One plus one equals two – Will that do?

A randomized controlled trial to evaluate collegial midwifery practice to prevent perineal trauma

Project plan

2018-12-03

Ethical approval no 2018/476

Purpose and aims

The purpose of this study is to evaluate a clinical practice to reduce severe perineal trauma. This clinical practice involves collegial midwifery assistance during the second stage of labor, where an additional midwife is present during the active phase of the second stage of labor and the birth of the baby. The midwife responsible for the birth is the primary carer of the woman and the other midwife observes the birth or assists the primary midwife if asked to.

Specific aims:

Does the clinical practice with a second midwife present during the second stage and the birth of the baby

- reduce severe perineal trauma (grade III-IV)?
- reduce vaginal tears?
- reduce perineal trauma grade II?
- reduce pelvic floor-related symptoms one year after the birth?
- How do midwives divide work assignments and responsibility between them during the second stage of labor?
- How do women experience having one or two midwives attending the birth of the baby?
- How do women experience midwifery care methods used during the second stage of labor to prevent perineal trauma?

Background

Most women sustain some form of perineal trauma when giving birth vaginally (1). Perineal injuries are classified as grade I-IV (2). A first-degree tear only includes perineal skin or mucosa, whereas a second-degree tear includes muscles in the perineal body. A tear involving a part or the whole of the anal sphincter muscle complex is graded III-IV (2). Data from the Swedish National Birth Register show that 4% of first-time mothers suffered a tear affecting the anal sphincter (3). National registers in Sweden only collect data on severe perineal trauma affecting the anal sphincter but in a recent regional Swedish study 78% of the primiparous women experienced second-degree tears (4). The consequences of second-degree tears and severe perineal trauma are pain (5), dyspareunia (6), and an increased risk of symptomatic pelvic organ prolapse later in life (7). A severe consequence of perineal trauma is anal incontinence, mainly caused by tears affecting the anal sphincter muscle (8, 9). However, second-degree tears may also lead to anal incontinence (8). This may be related to a lack of support from the perineal body due to poor repair. Furthermore, perineal

trauma is known to be misclassified, with consequent under-reporting of injuries affecting the anal sphincter complex (10).

Risk factors for severe perineal trauma (grade III-IV) are giving birth vaginally for the first time, having an assisted vaginal birth, giving birth vaginally after a previous caesarean section, or giving birth to a baby that weighs more than 4000g, and the risk increases with age (1, 11-13). Some of the midwifery care methods used to prevent perineal injuries have been evaluated in clinical trials but there are still gaps in our knowledge (14). Even if scientific evidence is lacking for most of the preventive strategies used by midwives except for warm compresses held at the perineum (14), midwives believe that a slow and controlled birth is a key factor in prevention. Several studies indicate that a combination of strategies can be effective in preventing perineal trauma (4, 15-17). Giving birth is a profound experience for the woman and her partner and an experience that has significance for the woman all her life (18). The second stage is considered to be the most stressful part of the labor for the woman and her unborn baby, and consequently also for the midwife (19). Despite this, there is still a lack of knowledge about how women experience the second stage and the methods midwives use to facilitate birth and prevent perineal trauma (14). Traditionally midwives have asked colleagues for a second opinion or to assist in complicated situations, or in obstetric emergencies. Recently a new clinical practice has been introduced in approximately 50% of the maternity wards in Sweden to reduce severe perineal trauma (20). This procedure involves two midwives attending the woman during the second stage of labor. The midwife responsible for the birth calls for the second midwife when the active phase of the second stage has started and the presenting part of the baby is visible. The second midwife observes the birth and can assist the midwife responsible for the birth if needed. An unpublished survey from one maternity ward in Sweden showed that most of the midwives appreciated this way of working but were uncertain as to whether it actually reduced the prevalence of severe perineal trauma (20). Furthermore, this clinical practice might have negative side-effects or unintended consequences. The maternity wards that practise this method have not increased the number of midwives. It could be argued that there is a risk that other women in labor will be left unattended for longer periods when two midwives assist at births. How midwives share the responsibility and communicate are factors that needs to be evaluated scientifically.

Project design

This is a parallel multicentre randomized controlled trial. Women expecting their first child will be randomized to either having one midwife assisting the active phase of the second stage of labor and the birth of the baby (standard care) or to having two midwives present.

That means that if the woman is randomized to the intervention, the midwife responsible for the birth is assisting the woman as usual but asks a second midwife to be present in the birthing room ready to help her if necessary (intervention). The study is designed according to CONSORT statements (21).

The hypothesis in this study is that the collegial presence of another midwife during the second stage of labor will reduce perineal trauma grade III-IV (primary outcome).

Data from the National Birth Register show that 4.1% of first-time mothers suffered severe perineal trauma in Sweden 2017. The prevalence of severe perineal trauma varies between different regions in Sweden (3). To be able to detect a 50% reduction in severe perineal trauma grade III-IV from 4.1% to 2.0% with 80% power and a 95% level of significance, 1052 women in each group will be needed. The 50% reduction is based on regional figures after a change in practice and is therefore clinically significant. Allowing for a possible drop-out rate of 20% and another drop-out of 20% for possible cases of obstetric emergencies where another midwife will be needed regardless of randomization, this will result in 1473 women in each group and 2946 women in total. To ensure that there are no adverse side-effects of the intervention interim analyses will be performed by a data monitor not otherwise involved in the trial every 6 months until the end of the trial. In the interim analysis, the distrubution of the intervention and standard care will be estimated among women with no perineal tears, women diagnosed with a third- or fourth-degree tear (OASI), and neonatal outcome (apgar score at 5 minutes and arterial blood gas from the nuchal cord).

The primary outcome is the prevalence of severe perineal tears grade III-IV.

Secondary outcomes are the prevalence of second-degree tears, vaginal tears, women's experiences of two midwives attending the birth and midwives' experiences of the intervention. Additional secondary outcomes regarding the woman are: the prevalence of episiotomy, first-degree tears, intact perineum (no tear), labial and periurethral tears, postpartum bleeding >500 ml, birth position, instrumental delivery, urinary incontinence, anal incontinence, symptoms of pelvic organ prolapse and sexual function after one year, and self-reported mental health one month and one year after birth. For the one-year follow-up the following validated questionnaires will be used: PFIQ7, PFDI-20, and PISQ-12 and EPDS (22-24). Secondary outcomes regarding the newborn child are: Apgar scores at 5 minutes, umbilical cord blood gases, and breastfeeding within two hours after birth.

Inclusion criteria: Swedish speaking women expecting their first child or with a prior caesarean section opting for a vaginal birth, with a singleton live foetus in cephalic presentation from gestational week 37+0.

Participating clinics: The maternity ward at Karolinska University Hospital Huddinge and Solna, and the maternity wards at SUS Malmö and Lund. With four participating clinics the time for patient recruitment will be shortened and this will also increase the generalizability of the results.

Randomization process: It will not be possible to blind either women or midwives in this study. The participants will be randomly allocated (1:1) to the intervention group (collegial presence of another midwife during the second stage) or to the standard care group (one midwife is responsible for the care during the second stage). Randomization will take place at the start of the second stage. To allow for equal distribution between the groups, block randomization in blocks of ten will be used. The midwife in charge will be responsible for the randomization process. Sealed and opaque envelopes will be used and will be prepared with a unique code consisting of a first code letter identifying each study site, a second code letter identifying which group it belonged to (intervention or control) followed by a consecutive number.

Data collection: After the birth the tear will be diagnosed together with a midwife or an obstetrician who has not been involved in the birth. Tears will be sutured according to the guidelines at each participating study site. The midwife responsible for the birth will complete a questionnaire which will contain questions regarding the woman; labor and birth variables, methods of preventing perineal trauma, questions regarding the newborn, diagnosis of the tear and how the tear was sutured. If a second midwife has been present during the second stage (intervention) the responsible midwife (midwife no 1) will also complete questions on the assistance she got from the second midwife and how this assistance was experienced. Data will also be retrieved from the participating women's records by using the local database of each study site (Obstetrix). When the intervention has taken place the second midwife will also complete a questionnaire. This questionnaire will contain questions on what assistance she gave the midwife responsible for the woman (if any) and how she experienced being present during the second stage of labor. The questionnaires completed by the midwives will be coded with the same code as the participating woman received when she was allocated to the intervention or standard care.

The questionnaire regarding women's experiences of the intervention or standard care and the methods used to prevent perineal trauma will be sent by email one month after the birth. The questionnaires used are a study specific questionnaire and EPDS (23). The follow-up with validated questionnaires regarding pelvic floor symptoms will be sent to the women one year after birth. The questionnaires used are PFIQ7, PFFDI-20, PISQ-12, FSFI and EPDS

(22-24). If the woman does not complete the questionnaire in two weeks, she will be reminded, and the questionnaire will be sent by mail.

Analysis

Descriptive statistics will be used to present the data. For comparison between the two groups, t-tests and Chi-square tests will be performed depending on variable characteristics. The primary analysis will comprise intention-to-treat analysis for both primary and secondary outcomes. Multivariable logistic regression will be performed to adjust for potential confounders and will be presented as odds ratios with 95% confidence intervals. In addition, per protocol analysis will be performed. Secondary analyses will compare secondary outcomes using t-tests and Chi-square tests depending on variable characteristics in the research questions. Outcomes based on scores will be analysed by non-parametric tests. The project has access to a statistician from Lund's University.

Clinical significance

The number of women seeking care for pelvic floor problems related to childbirth is increasing. Improving the health and well-being for women giving birth is important on apersonal level but also for society. There is an ongoing debate in the Swedish media and among women regarding severe perineal trauma. Childbirth organizations are upset that care providers are not able to prevent injuries and find it extraordinary that gaps in our knowledge still exist in this field of research. Many women are afraid of giving birth vaginally because they fear an extensive tear and the consequences such a tear might have on their life. Some women are so fearful that they request a caesarean section. Hence, it is imperative to fill this gap in knowledge and implement and implement evidence based care. Furthermore, many interventions used in labor and birth have been introduced without any evaluation and analyses as to whether they have any unintended consequences. The results from this study will show whether this clinical practice, which approximately 50% of all maternity wards in Sweden already have adopted is preventive or not, or if it has any negative side effects. If the presence of a second midwife can be demonstrated to be preventive, the practice can be implemented in all the maternity wards in Sweden. Otherwise health care resources could be used more effectively. The results from this study will also generate knowledge about women's experiences of the midwifery care methods to prevent perineal trauma. This knowledge is currently lacking and is important as care should be both effective and of value to women.

Ethical approval 2018/476

The study has ethical approval from the Ethics committee in Lund no 2018/476 and is

planned in accordance with Swedish law for research concerning humans (SFS 2003:460) and the Declaration of Helsinki regarding research involving human subjects. Research during labor and birth needs careful planning since giving birth is a profound life-experience for the woman and her partner and the woman is in a vulnerable position. At the same time, it is important to evaluate preventive methods used in clinical practice. As the intervention is already in use it has been considered possible and ethical to evaluate in a clinical trial. The study has received financial support from FORTE and SUS Funds.

References

1. Baghestan E, Irgens LM, Bordahl PE, Rasmussen S. Trends in risk factors for obstetric anal sphincter injuries in Norway. Obstetrics and gynecology. 2010;116(1):25-34.
2. Fernando RJ, Sultan AH, Freeman RM, Adams EJ. The Management of Third- and Fourth-Degree Perineal Tears https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg29/2015 [Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-29.pdf.
3. Stephansson O. Årsrapport 2016 Graviditetsregistret. Tema: Psykisk ohälsa https://www.medscinet.com/gr/uploads/hemsida/dokumentarkiv/GR_%C3%85rsrrapport_2016_2.1.pdf: Graviditetsregistret; 2017 [
4. Edqvist M, Hildingsson I, Mollberg M, Lundgren I, Lindgren H. Midwives' Management during the Second Stage of Labor in Relation to Second-Degree Tears-An Experimental Study. Birth (Berkeley, Calif). 2016.
5. Macarthur AJ, Macarthur C. Incidence, severity, and determinants of perineal pain after vaginal delivery: a prospective cohort study. American journal of obstetrics and gynecology. 2004;191(4):1199-204.
6. Rathfisch G, Dikencik BK, Kizilkaya Beji N, Comert N, Tekirdag AI, Kadioglu A. Effects of perineal trauma on postpartum sexual function. Journal of advanced nursing. 2010;66(12):2640-9.
7. Tegerstedt G, Miedel A, Maehle-Schmidt M, Nyren O, Hammarstrom M. Obstetric risk factors for symptomatic prolapse: a population-based approach. American journal of obstetrics and gynecology. 2006;194(1):75-81.
8. Woodman PJ, Graney DO. Anatomy and physiology of the female perineal body with relevance to obstetrical injury and repair. Clinical anatomy (New York, NY). 2002;15(5):321-34.
9. Schei B, Johannessen HH, Rydning A, Sultan A, Morkved S. Anal incontinence after vaginal delivery or cesarean section. Acta obstetricia et gynecologica Scandinavica. 2018.
10. Andrews V, Sultan AH, Thakar R, Jones PW. Occult anal sphincter injuries--myth or reality? BJOG : an international journal of obstetrics and gynaecology. 2006;113(2):195-200.
11. Raisanen S, Vehvilainen-Julkunen K, Cartwright R, Gissler M, Heinonen S. A prior cesarean section and incidence of obstetric anal sphincter injury. International urogynecology journal. 2013;24(8):1331-9.
12. Raisanen SH, Vehvilainen-Julkunen K, Gissler M, Heinonen S. Lateral episiotomy protects primiparous but not multiparous women from obstetric anal sphincter rupture. Acta obstetricia et gynecologica Scandinavica. 2009;88(12):1365-72.

13. Elvander C, Ahlberg M, Edqvist M, Stephansson O. Severe perineal trauma among women undergoing vaginal birth after cesarean delivery: A population-based cohort study. Birth (Berkeley, Calif). 2018.
14. Aasheim V, Nilsen ABV, Reinar LM, Lukasse M. Perineal techniques during the second stage of labour for reducing perineal trauma. The Cochrane database of systematic reviews. 2017;6:Cd006672.
15. Laine K, Pirhonen T, Rolland R, Pirhonen J. Decreasing the incidence of anal sphincter tears during delivery. Obstetrics and gynecology. 2008;111(5):1053-7.
16. Basu M, Smith D, Edwards R. Can the incidence of obstetric anal sphincter injury be reduced? The STOMP experience. European journal of obstetrics, gynecology, and reproductive biology. 2016;202:55-9.
17. Basu M, Smith D. Long-term outcomes of the Stop Traumatic OASI Morbidity Project (STOMP). International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics. 2018;142(3):295-9.
18. Simkin P. Just another day in a woman's life? Women's long-term perceptions of their first birth experience. Part I. Birth (Berkeley, Calif). 1991;18(4):203-10.
19. Kopas ML. A review of evidence-based practices for management of the second stage of labor. Journal of midwifery & women's health. 2014;59(3):264-76.
20. Emanuelsson Å, Lönnqvist P. Barnmorskans upplevelse av kollegial närvaro under förlossningens utdrivningsskede [Magisteruppsats]. Akademin för vård, arbetsliv och välfärd, Borås Högskola; 2015 [Available from: http://www.diva-portal.org/smash/get/diva2:901989/FULLTEXT01.pdf.
21. CONSORT statement - transparent reporting of trials 2010 [Available from: http://www.consort-statement.org/Media/Default/Downloads/CONSORT%202010%20Explanation%20and%20Elaboration%20Document-BMJ.pdf.
22. Teleman P, Stenzelius K, Iorizzo L, Jakobsson U. Validation of the Swedish short forms of the Pelvic Floor Impact Questionnaire (PFIQ-7), Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Acta obstetricia et gynecologica Scandinavica. 2011;90(5):483-7.
23. Cox JL, Holden J, Henshaw C. Perinatal mental health : the Edinburgh Postnatal Depression Scale (EPDS). London: RCPsych Publications; 2014.
24. Wiegel M, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. Journal of sex & marital therapy. 2005;31(1):1-20.