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Sharp compared with blunt fascial incision at cesarean delivery: a randomized controlled trial with each case as her own control

Anna J.M. Aabakke [a,*], Kristine J. Hare [b], Lone Krebs [a], Niels J. Secher [c,d]

[a] Department of Obstetrics and Gynecology, University of Copenhagen, Holbæk Hospital, Denmark
[b] Department of Obstetrics and Gynecology, University of Copenhagen, Hvidovre Hospital, Denmark
[c] The Research Unit Women's and Children's Health, The Juliane Marie Center, Copenhagen University Hospital, Rigshospitalet, Denmark
[d] Department of Obstetrics and Gynecology, Aarhus University Hospital, Denmark

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ABSTRACT

Objective: To compare patient preference for either sharp incision with scissors or blunt manual cleavage of the fascia at cesarean delivery in a randomized controlled trial in which each woman was her own control.

Study design: Women undergoing primary cesarean delivery ($n = 34$) were randomized to side distribution of sharp or blunt incision of the fascia (sharp right and blunt left or blunt right and sharp left) and followed three months postoperatively. The primary outcome was patient preference for the right or left side of the scar 3 months postoperatively and modeled by polytomous logistic regression. The secondary outcome was difference in pain between the two sides measured on a 0.0–10.0 numerical rating scale at 1, 3, and 7 days and 1 and 3 months postoperatively. Pain scores were analyzed with a Wilcoxon signed rank test.

Results: 28 cases were analyzed and no significant difference was found in preference after three months. Nine women preferred the sharp (32%, 95% CI 16–52%) and 7 the blunt side (25%, 95% CI 11–45%) ($P = 0.804$). Pain scores did not differ significantly between the two sides at any time postoperatively either at rest or during mobilization.

Conclusion: No significant difference was found in patient preference with regard to sharp or blunt incision of the fascia, nor was there a significant difference in postoperative pain scores.

Clinical Trial Registration: ClinicalTrials.gov: www.clinicaltrials.org; NCT01297725.

1. Introduction

Cesarean delivery rates in the United States, Latin America and Europe are presently around 30% [1–3] and are increasing worldwide [4,5]. Because cesarean delivery is a common procedure, the surgical techniques should be evidence-based [6]. Two types of abdominal entry methods – Pfannenstiel and Joel-Cohen – have been compared in several studies which have examined the postoperative results of a combination of techniques to open the abdominal wall layers [7–10]. To the authors' knowledge, however, no studies to date have focused on the techniques used to incise the fascia. The fascia can be opened either sharply with scissors or bluntly by traction. Both techniques are presently practised according to the choice of the surgeon. It is unknown if one method causes more pain than the other.

Studies of surgical techniques commonly have objective outcomes, but the subjective preference of the patient should not be neglected. The aim of this study was to compare blunt and sharp extension of the fascia at cesarean delivery in a study design in which each patient served as her own control. This design eliminates several confounders and strengthens the statistical analysis [11].

2. Materials and methods

This was a single-center, prospective, randomized, controlled, double-blind study with each case as her own control. Before patient enrollment, the trial was approved by the regional ethics committee (reg. no. H-2-2010-129) and the Danish data protection agency and was registered with ClinicalTrials.gov (reg. no. NCT01297725; 16/02/2011). We followed the CONSORT recommendations for reporting randomized, controlled, clinical trials with non-pharmacological treatment [12,13].

* Corresponding author at: Department of Obstetrics and Gynecology, University of Copenhagen, Holbæk Hospital, Smedelundsgade 60, 4300 Holbæk, Denmark. Tel.: +45 5948 4268.
E-mail addresses: anae@regionsjaelland.dk, aabakke@gmail.com (Anna J.M. Aabakke).

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2.1. Participants

Eligible participants were women with no history of previous lower abdominal surgery undergoing scheduled primary cesarean delivery. Patients had to be able to speak and understand Danish and provide informed oral and written consent. Exclusion criteria were age below 18 years, pre-pregnancy diabetes mellitus, ongoing infection, daily use of immunosuppressives, alcohol and drug abuse, diseases with chronic pain (e.g. fibromyalgia), and BMI above 35. Participants were recruited from January to July 2011 at Hvidovre University Hospital, Copenhagen, Denmark, which has the largest obstetric unit in Denmark with more than 6000 births yearly, and followed for 3 months. Participants received no financial compensation.

2.2. Design

Women were enrolled by one of three investigators, and all recruited women gave written informed consent to participate and were consecutively numbered. Patients were randomized to side distribution of sharp or blunt opening of the fascia (sharp right and blunt left or blunt right and sharp left) and included when surgery had been performed. Recruited women were replaced if procedures did not follow the protocol. Randomization was computer-generated at a 1:1 allocation ratio by a third party not otherwise involved in the trial. The allocation was concealed in 30 identical opaque, sequentially numbered sealed envelopes. The appropriate numbered envelope was opened by the surgeon shortly before initiation of the cesarean delivery, and the allocation was not spoken out loud in the operating theater. All surgeons were instructed in the surgical techniques by a video especially produced for the study (Supplemental Digital Content, Video 1). All women had spinal anesthesia with 10 mg bupivacain, 2.5 μg sufentanil and 0.1 mg morphine, and standard procedures for anesthesia were followed.

The surgical procedure was as follows. A Joel-Cohen incision was placed 3 cm below the line joining the anterior superior iliac spines, and the subcutaneous tissue and the fascia incised in the midline only. On the "sharp" side the subcutaneous fat was dissected with a finger, and the fascial incision extended with the tip of a pair of scissors (Fig. 1a). On the "blunt" side, the fascia and subcutaneous tissue were dissected in one pull with the fingertips placed under the rectus muscle (Fig. 1b). The rest of the cesarean delivery procedure was performed using the same techniques bilaterally. A bladder flap was not made and the placenta was delivered spontaneously with gentle cord traction and uterine massage. The fascia was closed with a continuous polyglactin 910 suture (Vicryl Plus; Ethicon Inc., a company in Johnson & Johnson, Norderstedt Hamburg, Germany). If the subcutaneous fat layer was more than 2.5 cm thick, single polyglactin 910 sutures were placed. The skin was closed with subcuticular sutures (Vicryl Rapide 3-0; Ethicon Inc., Nordersted, Germany). All women received 1.5 g i.v. cefuroxime preoperatively.

Postoperative analgesics consisted of a diclofenac 100 mg suppository immediately after surgery and oral paracetamol 1 g and oral diclofenac 75 mg twice daily until the 5th postoperative day. Rescue analgesic was oral ketobemidone 10 mg combined with 50 mg dimethylaminodiphenylbuten. Patients were mobilized on the day of surgery. Trial assessment took place on the 1st, 3rd and 7th postoperative day and again 1 and 3 months postoperatively by telephone interview carried out by one of two investigators.

Participants, care-givers and outcome assessors were blinded to the allocation. The allocation list was stored in a locked room by a third party not clinically involved in the study. Data were recorded on clinical registration forms, and after completed follow-up entered into EpiData Entry version 3.1 (EpiData Association, Odense, Denmark). Data were cleaned and consecutively locked. A copy of the locked data was passed on in exchange for the allocation list before it was broken.

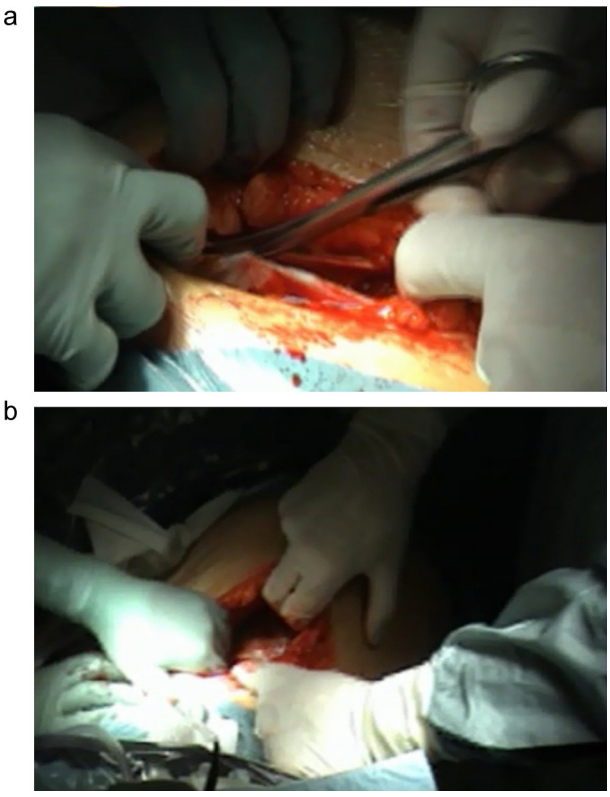

Fig. 1. (a) Sharp opening of the fascia and (b) blunt opening of the fascia.

2.3. Outcomes

The primary study outcome was the woman's overall preferred side 3 months postoperatively (right/left/no difference). Secondary outcomes were (a) side with more pain (right/left/no difference) and (b) difference in pain scores (absolute and relative) between the two sides 1, 3 and 7 days and 1 and 3 months postoperatively, and (c) the occurrence and side distribution of infection assessed after 1 and 3 months. Pain was measured on a numerical rating scale from 0.0 (no pain) to 10.0 (worst pain imaginable) on each side of the scar at rest and during mobilization and assessed by telephone interview. The absolute difference was calculated by subtraction of the scores. The relative difference in pain scores was calculated as: absolute difference/maximum pain score at the time × 100%. Infection was defined as the occurrence of any infection reported by the patient and the treatment was registered. During assessment of the primary outcome patients were asked to list the reason for their preference (pain/cosmetics/change in sensitivity).

2.4. Statistics

Calculation of sample size for the primary effect variable was based on the following reasoning: if the probability of having a preference is 0.062, then the probability of detecting at least one woman with a side preference out of 25 women is 0.80. Due to the