



Acupuncture for pain management after cesarean section – a randomised placebo controlled investigation

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OBJECTIVE

Pharmacological approach for pain control in patients after caesarean section (CS) is often insufficient (1,2). Acupuncture is a promising tool to supplement conventional pain treatment after CS (3). **The aim** was to investigate the effectiveness of acupuncture as an additional method of analgesia in patients after CS in comparison with placebo intervention.

METHODS

DESIGN

- Randomised (randomisation concealed from personnel)
- Study groups: verum acupuncture (N=60) vs. placebo acupuncture (N=60)
- Blinded (patients, staff, assessors of the outcome)
- Mono-center (university hospital) from Sep 2015 to May 2017
- Approved by the Institutional Ethics Committee
- Registered at clinicaltrials.gov as NCT 02364167

PARTICIPANTS

Inclusion Criteria:

- scheduled to elective CS procedure in spinal anaesthesia (SpA)
- 19-45 years of age
- ASA physical status 1-3

Exclusion Criteria:

- SpA contraindicated
- chronic pain conditions (under opioid medication)
- history of psychiatric disorders
- CNS-targeted medication
- unable to understand the consent form and fill in the study questionnaire

INTERVENTION

- Body and ear acupuncture (Fig. 1)
- Placebo procedure (Fig. 2 C & D)

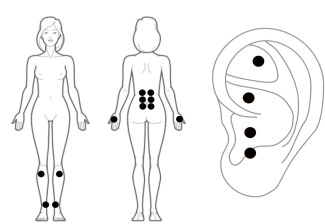


Fig. 1. Following acupoints were needed bilaterally: body acupuncture L14, ST36, SP6 and BL25-27; auricular acupuncture: MA-SC, MA-TF1, MA-IC1 & MA-AT1. Spine intradermal needles (6 x 0.14 mm) were used for body and New Pynox (1.5 x 0.2 mm) for auricular acupuncture.

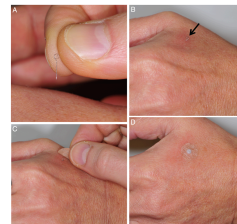


Fig. 2. Intradermal Spine needles and New Pynox Placebo used as adhesive tape. A: Spine needle over acupoint L14. B: the tip of the needle is visible after placement. C-D: Needle and tape (New Pynox Placebo).

METHODS

OUTCOME MEASURES

- Pain intensity on movement and at rest using Verbal Rating Scale (VRS-11; Fig. 3)
- Analgesics requirement after CS surgery
- Life quality items
- Patients' satisfaction with pain treatment
- Recovery profile (ambulation)
- Quality of blinding (patient and study personnel)

Fig. 3. Study questionnaire in German language, validated in previous investigation (4)

RESULTS

FLOW OF THE STUDY

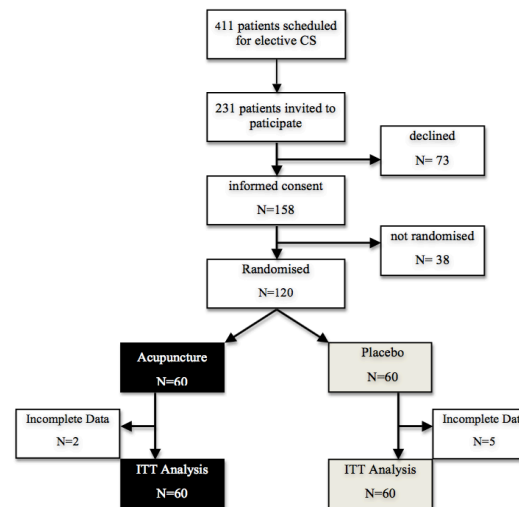


Fig. 4. Flow diagram of the study. ITT: Intention-To-Treat Analysis

RESULTS

- Baseline data (demographics and perioperative parameters) were comparable between both study groups
- Patients from acupuncture group reported less pain on movement on the 1st day following CS (4.7 ± 1.7 vs. 6.0 ± 2.0 ; mean \pm SD; $P=0.001$) in comparison with patients, who received placebo intervention (Fig. 5A), whereas the requirement for analgesic medication was comparable
- Patients, who received acupuncture, returned to their daily activity and ambulated earlier than the patients from placebo group ($P<0.01$; Fig. 5B)
- Quality of blinding was sufficient (the majority of patients believed, that they had received acupuncture)
- Other outcome parameters were comparable between study

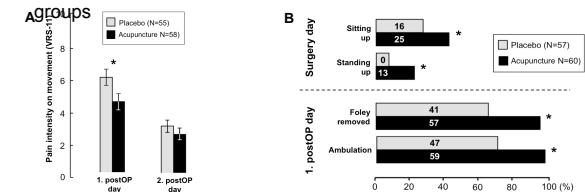


Fig. 5. A: Pain intensity on movement on the 1st day following caesarian section (CS), which was performed in spinal anaesthesia. Data are mean and 95% CI; * $P<0.001$ in Student's *t*-test; VRS=Verbal Rating Scale from 0 to 10. B: Recovery profile of patients after CS and time for removal of Foley catheter. Values are (%) and absolute number of patients, * $P<0.01$ in chi-square test

CONCLUSION

- Acupuncture improves clinically relevant pain and accelerates the ambulation of patients after caesarian section in comparison to placebo procedure with no side effects
- With additional consideration of personnel and time expenditures, acupuncture can be recommended for postoperative pain control in patients scheduled for caesarian section in spinal anaesthesia

REFERENCES

- (1) Gerbershagen et al. Pain intensity on the ridge day after surgery: a prospective cohort study comparing 179 surgical procedures. *Anesthesiology* 2013; 118: 934-44
- (2) Marcus et al. Quality of pain treatment after caesarean section: Results of a multicentre cohort study. *Eur J Pain* 2015; 19: 929-39
- (3) Hesse et al. Acupuncture for pain control after Caesarean section: a prospective observational pilot study. *Acupunct Med* 2016; 34: 14-9.