Project plan

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Project title - Is there an association between patient-reported complications after a perineal tear and patient perceived care quality?

Background and purpose of the study - Every year approximately 120 000 women give birth in Sweden. Of these, 17,6 % are caesarean sections which leave the vast majority to be vaginal deliveries (1). Through vaginal childbirth, there is a risk of causing a perineal tear. An observational study shows that up to 78% of Swedish women undergoing vaginal delivery receives a perineal tear (2). Perineal tears can later cause complications, such as infections, suffering from pain, dyspareunia, urinary and faecal incontinence. Many of the affected women also describe a feeling of being omitted, helpless and not taken seriously by healthcare (3). Perineal tears are categorized into sub-groups depending on the extent of the injury affecting tissues and muscle layers(4), see table 1:

Table 1: Description of the different perineal tear grades

Degree	ICD-10 code and description (5)	Responsible for the suturing in Sweden
2	**O70.1 Second degree perineal laceration during delivery** Perineal laceration, rupture or tear involving fourchette, labia, periurethral tissue, slight skin, low vagina, vulva, pelvic floor, perineal muscles and vaginal muscles.	Midwife
3	**O70.2 Third-degree perineal laceration during delivery (OASIS)** Perineal laceration, rupture or tear as in O70.1, also involving: anal sphincter, rectovaginal septum and sphincter NOS	Obstetrician
4	**O70.3 Fourth-degree perineal laceration during delivery (OASIS)** Perineal laceration, rupture or tear as in O70.2, also involving: anal and rectal mucosa.	Obstetrician

During 2017, 3669 women with a perineal tear were registered, 47,5% obtained a grade 2, 48,4% had a grade 3 and 4,1% received a grade 4 perineal tear (6). Lately, several studies on how to prevent and treat grade 3-4 perineal tears have been reported (7-10). However, there is a lack of scientific knowledge and clinical treatment options regarding grade 2 perineal tears. Although, grade 2 perineal tears constitute a large group of child birthing women (11). Furthermore, there is limited research on how obstetric care is perceived by the patient (3). Therefore, this study will include and compare grade 2, 3 and 4 perineal tears to find out if there is a difference in patient-perceived care.

Every patient experience healthcare in a certain way based on their own perceptions and expectations. Therefore, what the concept "quality of care" implies may differ between

patients. Additionally, many tools to measure the quality of care exists (12, 13) which make it difficult to agree on what care-quality is with a universal definition. As of today, healthcare stands with no consensus in this matter.

By using a patient-centred questionnaire this study will examine how the childbirth experience and the subsequent care are apprehended by the patient after a perineal tear of grade 2, 3 and 4 and if this affects patient-reported complication. The aim of the study is to investigate perceived quality of care, among women with perineal tear of grade 2, 3 and 4, in relation to reporting a complication or not.

Materials and Methods - In 2014 the Perineal Laceration Register (PLR) was formed as a subdivision from the National Quality Register of Gynaecological Surgery (GynOp-register)(15). PLR aims to identify women with perineal tear after childbirth, offer follow-up and to allow national comparisons. The reporting of perineal tears varies between Obstetric clinics, 43 of Sweden's 46 clinics register grade 3 and 4 perineal tears in the PLR. Out of these 43 clinics, 17 also register grade 2 perineal tears in the register, corresponding 39,5%.

PLR extracts data from medical records and contains self-reported data from affected women, at three occasions by web or postal questionnaires; *shortly after receiving a perineal tear* (The first questionnaire; Q1), at *eight weeks* after childbirth (The second questionnaire; Q2) and *one year* after childbirth (The third questionnaire; Q3). Q1 comprises questions on bowel function, urine and faecal incontinence, and vaginal function before pregnancy. Q2 focus on follow-up of bowel, urinary and vaginal function after receiving a perineal tear. Some of the questions in Q2 are "The Patient Reported Outcome Measures" (PROM-questions). The patient will for example rate if they developed no complications, mild complications, or severe complications after the repair of a perineal tear. Q3 aims to follow up women one year after repair of a perineal tear. Q3 contains similar questions as Q2.

All women responding Q2 on the web were, in addition, asked to respond to "The Patient Reported Experience Measures" (PREM-questions), in this particular case called Quality from patients' perspective(QPP). QPP-questions were developed and validated by investigators at Karlstad University to expand the knowledge on perceived care quality(12, 13). One of the main developers of QPP-questions in general, Barbro Wilde Larson, participated when PLR developed their QPP-questionnaire for gynecological patients. The QPP-questionnaire consists of 23 questions in total. The selected questions used in this study focuses on: if the patient were satisfied with given information regarding operation method, information how to adjust to daily activities after returning home and how the patient perceived the treatment from healthcare personnel. All QPP-questions are graded in relation to its importance for the patient. The QPP-questions are sent to the patient together with Q2 (15).

In this study, data were collected during a specific time period, 20150815-20181218, summing approximately 11000 women. Around 73% of the women replied to Q2, of these roughly 78% filled the form on the web. Furthermore, around 60% went on answering the QPP-questions.

Data will be analysed in SPSS with frequency analysis, Chi-2test and univariate and multivariate logistic regression analysis.

Specific goal/Expected significance - The healthcare faces a large challenge in present time - to treat and guide women through the sequences of perineal tears(16). As described, a perineal tear can cause physical pain as well as mental distress. Since women have described feelings

of not being able to breastfeed properly because of pain while sitting up and not having the energy to help with chores at home, a perineal tear does not only affect the woman herself but also the infant and family (3). If the results in this study indicate associations between patient experienced complication and the perceived quality of care; clinics and health professionals have a possibility to improve their care, based on identified deficiencies.

Medical or clinical relevance of the project - Swedish Association of Local Authorities and Regions and the Swedish government have determined that investments in maternal healthcare are necessary (17). In 2018 the government partitioned 1,8 billion Swedish kroner to obstetric care, with the purpose to improve healthcare during pregnancy, childbirth and after childbirth (18). Furthermore, The Swedish National Board of Health and Welfare completed a national mapping of obstetric care after childbirth. Their assessment and conclusions were that follow-ups of women's health after childbirth needs to be improved, as well as the availability to support after childbirth (19).

According to the Health and Medical Service Act, all counties in Sweden have a responsibility to provide the patient with equal healthcare and good care quality (20). In order to fulfil this requirement, further studies are needed how to treat and prevent perineal tears of all grades. Additionally, the results of this study will be presented at the yearly GynOp meeting. All clinics will be able to take part in the results regarding the given quality of care.

Planned format and language of the essay - This project aims to follow the template for the scientific peer-reviewed BMC Pregnancy and Childbirth.

Timetable

1. Reading and writing Project Plan: estimated time 4-5 weeks.
2. Experimental work/collection of data: Data has already been collected in the GynOp-register.
3. Data analysis and interpretation of results: 3-4 weeks
4. Writing, revising and completing the report: 10 weeks
5. Preparation for presentations: 1 week

Ethics - The project was approved by the Ethical Board in Linköping (Dnr:2015/110-31Ö) and also the Ethical Board in Umeå (Dnr:2016/144-31).

All questionnaires are voluntarily answered by women affected by a perineal tear. When responding to Q1, shortly after receiving a perineal tear, the patient receives information from a compulsory legislative text for national registers, informing the patient that shared data may be used in future research and quality assessment of Obstetric care. If the patient chooses to opt out of participating, they can do so at any time and no explanation is needed. If the patient choose to answer the question-forms they give their consent to participate in further research. Excerption of data for research is only allowed after given approval from an Ethical board and the board of PLR. Retrieval of data for a study does not give access to identification numbers and the patient will be anonymous. Since the data consist of information that involves women at a vulnerable state this study can be perceived as revealing. However, since results will be presented on a group level with 4254 participating cases there will not be possible to identify specific individuals.

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