Effects of electroacupuncture on local anaesthesia for inguinal hernia repair: a randomised placebo-controlled trial

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ABSTRACT
Objective To assess the effect of electroacupuncture (EA), akin to percutaneous electromeurostimulation, on pain and biochemical measures during and after inguinal hernia repair.
Methods Thirty-three patients were randomised to EA (n=16) or sham transcutaneous electrical nerve stimulation (TENS) control (n=17). EA was applied at different frequencies, through needles inserted around the incision, over selected peripheral nerve branches and in the ear, from 30 min before surgery until the end of surgery, when needles were removed. All patients also received routine sedation and local anaesthesia.
Results There was no difference between the pain scores in the groups receiving EA and sham TENS in the immediate postoperative period, which may be owing to adequate levels of analgesia from conventional techniques. On the fourth and seventh postoperative days, less pain and lower consumption of analgesic drugs were reported in the treatment group. Seroma occurred more frequently in the control group, which also had higher glucose blood levels in the immediate postoperative surgery period. The single case of chronic postoperative pain occurred in the control group.
Conclusions The sample size was too small to draw any conclusions about the effect of EA on pain and other parameters following inguinal hernia surgery, but our observations suggest that future studies in this area are justified.

INTRODUCTION
The use of electrical stimulation for therapeutic purposes has been reported for more than 6000 years,1 and has advanced considerably since the 1960s. Currently, electroacupuncture (EA), percutaneous electromeurostimulation (PENS) and transcutaneous electrical nerve stimulation (TENS), are the most commonly used techniques. EA and PENS both involve inserting needles and in EA the needles may be inserted into either classical acupuncture points or points chosen for their innervation. These methods are widely employed for different clinical conditions, including the control of pain, such as that related to surgical procedures.2–7

Although Chinese authors report success for the use of acupuncture in surgical analgesia at rates as good as 80%, its efficacy for this purpose remains uncertain. Murphy and Bonica8 observed a satisfactory response only in 30% of cases, while in Mann’s observational study9 success did not exceed 10%. Currently, it is clear that acupuncture alone is not sufficiently reliable to replace modern anaesthetic techniques, but that when combined with general or local anaesthesia it can contribute to the control of pain and of other unwanted effects during the postoperative period, reducing the need for pharmacological analgesic agents and avoiding their side effects, such as gastritis, changes in blood pressure and nausea and vomiting.7 10–13 These benefits, however, have been overestimated in non-randomised clinical trials.14

The main purpose of this randomised double-blind placebo-controlled clinical trial was to evaluate whether the use of EA before and during surgery for inguinal hernia would produce preoperative and postoperative (immediate and delayed) pain reduction, and to explore whether pain reduction correlated with other clinical aspects and laboratory measures.

PATIENTS AND METHODS
The protocol of this trial was approved by the Committee for Ethics in Scientific Research of the Medical School of the Fluminense Federal University (UFF)/Antônio Pedro University Hospital, under the number 008/07 and catalogued at the Brazilian Ministry of Health under the number FR 122617.

Patients
Patients were recruited from the waiting list for surgery of inguinal hernia at the Orêncio de Freitas Hospital (HOF) of the National Public Health System, in Rio de Janeiro, Brazil. Patients of either gender, between 18 and 75 years old, and considered fit to undergo such surgery after preoperative tests were eligible for inclusion. Patients were excluded who had chronic severe anxiety disorder, uncontrolled hypertension, severe obesity and those with irreducible, recurrent or complex (bilateral, affecting the abdominal wall) hernia, with liver or kidney chronic failure, with history of significant bleeding or taking anticoagulant agents, or with chronic use of analgesics or addictive drugs (cocaine, crack), as well as those who were pregnant, fitted with a pacemaker and unable to read.

After being informed about the trial and the techniques to be used, two patients were excluded because they were unable to read, one dropped out for fear of the procedures. Forty patients gave fully
informed consent and were allocated to treatment or control group on arrival at the surgery centre, according to a computerised sequential randomisation in blocks of 10 designed to provide an approximately matched number of participants in each group at any point in the study. Seven patients were excluded from the trial just before its start, because they had blood pressure readings above 150×100 mm Hg, a contraindication for surgery with local anaesthesia. These patients were transferred to another surgical team and were operated on under general anaesthesia.

The sample size calculation was based upon the expected acute pain relief of 3% from the placebo effect in the control group, and of 60% at the PENS group, using values from a review by Pomeranz. Using power of 95% and a significance level of 5%, we calculated that a minimum sample size of 17 subjects in each group was required.

**EA and sham TENS**

An electric pulse generator programmed to deliver alternate, rectangular/exponential asymmetric current with a duration of 0.6 ms (Sikuro Company, Rio de Janeiro, Brazil) was used. Two acupuncture needles (manufactured, autoclaved) of 150 mm by 0.50 mm, were inserted subcutaneously, one 4 cm above and parallel to the surgical incision and the other 2 cm below the inguinal ligament on the thigh, directed medially, for local and segmental neuromodulatory effects (figure 1). These needles, after being connected to the pulse generator device, were covered with adhesive dressing.

Other acupuncture needles (40 mm by 0.25 mm/Dong Bang-Korea) were inserted using a guide tube in sites at the limbs close to nerve branches in order to elicit supraspinal effects of the neurostimulation, and in one ear, at the Heart point in the fossa triangularis (Cranial nerve X)—and at the Shenmen point in the fossa triangularis (Cranial nerve V). The needles in the limbs were manipulated to obtain either a muscle response (twitch or fasciculation) and/or paraesthesia—dull or numbing sensation, and then connected to the electrostimulator in pairs: SP6 connected to S36 and P6 to LI4, bilaterally. The auricular needles were also connected to the device.

A pattern for the stimulation frequencies of EA was adopted, which increased progressively over time. The starting frequency was 3 Hz in continuous mode for 5 min, which was then increased in steps of 5, 10, 20, 50, 100, 160 Hz and finally up to 240 Hz after 30 min, at an amplitude that was comfortable for the patient. After this time, sedation and local anaesthesia were given in preparation for surgery. The electrical stimulation lasted throughout surgery at 240 Hz, and the amplitude was increased when the stimulus could not be felt owing to accommodation. The sensation produced by the stimulation at the peri-incisional sites was reported even under local anaesthetic, when the amplitude was raised to the maximum of the stimulator, but was completely abolished during surgery.

The control group received sham TENS at the same sites (except the ear points) for the same period of time, through disposable paediatric electrocardiogram electrodes (Hal Ind. & Com. Ltd, São Paulo, Brazil) connected to the stimulator adapted by the manufacturer to emit a sound signal without delivering current.

The patients were informed that the study intended to assess the efficiency of two different electroneurostimulation techniques, one of them perceptible and the other, subliminal.

**Anaesthetic procedures**

Preoperative sedation was induced with pethidine 50 mg and diazepam 10 mg, each diluted by 10 ml of distilled water, applied in steps of 2 ml intravenously during surgery. The local anaesthesia was applied using a standard 20 ml solution with lidocaine 2% and marcareine 0.5% diluted in 40 ml of distilled water, infiltrated in skin, subcutaneous and muscle planes, according to the Lichtenstein step-by-step technique.

The amount of sedatives and local anaesthetic was determined by the patient’s need as indicated by the surgeon, respecting patient comfort and the monitored pain markers (blood pressure, heart rate). If requested, the anaesthetist could adopt other procedures during the surgery.

**Outcome measures**

The main author of this trial was responsible for recording the outcome data in a special file only during the surgery, and the resident doctors, blind to group allocation, completed data sheets at the immediate postoperative period and 2 weeks later, at the outpatient clinic. Nurses dealing with the patients were also blinded to the patients’ group allocation.

The control and treatment groups were compared according to the following parameters:

(A) Amount of sedative drugs, local anaesthetics and of other anaesthetic procedures (if necessary) used during the perioperative period.

(B) Postoperative pain, measured by visual analogue scale in which 0 corresponds to absence of pain, and 10 to the worst imaginable pain, immediately after the surgery and every 4 h if the patient was awake, or if the patient requested analgesics. This was the main outcome measure which determined the sample size.

(C) Heart rate and blood pressure at admission, during and immediately after surgery and before discharge from the hospital.

(D) Blood glucose levels and white cell count at the same time points and during surgery. The operations were performed between 15:00 and 18:00, and the last sample of blood was taken the next morning between 10:00 and 12:00, 15–20 h after surgery.

(E) Highest pain of the day recorded by the patient every day until the 14th day after surgery, as well as number and dose of any prescribed drugs taken.

**Figure 1** Peri-incisional needles. → indicates a pen mark for future incision.
Results

The treatment groups were comparable for demographic aspects, such as gender (there were only men in both groups), age, grade of formal education and ethnic origins. Except for the pain related to the inguinal hernia, which was slightly greater in the control group, the groups were identical for other clinical aspects (table 1). The duration of electrical stimulation and of the operation, as well as the amount of sedative and local anaesthetics used in the surgery were similar in both groups (table 2). No patient had any need for supplementary anaesthetic procedure.

There was no statistically significant difference between the groups in the measures of heart rate and other haemodynamic variables before, during the surgery and after patient discharge. Heart rate varied from an initial 71±10 bpm to 75±10; 69±6 and 69±7, respectively, in the control group and from 72±12 to 72±11, 69±10 and 71±9, respectively, in the treatment group. The systolic blood pressure increased slightly during the operation, from 131±16 to 141±17 in the control group and from 135±15 to 141±11 in the treatment group, while the diastolic blood pressure showed a tendency to fall during the procedure, with maximum values during the surgical time of 91±7 and 92±7, respectively.

For the main outcome, no statistically significant difference between the groups was found for the visual analogue scale measures of pain, in four periods during the first 12 postoperative hours (table 3). There was also no difference in the use of analgesics—in the treatment group, eight patients took dipyrone 500 mg, and two took 1000 mg; in the control group, nine took 500 mg, and two took 1000 mg; in the control group but in none of the treatment group (p<0.05; no signifi cant difference). Seroma occurred in six patients in the postoperative review (7th and 14th days) and did not show a statistically signifi cant difference. Seroma occurred in six patients in the control group but in none of the treatment group (p<0.05; no signifi cant difference).

In the control group, one patient reported continuous burning pain at the site of incision, and at 1 month after the surgery, sharp testicular pain elicited by minor physical exertion, although no pain was reported during his operation, in the immediate postoperative period or at the 2-week follow-up. After 5 months with pain this patient was referred to the Acupuncture Outpatient Department.
Service where he was treated once with paraspinal injections of lidocaine 1% for desensitisation, as described by Fischer, and four times with PENS at 10 Hz for 20 min, in the same sites of the injections and in trigger points at the pelvic girdle, resulting in complete remission of his pain.

No episodes of nausea or vomiting or adverse effects of EA were seen.

Laboratory tests showed that changes in white cell concentrations were similar in the two groups (p>0.05), showing leucocytosis, neutrophilia (segmented) and relative lymphopenia as shown in table 4. However, blood glucose was significantly higher in the immediate postoperative period in the control group (table 4). Data in table 5 show the efficacy of patient blinding, with both groups equally confident about the treatment.

**DISCUSSION**

In this study a combined EA and local anaesthesia technique was used to evaluate the EA efficacy for pain relief and control of other clinical manifestations related to inguinal hernia surgery. No significant effects were found in this small study in the current setting and design.

There is a wide diversity of electrical stimulation techniques for surgical analgesia and the control of postoperative pain. Standard parameters have been established for the use of EA for this purpose and were used by us: peri-incisional subcutaneous needles, puncture at sites close to nerve branches and in the ear, starting electrical stimulation before incision (pre-emptive analgesia) and finishing at the end of the surgery. To obtain the benefits of each range of frequency, a variable frequency was adopted in this trial.

In a PubMed search (December 2008), no randomised studies using PENS or EA for the control of postherniorrhaphy pain were found, though some using TENS were available. Among them, two reported negative results, while the study of DeSantana was positive. In a study with 40 participants

**Table 4**  Global and differential white cell count and blood glucose before surgery, immediately postoperative and at discharge

<table>
<thead>
<tr>
<th></th>
<th>Control group (n=17)</th>
<th>Treatment group (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>Postoperative</td>
</tr>
<tr>
<td>Total leucocytes</td>
<td>7696±2052</td>
<td>8673±2352</td>
</tr>
<tr>
<td>% Of segmented</td>
<td>54±9.7</td>
<td>62.7±9.5</td>
</tr>
<tr>
<td>neutrophils</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Of lymphocytes</td>
<td>31.5±7.1</td>
<td>24±8.7</td>
</tr>
<tr>
<td>% Of eosinophils</td>
<td>5.1±3.9</td>
<td>3.6±3</td>
</tr>
<tr>
<td>Glucose (mg%)</td>
<td>90±16</td>
<td>112±3.49*</td>
</tr>
</tbody>
</table>

p Value=0.0152. All other comparisons showed no significant differences.

*Wilcoxon rank-sum test.

**Table 5**  Validation of blinded method-credibility scale

<table>
<thead>
<tr>
<th>Questions</th>
<th>Control group (n=17)</th>
<th>Treatment group (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Moment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(A) Do you believe in this treatment for your postoperative pain relief?</td>
<td>16 1 – – –</td>
<td>14 1 – – 1</td>
</tr>
<tr>
<td>(B) In your opinion does this procedure have the potential to be effective?</td>
<td>13 3 – – 1</td>
<td>16 – – –</td>
</tr>
<tr>
<td>2nd Moment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(C) Would you have confidence to recommend this treatment to a friend who would be submitted to the same surgery?</td>
<td>17 – – –</td>
<td>15 – 1 –</td>
</tr>
<tr>
<td>(D) How much do you think that this treatment was responsible for your postoperative pain relief?</td>
<td>17 – – –</td>
<td>15 – 1 –</td>
</tr>
</tbody>
</table>
randomised to two groups, the author used TENS at 100 Hz to
four electrodes placed above the incision line and in the thigh,
at 2 and 4 h after the surgery. Pain was assessed at 2, 4, 8 and 24 h,
and remained unchanged in the control group, which
needed greater doses of analgesic (EV dipyrone), while the
treatment group reported a significant reduction of pain over
24 h. The operating technique was the same as in our study,
but the anaesthesia was epidural with lidocaine 2%, and TENS
was used after the operation and only around the incision.

Compared with that trial, the parameters of electrical stimula-
tion we used covered a wider range of the different modalities of
neurobiological effects of the technique: stimulating nerve
branches at the extremities adds systemic analgesic effects to the
segmental effects; low frequencies were used to modulate sec-
ondary hyperalgesia by means of segmental and supraspinal
mechanisms; higher frequencies reduce primary and secondary
hyperalgesia by the same mechanisms; whereas frequencies
higher than 100 Hz locally raise the excitability threshold of
nociceptors.7 11 13 28–32

Considering that EA, PENS and TENS effects derive from
common biological mechanisms7 13 14 24 29 33 and that the anti-
ociceptive treatment that is started before the surgical incision
tends to be more efficient than that performed after the anaes-
thetic recovery,34 the failure to demonstrate analgesic effects in
the immediate postoperative period (first 12 h) is not attrib-
utable to the different techniques used in this trial, compared
with that of DeSantana.27 We believe that the anaesthetic pro-
cedures in our study were sufficient to control the immediate
postoperative pain and thus did not allow any analgesic prop-
erties of EA to be appreciated in this period. For this reason, our
study data cannot be used for future sample size calculations.

Unpublished data, based on personal observations during a
practical course promoted by the Rio de Janeiro Medical
Acupuncture Society, when EA was used in four operations
(breast surgery, haemorrhoids and anal fistula correction, thy-
roidectomy and inguinal hernia), led us to expect some analgesic
effect during surgery that could be evaluated by a reduced con-
sumption of sedatives and local anaesthetics. This was not
confirmed.

On the other hand, the control group had a greater intensity
of pain before surgery (table 1). Although of low intensity and only
delicited by physical exercise, it is reasonable to presume that a
greater sensitisation of this group has occurred. It is known that
the antinociceptive effects obtained with low-frequency peri-
pheral neurostimulation can last for 72 h or a little more,24 and
therefore, analgesia observed after the 4th day is not likely to be
attributable to the EA treatment.

The incidence of chronic postoperative pain following ingui-
nal hernia surgery is estimated to be about 12%,35 36 varying
between 0% and 37% in different studies.37 Our rate was 6%,
and occurred only in the control group, though the small sample
does not allow any conclusion.

The dimensions of the oedema did not differ between groups,
but the development of seroma only in the control but not in the
treatment group was significant (p=0.018), and may be attrib-
utable to the local and segmental (autonomic) effects of
EA.14 30 39

Surgical stress is a physiological reaction that produces endo-
crine, immune and haematological changes, which may contrib-
ute to negative outcomes and subsequent morbidity. Prominent
among these changes are a rise in pancreatic secretion of gluca-
gon and of liver glycosylgenolysis and gluconeogenesis, reduction
of insulin release and rise in blood glucose.39 During surgical
stress, leucocytosis also occurs with increased neutrophils, and
reduced lymphocytes and eosinophils.40 41 These cellular changes
were seen in both groups in this study. As the blood glucose level
in the immediate postoperative period was normal in the treat-
ment group, but raised in the control group, this may be an indi-
cation that EA relieved surgical stress to some extent, through
supraspinal effects.28–32

Many authors have discussed the problem of blinding clini-
cal trials of physical treatments.17 44–46 We used sham TENS as
placebo, so that the patients receive the same clinical care as
those in the treatment group, allowing control of non-specific
effects of the doctor–patient relationship. The use of credibil-
ity scales to validate the blinding in trials of physical treat-
ments has been recommended,44–46 and in our trial showed
identical results for both groups. The placebo effect50–52 could
contribute to analgesia in the immediate and late postopera-
tive periods, but this effect could not be evaluated, since we
had no other control group given only sedation and local
anaesthesia.

Postoperative nausea and vomiting are common in patients
after general anaesthesia or morphine (and are controllable by
peripheral nerve stimulation5), though not after local
anaesthesia.

In conclusion, the absence of a preoperative analgesic effects
of EA is consistent with data from other literature.5 9–11 The sam-
ple size is too small to draw definitive conclusions. The obser-
vations suggest that future studies can justify the use of the
technique aiming at postoperative hypoalgesia and at avoiding
local seroma.

The possibility of obtaining better results with a different
choice of anatomical sites and stimulation techniques must to be
considered. These choices include: (A) paravertebral electrical
stimulation at L1–L2 levels—the origin of ilio-inguinal, ilio-hy-
pogastric, genito-femoris and cluneal nerves, or at the anterior
superior iliac crest—where the first two nerves are below the
surface, avoiding possible interference of peri-incisional nerve
block by local anaesthetic over the stimulation effect; (B) the use
of frequencies at kHz levels that hyperpolarise all the afferent
fibres and might also produce stronger segmental analgesic
effects53; (C) the use of stimulation techniques in the immediate
postoperative period.

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Competing interests None.

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Committee—Fluminense Federal University.

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