

Caesarean section wound infiltration with ropivacaine versus placebo: Survey of chronic pelvic pain after 4 years' follow-up

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Objective. To test the hypothesis that optimal management of postoperative pain may reduce the risk of developing chronic pelvic pain in women who undergo caesarean section.

Methods. In a randomised trial in 2006/2007, ropivacaine was infiltrated through all the layers of the anterior abdominal wound in patients undergoing caesarean section. The outcome was a reduction in severe pain or the need for rescue narcotic analgesia within 1 hour after the operation in the ropivacaine group compared with a placebo group (relative risk 0.51; 95% confidence interval 0.38 - 0.69). A follow-up study 4 years later was designed to assess the prevalence of chronic pelvic pain by carrying out telephonic interviews with these women, of whom 77 were contactable and 75 were analysed. Data and statistical analysis were done using Microsoft Excel (2007), Epi Info (version 343) statistical and Review Manager 5 software.

Results. Three out of 40 women in the ropivacaine group and 3/35 in the placebo group had persistent pelvic pain (total rate of chronic pelvic pain 8.1%).

Conclusion. There was no significant difference in the prevalence of chronic pelvic pain between the ropivacaine wound infiltration group (7.5%) and the placebo group (8.6%) after 4 years' follow-up.

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Ten to fifty per cent of patients who have surgical procedures may develop chronic pain, which can be severe in 2 - 10% of those afflicted.^[1] Chronic pain can be defined as prolonged pain persisting for longer than the expected period of healing following an injury.^[2] Caesarean section is a common major obstetric procedure, with the possible complication of chronic postoperative pelvic pain^[3] as a result of adhesion formation, adenomyosis, and injury to nerves and blood vessels.^[4]

Acute postoperative pain is a recognised risk factor for the development of chronic pain.^[5] Specifically, suboptimally managed acute pain during the immediate postoperative period is a risk factor in the development of chronic pelvic pain after caesarean section. One of the principles of the prevention of chronic pain is optimal management of acute pain.^[6]

The pathophysiology of chronic pain following suboptimally managed acute injury is persistent stimulation of C fibres in the peripheral nerves, which gradually build up electrical responses in the central nervous system – i.e. it is a non-nociceptive pain.^[7] In this study, we followed up a randomised controlled trial in which wound infiltration with a local anaesthetic had been used to manage acute postoperative pain, with the aim of determining the incidence of chronic pelvic pain. In the index study, 50/100 women undergoing elective caesarean section at term under general anaesthesia received infiltration of ropivacaine into all layers of the wound including the peritoneum, and 50 received a saline placebo. Further analgesia was administered as demanded. Twenty-four of the patients who received the local anaesthetic and 47 of those given the placebo experienced severe pain or required a rescue narcotic analgesic within 1 hour after the operation (relative risk 0.51;

95% confidence interval 0.38 - 0.69).^[8] The hypothesis tested in the follow-up study was whether the significant acute pain relief obtained with ropivacaine local analgesia translated into a reduction in the risk of chronic pelvic pain after 4 - 5 years of follow-up.

Methods

Women who took part in the index study in 2006/2007^[8] were followed up in 2011; 77/100 could be traced. They were contacted telephonically and interviewed in both the indigenous *isiSwati/isiZulu* and English languages. They were asked their age, parity and level of education, about their general satisfaction with the index surgery, if they had had any other operation after the caesarean section, and whether they had experienced any non-cyclical pelvic pain lasting for 3 or more months. If they had experienced such pain, they were asked to describe it and indicate its severity. Women who had had repeat caesarean sections were asked to relate their experience of the trial caesarean section. Data were analysed using Microsoft Excel (2007), Epi-Info (version 343) statistical and Review Manager 5 software. The Human Research Ethics Committee of the University of the Witwatersrand, Johannesburg, South Africa, granted institutional approval of the study in February 2011.

Results

Of the 100 women sought, 77 were traceable. All who were traced agreed to be interviewed. The mean follow-up time was 4.4 years (standard deviation ± 0.28 ; range 4 - 5). Two women (one in each group) had a previous history of persistent pelvic pain for which they had undergone laparoscopic surgical intervention before the index caesarean section, and were therefore excluded from analysis (Fig. 1).

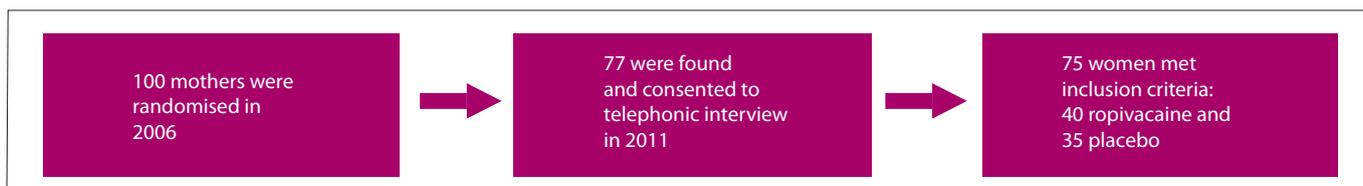


Fig. 1. Flow chart of women who participated in the index trial in 2006 and were available for the telephonic survey in 2011.

Table 1. Baseline characteristics of interviewed women who received ropivacaine v. placebo

	Ropivacaine (N=40)	Placebo (N=35)	p-value
Mean age (years)	32.9	35.4	0.41
Mean parity	2.12	2.41	0.45
Mean follow-up time (years)	4.42	4.38	0.51

Table 2. Outcome data on chronic pelvic pain and delivery preference in women who received ropivacaine v. placebo

	Ropivacaine (N=40) n (%)	Placebo (N=35) n (%)	Total (N=75) n (%)	Risk ratio (95% CI)
Chronic pelvic pain	3 (7.5)	3 (8.6)	6 (8.0)	0.92 (0.17 - 4.87)
Would have preferred vaginal delivery	4 (10.0)	4 (11.4)	8 (10.7)	0.92 (0.21 - 3.96)

CI = confidence interval.

Seventy-three (97.3%) of the remaining 75 women had grade 12 or higher education (all women who participated in the index trial had medical insurance cover). The baseline demographic characteristics in the ropivacaine and placebo (control) arms of the study were similar (Table 1). Three of the 40 women in the ropivacaine group and 5/35 in the control group had had a repeat caesarean section after the index caesarean section. Three women in the ropivacaine group (7.5%) and 3 in the control group (8.6%) had persistent pelvic pain (total rate of chronic pelvic pain 8.0%) (Table 2). Four of these 6 women reported that their pain was worse during winter or when it was cold, 3 described the pain as stabbing, and one each described the pain as pulling, crampy or burning. All took analgesics intermittently, but none had undergone laparoscopic surgery or hysterectomy for the pain. However, one woman said that she would not mind having surgical intervention to manage her pain.

None of the 6 women with chronic pelvic pain regretted that their babies had been delivered by caesarean section. Eight of the 75 (10.7%) would have preferred to deliver vaginally (Table 2) if they had not been advised to have a caesarean section to protect their baby as part of the mother-to-child transmission of HIV prevention programme. None of these 8 women had

chronic pelvic pain. One woman had had symptoms of postpartum depression, but had not sought medical intervention. All were satisfied with the levels of pain control and care that they had received after their caesarean section.

Discussion

A systematic review of 122 studies found an association between caesarean section and chronic, non-cyclical pelvic pain, but not dysmenorrhoea or dyspareunia.^[9] However, such associations could be due to confounding factors, and do not confirm causality. For example, women with pelvic conditions predisposing to chronic pelvic pain may be more likely to undergo caesarean section. Probably the only randomised trial with the potential to demonstrate an effect of caesarean section on chronic pelvic pain is the Term Breech Trial.^[10] In a 2-year follow-up, maternal outcomes were compared between women in the planned caesarean section group (of whom 89% had caesarean sections) and the planned vaginal birth group (of whom 44% had caesarean sections). There was no statistically significant difference between the groups with respect to dyspareunia (9/457 v. 6/460), pain deep in the abdomen (23/457 v. 27/460) or overall pain (38/457 v. 42/460).

The risk of developing chronic pelvic pain after caesarean section is variable. The rate

of 8.1% in this study is within the range of figures quoted in previous studies.^[2,5,9,10] The current study appears to be the longest follow-up assessing the risk of chronic pelvic pain in women who have undergone caesarean section, following a randomised trial. The prevalence of non-cyclical, persistent pelvic pain that lasted 3 months or more was the same in both arms of the study. A reason for failure to detect a difference in outcome may be that women in both arms of the earlier study received optimal pain control when they expressed the need for analgesics after the index caesarean section. The index trial was not designed to assess chronic pelvic pain, and this accounts for the inadequate sample size that may have prevented detection of a difference between the two populations. The results of the present study should therefore not be regarded as conclusive.

Conclusion

After a mean of 4.4 years, there was no significant difference in the prevalence of chronic pelvic pain between women who had received ropivacaine wound infiltration for pain control after caesarean section v. those who had received placebo.

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