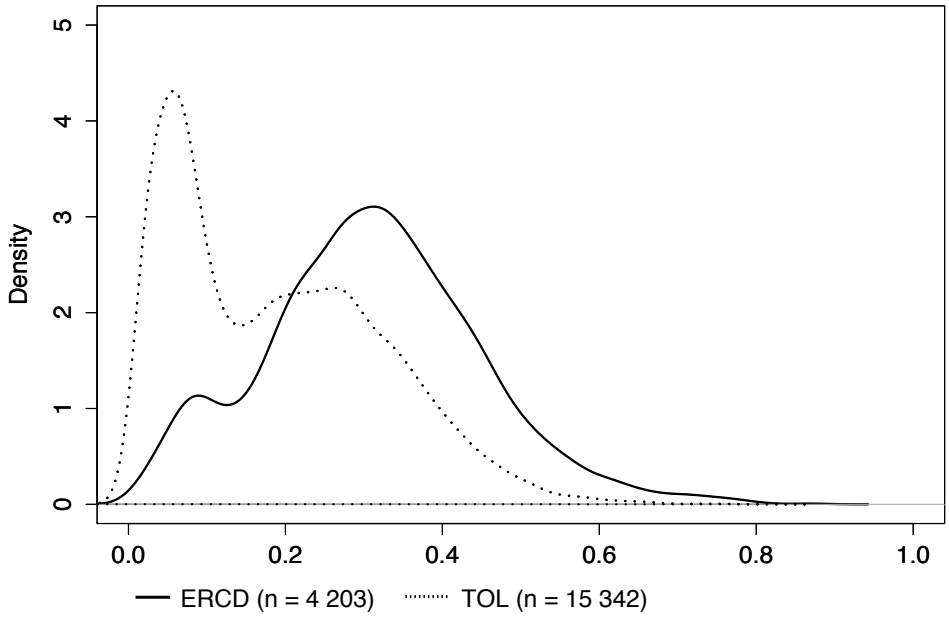


***Figure 2.*** *Distribution Propensityscore before matching*

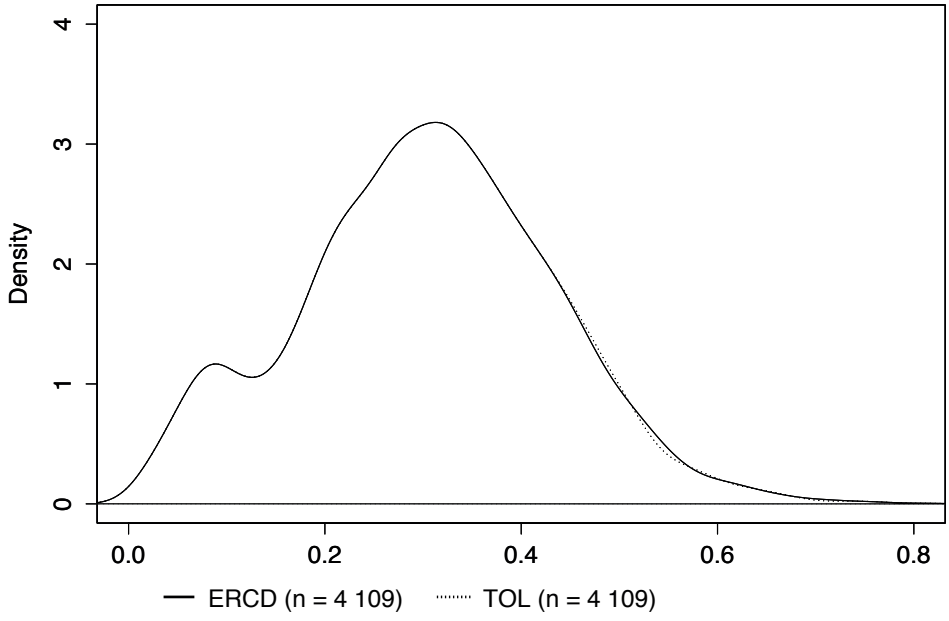


***Figure 3.*** *Distribution Propensityscore after matching*

***Table 2.*** *Baseline characteristics of the matched cohort*

| | **ERCD n=4109 (%)** | **TOL n=4109 (%)** | **Standardized difference (%) Before matching** |
|---|---|---|---|
| **Caucasian** | 3579 (87.1) | 3579 (87.1) | -0.4 |
| **Low Social economic status (SES)** | 886 (21.6) | 901 (21.9) | 1.5 |
| | | | |
| *1st Pregnancy* | | | |
| **In Vitro Fertilisation** | 46(1.1) | 37(0.9) | -1.8 |
| ***Age** | 29.7(4.2) | 29.7(4.0) | -0.3 |
| **Non gestational diabetes** | 15 (0.4) | 18 (0.4) | -1.3 |
| **Preexisting hypertensive disorders** | 29 (0.7) | 29 (0.7) | 0 |
| **Pregnancy induced hypertensive disorder** | 771 (18.8) | 792 (19.3) | -1.0 |
| **Spontaneous labour** | 870 (21.2) | 916 (22.3) | 0.06 |
| **Malpresentation** | 470 (11.4) | 490 (11.9) | 1.3 |
| **Elective CS** | 674 (16.4) | 702 (17.1) | -0.3 |
| ***Gestational age** | 40.3 (1.3) | 40.3 (1.4) | -1.1 |
| ****Birthweight (gr)** | 3713.9 (553.9) | 3711.5 (536.9) | 0.8 |
| ***Apgar** | 10 (9-10) | 10 (9-10) | 0.8 |
| **Male gender** | 2295 (55.9) | 2276 (55.4) | -1.5 |
| **Hemorrhage > 1000ml** | 151 (3.7) | 155 (3.8) | 0.6 |
| **Transfusion** | 38 (0.9) | 37 (0.9) | -0.3 |
| | | | |
| *2nd Pregnancy* | | | |
| **Pregnancy interval less than 15 months** | 123 (3) | 114 (2.8) | 1.9 |
| **In Vitro Fertilisation** | 28 (0.7) | 28 (0.7) | 0.3 |
| ****Age (years)** | 32.4 (4.1) | 32.4 (4.0) | -1.0 |
| ****Gestational age (weeks)** | 39.8 (1.0) | 39.8(1.1) | -0.8 |

*median and IQR
** mean and SD

***Table 3.*** *Outcome*

| | ERCD n=4109 n (%) | TOL n=4109 n (%) | P | Conditional Odds ratio (95% CI) |
|---|---|---|---|---|
| *Maternal* | | | | |
| **Hemorrhage > 1000ml** | 138(3.4) | 217 (5.3) | <0.001 | 0.6 (0.5-0.7) |
| **Transfusion** | 15(0.4) | 16(0.4) | 1.0 | 0.9 (0.4-2.2) |
| **Uterine rupture** | 1(0.02) | 9 ( 0.2) | 0.02 | 0.1 (0.003-0.8) |
| **Placental abruption** | 0 (0.0) | 1 (0.0) | 1.0 | 1.0 (0.0-39) |
| **Composite *** | 140 (3.4) | 225 (5.5) | <0.001 | 0.6 (0.5-0.8) |
| | | | | |
| *Neonatal* | | | | |
| **5 minuten Apgar below 7** | 34 (0.8) | 101(2.5) | <0.001 | 0.3 (0.2-0.5) |
| **Perinatal death** | 1(0.02) | 5 (0.1) | 0.2 | 0.2 (0.004-1.8) |
| **Birth trauma**** | 1(0.02) | 13 (0.3) | 0.002 | 0.08 (0.002-0.5) |
| **Meconium aspiration** | 0 (0.0) | 7 (0.2) | 0.02 | 0 (0.0-0.7) |
| **Infant respiratory distress syndrome** | 45 (1.1) | 27 (0.7) | 0.04 | 1.7 (1.0-2.8) |
| **Infection** | 7 (0.2) | 10 (0.2) | 0.6 | 0.7 (0.2-2.0) |
| **Composite***** | 87 (2.1) | 141 (3.4) | <0.001 | 0.6 (0.5-0.8) |

* Hemorrhage, transfusion, uterine rupture and placental abruption
** Intracerebral bleeding, cephalic haematoma, brachial plexus leasions and facialis nerve laesions
*** Perinatal death, birth trauma, low apgar, meconium aspiration, wet lung and infection

## DISCUSSION

In this study we investigated the safety of VBAC after spontaneous start of labour compared to ERCD after 39 weeks in women with a history of a term CD after balancing covariates by propensity score matching. In the unmatched cohort, 74% of the women having a TOL succeeds to deliver vaginally. This rate is lower after matching (65.6%) because covariate distribution in the TOL cohort has been adjusted in order to match the ERCD cohort. For example, after matching, the TOL women have higher first delivery gestational age and birthweight, compared to the TOL cohort before matching. After matching, the characteristic are almost equal to the ERCD cohort. The necessity for balancing covariates is reflected by this change in outcome(9).

After balancing covariates by propensity score matching, we found short term maternal and neonatal outcomes such as uterine rupture, hemorrhage, low 5 minute apgar score, birth trauma and meconium aspiration to occur more often in the group attempting a TOL compared to ERCD. IRDS occurred more often in the ERCD group. The overall number of adverse maternal and neonatal outcomes were low.

### Comparison other studies

Gilbert et al (11) performed a similar study, but also included multiparous women with prior vaginal deliveries. They found a VBAC success rate in their matched cohort of 68.1%. In our matched cohort the VBAC success rate was 65.6%. They found maternal composite morbidity to be 33% lower in the ERCD group (OR 0.67; 95% confidence interval [CI], 0.53–0.83); the odds of major maternal morbidity were 65% lower (odds ratio, 0.35; 95% CI, 0.20 – 0.62). The neonatal composite adverse outcome was lower in the ERCD group by 33% (odds ratio, 0.67; 95% CI, 0.55– 0.80). Our results are in complete agreement, although our primary outcomes differed.

The rate of uterine rupture in our cohort was low (0.2%), 9 cases were reported in the TOL group and 1 in the ERCD group. Gilbert et al had 31 cases (0.8%) of uterine rupture in their matched cohort of 3981 women, all these cases occurred in the TOL group.

Holm et al found that the highest transfusion rate (3.23%) was seen for intended vaginal delivery after a previous CD. Following a previous CD, the risk of red blood cell transfusion was significantly lower in the planned CD group compared with an intended vaginal delivery (OR 0.67; 95% CI 0.56–0.79; $P < 0.001$). Our rates of hemorrhage were 3.4% in the ERCD and 5.2% for TOL, we did not find significant difference between the two cohort in transfusion rates. (12)

### Interpretation

The results of this analysis are applicable for the comparison of the outcomes of a spontaneous TOL and an ERCD after 39 weeks in women without a history of vaginal

birth. Some women will require a labor induction, for these women risks might be higher than reflected in our data, since induction of labor is associated with higher rates of failed TOL and uterine rupture. The contrary is applicable for women with a history of CD and a previous vaginal birth. Risk may be lower since the rate of successful TOL are higher after previous vaginal birth. (6,13)

**Strengths and Limitations**

We explored the available data thoroughly, adjusting for possible confounders by using propensity score matching to make comparison as appropriate as possible. In comparison to Gilbert et al, we only included women with a first birth caesarean, and analyzed the subsequent ongoing pregnancy. This way our study reflects the risks of TOL without prior vaginal birth, all women in our study were nulliparous for vaginal delivery.

We were only able to asses the short term outcomes, and did not take in account the duration of hospitalization, amount of wound infection/endometritis, thrombotic events, need for postpartum pain medication and recovery period. It could very well be that the long term effects especially maternal outcomes will be in favor of the TOL in the end. We only reported on the short term effects, being the risk of the first repeat caesarean. We need to further investigate the long term effects of the ERCD and where the nadir lies in case women have a wish of more than two children.

Outcomes like uterine rupture, hysterectomy and blood transfusion are probably underreported in our database, leading to an underestimation of the effect. The baseline characteristics are lacking some of the obvious variables such as maternal BMI and smoking because entry of these variables is not obligatory and therefore mainly missing. Unreliable data entry, especially concerning the rare outcomes makes it impossible to draw conclusions despite the large national database.



## CONCLUSION

For women with a first birth CS, ERCD seems to be a safe option for the subsequent pregnancy. Attempting a TOL after spontaneous labor incorporates slightly more maternal and neonatal risks, but the adverse events are mainly short term effects and might not always outweigh the 74% chance of successful TOL. Leaving us with the remaining question; when do we think VBAC is safe (enough). What number needed to treat do we and our patients accept. In clinical practice the patient preference is becoming increasingly important in choosing between ERCD and VBAC. Patient preference studies should be conducted to evaluate and optimize our way of counseling. Further longitudinal studies should be performed to look at the long term effects on maternal and neonatal outcomes of having one or multiple ERCD's. Finding a way to lower first birth CD rates will be the real solution of the VBAC safety issue.

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