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Wrist acupressure for post-operative nausea and vomiting (WrAP): A pilot study

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Summary Post-operative nausea and vomiting are undesirable complications following anaesthesia and surgery. It is thought that acupressure might prevent nausea and vomiting through an alteration in endorphins and serotonin levels. In this two-group, parallel, superiority, randomised control pilot trial we aimed to test pre-defined feasibility outcomes and provide preliminary evidence for the efficacy of PC 6 acupoint stimulation vs. placebo for reducing post-operative nausea and vomiting in cardiac surgery patients. Eighty patients were randomly assigned to either an intervention PC 6 acupoint stimulation via beaded intervention wristbands group ($n = 38$) or placebo sham wristband group ($n = 42$). The main outcome was assessment of pre-defined feasibility criteria with secondary outcomes for nausea, vomiting, rescue anti-emetic therapy, quality of recovery and adverse events. Findings suggest that a large placebo-controlled randomised controlled trial to test the efficacy of PC 6 stimulation on PONV in the post-cardiac surgery population is feasible and justified given the preliminary clinically significant reduction in vomiting in the intervention group in this pilot. The intervention was tolerated well by participants and if wrist acupressure of PC 6 acupoint is proven effective in a large trial it is a simple non-invasive intervention that could easily be incorporated into practice.

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Introduction

The burden of caring for patients post cardiac surgery in the Australian healthcare system is huge, with the Australian Institute of Health and Welfare (AIHW) annual report identifying that around 179,000 procedures of the cardiovascular system were performed between 2011 and 12.[1] Cardiovascular disease is one of the major expensive disease groups in Australia, costing about $7.9 billion in 2008—2009, with over half of this spent on patients admitted to hospital.[2] Reported rates of post-operative nausea and vomiting (PONV) for cardiac surgery patients vary. Studies from the 1990s through to 2014 indicate that the incidence of PONV post cardiac surgery has remained high, with rates reported from 26% to 54.1%,[3–6] and a Korean study finding 71% in the placebo arm of a trial testing the efficacy of ondansetron and ramosetron in reducing PONV.[7]

Patients rank nausea the fourth and vomiting the most undesirable of 10 negative post-operative outcomes[8] and patient dissatisfaction with anaesthetic care is strongly related to PONV.[9] PONV can delay transfer from the recovery unit by up to 20 min,[8] and also delay hospital discharge or result in readmission. Vomiting can produce imbalances in body electrolytes, cause bleeding and place tension on sutures and wounds[8] and disrupt absorption of medications resulting in dysrhythmias, fluid volume overload and pain leading to post-operative complications for cardiac surgery patients.[3] Patients may also be reluctant to actively participate in post-operative recovery activities such as mobilising, and deep breathing if they have PONV.[3] It is also reported that cardiac surgery patients can experience persistent gastrointestinal symptoms including nausea up to 4—6 weeks post surgery.[3] A systematic review has concluded that PONV is reported to affect around 80 of every 100 individuals and that if all 100 were given an antiemetic about 28 would benefit.[10] Evidence suggests that acupressure might limit PONV associated with anaesthesia/PONV.[11]

Acupressure has been practised for centuries and is a traditional Chinese medicine based on life energy (Qi) flowing through channels in the body known as meridians.[12] Acupressure, it is posited, restores equilibrium to disturbances affecting the body's homeostasis by stimulating specific points (acupoints) that link meridians to body organs.[12] The mechanism for the action of acupressure has not been scientifically investigated fully, but it is thought that it may prevent nausea and vomiting through alterations in serotonin and endorphin levels.[13] Stimulation of the PC 6 acupoint for treating nausea and vomiting was reported in the early 1990s.[14] The World Health Organisation (WHO) endorses acupressure as a therapeutic intervention[15] and a consensus on acupuncture point locations was reached by WHO (Western Pacific Regional Office) and guidelines published.[16] The PC 6 acupoint is the meridian point in the pericardium channel, located on the inner forearm between the extensor carpi radialis and palmaris longus tendons, one sixth of the distance from PC 7 on the medial wrist crease to PC 3 in the cubital fossa.[16] For this current study the PC6 acupoint was determined by measuring the distance between the palmar wrist crease and inner forearm with a tape measure, and placing the bead on the wristband between the two tendons a sixth of the distance measured. This method is much more accurate than the previously used procedure of using the three middle fingers on the inside of the patient's wrist to measure distance.

PC 6 acupoint can be stimulated using a range of methods (e.g. acu-stimulation device, acupressure, acupuncture, capsicum plaster), however stimulation of the *correct* acupoint is the crucial issue.[11] A recent Cochrane systematic review and meta-analysis of 40 trials totalling 4858 participants reported a clear positive effect of PC 6 acupoint stimulation on nausea (RR 0.71, 95% CI: 0.61—0.83); vomiting (RR 0.70, 95% CI: 0.59—0.83); and, need for rescue anti-emetics (RR 0.69, 95% CI: 0.57—0.83).[11] There was however heterogeneity of studies in this review with studies conducted in various clinical settings and with different populations, suggesting that, 'on average', the intervention is known to be effective. The report of the quality of the studies reviewed indicated concerns regarding allocation sequence generation and allocation concealment.

There is an evident need for a large rigorously designed and implemented placebo-controlled RCT to test the efficacy of PC 6 stimulation on PONV in the post-cardiac surgery population. Undertaking a feasibility study initially, however ensures that such a subsequent larger trial is methodologically rigorous, feasible, and economically justifiable.[17,18] As such, this pilot study purpose was to obtain reference data, test feasibility, obtain effect estimates and identify potential problems[19] that could feedback to and inform the design of a future definitive research protocol.

Materials and methods

Design

The WrAP pilot study was a two-group, parallel, superiority, RCT that randomly assigned post-operative adult cardiac surgery patients to PC 6 acupoint stimulation via a beaded wrist band or no stimulation using a sham non-beaded wrist band. The participants were post-operative adult cardiac surgery patients. Feasibility outcomes were defined a priori as: Eligibility: ≥75% of patients screened will be eligible; Recruitment: ≥70% of eligible participants will agree to enrol; Protocol fidelity: ≥95% of participants in intervention group will have their wristbands correctly positioned for 36 h post admission to the ICU: Retention: <15% of patients will be lost to follow up; Missing data on occurrence of PONV: <10%. As well as the feasibility outcomes, outcomes in relation to post-operative nausea or vomiting (PONV) were defined as well as the need for rescue anti-emetic therapy. The primary end point was the occurrence of nausea (on a 10 point scale — see Table 2) or vomiting (retching or vomiting) within 36 h of the end of surgery. Secondary endpoints were the need for rescue anti-emetic therapy and post-operative nausea or vomiting (PONV) outcomes categorised into early (≤16 h) and late (>16 h including repeat events). Finally quality of recovery was assessed on the morning of the fourth post-operative day. The Consolidated Standards of Reporting Trials (CONSORT) guideline,[20] with its official extension of Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA),[21] was used to guide the study design and reporting of results.