Comparison of the wrist acupuncture point P6 with pharmacological management to prevent postoperative nausea and vomiting in patient's under laparotomy: a double blind study

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Abstract

Background and Aims: Acupuncture as an available alternative medicine could be effective for some problems such as postoperative nausea and vomiting (PONV).

In high risk patients, the incidence of PONV has been even reported as 70% leading to prolonged hospital stay and need for preventive pharmacologic medication.

We aimed to assess effectiveness of this method, in comparison to common medications, to prevent PONV in these patients.

Methods: This was a randomized double-blinded prospective clinical trial study. 100 scheduled patients who were candidates for elective laparotomy were randomly assigned into two groups: control group (pharmacological) receiving metoclopramide in combination with dexamethasone and acupuncture group receiving P6 acupuncture bilaterally.

Results: The overall prevalence of PONV in the acupuncture group was 4% and in the control group was 2% without significant difference (p = 0.588). In the multivariate regression model and with the presence of baseline variables including gender, type of anesthetic agents, operation time, and recovery time were recorded.

No difference was detected between the prevalence of PONV between acupuncture and pharmacological combination therapy groups (OR = 1.679, 95%CI: 0.122 – 23.076, P = 0.698). Common complications such as tachycardia, local pain, or skin allergy were not detected in any of the study groups.

Conclusion: Single insertion of acupuncture needle could have similar effectiveness on preventing PONV as the pharmacologic combination of metoclopramide and dexamethasone, however due to the side effects of multi medications especially drugs that are used for general anesthesia, the use of acupuncture could be preferred.

Key words: acupuncture, laparotomy, PONV

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Introduction

Despite visible progression in prevention and control of postoperative nausea and vomiting (PONV), the overall prevalence of this complication has remained high (1,2).

In high-risk patients, the incidence of PONV has even been reported as 70% (2) leading to prolonged hospital stay and requiring hospitalization in intensive care units as well as a high cost burden. Also, PONV is considered to be a postoperative unfavorable event resulting in high patient dissatisfaction especially in patients under laparotomy.

Regarding pathophysiology of PONV, stimulation and activation of four neural receptors including cholinergic, dopaminergic, histaminic, and serotonergic receptors has been revealed (3,4).

In this line, the main mechanisms of more applicable drugs for preventing PONV are based on affecting these receptors (5-7). Among these, high dose metoclopramide has been successfully used in managing chemotherapy-related nausea. However, because of its potential side effects, the use of a low dose of this drug has been more recommended, but without therapeutic effects in most previous studies (8). Besides, various alternative treatments such as acupuncture have been paid more attention, but with unknown cause of effects on PONV.

According to the importance of presenting a cost-benefit method with minimizing side effects for preventing PONV, the application of alternative methods such as acupuncture is now hopeful(9-14).

According to the advantages of acupuncture regarding its low cost and also low complications, we aimed to assess effectiveness of this method in comparison to common pharmacologic medications to prevent PONV in patients who are undergoing laparotomy.

Methods

In a randomized double-blinded clinical trial prospective study, 100 scheduled patients who were candidates for laparotomy during a one year period in our center were assigned in this study, after fulfilling the eligibility criteria and signing the informed consent.

Inclusion criteria include all patients who were candidates for elective laparotomy , aged between 18 and 70 years old, (ASA) physical status classification of I or II, undergoing general anesthesia, no history of PONV or motion sickness, no use of antiemetic 24 hours before surgery, willing to participate and who signed an informed consent form were eligible for this study

The main exclusion criteria were opium use, drug misuse or alcohol dependency, history of neurological or psychological disorders, the presence of local wound infection or scar at the site of acupuncture needle entry in wrist , age less than 18 years or more than 70 years, or existence of disorders with acute or chronic nausea or vomiting, or prolonged surgery longer than 2 hours, nausea or vomiting 24 hours before surgery, pregnant or lactating women, recipients of chemotherapy or radiation therapy during the previous 7 days, and refusal to accept acupuncture.

Baseline characteristics including demographics, duration of surgery, length of recovery stay, type of anesthetics, presence of PONV during recovery time and method of preventing PONV, were recorded.

The included patients were randomly assigned according to computer-generated in balanced block randomization and an independent researcher randomly allocated the patients to either of the two study groups following induction of anesthesia.

The patients and investigator who was collecting the data were all blinded to the study groups, the control group (receiving metoclopramide in combination with dexamethasone) and the case group (receiving acupuncture).

In the case group, acupuncture was induced by entering a specific needle at P6 point anterior to wrist nearly 30 minutes before end of surgery.

P6 point was set on anterior to forearm at 2 cm of transverse ‘carpal crease’ between tendons of flexor carpi radialis and Palmaris lungus muscles.

For the acupuncture group, after skin cleaning with 75% alcohol swab, sterile and disposable stainless steel needles (0.25 × 25 mm, China) are quickly and perpendicularly inserted into the skin at P6 acupoints bilaterally to a depth of 10 mm. In this group, downward pressure and upward lifting combined with twirling the needle was used.

The needles were kept in place for 30 minutes and manipulated manually every 10 minutes to maintain the de qi sensation. When the treatment time was over, all needles were carefully taken out and the puncture sites covered with sterile swabs to avoid bleeding. The control groups received intravenous metoclopramide (10 mg) and dexamethasone (8 mg) after beginning surgery and also the same site of P6 was covered with sterile swabs for blinding.

The study period for each case was 24 hours after the surgery. A nurse researcher who was not involved in the patients management recorded anesthesia time, surgery time, endotracheal intubation time, patient demographics and preoperative data for each patient.

Demographic and preoperative data included: age, gender, race, weight, height, acupuncture experience, Smoking history.

Another blinded observer recorded the postoperative data, which included administration of a rescue antiemetic, patient satisfaction with PONV management, and episodes of vomiting or nausea at postoperative period.

During recovery time, the blinded researcher assessed the patients regarding PONV and side effects of used medications, after fulfilling the eligibility criteria and signing the informed consent.

Nausea is a subjective sensation which should be evaluated by the patient, not by the observer. Thus, the observer requested the patients to evaluate their nausea score using a standard visual analogue scale (VAS) (0, no nausea at all; 10, worst imaginable nausea). Vomiting, which is defined as the ejection of contents of the stomach through the mouth, was reported by the patients and assessed by the blinded observer.

Data were analyzed by the statistical software SPSS version 20 for windows (SPSS Inc, Chicago IL). Quantitative variables were presented as mean standard deviation, and categorical variables were presented by absolute frequencies and percentages. Continuous variables were compared using t test. Whenever the data did not appear to have normal distribution or when the assumption of equal variances was violated across the group, Mann-Whitney U test was used. Categorical variables were compared using chi-square test. Fisher exact test was used when more than 20% of cells with expected count of less than 5 had been observed. The multivariate logistic regression analysis was used to assess difference in response rate between the two treatment methods with the presence of baseline characteristics. P values of ≤ 0.05 were considered statistically significant.

Results

In this study, 50 patients were treated with acupuncture and 50 with combination pharmacological drug therapy including metoclopramide and dexamethasone. There was no difference in male distribution between the two groups (32% versus 26%, p = 0.509).

Regarding anesthesia protocol, in the acupuncture group, 56% received propofol and 44% received nesdonal, while in the other group, 36% received propofol and 64% were anesthetized using nesdonal (p = 0.45). The mean of operation time in the acupuncture group was 85.50 ± 4.87 minutes and in the control group was 85.00 ± 4.04 minutes with no significant difference (p = 0.578).

Also, mean of recovery time was not different between acupuncture and control groups (19.30 ± 1.75 minutes and 19.1± 1.94 minutes (p = 0.890).

The overall prevalence of PONV in the acupuncture group was 4% and in the control group was 2% without significant difference (p = 0.588).

In the multivariate regression model and with the presence of baseline variables including gender, type of anesthetic agents, operation time, and recovery time, no difference was found between the prevalence of PONV between acupuncture and drug combination therapy groups (OR = 1.679, 95%CI: 0.122 – 23.076, P = 0.698). Common complications such as Tachycardia, local pain, or skin allergy were not detected in any of the study groups.

Discussion

Our study could potentially confirm that acupuncture point P6 stimulation is an effective adjunct similar to the pharmacologic antiemetic drug therapy for the prevention of PONV in patients undergoing laparotomy with just P6 acupuncture points bilaterally for 30 minutes without any electrical stimulation. This is the same result of Jian-qin Lv et al. in 2013 (15) in craniotomy patients.

The results of this study showed no difference in the prevalence of PONV between the two groups which confirms the result of study of Reza Rastegari et al. (16) In fact, the overall prevalence of PONV in the acupuncture and control group was 4% and 2% respectively which was considerably lower than that reported previously (20% to 30%). This be due to a 'placebo effect' induced by the covering on the P6 point.

Also, the effect of acupuncture on preventing PONV was similar to the combination of two common drugs including metoclopramide and dexamethasone that was consistent with other studies.

Chen et al. (17) found that the effect of acupuncture and ondancetrone on laparoscopic-related PONV was similar. In Cheong et al. (18) meta-analysis, acupuncture type P6 point significantly reduced vomiting within 6 hours of surgery and nausea within 24 hour of surgery.

Holmer and colleagues (19) showed that using acupuncture point stimulation before surgery can effectively prevent nausea, but not vomiting occurrence in comparison with oral medications.

In another study, Ouyang et al. (20) indicated that in different study time points, the rate of PONV ranged between 2 to 12 % in the acupuncture group and 2 to 28% in the control group with a significant difference.

Grupe(21) also showed lower postoperative pain as well as lower PONV in acupuncture than in the control group. Finally, Streitberger et al. (22) showed that stimulating with acupuncture could potentially reduce PONV.

In total, considering the side effects of metoclopramide and dexamethasone and according to the similarity of the effects of acupuncture and these two drugs, the use of acupuncture point stimulation can be a suitable alternative for preventing PONV in different types of surgeries.

In conclusion, single insertion of an acupuncture needle could have similar effectiveness on preventing PONV, the same as a pharmacologic combination of metoclopramide and dexamethasone, however due to the side effects of medications, the use of acupuncture point stimulation is preferred.

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