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Aluminium foil for the prevention of post-amputation pain: a randomised, double-blinded, placebo-controlled, crossover trial

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Abstract

Introduction: Phantom limb pain (PLP) is a painful sensation perceived in the missing limb after amputation. The underlying pathophysiology remains unclear. Until recently, only opioid analgesics have been proven to be effective in prospective studies. Anecdotally, patients with PLP employ self-help measures, sometimes including 'wrapping up' or rubbing their stump with aluminium foil for relief. Our hypothesis is that wrapping an amputation stump with aluminium foil perioperatively will prevent PLP in the postoperative period.

Methods: From September 2007 to September 2009, 32 consecutive patients were included in a crossover, double-blinded, randomised clinical trial. Perioperative fitting of an aluminium stump bandage was compared with a placebo paper foil. Scores were noted daily in a variable diary. The observation period was 2 weeks: in the first week participants were double blinded, and in the second week there was a change of bandage from aluminium to placebo or vice versa. A visual analogue scale (VAS) score was used as primary research variable. Secondary variables were use of analgesics, VAS measures of wound pain and the incidence of wound infections. Statistical analysis was done by means of Student's *t*-test for non-paired observations.

Results: Baseline characteristics were similar between groups. A period effect (p= 0.84) and treatment–period interaction (p = 0.79) were not present. There was no significant difference (mean difference 0.42) between both treatments in PLP VAS scores (95% CI −2.56 to −1.81, p = 0.71). VAS measure of wound pain showed no significant difference between both groups (mean difference 0.34, 95% CI −2.32 to −1.66, p = 0.72). Also, the other secondary endpoints did not differ.

Conclusion: Patients receiving an aluminium foil stump wrapping do not experience less phantom pain than with a placebo.

Chronic pain musculoskeletal pain neuralgia pain pain management pain perception pain postoperative pain referred phantom limb

Introduction

Phantom limb pain (PLP) is a painful sensation perceived in the missing limb after amputation.[1] It must be differentiated from non-painful phantom phenomena and residual-limb pain (pain in the residual portion of the limb or stump).

The incidence of PLP varies from 50% to 90%,[2,3] but diminishes with time.[4] PLP is complex and multidimensional and the underlying pathophysiology remains unclear. Factors associated with PLP include lower leg amputation, amputation on both legs and preoperative pain.[4,5] In approximately 50%, the onset of PLP occurs within the first 24 hours. For another 25%, PLP begins within the first week and, in a minority of patients, the onset of PLP occurs many months, or even years, after amputation. [6]

The mainstay treatment for PLP is predominately pharmacological. However, most studies have been uncontrolled short-term assessments of small samples of patients.[7] A maximum benefit of about 30% has been reported from treatments such as surgical interventions (e.g. sympathectomy, rhizotomy), pharmacological approaches (e.g. nerve

blocks, local anaesthetics), physical therapy (e.g. ultrasound, transcutaneous electrical nerve stimulation [TENS]) and psychological treatments (e.g. psychotherapy, biofeedback, hypnosis). These reports of beneficial interventions have been generally supported by small research samples, flawed research designs, transient effects or below-expected rates of placebo response.[8,9]

As yet, only opioids have proven to result in pain reduction in a randomised trial.[10,11] Two trials have found a positive effect with the use of an electromagnetically shielding stump stocking interwoven with metal.[12,13]

Anecdotally, patients with PLP employ self-help measures, sometimes including 'wrapping up' or rubbing their stump with aluminium foil for relief. In our practice we have encountered multiple amputees claiming a benefit from this method. Also, entering 'tin foil AND phantom pain' or 'aluminium foil AND phantom pain' in an Internet search engine will yield several results, referring to blogs and personal websites describing patients' both positive and disappointing experiences with aluminium foil stump wrapping. The mechanisms underlying this supposed effect are unclear. In contrast to the metal interwoven stump stockings used in two prior investigations,[12,13] aluminium foil does not carry any ferromagnetic properties.

Our hypothesis is based on the experience of patients with established PLP who employ aluminium foil stump wrapping and claim relief from their symptoms. We hypothesised that wrapping an amputation stump with aluminium foil perioperatively will prevent or diminish phantom pain in the postoperative period.

Patients and methods

Thirty-two consecutive patients were included in a prospective single-centre, crossover, double-blinded, placebo-controlled, randomised clinical trial from September 2007 to September 2009 (Figure 1).

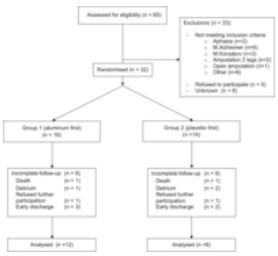

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Figure 1.

Trial flow diagram.

Inclusion criteria were as follows: consenting adults over the age of 18 years; the ability to communicate adequately; and a single lower extremity amputation due to peripheral vascular disease or diabetic neuropathy. Patients with a recurrent or second amputation or guillotine amputation were excluded. The randomisation was stratified by the level of amputation and diabetic neuropathy without macrovascular disease. After completing a preoperative pain questionnaire, patients were allocated to one of the two treatment groups, aluminium first or placebo first, using sealed opaque envelopes with computer-generated randomisation numbers. An independent research fellow performed the randomisation. The surgeon was informed about the randomisation outcome in the operating room. Stratification for amputation level and reason for amputation (critical ischaemia or diabetic neuropathy) were performed. Patients, nurses and residents on the ward were kept blinded to the allocated treatment sequence. The Medical Ethical Committee in the Onze Lieve Vrouwe Gasthuis Amsterdam approved this study (WO 07017).

Surgical technique

Skin closure was done with staples in all patients. Immediately after surgery, the patients had a stocking fitted to their amputation stumps. Each stocking was composed of a sterile wound dressing and a wrap of aluminium foil or paper, covered by a stump cotton wool bandage in the operating room. Qualities of the stocking – exterior view, size, weight, compression and lining – were identical.

Postoperative care

Postoperatively, all patients were treated equally with regard to feeding, pain regulation, mobilisation and postoperative care. The wound was inspected on day 5, on which patients and nursing staff were unblinded. The trial bandage was changed on day 7; patients with aluminium wrapping were given the placebo paper and vice versa. After 14 days the bandages were removed for final inspection and analysis. Pain medication

consisted of standard paracetamol 500 mg six times a day, or piritramide 10 mg or tramadol 50 mg three times per day, when demanded by the patient. The use of other analgesics and neuroleptics was avoided. The use of any analgesics was recorded prospectively.

Primary and secondary research variables

A visual analogue scale (VAS) measure of PLP served as the primary research variable, which was scored daily. Secondary variables were the use of analgesics, VAS measure of wound pain (scored daily) and the incidence of wound infections (scored on day 5 and 14). A mean VAS measure was calculated for both treatments. For the analysis the mean of the daily scores for aluminium bandage and placebo were compared. Incomplete follow-up was defined as three or more absent daily scores by any cause per treatment per patient.

Comorbidities present were diabetes mellitus (type 1 or 2), cardiovascular disease (angina pectoris or heart failure), chronic kidney disease (creatinine > 180 µmol/L), hypercholesterolaemia and hypertension. The manuscript was written with the Consort Statement as guidance.

Statistical analysis

Patients were analysed according to the intention-to-treat principle. A power analysis ($\alpha = 0.05$, $\beta = 0.2$) was based on the VAS score of PLP. A difference in two points on the VAS measure (± two standard deviations) between the two groups was considered as a clinical significant difference. This difference revealed that a sample size of 23 treatments had to be included in each arm. In anticipation of a drop-out rate of 10%, a group size of 30 in each treatment arm was considered necessary. Owing to the crossover design of this study, two groups of 15 patients were randomised into aluminium first or placebo first. Both treatments were compared using the chi-squared test or Student's *t*-test, one or two samples when appropriate. Association with the primary research variable was tested by means of analysis of variance (linear regression) and Pearson's correlation coefficient. A *p*-value of < 0.05 was considered statistically significant. For statistical analysis, the SPSS 17.0 (SPSS, Chicago, IL, USA) software package was used.

Results

Baseline characteristics are shown in Table 1. Fifteen right limbs and 17 left limbs were included. There were no differences between the two groups.

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Table 1.

Baseline characteristics.

First of all, a period effect was tested by a two-sample *t*-test in order to compare the differences between the treatment for 2 weeks in the two patient groups. Differences were excluded (confidence interval [CI] of the difference −1.68 to −1.39; $p = 0.84$). Also, no treatment–period interaction was present, excluding any interaction between the patients' average response, regardless of the order in which they were received, to the two treatments (95% CI of the difference −2.12 to −1.63; $p = 0.79$).

The mean difference in PLP score at the end of the study period was 0.42 points: aluminium scored slightly higher than PLP (Table 2). However, this was not significant. Also, VAS measures of wound pain at the end of the study period did not show any significant difference between both groups. There was no association between PLP and wound pain ($p = 0.32$, using Pearson's correlation test). In the entire study population, three patients did not experience any PLP and two patients had a mean VAS measure higher than 4. There were no predictive factors associated with PLP (linear regression analysis).

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Table 2.

Results at the end of the study period.

On day 5 (wound inspection) patients treated with aluminium foil experienced more PLP and wound pain, the latter difference being significant (95% CI 0.27–3.36, $p = 0.023$). The rate of uncomplicated wound healings did not differ between both groups ($p = 0.31$). Three patients underwent a second amputation due to wound infections.

In the entire study population, eight patients received morphine analgesics, two patients

experienced epidural analgesia, seven patients required tramadol hydrochloride and the remaining patients used paracetamol. There was no significant difference between both treatments in use of analgesics ($p = 0.69$).

Discussion

We demonstrated that patients who received an aluminium foil stocking experienced a mean of 0.42 VAS points higher for PLP than placebo in the immediate postoperative period. This difference was not statistically significant. Also, there was no difference in wound pain, use of analgesics, wound healing or stump infections over the complete study period.

These results contrast with two randomised trials investigating local stump care in order to prevent PLP, reporting significant differences using a metal-interwoven stump liner.[12,13] Kern et al.[13] performed a double-blinded, crossover trial in a total of 30 leg amputees, comparing a stump stocking interwoven with metal with a dummy. Each stump stocking was worn for 2 weeks after a 2-week baseline period without a stocking. Stump stocking interwoven with metal versus reduced pain significantly more often than the dummy stocking (77.3% vs. 36.4%, respectively; $p < 0.008$). Conine et al.[12] used a linen fabric with ultra-thin steel threads (Farabloc) worn over the stump. In this second randomised, double-blinded, crossover trial, 34 patients reported their pain relief level on a VAS during a pretreatment period; Farabloc or placebo treatment period; no-treatment or 'washout' period for the control of any carry-over effect; and an alteration in treatment period. The results were statistically significant ($p < 0.001$) in favour of the Farabloc period. Of the 34 subjects, 21 reported their greatest pain relief during Farabloc intervention.

Another single-blinded, crossover study in untrained subjects on delayed-onset muscle soreness demonstrated significantly reduced pain, strength loss and serum inflammatory markers when double Farabloc wrapping of the thigh after exercise was compared with placebo fabric.[14] These research studies have not determined the mechanism by which Farabloc reduced PLP or delayed-onset muscle soreness. The possible explanation for our negative results is the use of aluminium instead of a ferrous metal. If changes in the electromagnetic field are assumed to have an analgesic effect, aluminium will fail because of the absence of ferromagnetic properties. Farabloc is made of 9.5% steel wire consisting of iron, nickel and chromium, all of which have ferromagnetic properties.

Chronic pelvic pain, whiplash injuries and lumbar radiculopathies also responded favourably to electromagnetic fields.[15⇓–17] In patients with complex regional pain syndrome type 1, however, a beneficial effect could not be demonstrated.[18]

Whereas several small, randomised, controlled studies have reported a reduction in the proportion of patients with PLP when additional epidural anaesthesia was used before and during surgery, one large randomised controlled study found no beneficial effect on PLP.[19] Epidural analgesia use was equally divided in our patients, so this did not disturb the outcomes.

Descriptive studies have identified factors that may contribute to the development of PLP: the degree of preamputation pain, below knee amputation, bilateral amputation, acute postoperative pain (including pain due to proinflammatory processes) and psychological factors.[4,5,20]

PLP has a negative effect on quality of life (QoL) and is related to depressive symptoms.[21,22] A recent systematic review found a summary quality score of 50% or more in 10 studies, with the maximum being 81%.[23] However, these 15 cross-sectional studies and four prospective studies were found to be heterogeneous with respect to the study objectives and instruments used to assess QoL. Additionally, some obscurities were found in the methodological aspects and study population characteristics of most of these studies.

At the moment, only opioids have shown proven efficacy in randomised trials in the treatment of PLP,[10,11,24] with a pain reduction of more than 50% in more than 40% of patients. This supports the theory that PLP originates from the central nervous system.[25] Accordingly, the key to success is influencing cortical reorganisation and preventing or extinguishing a pain memory. Flor and Birbaumer[26] maintained that defective stump information is likely to generate ectopic discharge from the posterior root ganglion, consequently resulting in PLP.

Our study has limitations. First, blinding was interrupted at day 5, because of the regular wound inspection. Second, 12 of 32 patients could not be analysed for the primary variable. This was because of early hospital discharge, complications (delirium) and death (Figure 1). Five patients were lost to follow-up. The fact that this study is therefore underpowered unfortunately weakens our conclusions and may warrant further investigations on this topic in a larger sample of patients. Considering all patients – including those who failed to meet the inclusion criteria – we can conclude that we investigated a patient group with severe morbidity. Third, the preoperative pain score was (non-significantly) lower in the patients who started with the aluminium foil. A type 2 error, however, is unlikely, because although pain scores were lower in the aluminium-first group, postoperatively they tended to be higher during aluminium treatment.

In conclusion, there are small, non-significant differences in the perception of PLP and

wound pain in favour of placebo foil stocking over aluminium foil after a lower limb amputation. There is a tendency for increased wound pain. The use of aluminium foil stump wrapping in wound bandages for lower leg amputations for the reduction of PLP cannot be recommended based on the results of this study.

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