

Randomized sham-controlled trial of acupuncture for postoperative pain control after stapled haemorrhoidopexy

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Abstract

Aim Haemorrhoidectomy usually causes moderate to strong postoperative pain. Chinese studies have found that acupuncture may have an analgesic effect in post-haemorrhoidectomy patients. This is the first Western study aiming assess the efficacy of acupuncture as an adjunct analgesic therapy after stapled haemorrhoidopexy.

Method In a randomized controlled trial, 50 patients were allocated to three groups. Conventional drug therapy (oral diclofenac and metamizol, local lidocaine) served as baseline analgesia. In the control group ($n = 17$) only this regimen was used. In addition to baseline analgesia, 17 patients received verum acupuncture. Sham acupuncture was performed on 16 patients. Being the primary outcome measure, pain was measured twice daily using the numerical rating scale (NRS) and compared statistically by repeated-measures analysis of variance. The study was registered (DRKS00003116).

Results After verum acupuncture, pain intensity was not significantly lower when compared with conventional analgesia (primary hypothesis, $P = 0.057$), but was when compared to sham acupuncture ($P = 0.007$). In the afternoon of postoperative day 1, for example,

NRS was 2.7 (SD 1.5) in the verum group, but 4.0 (1.0) in the sham group and 4.1 (1.9) under conventional analgesia. Furthermore, significantly fewer rescue analgesics were necessary if verum acupuncture was applied. Cardiovascular parameters were stable in all three groups, and no complications were recorded.

Conclusions In posthaemorrhoidectomy patients, acupuncture appears to be an effective adjunct to conventional analgesia. Further studies are necessary to confirm these observations and to refine the acupuncture technique.

Keywords Haemorrhoidopexy, acupuncture, randomized controlled trial, postoperative pain

What is new in this paper?

In this first Western study on posthaemorrhoidopexy acupuncture, the acupuncture group experienced slightly less pain than both the sham acupuncture and conventional analgesia groups. Acupuncture as an adjunct to conventional analgesia should be explored in further clinical studies.

Introduction

Stapled haemorrhoidopexy was initially developed by Longo and has become an important option in the treatment of haemorrhoids [1,2]. One advantage of this technique is the reduced extent of postoperative pain [2–4]. Nevertheless, stapled haemorrhoidopexy still

causes moderate or even strong pain in most patients. Various attempts, such as less invasive stapling [5], local nerve blocks [6] or flavonoids [7], have been tried to alleviate posthaemorrhoidopexy pain, but most have remained essentially unsuccessful. According to evidence-based guidelines [3], conventional analgesics (nonsteroidal anti-inflammatory drugs, paracetamol and opiates) should be used in combination for pain therapy after haemorrhoidal surgery. The role of alternative interventions is much less clear.

Acupuncture has been a major part of healthcare in China for centuries and was also used even as a primary

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treatment for haemorrhoids. Based on these experiences, Chinese researchers have started to assess acupuncture as a method for pain relief after haemorrhoidal surgery. Recently, three clinical trials found acupuncture to have analgesic effects in posthaemorrhoidectomy patients [8–10]. Chinese researchers, however, often do not adhere to well-established methodological standards when performing or reporting randomized clinical trials [11,12]. In addition, it is difficult to judge the transferability of study results from China to Europe because patient expectations and therapist expertise are likely to be different in the Eastern and the Western hemispheres [13].

This trial was therefore initiated to evaluate the analgesic effects of acupuncture in Western patients who underwent stapled haemorrhoidectomy. In order to estimate the importance of a placebo effect, the study design was blinded and included a sham acupuncture group.

Method

Study design and patients

This randomized controlled patient-blind trial was initiated at a single-institution community teaching hospital. The university ethics committee approved the study protocol and consent form, and the study was registered with the German Clinical Trials Register (DRKS0000-3116) shortly after the start of recruitment. The aim of the study was to compare the analgesic effect of verum acupuncture, sham acupuncture and conventional analgesia in posthaemorrhoidectomy patients. The hypothesis of the study was that verum acupuncture reduces pain to a greater extent than both sham acupuncture and conventional analgesia.

All adult patients undergoing stapled haemorrhoidectomy were evaluated for participation. Inclusion criteria were a clinical diagnosis of third- or fourth-degree haemorrhoids and written informed consent. Exclusion criteria included any coexisting colorectal disorder, concomitant analgesic medication, impaired coagulation, coexisting infectious disease and pregnancy. After creating a computer-generated random list, group allocations were stored in sequentially numbered, opaque, sealed envelopes. On the morning of surgery, individual patients randomized themselves to one of the three groups by picking one of envelopes (but without opening it). Each patient was well aware of the fact that the design of the study was patient-blind and included a sham acupuncture group. Patients and hospital staff were advised not to ask for or give any information on individual group assignments. On request, but not before discharge from

hospital, acupuncture patients were told which type of acupuncture they had received.

Anaesthesia and surgery

Anaesthesia started with premedication (midazolam 7.5 mg orally) and followed a standard protocol. For induction of total intravenous anaesthesia, propofol (4 mg/kg bodyweight) and fentanyl (0.1–0.2 mg/kg bodyweight) were administered intravenously (IV). If necessary, anaesthesia was prolonged using additional doses of remifentanyl. If patients reported pain in the postoperative recovery unit, they received morphine (5–15 mg IV) and metamizol (1–2.5 g IV). The recovery unit staff was unaware of the patient's group allocation, so that patients received these drugs regardless of group assignment. After spending about 1 h in the recovery unit, patients were transferred to the normal ward.

Stapled haemorrhoidectomy was performed according to conventional surgical standards [1,14]. After insertion of an anal dilator, a pursestring suture was placed 2–3 cm cranially to the dentate line. Using a PPH33-03 (Ethicon®, Norderstedt, Germany) circular stapler, a circumferential strip of mucosa was then resected. Since nearly all study patients were last on the day's surgery list, surgery ended between noon and 1 p.m. in most cases.

Conventional analgesia

After surgery, all patients received the same analgesic drug regimen, which consisted of diclofenac at 50 mg orally three times a day and metamizol 500 mg orally four times a day. Furthermore, 5% lidocaine ointment was applied locally. This medication was discontinued if the patient was discharged from hospital or was pain-free.

In addition to this regular baseline analgesia, the following rescue analgesics could be applied, if a patient reported strong pain and requested additional therapy: oxycodone (10–20 mg orally, depending on body weight) or piritramide (15 mg IV as a slow infusion over 30 min).

Verum acupuncture

Patients in this group received acupuncture in addition to conventional analgesia. Acupuncture was first performed on the day of surgery at 4 p.m. and then repeated every morning and afternoon on postoperative days 1 and 2. The following six acupuncture points were treated: Du2 (yao shu, median line, location of hiatus sacralis), Du20 (bai hui, in the middle of the both apices auricularae), Bi30 (bai han shu, region foramen sacrale, right-sided paravertebral point at L2 level), Bi57 (cheng shan, hollow

between the both gastrocnemial muscles), Ma44 (neiting, interdigital between the second and third toe of the left foot) and Pe6 (neiguan, between tendons of flexor carpi radialis and palmaris longus on the distal forearm). In order to locate acupuncture points exactly, electrical skin resistance was first measured by means of a SVESA 1070 pen (SVESA Electronic Devices Inc., Munich, Germany). Points of lower skin resistance were marked and disinfected before acupuncture.

Sterile disposable stainless-steel needles of 30 mm length and 0.3 mm diameter (size no. 5; Seirin Co. Ltd, Shizuoka City, Japan) were used for acupuncture. Needles were passed quickly through the epidermis and inserted perpendicular to the skin down to a depth of about 15 mm. An acupuncture sensation (also known as de qi) was aimed for. Needles were removed after about 20–30 min.

Sham acupuncture

In the sham acupuncture group, localization of acupuncture points was simulated using the same technique as in the verum group. However, needles were placed well away from meridians. The frequency of acupuncture sessions ($n = 5$), the number of needles ($n = 6$) and the body regions of needle placement were the same as in the verum acupuncture group. When interacting with the patient, the therapist pretended to perform verum acupuncture thus maintaining blinding of the patient. All acupuncture was performed by a specifically trained investigator under supervision of a physician possessing a board certificate in acupuncture therapy.

Outcome criteria

Pain intensity on postoperative days 0–2 was chosen as the primary outcome measure. As pain was measured twice a day (at 8 a.m. and 4 p.m.) using the numerical rating scale (NRS), five NRS values therefore served as a database for the primary hypothesis tests. In the two acupuncture groups, pain was measured immediately before acupuncture therapy. For secondary analyses, pain was also measured shortly after each acupuncture therapy.

The necessity for rescue analgesics was recorded during the study phase. For statistical analysis, the total number of days on rescue analgesics (oral or IV opioids) was calculated. Cardiovascular parameters (heart rate and blood pressure) were measured twice a day. All complications that occurred during the hospital stay were recorded.

Patients were discharged when they had no bleeding and pain intensity was < 3 on the NRS. Because patients in Germany have to stay in hospital for at least 2 days

after Longo's procedure, the length of hospital stay was expected to be the same in the three groups. Therefore, data on hospital stay were not collected.

Statistical analysis

Initially, a sample size calculation had indicated that 90 patients were necessary to detect a NRS difference of one (standard deviation 1.25) with 80% power. The difference of one was considered to be the smallest clinically relevant effect size, and the standard deviation was based on previous studies and our own clinical experience. However, as one of the investigators left the hospital during the course of the study, the study had to be terminated after the recruitment of 50 patients.

Two primary superiority hypotheses were tested in prespecified order. First, pain intensity was compared between the verum acupuncture group and the conventional analgesia group. Secondly, the difference between the verum and sham acupuncture groups was tested. Repeated-measures analysis of variance (ANOVA) was used for testing these hypotheses. Baseline comparisons and analyses of secondary outcomes were done by applying the χ^2 and conventional ANOVA with Scheffé's *post hoc* test. The paired Student's *t*-test was employed to analyse intraindividual changes in pain severity (i.e. pre- vs postacupuncture NRS). *P*-values equal to or smaller than 0.05 were considered significant. Figures show mean values with error bars indicating 1 standard deviation (SD).

Results

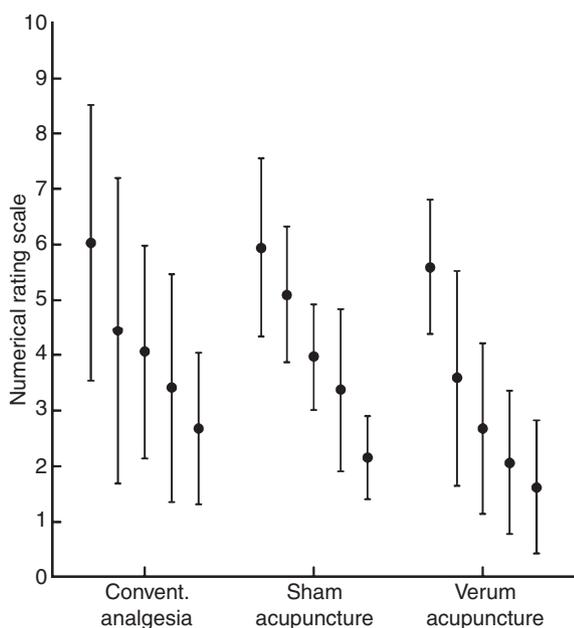
All operations were completed without complications, and all 50 patients completed the study according to protocol. The three groups were similar in size, and demographic characteristics showed no differences between the groups (Table 1), except for the fact that patients in the sham acupuncture group were slightly younger. Albeit being significant, this difference was judged to be the result of a play of chance. About half of the patients experienced perianal mild to moderate pain already preoperatively.

Postoperative pain tended to be less in the verum acupuncture group (Fig. 1), but the difference between the verum acupuncture and the conventional analgesia group was not significant ($P = 0.057$). The comparison of NRS scores between verum and sham acupuncture group revealed significance ($P = 0.007$), but this test must be considered exploratory due to the nonsignificance of the primary hypothesis. Comparing pain levels between sham acupuncture and conventional analgesia failed to detect a difference ($P = 0.972$). For example,

Table 1 Demographic baseline characteristics.

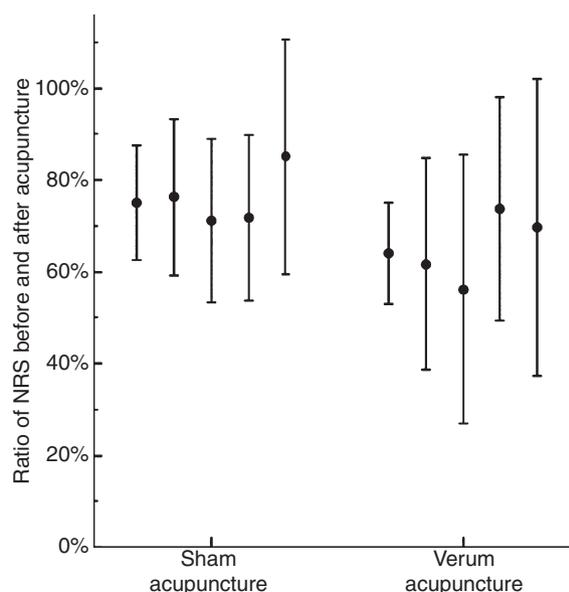
	Conventional analgesia	Sham acupuncture	Verum acupuncture	P-value
No. of patients	17	16	17	–
Men/women	14/3	9/7	8/9	0.09
Age (years)	57 ± 16	48 ± 17	62 ± 15	0.04
Body mass index (kg/m ²)	27.7 ± 4.0	27.3 ± 6.6	27.5 ± 4.6	0.97
Degree of haemorrhoids	2–3:2 3:7 3–4:6 4:2	2–3:0 3:8 3–4:8 4:0	2–3:2 3:9 3–4:4 4:2	0.47
Patients with pain before surgery	8 (47%)	6 (38%)	10 (59%)	0.47
NRS before surgery	1.3 ± 1.6	1.1 ± 1.8	1.3 ± 1.3	0.91

NRS, numerical rating scale.

**Figure 1** Postoperative pain between day 0 (p.m.) and day 2 (p.m.).

in the afternoon of postoperative day 1 (just before acupuncture patients received their third acupuncture treatment), NRS was 2.7 (SD 1.5) in the verum group, but 4.0 (1.0) in the sham group and 4.1 (1.9) under conventional analgesia.

When analysing the immediate pain-relieving effect of acupuncture (Fig. 2), both verum and sham acupuncture were able to reduce pain significantly. During each acupuncture session, pain intensity fell by about 20–40%, and this effect appeared to be stable over time. Patients who received verum acupuncture in addition to conventional drug analgesia required fewer rescue analgesics (Table 2). The verum acupuncture group had more time on rescue analgesics compared to conventional

**Figure 2** Relative changes in pain levels [postacupuncture numerical rating scale (NRS) divided by pre-acupuncture NRS] between day 0 (p.m.) and day 2 (p.m.).

analgesia alone ($P = 0.001$ in ANOVA and *post-hoc* test) and sham acupuncture ($P = 0.063$ in a *post-hoc* test).

Heart rate and systolic and diastolic blood pressure were normal in all patients over the complete study period, and there were no significant differences between the groups. Analgesia-related, surgery-related or general complications were not encountered. Specifically, no nausea, vomiting or acupuncture site reactions were observed.

Discussion

Although the difference between verum acupuncture and conventional analgesia was not statistically significant,

Table 2 Need for rescue analgesics.

	Conventional analgesia	Sham acupuncture	Verum acupuncture	P-value
Day 0 afternoon	13 (77%)	7 (44%)	6 (35%)	0.04
Day 1 morning	14 (82%)	10 (63%)	3 (18%)	0.001
Day 1 afternoon	9 (53%)	6 (38%)	1 (6%)	0.01
Day 2 morning	4 (24%)	3 (19%)	0	0.11
Day 2 afternoon	3 (18%)	2 (13%)	0	0.21
Time on additional analgesic drugs*	1.3 ± 0.7	0.9 ± 0.8	0.3 ± 0.5	0.001

*Time in days between day 0 afternoon and day 2 afternoon (possible range 0–2.5).

this study has partly confirmed the analgesic efficacy of acupuncture as an adjunct treatment in post-haemorrhoidopexy pain control. Acupuncture may help to achieve two important aims: First, to reduce the dosage of conventional drugs (and their side-effects), and secondly, to keep pain severity in a tolerable range. The difference from sham acupuncture was large and significant on exploratory analysis. This result lends not much support to the often debated argument that the effect of acupuncture can partly be attributed to a placebo effect [13].

A very important advantage of the present study therefore is its patient-blind design. Due to logistic reasons, however, it was not possible for a blinded evaluator to collect NRS data from patients. It can still be expected that interviewer bias had no or only minimal influence on pain measurements, because all pain data were collected by the same person asking the same question every morning and afternoon. In addition, the comparison of pain levels immediately before and after acupuncture showed that both verum and placebo acupuncture were perceived as pain-relieving. As the magnitude of this effect did not diminish with time, it can be assumed that patients truly believed they underwent verum acupuncture even if they received placebo acupuncture.

A comparison of the present study with previous Chinese studies shows that the selection of acupuncture points for perianal analgesia is not as straightforward as for other conditions. For example, the acupuncture point Du 2 (yao shu) was used by Xu *et al.* [9], whereas Zhao *et al.*, Li *et al.*, and Sun *et al.* placed needles in the point BL 57 (cheng shan) with good results [8,10,15]. Other groups have suggested that the point BL 54 (zhi bian) may also be connected to perianal pain perception [16]. Based on this literature, the present study included needling of the two apparently most relevant points Du 2 and BL 57. However, acupuncture was performed on six different points, which is a relatively high number compared with the Chinese studies, where only one or two points were stimulated. This decision was partly

motivated by the fact that the Chinese studies used electroacupuncture, while the present study employed only conventional acupuncture. Future studies should therefore reexamine the different acupuncture points and the best way to stimulate them.

Selection of the anaesthetic technique also may influence postoperative pain. Therefore, it may appear questionable whether the present results (obtained after general anaesthesia) can be transferred to other settings, where regional anaesthesia is conventionally applied for haemorrhoidal surgery. One study, however, found no differences in postoperative pain levels between different forms of anaesthesia [17]. Fewer data are available for local anaesthesia, since this procedure has not yet become standard [18]. Overall, there is no evidence suggesting that the results of the present study could not also be extrapolated to other forms of anaesthesia. Whether acupuncture possesses similar effectiveness in haemorrhoidectomy as well remains to be examined in the future.

In clinical practice, the successful introduction of acupuncture will depend on more practical criteria. First, an in-hospital acupuncture service would make no sense if the majority of haemorrhoid patients are being treated on a day-case basis. Secondly, in an ambulatory setting, but also inside the hospital, the application of rescue analgesics in patients with severe pain may be considered easier than the prevention of severe pain by means of acupuncture. This study, however, shows that prevention rather than treatment of pain leads to lower pain levels, most probably because patients tend to report their pain only with some delay. Additional delay to pain relief is often caused by the unavailability of ward staff and the time between drug administration and action. Therefore, anticipating severe postoperative pain and treating it before it occurs is generally preferable to treating it with delay, also because this increases patient satisfaction and reduces the need for unplanned treatment decisions. In addition, every reduction in opioid requirements lowers the incidence of opioid-related side-effects [19]. Future studies should assess the severity of postoperative nausea

and vomiting in more detail, also paying attention to the fact that acupuncture also may have a direct protective effect on these symptoms.

In summary, acupuncture after haemorrhoidectomy appears to have a pain-relieving effect. As confirmatory testing for a between-group difference narrowly missed statistical significance, further studies are necessary to confirm the present results.

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References

- 1 Corman ML, Gravie JF, Hager T *et al.* Stapled haemorrhoidectomy: a consensus position paper by an international working party – indications, contra-indications and technique. *Colorectal Dis* 2003; **5**: 304–10.
- 2 Jayaraman S, Colquhoun PH, Malthaner RA. Stapled versus conventional surgery for hemorrhoids. *Cochrane Database Syst Rev* 2006; CD005393.
- 3 Joshi GP, Neugebauer EAM, for the PROSPECT Collaboration. Evidence-based management of pain after haemorrhoidectomy surgery. *Br J Surg* 2010; **97**: 1155–68.
- 4 Laughlan K, Jayne DG, Jackson D, Rupprecht F, Ribaric G. Stapled haemorrhoidectomy compared to Milligan-Morgan and Ferguson haemorrhoidectomy: a systematic review. *Int J Colorectal Dis* 2009; **24**: 335–44.
- 5 Arroyo A, Perez-Vicente F, Miranda E *et al.* Prospective randomized clinical trial comparing two different circular staplers for mucosectomy in the treatment of hemorrhoids. *World J Surg* 2006; **30**: 1305–10.
- 6 Gerjy R, Derwinger K, Nystrom PO. Perianal local block for stapled anopexy. *Dis Colon Rectum* 2006; **49**: 1914–21.
- 7 Mlakar B, Kosorok P. Flavonoids to reduce bleeding and pain after stapled hemorrhoidectomy: a randomized controlled trial. *Wien Klin Wochenschr* 2005; **117**: 558–60.
- 8 Sun PL, Yang W, Zhang LC. Effect of electroacupuncture at Chengshan (BL 57) on postoperative pain of mixed hemorrhoids. *Zhongguo Zhen Jiu* 2011; **31**: 413–5.
- 9 Xu TS, Qian HH. Clinical observation on the effect of acupuncture-assisted anesthesia for 40 cases of mixed hemorrhoids surgery. *Zhen Ci Yan Jiu* 2009; **34**: 403–5.
- 10 Li N, He HB, Wang CW, Yang CM. Observation on therapeutic effect of electroacupuncture at Chengshan (BL 57) and Changqiang (GV 1) on hemorrhoidal pain. *Zhongguo Zhen Jiu* 2008; **28**: 792–4.
- 11 Wu T, Li Y, Bian Z, Liu G, Moher D. Randomized trials published in some Chinese journals: how many are randomized? *Trials* 2009; **10**: 46.
- 12 Zhao L, Liang FR, Li Y, Zhang FW, Zheng H, Wu X. Improved quality monitoring of multi-center acupuncture clinical trials in China. *Trials* 2009; **10**: 123.
- 13 Ernst E. Acupuncture: what does the most reliable evidence tell us? *J Pain Symptom Manage* 2009; **37**: 709–14.
- 14 Schmidt J, Dogan N, Langenbach R, Zirngibl H. Fecal urge incontinence after stapled anopexia for prolapse and hemorrhoids: a prospective, observational study. *World J Surg* 2009; **33**: 355–64.
- 15 Zhao K, Zhao F. Clinical application of chengshan (UB 57) acupoint. *J Tradit Chin Med* 1991; **11**: 11–3.
- 16 Zhang Y. The needling technique and clinical application of point Zhibian. *J Tradit Chin Med* 2004; **24**: 182–4.
- 17 Ong CH, Chee Boon Foo E, Keng V. Ambulatory circular stapled haemorrhoidectomy under local anaesthesia versus circular stapled haemorrhoidectomy under regional anaesthesia. *ANZ J Surg* 2005; **75**: 184–6.
- 18 Mariani P, Arrigoni G, Quartierini G *et al.* Local anesthesia for stapled prolapsectomy in day surgery: results of a prospective trial. *Dis Colon Rectum* 2005; **48**: 1447–50.
- 19 Sun Y, Gan TJ, Dubose JW, Habib AS. Acupuncture and related techniques for postoperative pain: a systematic review of randomized controlled trials. *Br J Anaesth* 2008; **101**: 151–60.