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A randomized controlled trial reducing cesarean delivery rates in China by introducing trial of labor after cesarean and electrohysterography

Kirsten Martine Johanna Thijssen^{a,b,c,d}, Maria Wilhelmina Elisabeth Frenken^{a,b,c},
Marieke Beatrijs Van der Hout-van der Jagt^{a,b,c,e}, Wang Li^f, Zhongfu Mo^f,
Michelle Elisabeth Maria Hermine Westerhuis^g and Guid Oei Swan^{a,b,c,e}

^aDepartment of Obstetrics and Gynaecology, Máxima Medical Centre, Veldhoven, The Netherlands; ^bDepartment of Electrical Engineering, Eindhoven University of Technology, Eindhoven, The Netherlands; ^cEindhoven MedTech Innovation Center (e/MTIC), Eindhoven, The Netherlands; ^dUniversity MC Utrecht, Utrecht, The Netherlands; ^eFaculty of Biomedical Engineering, Eindhoven University of Technology, Eindhoven, the Netherlands; ^fDepartment of Obstetrics and Gynaecology, The Maternal and Child Hospital of Shijiazhuang, Shijiazhuang, Hebei Province, P.R. China; ^gDepartment of Obstetrics and Gynaecology, Catharina Hospital, Eindhoven, The Netherlands

ABSTRACT

Objective: A cesarean delivery (CD) can affect health of both mother and child and future pregnancies. Since the abandonment of the one-child policy in China, obstetricians tend to perform a repeat CD rather than a trial of labor after cesarean (TOLAC). This study aims to reduce CD rates by increasing vaginal births after cesarean (VBAC) rates and introducing electrohysterography (EHG) for accurate monitoring.

Methods: In total, 82 women received counseling regarding TOLAC at the Shijiazhuang Sixth Hospital in China. Women opting for TOLAC were randomized for either external tocodynamometry (TOCO, i.e. standard care) or EHG. The primary outcome was the VBAC rate. Secondary outcomes were indications for CD, percentage of assisted vaginal deliveries, labor duration, maternal blood loss, complications and neonatal outcomes.

Results: After accounting for preterm delivery and dropouts, all counseled women opted for a TOLAC (100%). After randomization, 42 women were included in the TOCO-group and 37 in the EHG-group. Women did not receive pain medication and labor was not augmented with oxytocin. The VBAC rate was 71.4% in the TOCO-group, versus 78.4% in the EHG-group ($p=.48$). Birth was assisted with forceps in 11.9% of TOCO-group versus 2.7% of EHG-group ($p=.21$). One secondary CD (i.e. a shift from intended vaginal delivery to surgical delivery within the same labor) was performed because of a suspicion of uterine rupture (TOCO-group). Other indications for CD were: fetal distress, labor dystocia, fetal position, cephalopelvic disproportion. There were no significant differences in secondary study outcomes. No complications were reported.

Conclusion: This study showed an average VBAC rate of 75%, without any complications, in a hospital with no previous experience with TOLAC. The VBAC rate with EHG-monitoring was higher than TOCO, although this difference was not significant. To demonstrate a significant difference, larger clinical studies are necessary.

Trial registration: The Daily Board of the Medical Ethics Committee of The Maternal and Child Hospital of Shijiazhuang approved the study protocol (number 20171018, Dutch Trial Register NL8199).

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Introduction

The World Health Organization has expressed concern about the rising rate of cesarean deliveries (CD) around the world and stated that CD rates above 15% are no longer associated with reduced maternal, neonatal and

infant mortality [1,2]. The World Health Organization emphasizes that CD should only be undertaken when medically necessary in order to have beneficial effects [3]. A crucial aspect to consider regarding this statement is that CD are associated with multiple risks affecting health of both mother and child and future

CONTACT Kirsten Martine Johanna Thijssen  K.M.Thijssen@tue.nl  Faculty of Electrical Engineering, Eindhoven University of Technology, Eindhoven, The Netherlands

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pregnancies, for example, placental implantation and the uterine rupture risk [4,5].

In 1979, the one-child policy was introduced in China leaving women to give birth only once. Although there were some exceptions to this policy (families from ethnic minorities or families living in rural areas were often permitted to have more than one child), in general, a future pregnancy or childbirth was no longer taken into account when choosing the mode of delivery. This, combined with other socioeconomic changes, has contributed to an increased rate of CD [6–9]. The rates of CD in China have consequently risen to 58.5% in 2011 [10]. In 2015, the Chinese government announced the abolishment of the one-child policy and raised the permitted number of children per family to two, which eventually led to the lifting of all restrictions in 2021. This change in policy was associated with an increase in births in multiparous women (additional 5.40 million births (95% confidence interval 4.34 to 6.46 million) [11]. A slight decrease was seen in CD rate among nulliparous women [11]. However, the overall CD rate in China remained high, which could well be explained by the increase in elective repeat cesarean deliveries (ERCD) among women who have had a CD during the one-child policy era.

When pregnant after a previous CD, either an ERCD or a trial of labor after cesarean (TOLAC) can be chosen. A TOLAC can result in an actual vaginal birth after cesarean (VBAC) or a secondary CD; i.e. a shift from intended vaginal to surgical delivery within the same labor.

With the increasing rate of births from multiparous women, China faces an increased burden on maternity services [6]. This includes a rise in women pregnant after a previous CD, opting for either ERCD or TOLAC. Since gynecologists in China have had little exposure to TOLAC in previous years they might be inclined to perform an ERCD, mainly due to a fear of uterine scar rupture [12]. To safely manage a TOLAC, gynecologists need to be experienced and skilled. Moreover, enough resources should be available [7]. Adequate uterine monitoring is essential.

Current monitoring methods for uterine activity (UA) are the intra-uterine pressure catheter (IUPC), external tocodynamometry (TOCO) and electrohysterography (EHG). Until recently, IUPC has been considered the gold standard for monitoring UA. However, this method is invasive and requires ruptured membranes and sufficient cervical dilation. Complications like uterine and placental perforation are described with the use of IUPC [13], as well as an increased rate of intrapartum maternal fever [14]. As a result of these complications, routine use is not recommended. TOCO

and EHG on the other hand are noninvasive monitoring methods of which EHG is only recently introduced, but promising: EHG has a higher sensitivity compared to TOCO, respectively 89.5% and 65.3% [15]. Besides, EHG is less obese-sensitive [16].

During a TOLAC, attention must be paid to possible complications, such as infection, blood loss and uterine rupture [17]. The estimated incidence of uterine ruptures in women with scarred uterus in China is 0.79% [12]. Uterine ruptures have serious consequences for both mother and child [17]. Monitoring for signs of a possible uterine rupture is therefore an important aspect of the management of TOLAC. Signs and symptoms associated with uterine ruptures are abdominal pain (at the site of the previous uterine scar), hematuria, vaginal bleeding, hemodynamic instability of the mother, loss of station of the fetal presenting part, abnormalities in the fetal heart rate (FHR) and changes in UA, such as weakened UA or changes in amplitudes of contractions [18]. The hypothesis is that EHG, by providing more detailed information on UA than TOCO, may contribute to prompt recognition of a possible uterine rupture.

The aim of this study is to provide evidence to support use of EHG for clinical use to potentially increase the VBAC rate in China.

Material and methods

A randomized controlled trial was conducted at the labor ward of the Shijiazhuang Sixth Hospital in China to compare EHG (intervention) with TOCO (standard care) for monitoring UA during a TOLAC.

The Daily Board of the Medical Ethics Committee of The Maternal and Child Hospital of Shijiazhuang approved the study protocol (number 20171018, Dutch Trial Register NL8199).

Women were counseled about mode of delivery by their own gynecologist using a standardized document “counseling Mode of Delivery.” When opting for a TOLAC, women were screened for study eligibility.

Inclusion criteria were: aged 18 years or older, singleton pregnancy, cephalic presentation, 37 to 41 weeks of gestation and spontaneous onset of labor. Exclusion criteria were: estimated fetal weight >4000g, maternal age >40 years, classical vertical or T- or J-incision of uterus, previous uterine rupture, CD in previous 12 months, indications for a planned CD such as placenta praevia or vasa praevia, relevant fetal congenital malformation that can influence the delivery mode, primary infection of genital herpes simplex or active HIV, suspicion for abruption placentae and contraindications for the use of EHG (i.e. maternal abdominal

dermatologic diseases, water birth and external or internal electrical stimulators such as a pacemaker or a transcutaneous electrical nerve stimulator). After giving informed consent, women were randomized to either EHG or TOCO as intrapartum monitoring method. Randomization occurred in a 1:1 ratio using an electronic randomization program. Numbered sealed envelopes were prepared to directly randomize at the labor ward, which was done by someone who had no other involvement in this study. Due to the nature of the intervention, neither patients nor staff could be blinded for the allocation. However, researchers were blinded. Women were monitored using EHG or TOCO starting from the moment of admission to the labor ward until the child was born vaginally or until preparation for a secondary CD. During TOLAC, labor was not augmented with oxytocin and women did not receive pain medication.

EHG consisted of a single self-adhesive abdominal patch with three electrodes (Graphium, Nemo Healthcare, Veldhoven, The Netherlands). The patch was positioned at the maternal abdomen slightly above or next to the umbilicus to detect the electrical signals derived from the uterus. The abdominal skin was prepared using abrasive paper, thereby lowering skin impedance. Target values for impedance were set at $<5.0 \text{ k}\Omega$ (SIGGI II, MedCaT, Klazienaveen, The Netherlands). A translation module (PUREtrace, Nemo Healthcare, Veldhoven, The Netherlands) converted the electrical currents into a real-time tocogram. The translation module processed the data using digital filtering techniques to suppress electrical activity from sources other than the uterus. Additionally, it was converted into a measure for UA correlating with the intra-uterine pressure based on a mathematical model described by Rabotti et al. [19].

Both FHR and UA were displayed on a fetal monitor (Sunray Medical Apparatus, Guangzhou, China). Training sessions regarding EHG application and interpretation were organized during two weeks before start of this study to ensure adequate knowledge of uterine monitoring during labor. Besides the local project team, a researcher was available for technical questions during the enrollment of the first patients. Medical decisions were made by the obstetric caregiver. The researcher and local project team were not involved in these decisions. In case of uncertainty about the EHG signal, TOCO was available as well.

TOCO (Sunray Medical Apparatus, Guangzhou, China) consisted of an external button which was placed on the maternal abdomen to record the abdominal wall distension during uterine contractions. The button was held in place using an elastic belt, which was wrapped

around the waist. UA was displayed together with FHR on the fetal monitor of Sunray.

There are no previous studies nor pilot data evaluating the effect of EHG on VBAC rates. Since TOLAC was not yet introduced in this hospital (VBAC rate 0%), we expected the VBAC rate to increase to 50% in the TOCO-group and 80% in the EHG-group. To detect this difference with a power of 80% and a type I error of 5%, an analysis of 76 women (38 per group) would be required.

The primary study outcome was the VBAC rate. Secondary outcomes were: reason for secondary CD, percentage of assisted vaginal deliveries, estimated maternal blood loss, duration of first and second stages of labor (in minutes), complications (e.g. uterine ruptures), Apgar score <7 after 5 min, neonatal metabolic acidosis defined as an arterial umbilical pH level <7.05 and base deficit > 12 , and perinatal mortality.

The control arm (TOCO) was compared to the intervention arm (EHG) for all analyses. There was no cross-over between study-arms. Baseline characteristics of the included women were compared between both groups. Differences in percentages, mean and median values between groups were analyzed by Students *T* tests, Mann–Whitney *U* tests, Chi-square tests or Fishers exact test when appropriate. A *p*-value of $< .05$ was considered statistically significant.

Results

In total 82 eligible women received counseling between November 2017 and December 2019 and all of them opted for TOLAC (TOLAC rate of 100%). Two participants allocated to the EHG-group delivered prematurely and were therefore excluded. Due to equipment failure one participant was dropped-out from the EHG-group. Therefore, data from 79 women were analyzed; of which 42 in the TOCO-group and 37 in the EHG-group. Baseline criteria are shown in Table 1. There were no significant differences between the TOCO and EHG-group.

All women were monitored with their intended method. The quality of the EHG registrations was sufficient and a switch to TOCO was not required in any of the subjects. Also, none of the women allocated to TOCO received EHG.

The VBAC rate was 71.4% in the TOCO-group versus 78.4% in the EHG-group ($p=.48$) (Table 2). This VBAC rate consisted of spontaneous births (59.5% for the TOCO-group and 75.5% for the EHG-group, $p=.13$) and assisted births with forceps (11.9% for the TOCO-group and 2.7% for the EHG-group, $p=.21$). In the TOCO-group, one secondary CD was performed

Table 1. Baseline characteristics.

	TOCO (n=42)	EHG (n=37)	p value
Maternal age (years)	31.76±3.39	31.08±4.15	.43 ^a
Parity			.24 ^b
1	36 (85.7)	28 (75.7)	
2	5 (11.9)	9 (24.3)	
3	1 (2.4)	0 (0.0)	
Gestational age at birth (days)	276.38±6.46	276.97±6.69	.69 ^a
Oxytocin augmentation	0	0	NS
Pain medication (During trial of labor)	0	0	NS
Neonatal birth weight (g)	3355.48±383.90	3322.97±399.93	.71 ^a
Fetal sex			.93 ^b
Male	20 (47.6)	18 (48.6)	
Female	22 (52.4)	19 (51.4)	

All data presented as number (%), mean±SD or median [IQR].

^aIndependent samples *T*-test.

^bChi-square test.

Table 2. Outcomes.

	TOCO (n=42)	EHG (n=37)	p value
Vaginal birth after cesarean	30 (71.4)	29 (78.4)	.48 ^b
Spontaneous vaginal birth	25 (59.5)	28 (75.7)	.13 ^b
Assisted vaginal birth	5 (11.9)	1 (2.7)	.21 ^d
First stage labor duration (minutes)	446.82±213.80	400.10±172.17	.37 ^a
Second stage labor duration (minutes)	25.00 [41]	20.00 [12]	.05 ^c
	Minimum 6 Maximum 160	Minimum 0 Maximum 101	
5-min Apgar score <7	0 (0.0)	0 (0.0)	NS
Vaginal blood loss (mL)	300.00 [50]	300.00 [75]	.08 ^c
	Minimum 200 Maximum 800	Minimum 200 Maximum 500	
Complications	0 (0.0)	0 (0.0)	NS

All data are presented as number (%), mean±SD or median [IQR].

^aIndependent samples *T*-test.

^bChi-square test.

^cMann-Whitney *U* test.

^dFishers exact test.

due to a suspicion of uterine rupture (not confirmed during CD). Other reasons for a secondary CD were (expressed as TOCO (%) versus EHG (%)): fetal distress (9.5% versus 10.8%), labor dystocia (7.1% versus 5.4%), fetal position (2.4% and 2.7%), cephalopelvic disproportion (2.4% and 0%), or unknown reasons (4.8% and 2.7%). There were no significant differences between groups in first or second-stage labor duration or maternal vaginal blood loss. Neonatal metabolic acidosis was reported in one neonate in the TOCO-group. However, in 22 neonates, the arterial umbilical pH level was not measured. No 5-min Apgar scores <7 were observed in neonates. No complications occurred during labor, delivery or postpartum in any of the participants in this study.

Discussion

Within this study, TOLAC was introduced in a hospital with no previous experience with TOLAC. VBAC succeeded in 75% of cases, without any complications and without the use of oxytocin. The VBAC rate with EHG-monitoring was slightly higher (78.4%) as compared with TOCO-monitoring (71.4%), although this difference was not statistically significant.

This VBAC rate is similar compared to other studies. [20,21] We only included women with spontaneous onset of labor, which might have affected the results positively as we know that labor induction decreases the chance of VBAC [22]. On the other hand, no oxytocin was used in this study. Possibly, low dosages of oxytocin for labor augmentation could have increased the VBAC rate, as five women had a CD because of labor dystocia.

Considering this being a first introduction of TOLAC in this hospital, the VBAC rate was high. Training of caregivers prior to the start of the study might have had an influence on the high VBAC rate [23] Besides, the Hawthorne effect could also have had a positive influence on these outcomes, since caregivers were aware of the primary study outcome prior to the study. Blinding of women and caregivers was not possible given the nature of the study, but the researchers were blinded to the allocation of participants.

The maternal age of our study population is relatively high. This is probably a result of the abandonment of the one-child policy in 2015. Women who have had their first pregnancy before 2015, now opted for a second child [12]. This creates a high-risk population. However, in- and exclusion criteria for this study were chosen to create a study population comparable to a population eligible for TOLAC in everyday clinical practice.

One of the strengths of this study is the study design of a RCT. By introducing TOLAC in this hospital using both the widely used method of UA monitoring (i.e. TOCO) and the relatively novel method for UA monitoring (i.e. EHG), we were able to objectively assess the influence of the uterine monitoring method on the VBAC rate.

A previous study by Luo et al. showed that many Chinese obstetricians did not intend to recommend TOLAC to women with a previous CD [23], based on their concerns about TOLAC safety, medical lawsuits due to adverse delivery outcomes, as well as perceived attitudes of the pregnant women and their families. This phenomenon is present despite the attempts of the WHO to perform fewer CD and thus encourage vaginal births, also in women with a previous CD.

This, combined with the little experience with VBAC in this hospital, we assumed that the VBAC rate in the TOCO group would be lower than the VBAC rate in Western countries. The TOLAC rate in this study was much higher than expected, as well as the VBAC rate in both study groups.

Several alterations in uterine activity have been identified (while monitored with TOCO and IUPC) to be associated with uterine rupture, including hyperstimulation, decreased uterine activity, and both increased and reduced baseline tonus. [21]. With the introduction of EHG, obstetric caregivers might have felt more comfortable to perform TOLAC, as EHG may detect more subtle changes in UA, possibly preceding a uterine rupture [24]. Multiple studies already proved that EHG outperforms TOCO regarding sensitivity of uterine contraction detection [15,25]. In the EHG-group, less assisted births were performed compared to the TOCO-group. An explanation could be that during the second phase of labor, EHG-registration remained more accurate than TOCO, providing obstetricians with valuable information on the condition of both mother and fetus.

The technique of EHG also has the possibility to extract multiple parameters as entropy and vector, which may be of additional value to distinguish between uterine physiology and pathology, such as, for example, a uterine rupture. For this, more research is needed.

A limitation of this study is that only the main patient characteristics were collected, and we, therefore, have no information regarding education, socio-economic background or prior pregnancy losses. Cultural factors may have led to selection bias in this study. For future larger studies, we would recommend to take these factors into account for analysis. In our study population, no pain medication was administered, with the hypothesis that an (impending) uterine rupture can be detected more promptly. However, effective regional analgesia should not be expected to mask the pain of uterine rupture. Analgesia may thus be applied and may even encourage women to attempt TOLAC [22].

Moreover, labor was neither induced by balloon or prostaglandins, nor augmented with oxytocin. Yet in most countries, balloon induction and administration of low dosages of oxytocin are not contraindicated during TOLAC [26]. Nonetheless, a two- to threefold increased risk for uterine rupture is reported which might be caused by hyperstimulation following oxytocin usage [24]. Therefore, in these cases, close monitoring of oxytocin usage and UA is even more important to prevent complications.

As previously mentioned, EHG has a higher sensitivity for uterine contraction detection as compared to TOCO. Therefore, EHG could be of added value in clinics where oxytocin (and pain medication) is given during TOLAC.

In contrast to TOCO, EHG is not influenced by maternal obesity [16]. Although obesity is an increasing problem in China as well, the mean BMI is still much lower than in Western countries [27]. Possibly, when this study was performed in a Western population, the differences between the VBAC rates in the EHG- and TOCO-group would therefore be even bigger.

We have shown that the percentage of successful VBAC in a Chinese population is high with both TOCO and EHG. Based on the absolute reduction of 7% secondary CD with EHG monitoring (21.6%) versus TOCO monitoring (28.6%) in this study, the number needed to treat (NNT) with EHG would be 15, to prevent one CD. However, larger studies are required to demonstrate significant differences and to calculate NNT accurately. Based on this study, we would recommend future research with at least 600 participants per group to detect differences between the use of EHG and TOCO-monitoring during TOLAC. We would also recommend to evaluate both patient and user satisfaction. In this way, potential uptake barriers can be further identified to achieve successful implementation in China.

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Author contributions

W.L. and Z.M. facilitated the trial in Shijiazhuang Sixth Hospital. K.T. wrote the protocol, performed measurements and trained new EHG users in Shijiazhuang Sixth Hospital. M.F. performed the statistical analysis and joined K.T. in writing the article. W.L., Z.M., S.O., M. vd. H- vd. J. and M.W. supervised the project and reviewed the manuscript.

Disclosure statement

S.O. initiated the scientific research from which Nemo Healthcare BV and the described EHG device originated. There are no financial relationships between Nemo Healthcare and any of the authors.

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Nemo Healthcare B.V. supplied all disposable electrode patches and the translation modules were given on loan. Patients, who participated in the trial, were compensated with 150 Yuan which was paid by Nemo Healthcare B.V.

Data availability statement

The data that support the findings of this study are available from the corresponding author, KT, upon reasonable request.

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