CRITICALLY APPRAISED TOPIC

TITLE

Is Transcutaneous Electrical Nerve Stimulation (TENS) effective as a modality to reduce pain and pruritus in patients with burn injuries

AUTHOR

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Review date	April 2015		

CLINIAL SCENARIO

Pain and/or pruritus at the burn site are common side effects following serious burn injuries, and make it difficult for the patient to focus on therapeutic tasks secondary to pain and/or itching. The mechanism of pruritus secondary to burn injury is not fully understood. Both pruritus and pain are believed to travel along small C afferent fibres to the spinal cord. In accordance with the gate control theory, the thalamus discriminates the neuronal discharge patterns and is able to decipher between pain and itch. Investigators propose that transcutaneous electrical nerve stimulation (TENS) stimulates the rapid conduction of A fibres. These impulses block or "close the gate to" the transmission of noxious stimuli transported by the slower conducting C fibres (Steinhoff, 2006). Although TENS is hypothesized to reduce pain and/or pruritus, it is not used consistently in clinical practice. The purpose of this CAT is t determine whether there is evidence to support the use of TENS to reduce discomfort following major burn injury

FOCUSED CLINICAL QUESTION

Does Transcutaneous Electrical Nerve Stimulation (TENS) reduce pain and/or pruritus in adults who have sustained severe burn injury?

SUMMARY OF SEARCH

- Three studies investigating the effectiveness of TENS as a modality for the reduction of pain or pruritus were found. Each of the studies uses the VAS pain scale as the outcome measure
- All three of the studies are a randomized controlled trial design, though two of the studies are pilot studies and do not have a sufficient sample size to test a true effect. One of the RCT-pilot studies is a two period cross-over design; the other is an unblinded randomized controlled trial. The final RCT is double blinded and subjects are quasi-randomized by medical record number.
- TENS was applied for varying durations and frequencies throughout the studies. Two of the studies utilized conventional TENS procedures (high frequency/low intensity). The other investigates an auricular acupuncture-like TENS procedure at highest tolerated intensity for 60 second intervals for 15 minutes. Results for all three studies suggest a decrease in pain levels over time with the use of TENS.
- Key findings: The evidence presented in the studies included in this critical appraisal supports the use of TENS as a modality in the reduction of pain and/or pruritus in patients with burn injuries. However, this area requires more study and stronger evidence, as most the studies

presented here are pilot studies.

CLINICAL BOTTOM LINE

Studies suggest that both conventional TENS (high frequency/low intensity at site of discomfort) and auricular acupuncture-like TENS (lower frequency/higher intensity applied to ear) may be used as a modality to reduce pain and/or pruritus secondary to burn injury.

It appears that TENS may be a safe, non-invasive, non-habit forming option for managing pain and/or pruritus in patients with burn wounds in the remodelling stage of healing as well as other unspecified stages in the wound healing process.

Important note on the limitation of this CAT

This critically appraised topic has not been peer-reviewed by one other independent person/lecturer

SEARCH STRATEGY

Terms used to guide the search strategy

- **P**atient/Client Group: Persons who experience pain and/or pruritus secondary to burn injury
- **I**ntervention (or Assessment): Transcutaneous Electrical Nerve Stimulation (TENS)
- **C**omparison: burned persons with pain and/or pruritus who did not receive TENS or no comparison group
- **O**utcome(s): standardized pain measure

Databases and Sites Searched	Search Terms	Limits Used
OT Seeker PubMED PEDro Medline CINAHL	"burn injury" or "thermal injury" AND pain AND pruritus OR itching AND transcutaneous electrical nerve stimulation OR TENS	English language

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
Adults who received TENS as an intervention for the reduction of pain and/or pruritus secondary to a burn injury.
Exclusion Criteria

subjects with prior or co-morbid neurological, orthopaedic, or cognitive conditions; expert opinion or case study designs; non-standardized outcome measurements

RESULTS OF SEARCH

A total of *four* relevant studies were located and categorised as shown in Table 1 (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011). The case study featured in the table was not included in the final review as it did not meet specified inclusion/exclusion criteria.

Table 1: Summary of Study Designs of Articles Retrieved

Study Design / Methodology of Articles Retrieved	Level	Number Located	Author (Year)
Systematic Reviews	**1a**	**0**	
Individual RCTs of good quality	**1b**	**3**	**Kimball (1987)** **Hettrick (2004)** **Lewis (1990)**
Systematic review of cohort studies	**2a**	**0**	
Individual Cohort studies	**2b**	**0**	
Systematic review of case control studies	**3a**	**0**	
Individual case control studies	**3b**	**0**	
Case series and poor quality case control and cohort studies	**4**	**0**	
Expert opinion / case study	**5**	**1**	**Whitaker (2001)**

BEST EVIDENCE

The following studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Each study met the inclusion and exclusion criteria stated above.**

SUMMARY OF BEST EVIDENCE

Table 2: Description and appraisal of (Randomized Controlled trial) by (Kimball, 1987)

Aim / Objective of the Study:
To determine if the use of TENS is as effective as morphine in reducing pain after a Traverse (enzymatic debridement) procedure
Study Design
This study was a double-blinded (quasi) randomized controlled trial. Twenty-four patients were randomized to a TENS group (16) or a morphine group (8) based on the arithmetic sum of his/her medical record number. Patients of the TENS group received conventional TENS (high frequency, low intensity) during the debridement procedure at the site of pain. The patients of the morphine group were fitted with TENS electrodes at the site of pain, but the TENS unit was not activated. After the debridement, the patients of the morphine group received a dose morphine based on patient weight (this is standard of care at this facility). The patients of the TENS group received a dose of saline fluid in lieu of morphine. Pain measurements were assessed using the Visual Analogue Scale (VAS) and the Verbal Categorical Scale (VCS) at 15minute intervals during the first hour post debridement and hourly for the four hours following.
Setting
University of Alabama Hospitals Burn Center; Birmingham, AL
Participants
Twenty four patients were selected from among those admitted to the University of Alabama Hospitals' burn center between January 1, 1983 and May 15, 1983. The mean age was 40.9 years (range 18-71). Eighty-eight precent were males. The TENS group and the morphine group were compared at baseline for total body surface area (TBSA) percentage burned, range of body surface area burned and total Travase debridement days per patients. No statistical differences between groups were identified. Patient retention was 100%.
Intervention Investigated
Control
Electrodes were placed on the patient at the site of debridement in the dressing room prior to debridement procedure, though the TENS machine was not activated during the procedure. After the debridement the patient was returned to his/her room. There he/she received an injection of morphine (amount based on weight). The patient's pain level was then assessed by a blinded clinician using the Visual Analogue Scale (VAS)and the Verbal Categorical Scale (VCS). Pain level was assessed every 15minutes during the first hour after the debridement and then every hour for the four hours following. The procedure was repeated 1-5 days per patient as determined by the physician with a mean of 1.9 days per patient.
Experimental
Electrodes were placed on the patient at the site of debridement in the dressing room prior to debridement procedure. The TENS machine was activated during the procedure for patients of the experimental group (pulse width of 80-85msec, rate of 75-90pps). After the debridement the patient was returned to his/her room where he/she received an injection of saline solution in lieu of the standard of care procedure of a morphine injection. The patient's pain level was then assessed by a

blinded clinician using the VAS and VCS. Pain level was assessed every 15minutes during the first hour after the debridement and then every hour for the four hours following. The procedure was repeated 1-5 days per patient as determined by the physician with a mean of 1.9 days per patient.

Outcome Measures (Primary and Secondary)

Visual Analogue Scale (VAS): The VAS is a linear scale of pain levels from 0 (no pain) to 10 (unbearable, excruciating pain). Patients are asked to mark their current pain level from 0 to 10 along a horizontal line. Note: patients with bandaged hands were instructed to point to the representative point of the scale and the administrator marked the line for the patient.

Verbal Categorical Scale (VCS): Using the four-point VCS, patients label their pain level as "no pain", "moderate pain", "severe pain", "excruciating pain".

The patient's pain level was assessed by a blinded clinician using the VAS and VCS immediately upon return to his/her room after the procedure. Pain level was assessed every 15minutes during the first hour after the debridement and then every hour for the four hours following.

Findings

Mean and Standard Deviations of Pain on VAS

Time Intervals	**TENS**	**CI**	**Morphine**	**CI**
Initial	5.04+/- 3.27	3.44 to 6.64	5.69+/-3.28	3.42 to 7.96
15 min	4.68+/- 2.30	3.55 to 5.81	4.44 +/-2.40	2.78 to 6.10
30min	3.27+/- 2.47	2.06 to 4.48	3.60+/-2.21	2.07 to 5.15
45min	2.79+/-2.13	1.75 to 3.83	3.02+/-2.26	1.45 to 4.59
1hr	2.26+/-1.92	1.32 to 3.20	2.77+/-2.36	1.13 to 4.41
2hr	2.32+/-2.32	1.81 to 3.46	3.00+/-2.54	1.24 to 4.76
3hr	2.56+/-2.58	1.30 to 3.82	2.62+/-2.56	0.85 to 4.39
4hr	2.26+/-2.41	1.08 to 3.44	2.69+/-2.42	1.01 to 4.37

NB: CI's are calculated by the reviewer, and are not included in the original article

ANOVA Group x Time

Group: F=1.47; p=.2236

Time: F=7.69; p=<.001

Group x Time: F=.17;p=.0523

A two-way ANOVA reveals a significant decrease in pain level over time in both the TENS and Morphine groups, however no significant differences were noted between the groups at any time point. A Chi Square analysis of the VCS was performed in order to account for missing data points due to therapist/patient unavailability or patient sleeping. Chi Square outcomes included the following categories: missing data, patient asleep, mild pain, moderate pain, severe pain, excruciating pain. The analysis revealed no statistically significant difference between the groups (Chi Square=3.430; p=.6252).

Original Authors' Conclusions

The investigators concluded that TENS is as effective as morphine in reducing pain post debridement procedures. They suggest that future study in this area consist of a multivariate analyses that would identify factors that contribute to pain for various patients. These predictor variables would assist

clinicians in deciding between TENS or morphine for pain reduction in specific patients.

Critical Appraisal

Methodology

- Level of evidence: 1b; A (quasi) randomized controlled trial of good quality
- Groups were randomly assigned based on sum of medical record number
- Double blinded study

Selection/Bias

- Subjects were selected among patients admitted the University of Alabama Hospitals' Burn Center
  - **NOTE:** Selection process is not defined
- No statistical differences between characteristics of experimental and control group
  - **NOTE:** patient chart review was conducted retrospectively by an unblinded clinician. This process could bias group characteristic outcomes.

Pedro Score

- 7/11; no inclusion criteria defined; the use of medical record numbers as a randomization technique is considered to be quasi-randomization and does not satisfy the PEDro criterion; the authors do not address the issue of allocation concealment; the therapist who administered the intervention was not blinded.

Missing Information

- Burn depth
- Co-morbidities or co-occurring injuries
- Other pain medications with analgesic effects
- Prior pain conditions
- Duration of the TENS intervention is not stated
- Baseline pain score prior to debridement intervention

*The authors state that "other injuries", "medications", and "age" were collected from patient medical records retrospectively by an unblinded clinician. However, these variables are not described in the patient-characteristics descriptive data section nor are they controlled for within the statistical analyses. Reporting of the data is incomplete.

Interpretation of Results

This study found no statistically significant between groups when comparing pain level scores between the experimental (TENS) group and the control (morphine) group. Reviewer calculated confidence intervals demonstrate a high level of overlap at all time points, confirming a lack of clinically meaningful difference between the two groups. This outcome suggests that TENS is as effective as morphine in reducing pain levels after a debridement procedure. A further analysis may reveal which method more rapidly takes effect. This knowledge may be important in cases of excruciating pain.

It should also be noted that although the VAS pain scale and VCS scale are considered a valid measures of pain, any self-report of an outcome can be skewed based on patient interpretation of both his/her pain level and of the assessment tool itself. Pain is a complex outcome with many factors that affect one's perception of pain at any given moment. This point is stated by the authors as well (Kimball 1987, p.30)

This study is clinically significant in that it supports a non-invasive, non-addiction forming alternative to reducing pain levels in burn patients after a debridement procedure. Only 24 patients were included

in this study, thus the reporting of means and standard deviations provides data that may be skewed due to the small sample size. As a result, findings should be interpreted with caution. It may have been more appropriate to report median and mode data, which are less likely to be influenced by the small sample size. Future studies should include larger sample sizes to produce adequate power to investigate the true effect of this intervention.
Summary/Conclusion
This study suggests that TENS may be as effective as morphine at reducing pain levels in burn patients after a debridement procedure. The investigators did not include information regarding burn depth, prior pain conditions, co-morbidities or co-occurring injuries, or additional medications. Controlling for these co-variants may yield a different outcome. Furthermore, baseline pain levels were not assessed prior to debridement procedure. If one group had a greater mean burn size or depth then that group's baseline pain level may have differed from the other. Further studies in this area are warranted in order to determine TENS effectiveness at reducing pain levels within the burn population.

SUMMARY OF BEST EVIDENCE

Table 3: Description and appraisal of (Randomized Controlled Trial-pilot study) by (Lewis, 1990)

Aim/Objective of the Study:
To determine if the use of bi-lateral auricular acupuncture-like TENS is more effective than a placebo pill in reducing pain experienced after a debridement procedure and dressing change.
Study Design
This study was a two-point cross-over randomized controlled trial. Eleven patients were randomized into two groups. Each subject received two treatments: one auricular acupuncture-like (high intensity, low frequency to six points on the ear) TENS treatment and one placebo pill treatment with a minimum of 24 hours and maximum of 5 days between each session. Both treatments were administered in the subject's room within 15 to 75 minutes after wound debridement. Patients maintained a supine position for 30 minutes post procedure regardless of intervention administered. Patients were informed that both interventions provided analgesic effects. The VAS was completed by each patient immediately before treatment, immediately after treatment and at 15minutes, 30minutes and 1 hour post treatment. The VAS administrator was unblinded.
Setting
University of Alabama Hospitals Burn Center; Birmingham, AL
Participants
Eleven patients were selected from among those admitted to the University of Alabama Hospitals' burn center. Inclusion criteria included: 1. burns that involved less than 35% TBSA, 2. No burns on face, neck and ears, 3. extremity burns, including hip/buttocks and shoulder/scapula, 4. pain experienced in the burned area of the extremity just before treatment, 5. no opiate pain medications taken at least 24hrs before treatment, 6. eighteen years or older. Fifteen subjects started the protocol. Two were discharged and one was transferred from the burn unit before the study was complete. The eleven subjects analysed ranged in age from 24 to 70 with a mean age of 43.3. TBSA ranged from 3% to 30% with a mean of 13%. The paper states that gender, date of injury, type and degree of burn as well as location of burn was also collected from the medical

records. However, the authors do not include these variables in the descriptive statistics section.

Patients were excluded if they were pregnant or had a cardiac pace maker.

Intervention Investigated

Control

Treatments were administered when the patient was deemed medically stable by hospital staff, was able to respond appropriately, and was not receiving any narcotic pain medications.

Patients responded to a brief medical history questionnaire prior to treatment and the baseline VAS was administered. Patients then received the debridement/dressing change procedure. The patient was returned to his/her room within 15 to 75 minutes post debridement procedure. This period of time was variable secondary to time it took to dress the wounds post debridement procedure and the availability of staff to transport patients. Upon return to his/her room, each patient received a placebo pill from a supine position and remained there until the 30 minute post-treatment VAS was administered.

Patients were asked to drink nothing but water during this time. They could return to normal daily activity after the 30 minute post-treatment VAS was completed. Investigators instructed patients to inform them if they participated in any strenuous or painful activities during the next 30 minutes. Patients received no pain management treatments other than the intervention during the debridement procedure or for 60 minutes after the procedure.

The VAS was administered (unblinded): immediately post procedure, 15min post, 30min post and 1hour post.

All treatments took place between 7am and 3 pm.

Experimental

Treatments were administered when the patient was deemed medically stable by hospital staff, was able to respond appropriately, and was not receiving any narcotic pain medications.

Patients responded to a brief medical history questionnaire prior to debridement procedure and the baseline VAS was administered.

Patients then received the debridement/dressing change procedure.

Upon return to his/her room, the patient received TENS within 15 to 75 minutes. This period of time was variable based on time it took to dress the wounds after the procedure and the availability of staff to transport patients. To reduce anxiety each patient was familiarized to the TENS sensation prior to treatment. A sample stimulation was applied to the patient's hand or forearm. The TENS was then placed on six auricular points of the ear: shenmen (a general analgesic point), lung, dermis, and three points on the ear specific to burn location (i.e. shoulder, elbow, wrist). Each patient received the treatment from a supine position for 15 minutes and remained in that position until the 30 minute post-treatment VAS was administered.

Patients were asked to drink nothing but water during this time. They could return to normal daily activity after the 30 minute post-treatment VAS was completed. Investigators instructed patients to inform them if they participated in any strenuous or painful activities during the next 30 minutes. Patients received no pain management treatments other than the intervention during the debridement procedure or for 60 minutes after the procedure.

The VAS was administered (unblinded): immediately post procedure, 15min post, 30min post and 1hour post.

All treatments took place between 7am and 3 pm.

Outcome Measures (Primary and Secondary)

Visual Analogue Scale (VAS): The VAS is a linear scale of pain levels from 0 (no pain) to 10

(unbearable, excruciating pain). Patients are asked to mark their current pain level from 0 to 10 along a horizontal line.

The patient's pain level was assessed by an unblinded clinician using the VAS immediately before the debridement procedure and upon return to his/her room after the procedure. Pain level was then assessed at 15minutes, 30minutes and 60minutes post procedure.

Main Findings

Table 1. Descriptive statistics of pain levels using Visual Analogue Scale (cm)

Time	Condition	Mean average	SD	Median	Max	Min
Pretreatment	E	7.5	1.9	8.0	9.7	3.5
baseline	C	6.8	2.6	8.0	9.6	2.2
0 Minutes	E	4.2	3.5	4.4	9.7	0.2
posttreatment	C	5.1	3.1	5.9	9.2	0.9
15 Minutes	E	3.4	2.9	2.8	9.5	0.1
posttreatment	C	4.6	3.3	5.6	9.1	0.2
30 Minutes	E	2.8	2.9	2.4	9.5	0.1
posttreatment	C	4.5	3.4	4.9	9.2	0.4
60 Minutes	E	2.5	2.8	2.2	9.5	0.1
posttreatment	C	4.3	3.5	3.3	9.1	0.4

E, Experimental (n = 11); C, control (n = 11); SD, standard deviation.

*The above table provides descriptive statistics of the pain levels recorded for both the experimental and the control groups using the Visual Analogue Scale. (Lewis 1990, p.326)

Reviewer calculated Confidence Intervals for each of the above VAS mean scores

Pre-treatment baseline	E: 6.38 to 8.62; C: 5.26 to 8.32
0 minutes post-treatment	E: 2.13 to 6.27; C: 3.27 to 6.93
15 minutes post-treatment	E: 1.69 to 5.11; C: 2.65 to 6.55
30 minutes post-treatment	E: 1.09 to 4.51; C: 2.49 to 6.51
60 minutes post-treatment	E: 0.85 to 4.15; C: 2.23 to 6.37

Table 3. Mean percent pain reduction using Visual Analogue Scale

	Mean percent pain reduction	
Time (min posttreatment)	Experimental (n = 11)	Control (n = 11)
0	48.2 (5)*	31.3 (1)*
15	57.7 (5)*	38.7 (2)*
30	65.8 (5)*	41.3 (2)*
60	69.8 (7)*	44.2 (2)*

*Numbers in parentheses indicate number of patients reporting >70% pain reduction.

*The above table provides the mean percent pain reduction for each post treatment VAS assessment for both groups. The numbers in the parenthesis indicate the number of patients who reported a reduction in pain greater than 70%. By the 60 minute pain assessment 7 of 11 TENS patients reported

at least a 70% reduction in pain level. Only 2 or 11 placebo patients reported at least a 70% reduction in pain level by the 60 minute assessment. (Lewis 1990, p. 327)

ANOVA results:

Treatment (E/C): F=1.053, p=.329

Time of measurement: F=29.384, p<.001

Treatment by time: F= 5.135, p=.002

A two-factor repeated measures ANOVA indicated a significant decrease in pain levels over time (p<.001) with a greater decrease noted in the TENS group compared to the control group (p=.002). A post hoc Tukey analysis revealed significant differences (p < 0.05) between experimental and control groups at all times after treatment (but not at pre-treatment baseline). These results suggest that auricular acupuncture-like transcutaneous electrical nerve stimulation may provide effective pain management in patients with burns.

Original Authors' Conclusions

The investigators concluded that acupuncture-like TENS to the ear provided greater pain relief than a placebo pill in burn patients with less than 35% TBSA after a debridement and dressing change procedure. This study indicates that this patient population may an appropriate population for the use of acupuncture-like TENS for pain reduction. However, the sample size used for this study is small; further research is needed in this area.

Critical Appraisal

Methodology

- Evidence level: 1b; A randomized controlled trial (pilot)
- Groups were randomly assigned and served as their own controls (cross over design)
- Administrators of the study were unblinded

Selection/Bias

- Subjects were selected among patients admitted the University of Alabama Hospitals' Burn Center
  - **NOTE:** Selection process is not defined
- The paper reports that age, gender, date of injury, and percent TBSA was collected. However, the authors do not provide the descriptive statistical data of the subjects.
- This is a pilot study. The sample is not large enough to decipher a true effect. Furthermore, all patients in the study have a burn less than 35% TBSA. These outcomes do not apply to patients with severe burns.

Pedro Score

- 8/11; the paper reports that subjects were randomly allocated, but does not indicate whether or not the allocation was concealed; the therapist were not blinded to the treatments; assessors of VAS were not blinded.

Missing Information

- Burn depth
- Co-morbidities or co-occurring injuries
- Prior pain conditions

- Exact TENS frequency and duration measurements are not defined
- Investigators do not report gender, degree of burn, time since injury; though they indicate that they collected this information.

Interpretation of Results

This study demonstrated statistically significant differences between pain level scores between the experimental (TENS) group and the control (placebo pill) group. This outcome suggests that acupuncture-like TENS is more effective than a placebo pill in reducing pain levels after a debridement procedure. However, the sample size in this study is small and all patients had burns less than 35% TBSA. Further study is warranted.

As stated before, though the VAS pain scale is considered a valid measure of pain, any self-report of an outcome can be skewed based on patient interpretation of both his/her pain level and of the assessment tool itself. Pain is a complex outcome with many factors that affect one's perception of pain at any given moment.

This study suggests that TENS may be a a non-invasive non-addiction forming alternative to reducing pain levels in burn patients after a debridement procedure. It should be noted that sample size for this study is not large enough to measure a true effect. Reviewer calculated confidence intervals for each time period post-treatment suggest there may be no difference in reported pain levels between the groups. A larger sample size is required to determine results.

Summary/Conclusion

This study provides evidence that acupuncture-like TENS may be more effective than a placebo pill at reducing pain levels in burn patients after a debridement procedure. The investigators did not include information regarding burn depth, prior pain conditions, co-morbidities or co-occurring injuries. Controlling for these variables may produce a different outcome. This was a pilot study; a larger sample population is necessary in order to determine a true effect. Further studies in this area are warranted in order to determine the effectiveness of acupuncture-like TENS at reducing pain levels within the burn population.

SUMMARY OF BEST EVIDENCE

Table 4: Description and appraisal of (Randomized Controlled Trial-pilot study) by (Hettrick, 2004)

Aim/Objective of the Study:

To determine if the conventional TENS (high-frequency, low intensity) in conjunction with standard of care (SOC) procedures is more effective than receiving only standard of care procedures in reducing pruritus in burn patients during the remodeling phase of wound healing.

Study Design

This study was a randomized controlled trial (pilot). Thirty outpatients patients were randomized into two groups (10 patients dropped out): TENS group (11) or control group (9). Patients of the TENS group performed conventional TENS (high frequency, low intensity) at home for one hour per day, seven days a week for three weeks in addition to standard of care which included: pressure garments, skin and scar lubricant, soft tissue mobilization, physical or occupational therapy and anti-itching medication. The patients of the control group received only standard of care procedures.

The TENS group was educated about how to self-administer TENS. They were provided all supplies needed. The TENS group was asked to document daily usage in a log as well as complete a VAS score assessment before and after TENS use.

The control group was instructed to complete the VAS assessment at home once daily.

Setting

William Randolph Hearst Burn Center at New York Presbyterian

Participants

Thirty outpatients were recruited from the weekly outpatient burn clinics at William Randolph Hearst Burn Center at New York Presbyterian.

Inclusion criteria included: 1. Male or female, 2. 18-75 years old, 3. Partial- or full-thickness burns that healed spontaneously or required skin grafting, 4. Complaints of severe pruritus that rated at least 5/10 on VAS scale, 5. Remodeling phase of wound healing (red, raised, rigid scar tissue with recent re-epithelialization)

Exclusion criteria included: 1. Electrical burns, 2. Pregnancy, 3. History of epilepsy, 4. Pacemaker

Thirty subjects started the protocol. Ten subjects withdrew or did not complete the study according to protocol (four in the control group, six in the treatment group). These patients were not included in the analysis.

The two groups did not differ from each other with respect to level of pruritus prior to the beginning of the study. (t= .11, df= 18, p= .92). The remainder of patient demographics are listed in the table below. No analysis was performed to determine variability based on the variables below.

Additional subject demographics

	Control Group	**Treatment Group**
Mean age	44.5	49
Patient sex	6 males; 5 females	6 males; 3 females
Ethnic distribution	4 African American	1 African American
	4 Hispanic	5 Hispanic
	3 white	1 white
		2 Asian
Skin grafting	8 subjects	6 subjects
TBSA, %	13	12

*(Hettrick 2004, p. 238)

Intervention Investigated

Control

The control group received standard of care procedures which included: pressure garments, skin and scar lubricant, soft tissue mobilization, physical or occupational therapy and anti-itching medication. This group was instructed to complete the VAS assessment once daily at the same time each day for 3 weeks at home.

Experimental

The TENS group was educated about how to self-administer TENS (verbal instruction and demonstration to determine competency). They were provided all supplies needed. The TENS group was instructed to document daily usage in a log as well as complete a VAS score assessment before and after TENS use. This group self-administered TENS at home for one hour a day(same time each day), seven days a week for three weeks using the conventional TENS dosage (high frequency defined

as >180Hz and low intensity). Subjects were instructed to choose the burn site that caused the most discomfort. That site was considered the target site for the entirety of the intervention. The electrodes were placed on or near the site for each treatment.

Outcome Measures (Primary and Secondary)

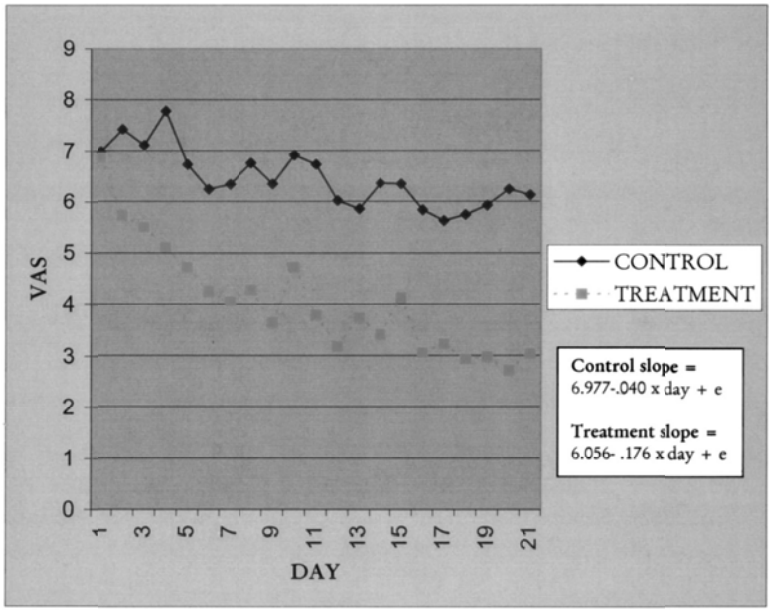
Visual Analogue Scale (VAS): The VAS is a linear scale of pain levels from 0 (no pain) to 10 (unbearable, excruciating pain). Patients are asked to mark their current pain level from 0 to 10 along a horizontal line.

The VAS was self-administered at home.

Main Findings

An ANOVA was used to analyse time trends in relation to VAS scores. The change in scores relative to time differed significantly between the groups (F= 5.96, df= 394, p<.02)

T tests were used to compare the slopes of the VAS mean scores of each group to 0:



Daily mean visual analog scale (VAS) scores; control vs treatment group. (Hettrick 2004, p.239)

-control group: t=-1.62, df=394, p=.11

-TENS groups: t= -3.51, df=394, p=<.02

The TENS group demonstrated a significant decrease in itch levels over the three weeks (p=.0086). The control group demonstrated a decreasing trend in itch levels over the three weeks. However, it was not significant.

Original Authors' Conclusions

The investigators concluded that conventional TENS + standard of care treatment provided greater itch relief than standard of care treatment only This pilot study indicates that the use of conventional TENS for itch reduction may be appropriate for this patient population. These results do not apply to children or adults over 75 years old or to those with burns that are not in the remodeling phase of wound healing. It should be noted that subjects in the TENS group reported their pruritus levels twice a day compared to the control group who reported scores once a day. This may have resulted in the

TENS group being more focused on their itch levels compared to the control group. Further study is warranted in this area.

Critical Appraisal

Validity

Methodology

- Level of evidence: 1b; A randomized controlled trial (pilot study)
- Groups were randomly assigned to TENS group or control group
- The intervention and VAS assessment was self-administered at home

Selection / Bias

- Subjects were recruited from the outpatient clinic at the William Randolph Hearst Burn Center at New York Presbyterian
  - **NOTE:** recruitment process is not defined
- This is a pilot study; effect size is not defined. The intervention and VAS assessment was self-administered by the subjects at home. Whether or not the treatment and/or the assessment were performed correctly at the same time daily cannot be determined.
- All of the patients continue to use anti-itch medications throughout the study. The frequency and application times of these medications were not recorded. It is unknown if these medications impacted the results.

Pedro Score

- 6/11; the paper reports that subjects were randomly allocated, but does not indicate whether or not the allocation was concealed; the therapists were not blinded to the treatments; assessors of the VAS were not blinded; the subjects were not blinded; the study did not provide both point measures and measures of variability for at least one key outcome

Missing Information

- Co-morbidities or co-occurring injuries
- Prior pain conditions
- Anti-itch medications are used by all patients. The authors do not record use frequency or application time
- Exact TENS intensity is not defined
- Statistical point measures/ measures of variability (CI, SD, SE, ranges etc)

Interpretation of Results

This study demonstrated statistically significant when comparing pain level scores between the experimental (TENS + SOC) group and the control (SOC only) group. This outcome suggests that conventional TENS + SOC may be more effective than SOC alone in reducing itch levels in outpatient burn subjects who experience pruritus during the remodeling phase of wound healing. However, this is a pilot study during which the intervention and VAS assessment were performed at home unsupervised. Furthermore, no standard deviations or confidence intervals were reported for this study. Further study is warranted.

As stated before, though the VAS pain scale is considered a valid measure of pain, any self-report of an outcome can be skewed based on patient interpretation of both his/her pain level and of the assessment tool itself. Pain is a complex outcome with many factors that affect one's perception of pain at any given moment.

This study is clinically significant, as it supports a non-invasive non-addiction forming alternative to reducing itch levels in outpatient burn subjects who experience pruritus during the remodeling phase of wound healing.
Summary/Conclusion
This study provides evidence that conventional TENS +SOC may be more effective than SOC alone in reducing pruritus levels in burn patients during the remodeling phase of wound healing. The investigators did not include information regarding burn depth, prior pain conditions, co-morbidities or co-occurring injuries which may impact outcomes. This was a pilot study. A larger sample population may be necessary in order to determine a true effect. Further studies in this area are warranted in order to determine the effectiveness of conventional TENS at reducing pain levels within the burn population.

Table [6]: Characteristics of included studies

	Study 1 [Kimball, 1987]	**Study 2 [Lewis, 1990]**	**Study 3 [Hettrick, 2004]**
Intervention investigated	TENS	Acupuncture-like TENS	TENS +SOC
Comparison intervention	morphine	Placebo pill	SOC
Outcomes used	VAS/VCS	VAS	VAS
Findings	No difference in VAS/VCS scores between groups	TENS groups demonstrated significantly less pain after procedure than placebo pill group	TENS group demonstrated significantly less pruritus than the control group.

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH

PRACTICE

- TENS is a non-invasive non-habit forming alternative to drugs (i.e. Analgesics or anti-histamines). Each of the studies presented in this review suggested that TENS may be an effective modality in reducing pain and pruritus among patients with burns.
- Multiple TENS units may be an expensive investment for some facilities. TENS units are likely not covered by insurance plans for the reduction of pain/pruritus post burn injury.
- TENS units are easy to use and may be self-administered at home.
- These studies were conducted among an adult population. Use of TENS in a pediatric burn population has not been investigated.

EDUCATION AND FUTURE RESEARCH

- Further study in this area is warranted based on the outcomes of the studies in this review. These studies use small sample sizes and most do not specify wound healing phase or details regarding TENS frequency and duration.
- A need exists for larger studies that explore the effect of TENS in conjunction with multiple variables such as burn depth, time post injury, age, ethnicity, wound healing phase, and percent of total body surface area burn.
- Future studies should investigate the effect of TENS at different frequencies, intensities and durations. Studies should investigate the effectiveness of acupuncture-like TENS vs. conventional TENS as well as the effects of TENS in children with burns.

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