

Original Article

A randomised controlled trial examining the effect of acupuncture at the EX-HN3 (Yintang) point on pre-operative anxiety levels in neurosurgical patients[‡]

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Summary

Pre-operative anxiety is an unpleasant state of psychological distress that occurs in up to 87% of patients awaiting neurosurgical procedures. Sedative medication is undesirable in this population due to the need for early post-operative neurological assessment. Acupuncture has previously been shown to reduce pre-operative anxiety, but studies involving neurosurgical patients are lacking. This single-centre, prospective, randomised controlled trial was designed to determine the effect of acupuncture at the EX-HN3 (Yintang point) on pre-operative anxiety levels in neurosurgical patients. The study was prospectively registered before participant recruitment. After measuring baseline anxiety levels, 128 patients were randomly allocated in a 1:1 ratio by a web-based computer program to receive either acupuncture at the EX-HN3 (Yintang) point (acupuncture group) or no intervention (control group). Participants were not blinded, but all analyses were performed by a member of the research team who was unaware of the group allocation. The primary outcome measure was anxiety level after 30 min, as measured by the six-item short form of the State-Trait Anxiety Inventory (possible score range 20–80). Sixty-two patients in each group were subsequently analysed. Median (IQR [range]) anxiety State-Trait Anxiety Inventory score reduced significantly in the acupuncture group (46.7 (36.7–53.3 [23.3–70.0]) to 40.0 (30.0–46.7) [20.0–53.3]), $p < 0.001$, with no change seen in the control group (41.7 (33.3–53.3 [20.0–76.7]) to 43.3 (36.7–50.0 [20.0–76.7]), $p = 0.829$). There were no adverse events in either group. Acupuncture at the EX-HN3 point reduces pre-operative anxiety levels in patients awaiting neurosurgery.

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Introduction

Pre-operative anxiety is an unpleasant state of psychological distress that affects 24–73% of patients awaiting surgery [1, 2]. The anxiety may start as soon as the

surgical procedure is planned and tends to increase over time, reaching its maximal level on admission to hospital [3]. In addition to its undesirable psychological effects, high levels of pre-operative anxiety have

been associated with reduced patient satisfaction [4], increased risk of postoperative nausea and vomiting (PONV) [5], and increased incidence of acute [6] and chronic [7] postoperative pain.

Neurosurgical patients have a higher incidence of pre-operative anxiety than other surgical populations, with studies suggesting that over 87% of patients awaiting intracranial [8] or spinal [9] procedures suffer from anxiety. The administration of anxiolytic medication, such as benzodiazepines, has been the traditional method for reducing pre-operative anxiety. However, in neurosurgical patients, in whom early assessment of neurological function is important, the ‘hang-over’ effect of such agents is undesirable.

Acupuncture has been investigated as a non-pharmacological method for reduction of anxiety. A recent meta-analysis suggested that acupuncture at the EX-HN3 (Yintang) and HT7 (Shenmen) points appeared to be an effective way of rapidly treating anxiety before medical procedures [10], although none of the studies included any neurosurgical patients. The aim of this study was to examine the effect of acupuncture at the EX-HN3 point on anxiety levels in neurosurgical patients immediately before surgery.

Methods

Following ethical approval, all patients aged ≥ 16 years presenting for neurosurgery between October 2015 and March 2016 were screened for enrolment. The study protocol and reporting were prepared according to the revised Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [11]. We did not study patients with any of the following conditions: inability to provide consent; pregnancy; contraindications to acupuncture; psychiatric conditions; previous experience of acupuncture; planned use of acupuncture for PONV prophylaxis; and use of any sedative medication in the 24 h before admission. After gaining written informed consent, all participants completed the six-item short form of the State-Trait Anxiety Inventory (STAI-S6) and Amsterdam Pre-operative Anxiety and Information Scale (APAIS) questionnaires in order to assess baseline anxiety levels before any intervention. The STAI-S6 is a standardised short form of the 40-item Spielberger State-Trait Anxiety Inventory that

has three anxiety-present and three anxiety-absent questions (Table 1). Scores from the STAI-S6 are prorated up to allow comparison with the full version of the questionnaire, with scores ranging from 20 (low anxiety) to 80 (high anxiety). The STAI-S6 has been shown to correlate well with the full version [12], but it is much quicker for participants to complete, which is advantageous in time-restricted studies. The Amsterdam Pre-operative Anxiety and Information Scale has four questions relating to anxiety (APAISa, Table 2) and has been shown to correlate well with the full version of the State-Trait Anxiety Inventory [13]. The scores from the anxiety elements of the questionnaire are added together, giving a possible total score of 4 (low anxiety) to 20 (high anxiety).

Table 1 Shortened six-item State-Trait Anxiety Inventory (STAI-S6) questionnaire. The scores for each answer are added together, giving a possible total score of 6–24. The total score was divided by 6 (the number of items) and multiplied by 20 to give a prorated score between 20 and 80 for purposes of comparison.

| | Not at all | Somewhat | Moderately | Very much |
|--------------|------------|----------|------------|-----------|
| I feel calm | 4 | 3 | 2 | 1 |
| I feel tense | 1 | 2 | 3 | 4 |
| I feel upset | 1 | 2 | 3 | 4 |
| I am relaxed | 4 | 3 | 2 | 1 |
| I am content | 4 | 3 | 2 | 1 |
| I am worried | 1 | 2 | 3 | 4 |

Table 2 Amsterdam Pre-operative Anxiety and Information Scale. Patients respond to the six questions using a five-point Likert scale, where 1 represents ‘not at all’ and 5 ‘extremely’. The scores from the anxiety elements of the questionnaire (questions 1, 2, 4 and 5) are added together giving a possible of total score of 4–20.

1. I am worried about the anaesthetic
2. The anaesthetic is on my mind continually
3. I would like to know as much as possible about the anaesthetic
4. I am worried about the procedure
5. The procedure is on my mind continually
6. I would like to know as much as possible about the procedure

Participants were randomly allocated to treatment groups in a 1:1 ratio using a web-based randomisation service (www.sealedenvelope.com). A randomly permuted blocks method was used to minimise any learning effect in acupuncture technique. All participants had been seen and assessed by their attending anaesthetist and neurosurgeon before any intervention. Participants who were assigned to receive acupuncture (acupuncture group) then underwent a single acupuncture session. This consisted of the insertion of a press-stud needle (0.2 mm × 1.5 mm Seirin Pyonex; Seirin Corporation, Shizuoka City, Japan) at the EX-HN3 (Yintang) point (Fig. 1), in conjunction with standardised information in the form of a spoken script (Appendix 1). All acupuncture was delivered by a single member of the research team (JM) who had been trained by a clinician with extensive acupuncture experience. The 'de qi' or needling sensation was not targeted during the acupuncture. Participants were told to manually stimulate the needle every 10 min by applying digital pressure in small, circular movements to the press-stud. The needle was left in place for 30 min and then removed. The STAI-S6 and APAISa questionnaires were then completed for a second time. No further intervention occurred before surgery, and



Figure 1 Location of the EX-HN3 (Yintang) acupuncture point (shown with an acupuncture needle in place).

all treatments took place at the patient's bedside in the theatre admissions unit. Participants assigned to the control arm had no intervention, but waited at their bedside (control group) for 30 min before completing the anxiety questionnaires for a second time. In both groups, intra-operative management (including provision of analgesia and anti-emetics) was left to the discretion of the attending anaesthetist.

The primary outcome measure was change in anxiety level, as measured by STAI-S6 score, after 30 min of acupuncture versus a non-intervention control. Secondary outcome measures included the following: change in anxiety level, as measured by the APAISa; patient reported postoperative pain scores in the post anaesthetic care unit (PACU), classified as none/mild or moderate/severe pain; opiate requirements in PACU; and incidence of PONV in PACU.

Pilot study data from neurosurgical patients in our institution found a mean (SD) pre-operative STAI-S6 score of 29.5 (14.7). Previous work has suggested that acupuncture may reduce anxiety levels by 25–37%, with a recent meta-analysis considering a 30% reduction in STAI-S6 score to be clinically significant [14]. In order to demonstrate a 30% reduction in STAI-S6 score with 90% power and 5% level of significance, we required 58 patients in each group. Allowing for a 10% dropout rate, we planned to recruit 128 patients in total. Data analyses were performed using SigmaStat v 3.1 (Systat Software, San Jose, CA, USA). After assessment of normality of distribution, anxiety scores were compared using Wilcoxon signed-rank test, with postoperative pain scores and opiate requirements in the PACU analysed using Fisher's exact test.

Results

In total, we recruited 128 patients to the study, of whom 124 (62 in each group) were analysed for the primary outcome measure (Fig. 2). The groups were well matched in terms of baseline characteristics and anxiety levels (Table 3). Within the population, 62/124 patients (50%, 33 in the acupuncture and 29 in the control group), could be classified as having significant anxiety (defined as APAISa \geq 10) [13].

Median (IQR [range]) anxiety level at 30 min (as measured by STAI-S6) reduced significantly in the acupuncture group: 46.7 (36.7–53.3 [23.3–70.0]) to

40.0 (30.0–46.7 [20.0–53.3]), $p < 0.001$, with no change seen in the control group: 41.7 (33.3–53.3 [20.0–76.7]) to 43.3 (36.7–50.0 [20.0–76.7]), $p = 0.829$. A similar reduction was seen in median (IQR [range])

APAI Sa level in the acupuncture group, but not in the control group: 10 (6–13 [4–20]) to 7 (4–10 [4–18]), $p < 0.001$ vs. 9 (6–13 [4–18]) to 8.5 (6–12 [4–18]), $p = 0.872$, respectively.

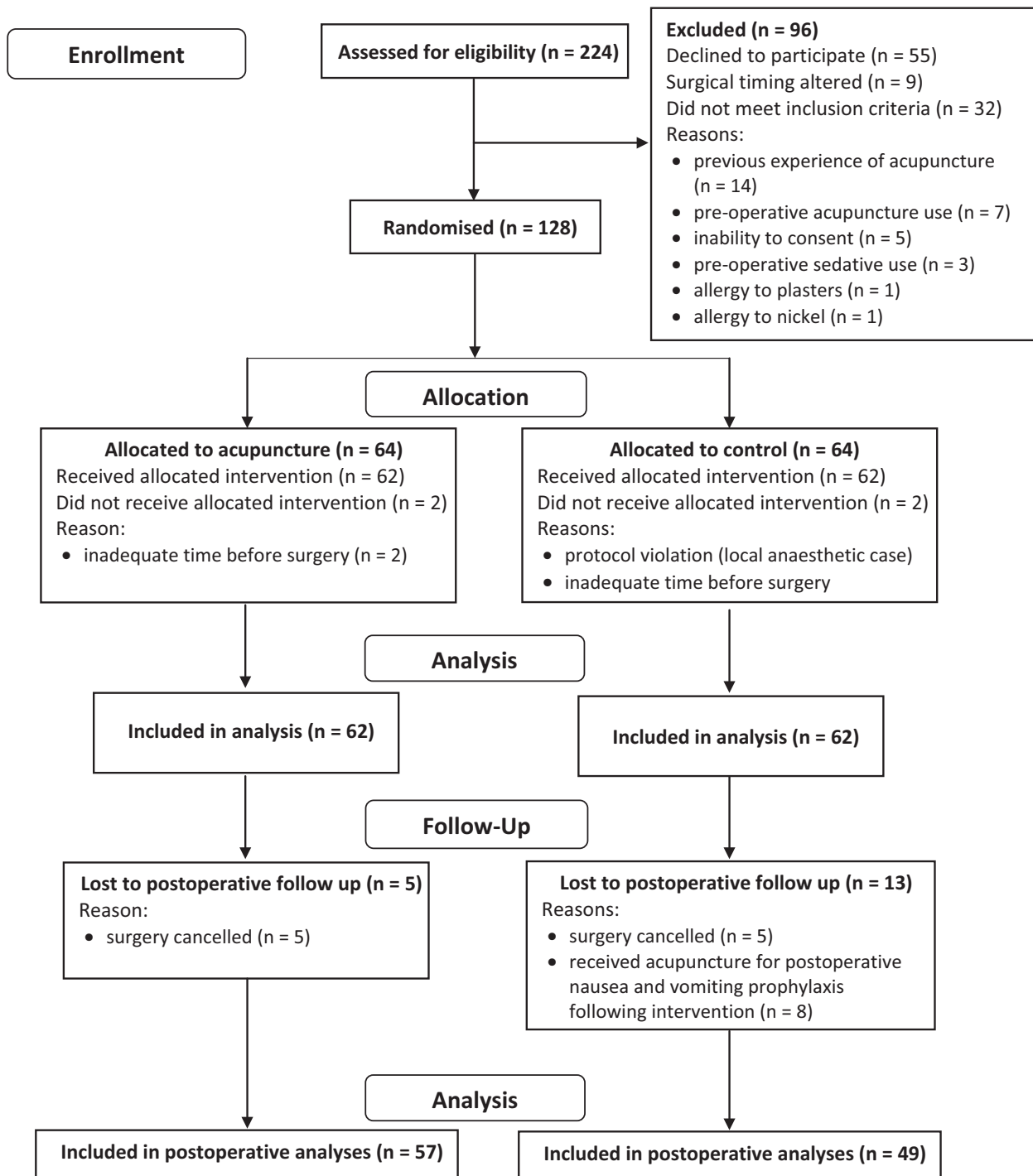


Figure 2 CONSORT flow diagram.

Table 3 Characteristics of neurosurgical patients receiving acupuncture or no treatment (control) for anxiolysis before surgery. Values shown are mean (SD), median (IQR [range]) and number.

| | Acupuncture group n = 62 | Control group n = 62 |
|------------------------|------------------------------|------------------------------|
| Age, years | 55 (13.6) | 54 (17.5) |
| Sex, female | 36 | 32 |
| Height, cm | 167 (11.0) | 168 (9.4) |
| Weight, kg | 83 (19.2) | 79 (20.6) |
| Cranial:spinal surgery | 19:43 | 29:33 |
| STAI-S6 | 46.7 (36.7–53.3 [23.3–70.0]) | 41.7 (33.3–53.3 [20.0–76.7]) |
| APAISa | 10 (6–13 [4–20]) | 9 (6–13 [4–18]) |

STAI-S6, Shortened State-Trait Anxiety Inventory; APAISa, Anxiety elements of the Amsterdam Pre-operative Anxiety and Information Scale.

The number of patients experiencing moderate/severe pain in PACU was similar in both groups (acupuncture group 28/57 vs. control group 21/49, $p = 0.520$). Opioid administration rates in PACU were also similar, with 26/57 in the acupuncture group and 21/49 in the control group receiving morphine and/or fentanyl ($p = 0.846$).

The incidence of PONV was very low in both groups: 2/57 in the acupuncture group and 1/49 in the control group ($p = 1.000$).

There were no adverse events reported in any of the patients who received acupuncture.

Discussion

We have shown that 30 min of acupuncture at the EX-HN3 point resulted in a 14% and 30% reduction in pre-operative anxiety levels (as measured by the STAI-6 and APAISa questionnaires, respectively) in patients awaiting neurosurgical procedures. A large proportion of our study cohort were anxious, with 50% having APAISa ≥ 10 , which is similar to other studies of neurosurgical patients; Perks et al. found 55% of their patients had a pre-operative APAISa score ≥ 10 [8]. The overall mean STAI scores were also similar to other neurosurgical studies [15, 16], suggesting our cohort is representative of the neurosurgical patient population. The high anxiety levels were present despite the patients having already been seen and assessed by both their caring anaesthetist and surgeon, which has previously been shown to decrease pre-operative anxiety [3, 17, 18]. There was a greater proportional reduction in anxiety levels when measured using the APAISa rather than the STAI-6.

Although the full Spielberger State-Trait Anxiety Inventory is considered the gold standard for anxiety measurement, the APAISa has excellent correlation with this (Cronbach's α 0.84) [3]. It has the advantage of being quicker to complete, and it is the only anxiety measure specifically designed for use in the pre-operative setting. It could be argued, therefore, that we should have only used the APAISa scale in our study to measure anxiety. However, as the majority of previous studies investigating pre-operative anxiety have used the Spielberger State-Trait Anxiety Inventory, we used this scale to allow comparisons between studies to be made more easily. While the Spielberger State-Trait Anxiety Inventory is considered to be the gold standard for measuring general anxiety levels, there is no consensus about what assessment tool is best for measuring pre-operative anxiety. We did observe different patterns of anxiety levels between the two measurement scales; when measured by the STAI-6 score, anxiety levels fell in the acupuncture group, and increased (although not significantly) in the control group. In contrast, the APAISa scores decreased in both groups, although this fall only reached statistical significance in the acupuncture group. This may suggest that the two assessment tools have a different distribution of scores that are not adequately reflected by the median values. However, if mean (SD) values are considered for both measurement tools and analysed using a paired t-test (as the mean and median values were similar, and the data not highly skewed), then anxiety levels only decreased in the acupuncture group, with control group values unchanged; STAI: acupuncture 44.95 (10.8) to 37.85 (9.94), $p < 0.001$ vs. control

43.98 (14.8) to 43.76 (13.7), $p = 0.80$; APAISa acupuncture 10.13 (4.26) to 7.76 (3.75), $p < 0.001$ vs. control 9.48 (3.80) to 9.37 (3.84), $p = 0.63$. This suggests that the decrease in anxiety was due to a true difference between the interventions and was not affected by the measurement tool used.

A recent meta-analysis on the use of acupressure for the management of anxiety concluded that acupressure was an effective anxiolytic, with a 'medium' treatment effect size observed [10]. This review included five randomised controlled trials ($n = 314$), but two of the studies examined anxiety in patients during transport, as opposed to before surgery. In addition, none of the studies recruited neurosurgical patients, and none were undertaken in the United Kingdom. The latter point is of interest, as cultural beliefs and expectations (which will vary between different societies and populations) have been shown to influence the magnitude of the treatment effect seen with acupuncture [19]. To this end, we have demonstrated that acupuncture is a useful tool for managing pre-operative anxiety, and is effective even when administered in a busy pre-operative environment by a non-specialist practitioner (in the present study, a third-year medical student).

The precise mechanism by which acupuncture exerts its anxiolytic effect has yet to be determined. Functional MRI imaging has suggested that acupuncture decreases activity in the limbic system, amygdala and hypothalamus [20]. This suggests that the observed anxiolysis may be either due to a direct, central sedative effect or by attenuation of the sympathetic nervous system response. Further work is needed to further clarify the underlying mechanism and locate the optimal acupuncture point for anxiety reduction.

There was no difference between acupuncture and control in our secondary outcome measures of postoperative pain scores and incidence of PONV. The choice of regimen for postoperative analgesia was decided by the attending anaesthetist, and was therefore not standardised between groups; the study was also not powered to detect any difference in this end-point. A meta-analysis has suggested that acupuncture is associated with a small reduction in early postoperative pain intensity, but none of the included studies used the

EX-HN3 acupuncture point [21]. Acupuncture at the PC6 point has been shown to reduce the incidence of PONV [22]; however, in our study, the rate of PONV was very low in both groups. This is likely to be due to the widespread use of total intravenous anaesthesia, which is the standard anaesthetic technique for neurosurgery at our institution.

Our study has some limitations that require discussion. First is the use of a non-intervention control as opposed to using sham acupuncture. The major issue in interpretation of clinical acupuncture research has been the focus on finding a true sham and the misguided attribution of clinical significance to the difference between real and sham effects. Of greater benefit is a pragmatic comparison with usual care, in this case, no other anxiolytic. This decision was made after careful consideration and discussion with experts in the field of acupuncture (Dr Adrian White, personal communication). Sham acupuncture may not be as inert as has previously been believed, with some claiming that it has a direct physiological action [23, 24]. Any needling of the skin induces a mild painful stimulus, which is an identical effect to that produced by 'true' acupuncture at a recognised point. A meta-analysis of 32 trials showed that sham acupuncture had a moderate effect size, compared with no acupuncture (standardised mean difference in outcome measure 0.45, 95% CI 0.57–0.34) [25], and as such had the potential to be a confounding factor in randomised controlled trials. Two trials investigating acupuncture for anxiety have utilised non-intervention control and sham acupuncture [26, 27]. Both demonstrated reductions in anxiety with the use of sham acupuncture, but not in the non-intervention control (although to a lesser degree than that seen with acupuncture at a recognised point). It is possible that the administration of acupuncture in the intervention group may have acted as distraction therapy, and this could have contributed to the observed reduction in anxiety levels. However, the period of intervention was very short, with the patient instructions and application of the acupuncture needle taking less than 1 minute, with the remainder of the study period being identical in both groups. It is likely, therefore, that any distraction which did occur was minimal, and was unlikely to have impacted on anxiety levels 30 min later. Second, the participants

could not be blinded to the chosen intervention, which may have introduced bias. It is impossible to measure the specific effect of sham acupuncture, since there is no potential for a blinded control. All data analyses were, however, done by a member of the research team blinded to the group allocation. Third, as we only recorded anxiety scores after 30 min, we have not determined the duration of the anxiolytic effect of acupuncture; future work could investigate this, which would allow the optimal time for acupuncture administration to be identified. Finally, the magnitude of the effect of acupuncture on anxiety was not as great as we had anticipated when undertaking our power calculation. On the basis of previous work, we had anticipated a 30% reduction in anxiety levels when measured by STAI-6. Although acupuncture resulted in a 30% reduction in APAIS scores, STAI-6 anxiety scores only decreased by 17%, meaning that the study was not powered to 90% as we had planned; a post hoc calculation showed that 69 patients in each group would have been required for our population with our population who had a mean (SD) STAI-6 score of 44 (12.9). However, the study was still adequately powered (greater than 80%, 51 patients required in each group), so a type-2 error is unlikely.

In summary, acupuncture at the EX-HN3 reduces anxiety levels in patients awaiting neurosurgical procedures. As acupuncture is a cheap, well-tolerated procedure that is simple to administer and has no prolonged effect on conscious levels, it should be considered a useful therapy for the anxious patient in the immediate pre-operative period.

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Appendix: Standardised script of explanation given to neurosurgical patients receiving acupuncture at the EX-HN3 (Yintang) point

‘Acupuncture is the needling of points on the body which can promote health and well-being. The point we are using in our study is known as the Yintang point located between the eyebrows and is used for relaxation. The needle is very small and attached to a plaster (*investigator shows an example of the press-stud needle*). You shouldn’t feel a thing, but you may experience some sensations such as tingling or warmth, and you should begin to feel calm and relaxed. It is very safe, with only a small chance of bruising. We will leave the needle in for 30 minutes. You are free to do what you like in this time, but we advise that every 10 minutes or so you use your finger to apply pressure in a circular motion for about 1 minute. I will return after the 30 minutes are up to remove the needle before your surgery and ask you to complete a second set of questionnaires’.