

Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain

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Abstract

Aim. We investigated the literature of randomised placebo-controlled trials to find out if transcutaneous electrical nerve stimulation (TENS) or acupuncture-like transcutaneous electrical nerve stimulation (ALTENS) can reduce analgesic consumption after surgery.

Results. Subgroup analysis for adequate treatment (pulse frequency: 1–8 Hz [ALTENS] or 25–150 Hz [TENS], current intensity: “strong, definite, subnoxious, maximal tolerable” or above 15 mA, and electrode placement in the incision area) were performed. Twenty-one randomised, placebo-controlled trials with a total of 1350 patients were identified. For all trials, the mean reduction in analgesic consumption after TENS/ALTENS was 26.5% (range –6 to +51%) better than placebo. Eleven of the trials comprising 964 patients, had reports which stated that a strong, subnoxious electrical stimulation with adequate frequency was administered. They reported a mean weighted reduction in analgesic consumption of 35.5% (range 14–51%) better than placebo. In nine trials without explicit confirmation of sufficient current intensity and adequate frequency, the mean weighted analgesic consumption was 4.1% (range –10 to +29%) in favour of active treatment. The difference in analgesic consumption was significantly ($p = 0.0002$) in favour of adequate stimulation. The median frequencies used in trials with optimal treatment was 85 Hz for TENS and 2 Hz in the only trial that investigated ALTENS.

Conclusion. TENS, administered with a strong, subnoxious intensity at an adequate frequency in the wound area, can significantly reduce analgesic consumption for postoperative pain.

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Keywords: Transcutaneous electrical nerve stimulation; Postoperative pain; Analgesic consumption

1. Introduction

Transcutaneous electrical nerve stimulation (TENS) is a modality that in experimental settings has been able to reduce pain (Walsh and Baxter, 1996). However, the gap from promising laboratory research to clinical effectiveness is difficult to bridge and the clinical literature on TENS seems equivocal and inconclusive in several areas (Carroll et al., 1997; Milne et al., 2001).

Systematic reviews for the treatment of postoperative pain, have concluded that there is little—if any—evidence in favour of TENS (Carroll et al., 1996; Reeve et al., 1996). The Bandolier evidence-based health care web site relies on one of these review conclusions as the best available evidence and states: “*Clinical bottom line: TENS is not effective in the relief of postoperative pain. Patients should be offered effective methods of pain relief*” (Bandolier, 2000). However, this advice may be based on an evaluation model that is volatile, because trials with possible ineffective treatment dose were not excluded (Bjordal and Greve, 1998). Information from the reports of trials included in these reviews suggests that

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low, and possibly ineffective, current intensities of 0–15 mA (Cuschieri et al., 1985) or sensory threshold intensity were used (Smedley et al., 1988).

We have previously used a model for evaluating the scientific evidence for therapies with unknown optimal treatment procedure. The model allows for testing the hypothesis that an assumed optimal dose exists, and for other electrophysical agents, this model has aided identification of specific treatment doses and procedures that were significantly more effective than others in tendinopathies (Bjordal et al., 2001).

Another problem with previous systematic reviews on TENS and postoperative pain is that, although outcome measures have not been standardised, dichotomised interpretation (positive or negative) of pain scores seem to be the source of conclusions about ineffectiveness. Systematic reviews on TENS and postoperative pain also dichotomise complex trial data as positive or negative, which may overlook clinically relevant effects. This has led to inconsistency in the interpretation of trial outcome by reviewers. For example, Conn et al. (1986) reported that there were no differences between active and sham TENS in postappendectomy pain relief. The review by Carroll et al. (1996) judged this finding as negative outcome based on the lack of differences in pain relief scores between the groups. However, the review by Reeve et al. (1996) judged Conn et al.'s study as positive outcome, possibly based on the finding that TENS significantly reduced the need for additional analgesics when compared to sham.

Drug administration by patient-controlled analgesia (PCA) is common (Cook & Riley, 1997), and all available postoperative trials on TENS use analgesic drugs as co-interventions. It is possible that pain scores in these trials may be compromised because patients were given free access to analgesics either by PCA or analgesic request. Truly, significant differences in pain scores can be expected in cases where drugs of variable effectiveness are compared. But trials comparing equally effective analgesic drugs, seldom find significant differences in VAS-scores (Kostamovaara et al., 1998; Ilkjaer et al., 1998; Forst et al., 1999), as most patients titrate their analgesic consumption to a similar and tolerable level of pain intensity. It is important to emphasise that experimental studies of TENS effectiveness only provides support for partial pain relief, whereas analgesic drugs have the potential to produce complete pain relief. One problem with high doses of analgesic drugs however, is that undesirable side effects such as depressed respiration, nausea, and sedation reduces patient satisfaction (Pang et al., 1999). A clinically meaningful perspective is if TENS can reduce analgesic consumption by PCA or analgesic request without significant increase in pain scores. Our hypothesis is that TENS can reduce PCA doses *without* increasing pain scores when compared to PCA combined with placebo TENS.

Surgery leads to a fairly standardised sequence of early recovery from oedema and postincision pain. The first 3-day postoperative sequence seems particularly suitable for assessing the size of effect from TENS. Statistical pooling of trial results can give a valid quantification of treatment effects in such cases (Thompson, 1991; Moore et al., 1998).

This meta-analysis of randomised placebo-controlled trials examines the reduction of analgesic consumption using TENS after surgery using assumed optimal TENS parameters. Thus, trials were included if TENS was administered at a subjective intensity that was described as “strong and/or definite subnoxious, and/or maximal non-painful, and/or maximal tolerable” or a current amplitude above 15 mA. There exists scattered evidence that pulse frequencies of 1–8 Hz for acupuncture-like transcutaneous electrical nerve stimulation (ALTENS) (Sjolund, 1988; Tulgar et al., 1991) or 25–150 Hz for conventional TENS (Sjolund, 1985; Johnson et al., 1989; Tulgar et al., 1991) provide better pain relief than other frequencies. For this reason these frequency ranges were assumed optimal in this meta-analysis.

2. Materials and methods

2.1. Literature search

A literature search for randomised controlled trials from 1966–2001 was performed on Medline, Embase, Cinahl, PedRo, and the Cochrane Controlled Trial Register as advised by Dickersin et al. (1994). Key words were: transcutaneous electrical nerve stimulation, transcutaneous electrical, acupuncture-like electrical, postoperative pain, TENS, ALTENS. Handsearching was also performed in National Physiotherapy and Medical Journals from Norway, Denmark, Sweden, Holland, England, Canada, and Australia. Additional information was gathered from researchers in the field.

3. Methods

3.1. Inclusion criteria

The trials were subjected to the following inclusion criteria:

- (1) Surgical in-patients were included.
- (2) Electrical stimulation performed with electrode placement on intact sensory innervated area around incision.
- (3) Randomisation reported.
- (4) Attempts of blinding reported.
- (5) Amount of analgesic consumption reported.
- (6) Endpoints within 3 days after inclusion.

3.2. Exclusion criteria

1. Trials listed as non-randomised in review by Carroll et al. (1996) (i.e., randomisation is not reported, a control group was included retrospectively, or group allocation was selected by authors).

3.3. Outcome measures

Main outcome measure is analgesic consumption. For each trial, analgesic consumption between active treatment group and placebo group was registered and differences between groups were calculated and presented as percentual differences. Secondary outcome measure was pain on a visual analogue scale.

3.4. Statistical pooling

In the statistical pooling, we used the mean percentual difference in analgesic consumption between groups in each trial and multiplied this value with the number of included patients in the trial. These products were added and divided by the total number of participating patients in all trials, which gives the mean weighted difference (MWD) in analgesic consumption between active treatment and placebo treatment from all the included trials:

$$\left(\sum [\text{Difference between groups for each trial (\%)} \times \text{number of patients in same trial}] \right) / \text{number of patients in all trials.}$$

3.5. Adverse events

The number of adverse events from TENS/ALTENS was registered.

3.6. Subgroup analysis

Analysis for trials, which described both of the following assumed optimal treatment parameters, was performed:

Pulse frequency: 1–8 Hz [ALTENS] or 25–150 Hz [TENS].

Current intensity: strong, definite, subnoxious, maximal tolerable [TENS] or above 15 mA.

A test for statistical significance of analgesic consumption differences, between the trials with assumed optimal treatment parameters, and the assumed non-optimal treatment parameters was performed with Students two-tailed *t* test ($p < 0.05$). If significant differences were found between assumed optimal and non-optimal treatment, an analysis of the median electrical

frequency and an analysis of side effects for the optimal treatment trials would be performed.

4. Results

4.1. Results of inclusion procedure

The literature search identified 128 reports with TENS, of which 51 were controlled trials. Nineteen of these had to be excluded as they met our exclusion criteria for non-randomisation as defined by Carroll et al. (1996). Another 11 trials (Rainov et al., 1994; Rosenberg et al., 1978; Pike, 1978; Stubbing and Jellicoe, 1988; Reuss et al., 1988; Hargreaves and Lander, 1989; Bayindir et al., 1991; Jones and Hutchinson, 1991; Laitinen and Nuutinen, 1991; Walker et al., 1991; Chiu et al., 1999) had to be excluded for various reasons (see Table 1).

The remaining 21 trials were randomised, placebo-controlled trials including 1350 patients fulfilling our inclusion criteria (Table 2).

4.2. Results for analgesic consumption regardless of stimulus parameters

The MWD in reduction of analgesic consumption was calculated to be statistically significant ($p = 0.005$) at 26.5% better than placebo for all 21 trials.

4.3. Results of subgroup analysis for assumed optimal treatment

Eleven trials, including 964 patients, (Lim et al., 1983; Jensen et al., 1985; Van der Ark and McGrath, 1975; Smith et al., 1986; Benedetti et al., 1997; Wang et al., 1997; Gilbert et al., 1986; Fodor-Sertl et al., 1990; Taylor et al., 1983; Hamza et al., 1999; Hershman et al., 1989), satisfied our criteria of assumed optimal treatment. They reported a MWD reduction in analgesic consumption that was 35.5% (range 14–51%) better in the TENS group than in the placebo TENS group (Fig. 1). The MWD between assumed optimal and assumed non-optimal TENS treatment was highly significant ($p = 0.0002$).

4.4. Results of subgroup analysis for assumed non-optimal treatment

In the 10 trials that used assumed non-optimal TENS treatment (Davies, 1983; Warfield et al., 1985; Galloway et al., 1984; Conn et al., 1986; Forster et al., 1994; Smedley et al., 1988; Navarathnam et al., 1984; Sim, 1991; Cuschieri et al., 1985; McCallum et al., 1988), the MWD in analgesic consumption between active TENS and placebo TENS was 4.1%, which was not statistically significant ($p = 0.56$).

Table 1

List of excluded trials given by first author, publication year, sample size, diagnosis, outcome and reason for exclusion

First author	Publication year	Number of patients	Type of surgery	Reduction (%) in analgesic consumption vs. control	Reason for exclusion	Assumed optimal treatment
Rosenberg	1978	12	Cholecystectomy	60	Lacks placebo treatment in control group	Yes (TENS)
Pike	1982	40	Hip prosthesis	73	Lacks placebo treatment in control group	Yes (TENS)
Hargreaves	1988	75	Abdominal	Missing (28% on VAS)	Lacks data on analgesic consumption	Yes (TENS)
Laitinen	1991	50	Cholecystectomy	-15 (data only for first 16 h)	Control group received Indomethacin	Yes (ALTENS/TENS)
Walker	1991	36 (48)	Total knee arthroplasty	11	Electrode placement not described	Yes (TENS)
Jones	1991	31	Abdominal	Missing (25% on VAS)	Lacks data on analgesic consumption	Yes (TENS)
Rainov	1994	234	Lumbar discectomi	39	Lacks placebo treatment in control group	Yes (TENS/ALTENS)
Stubbing	1988	40	Thoracotomy	-2	Lacks placebo treatment in control group	No (TENS, only slight tingling sensation)
Reuss	1988	64	Cholecystectomy	-5	Lacks placebo treatment in control group	No (TENS, "amplitude 0–50 A")
Bayinder	1991	89	Median sternotomy	75	Lacks data on analgesic consumption	No (ALTENS, sensory threshold)
Chiu	1999	60	Hemorrhoidectomy	46	Electrodes not placed around incision	No (Distant acupoint ALTENS)

4.5. Results for secondary outcome measure (pain on VAS)

The MWD in pain measured on VAS was not significant as only two trials reported significant reduction for the active TENS (Gilbert et al., 1986; Smith et al., 1986), while the remaining nine trials reported no significant differences in VAS for active TENS.

4.6. Results of median frequency in trials with optimal treatment

The median frequency for TENS of 11 trials with optimal treatment parameters was 85 Hz, while 2 Hz was used in the only trial that had an ALTENS group (Hamza et al., 1999).

4.7. Side effects and adverse events

No negative side effects from TENS/ALTENS were reported. The effect from TENS/ALTENS on opioid-

related side effects was reported in two trials with optimal treatment (Wang et al., 1997; Hamza et al., 1999). In TENS/ALTENS groups, patients reported 20.6% (mean \pm 20 SD) less nausea and 29.4% (mean \pm 21 SD) scored better on various scores of alertness. No adverse events from TENS/ALTENS were reported.

5. Discussion

The results suggest a significant dose-dependent effect from TENS in postoperative pain. A possible limitation of this interpretation, is that our selected main outcome measure has been analgesic consumption. If TENS is effective in relieving postoperative pain, it would either reduce VAS-ratings, analgesic consumption or both. We have assumed that by having free access to analgesics, most patients would use this to achieve a comfortable pain level. This assumption is supported by one trial with postoperative PCA, which showed that most, but

Table 2

List of included trials by first author, publication year, sample size, diagnosis, stimulation type, outcome for analgesic consumption, optimal/non-optimal stimulation

First author	Year	Type of surgery	Number of patients	Type of treatment	Mean effect vs. placebo (%)	Intensity of stimulation described	Optimal treatment	Notes
Van der Ark	1975	Abdominal/thorax	100	TENS	51	Strong (20–35 mA)	Yes	
Lim	1983	Abdominal	30	TENS	25	Strong	Yes	
Taylor	1983	Abdominal	77	TENS	32	Subnoxious	Yes	
Jensen	1985	Menisectomy	90	TENS	28	21 mCoulomb	Yes	
Smith	1986	Caesarean	18	TENS	22	30 mA	Yes	44% better than placebo on VAS
Gilbert	1986	Inguinal hernia	40	TENS	14	Max. tolerable	Yes	38% better than placebo on VAS
Hershman	1989	Cholecyst./colorect.	95	TENS	36	Definite tingling sensation	Yes	
Fodor-Sertl	1990	Thoracotomy	40	TENS	35	Strong < 40 mA	Yes	
Benedetti	1997	Thorax	324	TENS	35	Strong	Yes	
Wang	1997	Abdominal	50 (101)	TENS	42	Strong	Yes	
Hamza	1999	Gynaecological	100	TENS/ ALTENS	40	Strong	Yes	
Galloway	1984	Abdominal	40	TENS	29	Adjusted to each patients comfort	No (?)	10% better than placebo on VAS
Warfield	1985	Thoracotomy	24	TENS	10	Amplitude 7 (Tenzcare 6240)	No (?)	23% better than placebo on VAS
Davies	1983	Caesarean	32	TENS	17	Amplitude as wished	No	No effect of TENS after epidural analgesia
Navaratnam	1984	Thorax	31	TENS	14	Comfortable	No	29% better on expiratory lung flow
Cuschieri	1985	Abdominal surgery	106	TENS	-10	Comfortable max 15 mA	No	Time to analgesic request 24% better than placebo
Conn	1986	Appendicectomy	28 (42)	TENS	22	Tingling sensation, no discomfort	No	
Smedley	1988	Inguinal hernia	62	TENS	-6	Sensory threshold	No	
McCallum	1988	Lumbar laminect.	20	TENS	6	Comfortable	No	
Sim	1991	Cholecystectomy	30	TENS	5	0–5 mA comfortable	No	
Forster	1994	Coronary bypass	45	TENS	6	Strong, but comfortable	No	Frequency too high (258 Hz)

not all, titrated PCA consumption to achieve a tolerable level of pain intensity (Woodhouse and Mather, 2000). Consequently, the consumption of analgesics seems to be the most valid outcome measure, although one would also expect to find occasional significant results for VAS-scores, if the intervention was effective. It is interesting to note that the two trials (Gilbert et al., 1986; Smith et al., 1986) with the smallest reductions in analgesic consumption, recorded significantly better VAS-scores in the active treatment groups. We consider these

results to add further weight to a conclusion of TENS' effectiveness in postoperative pain.

Measuring interventional effects on mild pain remains a complicated issue, because several factors may have influence on the results. In addition, the inter-subject variance in registered pain scores is large, and does not necessarily reflect the physiological status of the patients (Tyler et al., 1996). Psychological factors like health locus of control, anxiety, and depression have been shown to significantly affect PCA consumption and pain

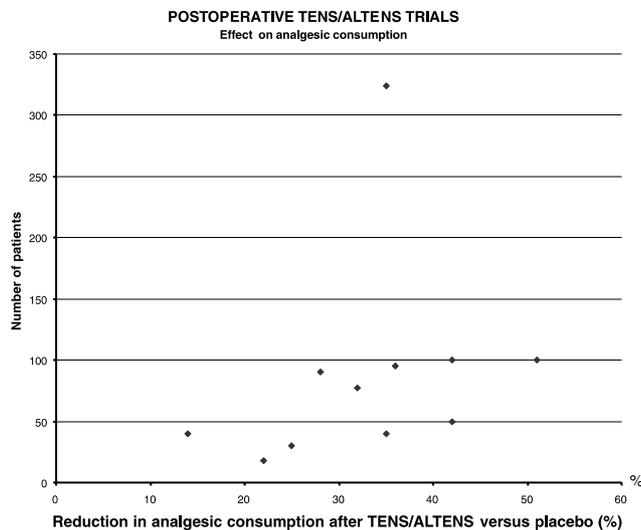


Fig. 1. Effect size plot for trials with optimal treatment procedure.

(Johnson et al., 1989; Gil et al., 1990; Thomas et al., 1995), while age seems to be of no significant importance (Gagliese et al., 2000). In one of the included trials, psychological factors were investigated separately, and no significant differences between groups were reported (Lim et al., 1983). We found no indication of uneven distribution of psychological factors between groups in the included trials. Interpretation of randomisation was performed rather strictly, in the sense that we excluded every trial that had been excluded by the randomisation criteria in previous reviews (Carroll et al., 1996; Reeve et al., 1996). We think that randomisation, combined with a rather large patient sample, most probably have secured an even distribution of possible psychological confounders in placebo and active treatment groups.

Apart from randomisation, adequate blinding has been considered to be an important trial quality factor that may affect outcome results. While earlier studies suggested that only a positive outcome was exaggerated by poor blinding (Schulz et al., 1995), more recent papers have reported that poor blinding causes the outcome variance in both directions to increase (Verhagen et al., 2000). Maybe some authors have used too low current intensities, in fear of compromising the blinding the respective treatment groups. However, in one placebo-controlled TENS-trial where a TENS-unit without batteries served as placebo, no significant difference between the groups was found when they were asked if their unit was active or sham (Deyo et al., 1990). In our material we have taken this further by showing that there was a significant difference in analgesic consumption between groups receiving an adequate strong, submaximal electrical stimulus, and groups given a non-optimal (but above sensory threshold) electrical stimulus. The latter group may be considered as a placebo group too. Because of the small differences in effect be-

tween groups receiving no electrical stimulus, and those receiving an inadequate electrical stimulus above sensory threshold, one possible implication is that future trials can use the latter as placebo treatment.

As all patients in hospital were under homogeneous environmental conditions during a period of 1–3 days, co-interventions were avoided, and withdrawals hardly occurred. In TENS-trials for chronic pain in out-patient settings, several extrinsic factors may be difficult to control. A postoperative hospital setting where patients have mild, postoperative pain, probably represents one of the “cleanest” possible clinical study situations, in which TENS effectiveness can be investigated.

Our findings are contrasting the negative conclusions on TENS effectiveness of previous reviews (Carroll et al., 1996; Reeve et al., 1996; McQuay & Moore, 1998). These reviews have dichotomised trial results into negative or positive outcome. The review by Carroll et al. has one clear punchline: the importance of randomisation. Although we agree on the importance of randomisation, dichotomisation is a potential source of bias. Inconsistency in the judgments between trial authors and different reviewers, has been described for TENS-trials (Johnson, 2000) and dichotomised interpretations of trial reports tend to be systematically biased towards the reviewers’ conclusion (Bjordal and Greve, 1998). Another important difference between our review and the others is that we have chosen a different and standardised main outcome measure (analgesic consumption).

Our literature search is more extensive, and includes several large, well-designed trials (Benedetti et al., 1997; Wang et al., 1997; Hamza et al., 1999) that have been missed out in earlier reviews. Consequently, the base for our conclusions should be broader and several aspects also suggest that the conclusions are robust to changes in exclusion criteria.

The non-randomised-controlled trials that were excluded from this review, have nearly all reported effects in favour of active TENS. In the heterogeneous sample of excluded randomised, controlled trials in Table 1, the same tendency of a significant pain-reducing effect from TENS is seen. Thus, any alteration of exclusion criteria for trial design, would not have altered our conclusion. In addition, the graphical distribution of results from optimal TENS treatment, resembles that of a “funnel-plot”. This is by some authors considered to strengthen the evidence of a positive effect from treatment (Egger et al., 1997).

The variation in effect size seems large across the TENS-trials, but it may be partly explained by differences in treatment procedures and patient samples. The two trials using analgesic medication by PCA (Wang et al., 1997; Hamza et al., 1999) provided larger reduction in analgesic consumption, than the trials where patients had to require rescue analgesics from the

nursing staff. Better pain relief has been reported for patients using PCA when compared to patients that had to require analgesics from the hospital staff (Passchier et al., 1993). Epidural analgesia may also influence the result by lessening the effect of TENS (Davies, 1983). There is also evidence that TENS is less effective after major surgical interventions like thoracotomy (Benedetti et al., 1997). TENS is a sensory modality which acts directly on the nervous system by activating A-beta peripheral fibres, and this leads to a reduction in central nociceptive cell activity (Garrison and Foreman, 1994). The physiological processes that generate the self-report of postoperative pain differ in their contribution for mild, moderate, and severe pain. Thus, the outcome of A-beta activity induced by TENS may also differ. The observation that TENS relieves rather than exacerbates A-beta touch evoked pain in patients with tactile allodynia highlights our lack of understanding of the effects of TENS induced A-beta afferent activity on different levels of pain and tissue damage (Devor, 2001).

TENS is no panacea that can substitute strong analgesics. Clinical use of TENS can be limited by the time required to educate patients on administration techniques. Evidence presented in this meta-analysis that TENS provides benefit over and above placebo, coupled with its ability to increase the self-efficacy of the patient with only minor adverse effects suggests a role for TENS in the management of postoperative pain.

6. Conclusion

There is credible evidence that TENS reduces postoperative pain through less analgesic demand during the first 3 days after surgery. In addition, there is some evidence that suggests a reduction of side effects, like nausea and sedation, from opioid analgesia. The effect of TENS is dose-dependent and requires a strong sensation of currents. The median stimulation frequency in trials with stimulation parameters within the assumed optimal dose range, was 85 Hz for conventional TENS.

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