Study protocol

„Effect of The mother's active pushing
at cesarean delivery "

The target and the reasons for the study

Caesarean section (C-section) is one of the most commonly performed operations for women all over the world. Currently around every 3rd baby (31.3 % on average) born in German hospitals is delivered by C-section(1)(2). Women who deliver by C-section have been reported to express less satisfaction with their birth experience than women delivering vaginally (3). Some women also express strong feelings of loss, failure, and anger during C-section(4). These feelings are likely related to stress, pain, and fatigue associated with major surgery and the psychological status of the patient and a stressor or trigger in the development of postnatal depression (4). Also, some studies suggested that the mother-infant bonding is affected by the mode of the delivery being worse with C-section.

In this study, we will evaluate how the participation of patients in the delivery process during the C-section by pushing will affect the patients' experience. This is done in anticipation that this participation will alleviate the severity of the intraoperative discomfort, the postoperative pain, and improve the breastfeeding and patient's satisfaction by granting the patient a higher feeling of control.

There are different techniques for performing C-Section of which some Techniques are performed with the participation of the mother and others without. Currently, there is no consensus on a standardised technique with convincing evidence of its superiority. The first approach of this modification of the C-section was described in 2008 by Smith et al. and was termed the ''natural caesarean'' (5).

In 2016, a prospective randomised controlled trial was conducted at the Charity Berlin Hospital, aiming to evaluate the safety of patient's delivery experience of the modified C-section (participation of the mother during C-section) and early skin-to-skin contact(STS). Parameters of perinatal outcome for both mother and infant were assessed using modified Likert-Scales and a standardized questionnaire. Primary outcome measures were birth experience and satisfaction for both parents. Parameters of breastfeeding, consecutive problems, APGAR Scores, blood loss and perioperative complications were secondary outcome measures. The trial concluded that birth experiences and

breastfeeding was rated significantly higher in the modified C-section group with the active participation of the mother compared to a classical C-section ($p < 0.05$). However, there were no significant differences regarding the neonatal outcome, intraoperative and postoperative complications. Major critics against

this study are that the authors did not analyse one factor but a combination of several factors which hinders clear evaluation. In addition, by creating a whole construct called “the charity birth”, several scientists criticize that this will promote C-section in cases where vaginal birth would be the suggested option. (6)

Therefore, we decided to only evaluate the effects of one technique during C-section. This does not promote C-section, however, might improve outcomes for patients who have to undergo C-section and alleviate postoperative negative effects caused by this procedure.

Characterisation of the subjects

Patients, who are getting a scheduled C-Section and having no contraindication for valsalva manoeuvres are eligible for this study. The gestational week should be between 37 and 42 weeks. Patients have to provide informed consent to this study. Patients must have epidural anaesthesia. They must understand the German language in order to understand information during C-section and correctly fill-out the questionnaires. Emergent C-sections or pregnant women known with chronic pain, severe preeclampsia or HELLP-Syndrome will be excluded

Inclusion criteria

- Minimum age of 18 years
- Written consent
- Pregnant women between 37 – 42 weeks
- No fetal abnormalities.
- Scheduled primary C-Section (category 3&4 NICE guidelines) with epidural anaesthesia

Excluding criteria

- Emergent C-section
- Contraindication for epidural anaesthesia.
- Multiple pregnancies
- Scheduled C-section with placenta previa, accreta, increta or percreta.
- Secondary C-section
- Contraindication for Valsalva manoeuvre

- Known psychiatric illnesses
- Known chronic Pain, taking Pain killers regularly

Studientyp

Prospective randomized single-centre study

Measurements, findings and observations

During the C-section, the patient will be guided to push after the uterotomy, aiming to participate in the process of delivery during the surgery. Patients will fill out a survey designed to assess pain severity and satisfaction level.

1. Intraoperative and Postoperative pain at different time points (day 0,1,2 postoperatively) depending on validated numerical pain Scale (7).
2. Psychological status and the satisfaction of the patient postoperatively using the validated Edinburgh Postnatal Depression Scale (EPDS)(8).
3. Neonatal outcome according to APGAR score and pH Level from the umbilical cord.
4. the breastfeeding depending on Breastfeeding Self-Efficacy Scale, Short Form (BSES-SF) (9)(10).
5. The duration of the surgery and its complications (intraoperative haemorrhage, wound complication, postpartum haemorrhage (PPH) and surgical injury).
6. A surgeon questionnaire evaluating the actual performance of the procedure.

A detailed description of the course of study

Antenatally, pregnant women will be evaluated for their eligibility for this study. Patients planned for primary C-section will be informed on preoperative visits. (category 3&4 NICE guidelines). If so, written informed consent will be collected from the patients prior to their participation in this study. Patients will be informed about the postoperative assessment in order to evaluate the effects of C-section techniques. As described in the patient information, there will be general information about the procedure and that communication and maternal participation will be evaluated. An explanation of pushing or not-pushing, which both represent standard-techniques, will not be provided in

detail, to avoid expectation bias. Patients will be randomized by the study assistant using a 1:1 strategy. Patients will be assigned an identifier number upon their enrolment to the study. The allocation of participants, to either the control or the test group, will be randomly allocated using R software. This is to eliminate any human interference or bias in patients allocation.

All participating surgeons will attend specialized training during which the study principles and the variations in C-section technique will be explained. Directly before surgery, surgeons will be informed about the randomization results.

Control group: non-pushing

This method describes the standard technique routinely performed by about 70% of all C-sections. After uterotomy the child will be delivered by the doctor without special information given to the patient. Patients will be informed about the feeling of abdominal pressure. The assistant will perform abdominal pressure to help deliver the baby. The umbilical cord will be clamped and the baby will be handed over to the midwife. The midwife will try to enable early skin-to-skin contact and perform routine care for mother and child.

Intervention group: pushing

This method describes the standard technique routinely performed by about 30% of all C-sections. After uterotomy the patient is informed that the child will be delivered soon. The surgeon explains and encourages the mother to push when she is asked to deliver the baby. The assistant will help the mother with abdominal pressure. During delivery, which routinely happens with three pushes, the surgeon informs the mother about the progress (head, shoulders, belly). After delivery, the surgeon directly shows the baby to the mother and praises the mother for her efforts. The umbilical cord will be clamped and the early skin-to-skin contact will be enabled if medically accepted.

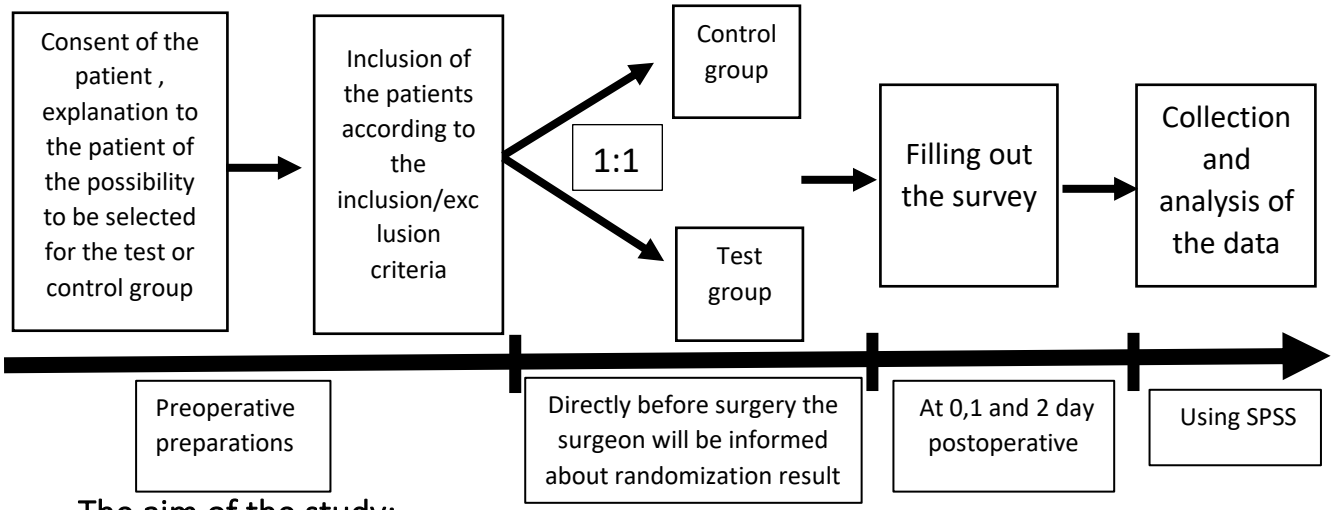
Methods

Since there is currently no standardized questionnaire for the assessment of the patient's well-being after the C-section, that's why we created the questionnaire in accordance of previous studies consisting of the following:

- validated numerical pain Scale for assessment of the intraoperative and postoperative pain.

- validated Edinburgh Postnatal Depression Scale (EPDS) for assessment of the Psychological status and the satisfaction of the patient postoperatively.
- Self-Efficacy Scale, Short Form (BSES-SF) for assessment of the breastfeeding at day 1-2 postoperative. Since the (BSES-SF) not validated in the German language, we will translate the questionnaire in Germany and validate it as a part of this study.
- We added extra questions on the questionnaire using a Likert scale for assessment of the patient's feelings during and after the surgery.

After surgery objective assessments will be documented including postoperative complications, blood loss, fetal outcome. The surgeon will fill out a survey investigating the surgeons' impression. Directly after child delivery patients will be first asked about the pain sensation durcing the delivery accordingt to a VAS scale. Postoperatively at4-6 hours after the surgery, patients will fill out the first survey. At day 1 and day 2 postoperatively, patients will fill out the following surveys. Data, which is collected from the surveys, will be encoded pseudo-anonymous. Recording of the complications will be performed in the first 3 days after delivery, as the usual hospital stay ranges between 3-5 days. This period covers all usual postoperative complications. Recording postpartum pain medications is essential as we cannot predict who will require which level of pain relivers (mild analgesics without opioids, weak opioids and strong opioids).



The aim of the study:

The aim of this study is to evaluate if the mother's active pushing during the C-section reduces pain during child delivery

Primary endpoints

- The severity of the intraoperative pain

Secondary endpoints:

- The severity of the postoperative pain
- Patient's satisfaction with the operation and her participation
- Patient's psychological status postoperatively
- Breastfeeding after early Skin to Skin contact (SSC)
- Neonatal Outcome
- Duration of the hospital stay, duration of the surgery and its complications (intraoperative Haemorrhage, wound complication, PPH and surgical injury)
- Surgeon's satisfaction with the procedure

The data collection and documentation

Data will be collected after taking the patient's written informed consent. Patients will be given pseudonyms. Only the study leader will have access to the files.

Data privacy:

Before a patient is enrolled in the study, written informed consent will be collected with the patient's verbal acceptance and signature to join the study. No personal or identifiable data will be published or passed on to third parties. The approval of the participants can be cancelled at any time. This cancellation will not influence further medical care. In the event of a dropout, the patient's data will be deleted and will not be included in the analysis. The data will only be used for scientific purposes. The results will be published in research reports, posters and scientific publications in accordance with the Data protection and privacy policy. The collected data will be archived for 10 years.

Unwanted events

There are no expected specific complications regarding this technique since both techniques are routinely used. However, potential surgical complications associated with cesarean section are:

- Maternal complication (Endometritis, wound complication, haemorrhage, infection, surgical injury of the urinary bladder, the small intestine and rarely the ureter), thromboembolism, Ileus, septic pelvic thrombophlebitis and rarely hysterectomy
- Fetal and neonatal risks (iatrogenic prematurity, Iatrogenic birth trauma, transient tachypnoea of the newborn and neonatal adaption syndrome)
- Anaesthetic complications.
- Complications regarding the Valsalva manoeuvre are only described for prolonged pushing during vaginal delivery. These complications are very unlikely during C-section. (11)

Only patients with indicated C-section will be included. Thereby, patients will not be exposed to additional risk as described above compared to vaginal delivery.

Evaluation /Biometrics

Descriptive statistics will be used to assess patients characteristics. Student T-test or Mann Whitney U test will be used to for continuous data to compare parametric or nonparametric data sets, respectively and the chi-square test will be applied for categorical data.

The primary evaluation should be based on the intention-to-treat population, i.e. all patients who were randomized will be included in the evaluation. With regard to the primary end point, a very timely recording will take place, so that only a negligible number of missing values can be assumed.

In case of doubt or missing values, it will be replaced by the maximum observed VAS values in the study, which is a relatively simple elimination procedure and is easy to implement. As sensitivity analyses other imputation methods will be performed.

We will conduct ANCOVA analyses to see how postoperative pain medication influences the study outcome. The WHO pain medication scale will be used to group the patients.

Power calculations

Biometric Analysis was performed with the kind assistance of Dr. Theodor Framke, Institut für Biometrie ,MHH. Please see the attached document.

There is a study from Berlin (6) on the subject, but this analysed a self-created composite variable on satisfaction and did not evaluate the sensation of pain seperately. There are no known studies which assessed the intraoperative pain during child delivery. The best approximation remains the direct postoperative pain. An older study (12) was a randomized four-therapy-arm study (placebo, diclofenac, propacetamol or diclofenac and paracetamol directly after delivery) which assessed postoperative pain after caesarean section at several time points. This study reflects the routine pain medication used in our clinics and was therefore selected.

In the study analysing postoperative pain after caesarean section the mean VAS scores at 6 hours ranged between 3.4 and 3.9 with a standard deviation of 1.7-2.0. Since we want to evaluate intraoperative pain, we exspect higher mean VAS scores between 6-7. We will calculate with a standard deviation of 2.0. Based on the findings of Armbrust et al and our clinical experience we expect a therapeutic effect of 15-20% which results in a mean VAS reduction of 0.8. Applying a two-sided T-Test for independent samples at a significance level of 0.05, a mean difference iof 0.8 between the groups and a standard deviation of 2, we will need 100 patients per treatment arm to detect a difference between both treatment groups with a power of 80%.

There is currently no prognostic factor that is known in advance to influence outcome in a certain direction. Thus, stratification is not planned.

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References:

1. Wacker J. Geburtshilfe. Kaiserschnitt vs. Natürliche Geburt. Geburtshilfe Frauenheilkd. 2010;70(10):840–3.
2. Beckmann M W, Bader W BI. Finanzierung und finanzielle Probleme von Leistungen und Strukturen im Fachgebiet Gynäkologie und Geburtshilfe im Jahr 2011 – allgemeine Aspekte und geburtshilfliche Versorgung. Geburtsh Frauenheilk. 2011.
3. MR DiMatteo. Cesarean childbirth and psychosocial outcomes: a meta-analysis.
4. Clement S. Psychological aspects of caesarean section. Best Pract Res Clin Obstet Gynaecol. 2001;15(1):109–26.
5. Smith J, Plaat F, Fisk NM. The natural caesarean: A woman-centred technique. BJOG An Int J Obstet Gynaecol. 2008;115(8):1037–41.
6. Armbrust R, Hinkson L, Von Weizsäcker K, Henrich W. The Charité cesarean birth: A family orientated approach of cesarean section. J Matern Neonatal Med. 2016;29(1):163–8.
7. Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. Pain. 2011;
8. Bergant AM, Nguyen T, Heim K, Ulmer H, Dapunt O. German version and validation of the Edinburgh depression scale (EPDS). Dtsch Medizinische Wochenschrift. 1998;123(3):35–40.
9. Dennis C. The Breastfeeding Self-Efficacy Scale: Psychometric Assessment of the Short Form. J Obstet Gynecol Neonatal Nurs. 2003;32(6):734–44.
10. Sitter-Trollmann P. „ Stillen und Selbstwirksamkeit – ein Beitrag zur präventiven Erfassung von Stillproblemen durch standardisierte Instrumente “. 2011;147. Available from: http://othes.univie.ac.at/16715/
11. Vaziri F, Arzhe A, Asadi N, Pourahmad S, Moshfeghy Z. Spontaneous pushing in lateral position versus Valsalva maneuver during second stage of labor on maternal and fetal outcomes: A randomized clinical trial. Iran Red Crescent Med J. 2016;18(10).
12. Diclofenac and/or propacetamol for postoperative pain management after cesarean delivery in patients receiving patient controlled analgesia

morphine, Sahar M. Siddik M.D., F.R.C.A., Marie T. Aouad M.D., 2001
https://doi.org/10.1053/rapm.2001.21828