

## Randomization is important in studies with pain outcomes: systematic review of transcutaneous electrical nerve stimulation in acute postoperative pain

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### Summary

We set out to examine the evidence for the importance of randomization of transcutaneous electrical nerve stimulation (TENS) in acute postoperative pain. Controlled studies were sought; randomization and analgesic and adverse effect outcomes were summarized. Forty-six reports were identified by searching strategies. Seventeen reports with 786 patients could be regarded unequivocally as randomized controlled trials (RCT) in acute postoperative pain. No meta-analysis was possible. In 15 of 17 RCT, we judged there to be no benefit of TENS compared with placebo. Of the 29 excluded trials, 19 had pain outcomes but were not RCT; in 17 of these 19 TENS studies, the authors concluded that TENS had a positive analgesic effect. No adverse effects were reported. Non-randomized studies overestimated treatment effects. (*Br. J. Anaesth.* 1996; 77: 798–803)

### Key words

Anaesthesia, audit. Pain, postoperative. Nerve, stimulation.

Transcutaneous electrical nerve stimulation (TENS) was developed originally as a means of controlling pain through the “gate” theory.<sup>1</sup> There is conflicting professional opinion on the use of TENS in acute postoperative pain. The recommendations of the Agency for Health Care Policy and Research (AHCPR)<sup>2</sup> for acute pain management state that TENS is “effective in reducing pain and improving physical function” while the earlier report of the UK College of Anaesthetists’ working party on pain after surgery<sup>3</sup> states that “TENS is not effective as the sole treatment of moderate or severe pain after surgery”. For postoperative pain some textbooks recommend or strongly recommend TENS,<sup>4–8</sup> although one at least is uncertain.<sup>9</sup> TENS is of doubtful benefit in labour pain,<sup>10</sup> but we could find no systematic review of its use in chronic pain.

The quality of methods used in clinical studies has been shown to be a key determinant of the eventual results. Schulz and colleagues<sup>11</sup> demonstrated that studies that were not randomized or which were inadequately randomized exaggerated the estimate of treatment effect by up to 40%. Studies which are

not fully blinded can exaggerate the estimate of treatment effect by up to 17%. We sought evidence of the effect of randomization in trials with pain as an outcome, in studies of TENS in acute postoperative pain.

### Methods

Several different search strategies were used to identify controlled studies for TENS in acute postoperative pain in both MEDLINE (1966–1995: Knowledge Server version 3.25: January 1996) and the Oxford Pain Relief Database (1950–1992).<sup>12</sup> The words “TENS” and “transcutaneous electrical nerve stimulation” were used in searching, including combinations of these words. Additional reports were identified from the reference lists of retrieved reports, review articles and textbooks.

Inclusion criteria were full journal publication, TENS and postoperative pain with pain outcomes. Reports of TENS for the relief of other acute pain conditions, such as labour pain, acute infections and procedures, or those where the number of patients per treatment group was fewer than 10 were excluded. Abstracts and review articles were not considered. Unpublished reports were not sought. Neither authors of reports nor manufacturers of TENS equipment were contacted.

Two types of control predominated—open studies compared TENS with conventional postoperative analgesia (i.m. opioid) or with disabled TENS instruments (sham TENS). Some studies used blinded observers. While there was no prior hypothesis that TENS could not be blinded adequately, it was determined that, despite the considerable efforts documented in some reports, adequate blinding was impossible in practice.

Each report which could possibly meet the inclusion criteria was read by each author independently and scored for inclusion and quality using a three-item scale.<sup>13</sup> Included reports received one point for randomization, a further point if this had been done correctly and a third if the number and

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reasons for withdrawals were given. Authors met to agree that studies were randomized or if the description of the method of randomization was adequate.<sup>11</sup>

Information on surgery, number of patients, study design and duration of treatment was extracted from randomized reports. The type of TENS equipment, its settings and the method and frequency of its use, and placement of electrodes were also extracted. Control group design and the use of TENS in these controls were similarly noted. Pain outcomes, overall findings and conclusions were noted for each report, together with adverse effect information.

A judgement was then made by us as to whether the overall conclusion of the randomized reports was positive or negative for the analgesic effectiveness of TENS. *Post hoc* subgroup analysis in the original reports was not considered in our judgement of overall effectiveness. Reports which had pain measures but which were not randomized or were inadequately randomized were examined for positive or negative analgesic effectiveness of TENS using the judgement of their authors.

## Results

Forty-six reports were considered; three did not have pain outcomes, three had fewer than 10 patients per group, three had methodological problems and one reported on pain during rather than after a procedure. These were not considered further.

Nineteen reports were either not RCT or the method of randomization was inappropriate (table 1). Seventeen of the 19 reports with pain measures excluded because they were either not randomized or inadequately randomized, were judged by their authors to have positive analgesic results for TENS in acute postoperative pain.

Seventeen randomized studies with pain outcomes were found. Of these, 15 were judged by us to show no analgesic benefit of TENS in acute postoperative pain.

## RANDOMIZED STUDIES

The randomized studies contained information on 786 patients (table 2). TENS was used after various operative procedures, including cardiothoracic, major orthopaedic and gastrointestinal surgery. Ten different TENS machines were used with different control settings and durations of treatment; individual titration of settings took place in six reports. Fourteen reports compared TENS with sham TENS without batteries, with batteries reversed or with sub-threshold stimulation; the other three compared TENS and i.m. opioid with i.m. opioid alone. Quality scores were generally 1 or 2 out of a maximum of 3. The most common outcome measures reported were analgesic consumption and a variety of pain score measurements. Information was not presented in formats which allowed extraction for meta-analysis (table 2).

### TENS vs sham TENS

Fourteen of the 17 included RCT compared TENS with sham TENS; no differences were found. One of the 14<sup>48</sup> reported no significant difference between TENS and sham TENS for analgesic consumption, but did report a statistically significant difference for pain intensity in favour of the active TENS; the published results, however, used a one-tailed statistical test which we judged inappropriate.

### TENS vs opioid control

Seven of the 17 included RCT compared opioid plus TENS with opioid alone, four of which also included sham TENS. Of the seven studies, five failed to detect any differences in analgesic consumption or pain measurements between TENS and non-TENS controls. Two reports were judged by their authors and by us to be positive.<sup>42,46</sup>

Pike<sup>42</sup> studied 40 patients after total hip replacement. The study had as its main outcome measure the number of pethidine injections in the first 2 days

Table 1 Non-randomized reports

Reference	Pain condition or operation type	Description	Authors' judgement about analgesic effectiveness
14	Upper abdominal	Not RCT	Positive
15	Cholecystectomy, hernia repair	Retrospective, not RCT	Positive
16	Upper abdominal	Inadequate randomization	Positive
17	Foot	Not RCT — matched case control	Positive
18	Caesarean section	Not RCT	Positive
19	General	Not RCT	Positive
20	Spinal fusion	Not RCT	Positive
21	Foot	Retrospective, not RCT	Positive
22	Urological	Not RCT	Positive
23	Urological	Not RCT	Positive
24	Urological	Not RCT	Positive
25	Abdominal, thoracic	Not RCT	Positive
26	Cholecystectomy	Not RCT	Negative
27	Thoracotomy	Inadequate randomization method	Positive
28	Laparotomy	Retrospective, not RCT	Positive
29	Low back	Not RCT	Positive
30	Lumbar, hip, gynaecological	Retrospective, not RCT	Positive
31	Knee and hip joint	Not RCT	Positive
32	Gastric bypass	Not RCT	Negative

Table 2 Randomized reports

Reference	Operation type	Study design and duration of treatment periods	No. of patients	TENS details	TENS control setting	TENS control	Pain outcomes	Results for pain outcomes	Judgement	Score
33	Appendicectomy	Parallel group TENS (15) Sham TENS (13) Standard postop. analgesia (14) 48 h	42	Dow Corning Wright, single channel, electrodes (either side of wound)	Fixed rate (tingling sensation preop.)	Sham TENS (not turned on)	VASPI @ 48 h, analgesic consumption (24 and 48 h)	No significant difference sham and active TENS for pain and drug consumption; significant difference for pain intensity control <i>vs</i> TENS and sham TENS ( $P < 0.01$ )	Negative	1
34	Abdominal	Parallel group Sham TENS (53) TENS (53) 72 h	106	Codman, dual channel, 2 electrodes (either side of wound)	Fixed rate (tingling sensation preop.) rectangular wave form, pulse width (170 ms), pulse rate 80 s <sup>-1</sup> , output 15 mA	Sham TENS (batteries reversed)	VASPI—average pain twice daily, Pmorphine consumption	No significant differences between TENS and sham TENS	Negative	2
35	Caesarean section	Parallel group (female) GA + TENS (10) Extradural + TENS (11) GA + Sham TENS (8) Extradural + sham TENS (6) 24 h	35	Stim-tec EPC Mini, Model 6011, dual channel (1 channel only used), 2 electrodes (either end of wound)	Amplitude individually titrated, wave fixed (during surgery)	Sham TENS (no batteries)	VASPI—hourly, time to first analgesic, analgesic consumption	No overall difference in analgesic consumption or pain	Negative	2
36	Coronary artery bypass	Parallel group (males) TENS (15) Sham TENS (15) Postop. analgesia (15) 72 h	45	Nuwave, Staodyn. 1 pair electrodes (T1-T5), 1 pair (either side of wound)	Individually titrated (tingling sensation)	Sham TENS (no current)	Pain (0–10) on cough and rest, opioid consumption	No significant differences TENS <i>vs</i> sham TENS	Negative	2
37	Cholecystectomy	Parallel group TENS (14) Remote TENS (12) Postop. analgesia (14) 48 h	40	3M Tenzcare, dual channel, site of electrodes not described	Individually titrated	Sham TENS (remote non-segmental)	VASPI, CATPI (4-point) @ 24 and 48 h, analgesic consumption	No significant difference TENS <i>vs</i> sham TENS for pain or analgesic consumption. Pain but not analgesic consumption significantly worse in control group ( $P < 0.05$ ) immediately after surgery	Negative	1
38	Herniorrhaphy	Parallel group (males) TENS (20) Sham TENS (20) 72 h	40	Dow Corning, Wright Care, dual channel, 2 electrodes (either side of wound)	Individually titrated—pulse duration 180 $\mu$ s, frequency 70 Hz, amplitude 7.5	Sham TENS (no current)	VASPI twice daily, analgesic consumption	No significant differences TENS <i>vs</i> sham TENS	Negative	1
39	Abdominal	Parallel group TENS (15) Sham TENS (15) 48 h	34	Neuromed 3722, 2 electrodes (either side of wound)	Individually titrated (tingling sensation)	Sham TENS (batteries reversed)	VASPI (2, 4, 6, 24, 48 h), analgesic consumption	No significant differences TENS <i>vs</i> sham TENS	Negative	2
40	Laminectomy	Parallel group TENS (10) Sham TENS (10) 24 h	20	Dow Corning, Wright Care, dual channel, 4 electrodes (at each end and on either side of wound)	Individually titrated, 180 $\mu$ s pulsed width, frequency 70 Hz	Sham TENS (no current)	PCA morphine consumption 24 h	No significant differences TENS <i>vs</i> sham TENS	Negative	2
41	Cardiac	Parallel group TENS (14) Sham TENS (17) 72 h	31	3M Tenz care Model 6240, dual channel, 2 pairs electrodes (either side of the wound and mid thoracic region)	Individually titrated—pulse rate 5, width control 3, amplitude	Sham TENS (no batteries)	5 point categorical pain intensity, analgesic consumption	No significant differences TENS and sham TENS	Negative	2
42	Total hip replacement	Parallel group TENS (20) Opioid control (20) 24 h	40	EPC TimeTech clinical stimulator, dual channel, 2 pairs electrodes (1 pr paravertebrally (L2-S2), between trochanter and coccyx, 1 pr above iliac crest, head of fibula)	Individually titrated, continual stimulation	Sham TENS (no current)	Global assessment, analgesic consumption	Significantly less pethidine consumed in TENS group on day 1 ( $P < 0.001$ )	Positive	1

contd over

Study ID	Procedure	Group	Electrodes	Stimulation	Sham TENS	Outcome	Significance	Notes
26	Cholecystectomy	Parallel group TENS (30)	EPC, electrodes placed within 2 cm of the wound	Pulse rate 50 s <sup>-1</sup> , pulsed width 170 ms, amplitude 0-50 A	Sham TENS (controls turned off)	No significant difference	Negative	1
43	Inguinal hernia repair	Opioid control (34) Parallel group (males) TENS (34) Sham TENS (28) 48 h	3M Tenzcare dual channel, 2 pairs of electrodes (over first lumbar vertebra and on either side of wound)	Individually titrated (tingling sensation), 70 Hz rectangular pulse, amplitude	Sham TENS (controls turned off)	No significant differences vs sham TENS	Negative	2
44	Thoracotomy	Parallel group TENS + Omnopon i.m. (20) Omnopon i.m. (20) 48 h	Dow Corning, Wright Care 2 channel, 2 electrodes (either side of incision)	Individually titrated, fixed pulse rate 70 s <sup>-1</sup> , rectangular waveform, pulse width 180 µs	Sham TENS (no current)	No significant differences vs sham TENS	Negative	1
45	Abdominal	Parallel group TENS (30) Sham TENS (22) Opioids i.m. (25) 72 h	MedGen, electrode placement not described	Fixed—pulse width 80 ms, frequency 40 Hz, amplitude individually titrated	Sham TENS (no current)	No significant differences vs sham TENS, or control	Negative	1
46	Abdominal and thoracic	Parallel group TENS (61) Sham TENS (39) 24 h post surgery until discharges, TDS × 20 min	Neuramed Model 3700, Meditronic, electrode site individually chosen	Frequency 100-150 s <sup>-1</sup> , output 20-35, pulse duration 250-400 ms	Sham TENS (no batteries)	Significant difference reported. 2/39 partial relief or complete relief sham TENS vs 34/61 with active TENS. Analgesic consumption not reported	Positive	1
47	Total knee replacement	Phase 2—parallel group TENS (18) Sham TENS (18) Postop. analgesia (12) 72 h	Strodynamic, continuous. No other information given; electrode placement not described	Amplitude setting individually titrated, pulse duration 100 µs at 70 s <sup>-1</sup>	Sham TENS (subthreshold stimulation)	No significant differences vs sham TENS or control	Negative	1
48	Thoracotomy	Parallel group TENS (12) Sham TENS (12) 48 h	3M Tenzcare 6240, 2 electrodes placed on either side of incision	Continuous stimulation, amplitude 7, pulse rate 3, pulse width 5	Sham TENS (no current)	No significant differences vs sham TENS. Positive result reported was with one-tailed test of statistical significance	Negative	2

after operation and a retrospective global rating. Patients with active TENS had significantly fewer pethidine injections on the first day after operation and higher scores on global rating of treatment. VanderArk and McGrath<sup>46</sup> recruited 100 patients undergoing abdominal and thoracic surgery in 2 months, and although there was more success with active TENS used for 20 min three times a day, maximal relief was “almost invariably associated with the first stimulation”. Generally there were no obvious differences between the use of TENS in these two positive studies and the 15 which showed no benefit.

Adverse events

No report described systematic recording of adverse events, nor were any reported.

Discussion

The “gold standard” in clinical trials is adequate randomization.<sup>11</sup> Non-randomized studies have been shown for nearly 20 yr to yield larger estimates of treatment effects than studies using random allocation.<sup>49</sup> The degree of exaggeration of treatment effect when randomization is inappropriate can be as much as 40%.<sup>11</sup> These findings underpin the inclusion criteria chosen in systematic reviews.

For TENS in acute postoperative pain, 17 of 19 reports with pain outcomes which were either not randomized or inappropriately randomized claimed TENS to be effective, compared with two of 17 randomized controlled trials.

The possibility of bias exists. The method of randomization was described in only two reports.<sup>16 27</sup> The method described was inadequate in both, one using a nurse to randomize patients<sup>16</sup> and the other using alternate allocation.<sup>27</sup> Reports which said only that they were randomized may have used an inadequate method.

That these data represent the lowest common denominator of information, essentially vote counting rather than a more sophisticated analysis, reflects the nature of the analgesic scoring methods that predominated in the original reports. Pain scoring using analogue or categorical scales was reported as means (an unreliable statistic<sup>50</sup>) or mean analgesic consumption, or time to first analgesic was used. None of these allowed data extraction for further statistical analysis or comparison between reports. While more rigorous pain scoring might have been used, there is no evidence that all of the reports suffered a systematic failure in analgesic measurement.

Inadequacy of blinding in clinical trials of analgesic interventions continues to be of concern,<sup>51</sup> although this may be less of an issue with pharmacological interventions.<sup>50</sup> Blinding of procedures is much more difficult than blinding of drug studies. Most of the TENS studies made attempts at blinding, for example by removing batteries from the TENS apparatus (sham TENS) or by using staff with no knowledge of the study or allocation to conduct the patient assessments. Lack of blinding has been estimated to exaggerate the estimate of

treatment effect of studies by some 17%.<sup>11</sup> Adequate blinding of TENS for both carers and patients is particularly difficult.<sup>52</sup> None of the reports was judged to have been blinded and this lowered the quality scores given to the 17 randomized studies. The fact that only two of the reports showed any positive effect of TENS in acute postoperative pain is all the more striking because of this potential over-estimation of treatment effect caused by lack of blinding.

The clear message of the reports considered in this systematic review is that adequate randomization is an important quality standard in studies with pain outcomes. Including non-randomized studies in reviews may give the wrong answer. The AHCPR guidelines on acute pain management included non-randomized reports, and this may explain their more positive attitude towards TENS.<sup>2</sup>

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