

Effect of P6 acustimulation on post-operative nausea and vomiting in patients undergoing a laparoscopic cholecystectomy

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Background Non-pharmacologic techniques such as electrical acustimulation may mitigate post-operative nausea and vomiting (PONV). The primary purpose of this study was to investigate the effectiveness of acustimulation on attenuating PONV. Moreover, we tested whether a pre- or a post-induction application of acustimulation results in differences in PONV reduction.

Methods In this prospective, double-blind, randomized, controlled trial, we studied 200 patients undergoing a laparoscopic cholecystectomy during propofol (induction) fentanyl/isoflurane/atracurium (maintenance) anaesthesia. In the acustimulation group ($n = 101$), subdivided into groups with pre-induction ($n = 57$) and post-induction ($n = 44$) acustimulation, an active ReliefBand[®] device was placed at the P6 acupoint. In the sham group ($n = 99$), also subdivided into pre-induction ($n = 55$) or post-induction ($n = 44$) groups, an inactive device was applied instead. The ReliefBand[®] remained in place for 24 h after surgery. Nausea and vomiting/retching were recorded at 2, 6, and 24 h post-operatively.

Results The incidence of early nausea (up to 2 h) was significantly lower in the acustimulation than in the sham group (29% vs. 42%; $P = 0.043$). No significant effect could be detected for retching/vomiting. Moreover, acustimulation showed no effect on PONV after 6 and 24 h. Risk factor analysis (female gender, non-smoker, history of PONV/motion sickness, and post-operative morphine usage) revealed a relative reduction in risk of 40% for nausea ($P = 0.021$) and 55% for retching/vomiting ($P = 0.048$) in patients with three or four risk factors present. The timing of (pre- vs. post-induction) acustimulation had no significant effect on PONV reduction.

Conclusion Acustimulation at the P6 acupoint reduces early nausea, but not vomiting, after laparoscopic cholecystectomy, irrespective of its pre- or post-induction application.

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POST-OPERATIVE nausea and vomiting (PONV) occurs in up to 30% of unselected patients and is the most frequent side effect after anaesthesia.^{1,2} Pharmacological prevention and treatment is able to reduce PONV to approximately 30%,³ with potential side effects of the drugs given.⁴ Different studies have shown that stimulation at the P6 acupuncture point is associated with a decreased PONV incidence.^{5,6} We have recently shown that acustimulation is able to significantly decrease all qualities of PONV in patients undergoing vaginal hysterectomy.⁷ Interestingly, we observed the highest PONV-reducing effect in patients who were at a high risk for PONV. However, in another study investigating patients undergoing a laparoscopic cholecystectomy, electrical stimulation at the P6 acupuncture point reduced only nausea but not

vomiting.⁸ Furthermore, a recent report demonstrated that unilateral stimulation of the P6 acupuncture point for assessment of neuromuscular blockade reduced nausea to the highest extent in the early post-operative period.⁹

Finally, optimum timing of acustimulation is still a matter of debate. Although it was suggested and we were able to show⁷ that pre-operative vs. post-operative acupoint stimulation made no difference in the incidence of PONV, one study suggested the best effect in reducing PONV when stimulation was administered after surgery.¹⁰

Accordingly, to evaluate the effects of the P6 acupuncture point on the incidence of PONV in patients undergoing a laparoscopic cholecystectomy, we performed a double-blind, randomized, prospective, and controlled study. Specifically, we

tested the primary hypothesis that acustimulation results in a reduction of all qualities of PONV (i.e., nausea and retching/vomiting). We also tested the secondary hypothesis that a pre- or a post-induction application of acustimulation results in differences in PONV reduction.

Finally, we tested whether acustimulation results in PONV reduction independent of known risk factors (female gender, non-smoker, history of PONV/motion sickness, and post-operative morphine usage) using a univariate and multivariate approach.

Methods

Sample size estimation

The sample size calculation was based on the PONV incidence within the first 6 h after surgery and was based on our previous study.¹ In that study, we found an incidence of early PONV (i.e., within the first 6 h after the operation) in the sham group of 55% and an incidence of 33% in the acustimulation group, respectively. We, therefore, defined this 40% relative risk reduction of PONV as a clinically relevant target of a potential antiemetic prophylaxis by P6 acustimulation for the present study and cohort. This indicated that including 176 patients would provide an 80% power to identify a statistically significant difference between the groups at a two-tailed α -level of 0.05 (type I error). Accordingly, to allow a margin of 'statistical safety', we aimed to include a total of 200 patients in the study.

Study design

For this single centre, prospective, randomized, double-blind study, we obtained approval from the ethic committee of the University of Duisburg-Essen and patients' written, informed consent before participation. Female and male patients older than 18 years with an ASA class I–III were eligible if scheduled to undergo a laparoscopic cholecystectomy requiring general anaesthesia. Exclusion criteria were patients with a cardiac pacemaker or implanted cardioverter/defibrillator, patients at risk for malignant hyperthermia, patients with an allergy to nickel/chrome, and change in surgical technique. Demographic and morphometric data as well as the risk factors that may influence PONV (e.g., PONV history, smoking history) were collected pre-operatively from the patients' records and by interviewing patients during the consenting procedure.¹¹

Patients were randomly allocated to four different groups: (A) Acustimulation starting before induction of anaesthesia ($n = 57$), (B) acustimulation starting directly after induction of anaesthesia ($n = 44$), (C) sham acustimulation starting before induction of anaesthesia ($n = 55$), and (D) sham acustimulation starting directly after induction of anaesthesia ($n = 44$), as determined by drawing a sealed envelope indicating treatment assignment. The investigators responsible for collecting data were blind to the treatments administered to the patients.

Acustimulation was provided by a commercially available device, the ReliefBand[®] (Woodside Biomedical, Carlsbad, CA, USA). The ReliefBand[®] is a non-invasive, FDA-approved, portable (34 g), battery-powered (two 3 V lithium coin cells), watch-like acustimulation device and capable of applying current at 31 Hz up to 35 mA gradable in five strengths. The skin contact surface has two flat metal electrodes through which electrical stimulation is applied transcutaneously. Both the active and the sham ReliefBand[®] devices were applied in the induction room to the P6 acupoint on the dominant upper extremity, located approximately 2–3 cm proximal to the distal wrist crease between the tendons of the flexor carpi radialis and the palmaris longus.¹² Sham ReliefBand[®] devices were prepared by inactivating the electrodes with a silicone cover, which was invisible for both patients and investigators. The ReliefBands[®] were activated (31 Hz, strength grade III) either before induction or directly after induction of anaesthesia depending on patients' group assignment and remained *in situ* and active for 24 h after surgery.

A standardized anaesthesia regimen was followed. Premedication was carried out with midazolam 7.5 mg orally on the day of surgery. General anaesthesia was induced with propofol (1–2 mg/kg i.v.), fentanyl (1 μ g/kg i.v.), and atracurium (0.5 mg/kg i.v.), and was maintained by isoflurane 0.8–1.6% endtidal in nitrous oxide (60–70%) at the discretion of the anaesthesiologist not involved in the study. All patients received 0.1 mg/kg morphine i.v. during surgery 30 min before the end of the operation. Analgetic therapy with morphine was continued in the post-anaesthetic care unit (PACU). A rescue therapy of 2 mg tropisetron was administered to any patient who experienced an episode of moderate or severe nausea, an episode of vomiting, or who requested rescue medication.¹³

Data collection

Morphine and tropisetron administration was recorded for 24 h in the PACU as well as on the ward.

Patients were evaluated for the occurrence of nausea, retching, vomiting, pain, and potential side effects of the ReliefBand[®] (skin irritation under the electrodes) by an investigator unaware of the patients' group assignment at the following intervals: 2 h in the PACU, and at 6 and 24 h according to recommendations for PONV trials.^{11,14,15} Nausea, vomiting, and retching were categorized (0 = no episode, 1 = at least one episode) and collected at 2, 6, and 24 h after surgery. Vomiting was defined as expulsion of stomach contents and retching as an involuntary attempt to vomit but not productive of stomach contents.

Statistical analysis

All data are presented as means (\pm standard deviation) until otherwise indicated. Parametric variables were compared using an unpaired Student's *t*-test. Categorical variables were compared using the χ^2 test. We used a multivariate binary logistic regression model to calculate odds ratios (ORs), 95% confidence intervals (CI), and *P*-values for the risk of PONV. PONV was defined as at least one episode of nausea, retching, or vomiting. Logistic regression analysis was performed in a stepwise backward manner using age, gender, body mass index, anaesthesia duration, post-operative morphine usage, smoking status, history of PONV, history of motion sickness, and acustimulation as covariates. Differences were considered statistically significant with an alpha error *P* of <0.05 . All statistical analyses were performed using two-sided tests and the software SPSS, version 15.0 (SPSS, Chicago, IL).

Results

We screened a total of 260 patients. A flow diagram of patients' recruitment is given in Fig. 1. Two hundred patients completed the study protocol. The demographic and morphometric characteristics and factors likely to influence PONV were not significantly different in the acustimulation and sham groups as were intraoperative variables (Table 1). There was a significant difference between acustimulation and placebo patients in experiencing early (up to 2 h) PONV (defined as at least one episode of nausea, retching, or vomiting). The incidence of early PONV was significantly lower in the acustimulation group compared with the sham group (30% vs. 43%; relative risk reduction: 31%; *P* = 0.031). Accordingly, the number needed to treat to prevent early PONV with acustimulation was 6.7. However, no significant PONV-

reducing effect of acustimulation could be detected for 6 h as well as for 24 h. Moreover, the requirement for rescue medication did not differ significantly between the treatment groups.

When we investigated the acustimulation effect on different PONV qualities, we could show that acustimulation was effective only on early nausea and resulted in a relative risk reduction of 33.9% for early nausea (Table 2, *P* = 0.043). There was no significant difference regarding nausea or vomiting/retching in the group of acustimulation pre-induction compared with post-induction (Fig. 2).

We next investigated whether established risk factors for PONV (female gender, non-smoker, history of PONV or motion sickness, and post-operative morphine requirement) as defined by Apfel¹⁶ influenced the effect of acustimulation (Fig. 3). Given that all patients received post-operative morphine therapy, the lowest score that could be achieved was 1. Figure 2 shows the proportions of the development of different PONV qualities in relation to all patients with symptoms. Using this approach, we could show that acustimulation was effective to mitigate early nausea (relative risk reduction 40%, *P* = 0.021; Fig. 3A) in patients with three to four risk factors. Interestingly, acustimulation was also effective in mitigating retching/vomiting when three to four risk factors were present (relative risk reduction 55%, *P* = 0.048; Fig. 3A). No significant acustimulation effect could be observed after 6 and 24 h (Fig 3B and C).

Finally, we investigated in a multivariable model including age, gender, body mass index, anaesthesia duration, post-operative morphine usage, smoking status, history of PONV, history of motion sickness, and acustimulation which risk factor or method is most capable of PONV prevention. Using a logistic regression analysis for the occurrence of PONV, we could show that for 2 h, no history of PONV (OR 0.4, 95% CI 0.2–0.8, *P* = 0.007), male gender (OR 0.4, 95% CI 0.2–0.9, *P* = 0.029), and acustimulation (OR 0.5, 95% CI 0.3–0.9, *P* = 0.033) were independent predictors for risk reduction of PONV. For 6 and 24 h, only no history of PONV (OR 0.3, 95% CI 0.2–0.6, *P* = 0.001) and male gender (OR 0.3, 95% CI 0.1–0.6, *P* = 0.001) were independent predictors for risk reduction of PONV.

Discussion

In the present study investigating patients undergoing a laparoscopic cholecystectomy, we show

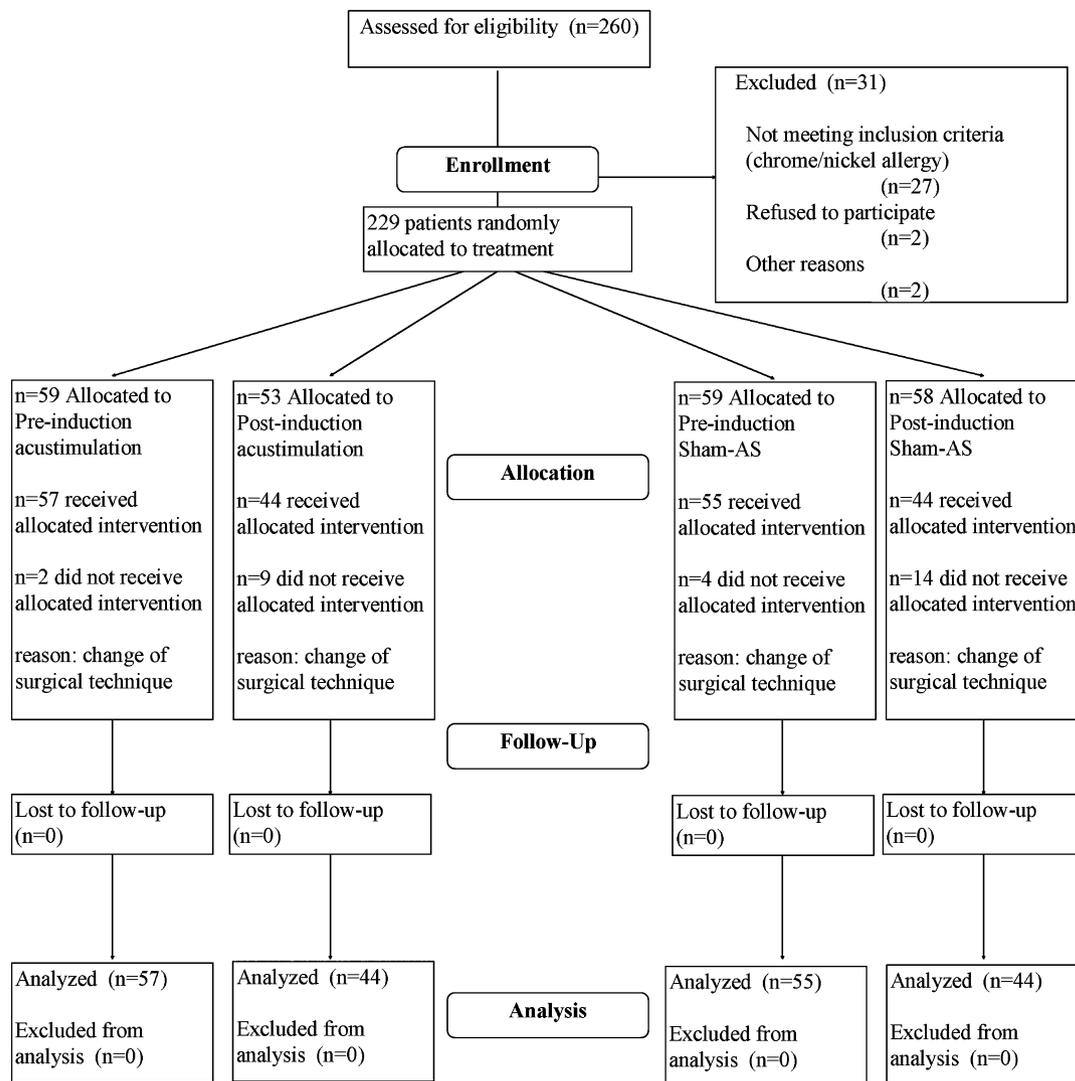


Fig. 1. Flow diagram of the acustimulation study comparing P6 acustimulation pre- and post-induction with sham acustimulation. The diagram includes detailed information on the intervention received. AS, acustimulation.

that acustimulation is effective in reducing the incidence of PONV in high-risk patients. We found an acustimulation-related relative risk reduction of 31%, which is comparable to other studies showing a relative reduction of PONV by 25%⁹ and consistent with the effect of well-established drug treatments.^{17,18} However, the PONV-reducing effect was only detectable in the early post-operative period (up to 2 h) while no PONV-reducing effect was seen later. Moreover, subgroup analysis regarding the different PONV qualities revealed that acustimulation was more effective in reducing nausea than in decreasing retching and vomiting. Finally, we could show that acustimulation was effective in preventing PONV regardless of whether applied of pre- or post-induction, thus

arguing against a patient’s bias. Our results, therefore, confirm in a mixed population of patients undergoing a laparoscopic cholecystectomy our former study investigating women undergoing vaginal hysterectomy in that we could show the highest acustimulation effect in high-risk patients and a more pronounced effect on nausea compared with retching/vomiting.⁷

The effectiveness of acustimulation for influencing nausea and vomiting is still a matter of debate. We could show a relative risk reduction for nausea in the whole group while acustimulation was significantly effective in the reduction of retching or vomiting only when three to four risk factors were present. This supports former studies showing better effects of acustimulation on nausea than on

vomiting. In our former study investigating the acustimulation effect in 200 women undergoing vaginal hysterectomy, we could demonstrate a relative risk reduction for nausea with at least three risk factors while acustimulation was significantly effective in the reduction of retching or vomiting only in the presence of four risk factors.⁷ In a recent report involving a nerve stimulator for acustimulation at the P6 point, Arnberger et al.⁹ found a significant antinausea effect but failed to demonstrate a significant decrease in the incidence of vomiting. These findings were also obtained in a study by Rusy et al.,¹⁹ who found a reduction in nausea but not emesis in paediatric patients. Finally, a study by Zarate et al.,⁸ also investigating patients undergoing a laparoscopic cholecystectomy, demonstrated an antinausea effect of acusti-

mulation without any effect on vomiting. However, the lack of a significant antiemetic effect with this acustimulation device may have been related to a sample size that was too small (because the prevalence of post-operative vomiting is much less than of post-operative nausea).

Our results indicate that acustimulation reduced PONV in patients at a high risk for PONV (i.e., when three or more risk factors for PONV were present, Fig. 2). In the higher risk group, we observed a relative risk reduction of 40% for nausea and of 55% for retching/vomiting while the relative risk reduction in the whole group was 34% for nausea and 38% for retching/vomiting. In the moderate-risk group, i.e., patients with only one to two risk factors, no clear treatment effect could be detected. A possible reason for this ob-

Table 1

Patient characteristics, duration of surgery and anaesthesia, and risk scores for post-operative nausea and vomiting (PONV), according to acustimulation or sham acustimulation.

	Acustimulation (n = 101)	Sham (n = 99)
Age (years)	54.7 ± 14.3	54.3 ± 15.6
Female sex (%)	73.3	67.7
Height (cm)	168.6 ± 8.9	168.5 ± 7.9
Weight (kg)	81.0 ± 16.4	80.2 ± 14.7
Anaesthesia duration (min)	91.0 ± 26.0	94.4 ± 24.1
Surgical duration (min)	63.1 ± 22.5	66.3 ± 20.9
Duration of acustimulation therapy (h)	25.2 ± 0.9	25.3 ± 0.8
Smokers (%)	32.7	22.2
History of motion sickness (%)	27.7	29.3
History of PONV (%)	25.7	28.3
Risk score for PONV (%)		
1*	8.9	4.0
2*	26.7	29.3
3*	37.6	43.4
4*	26.7	23.2

*Sum of risk factors (female gender, history of motion sickness or PONV, non-smoking status, post-operative morphine therapy).

Table 2

Relative risk reduction of acustimulation compared to sham acustimulation.

	Acustimulation (%)	Sham (%)	Relative risk reduction (%)	OR	95% CI	P-value
Nausea						
2 h	28.7	42.4	33.9	0.55	0.30–0.98	0.043
6 h	51.5	44.4	–15.8	1.33	0.76–2.31	0.319
24 h	40.6	43.4	6.5	0.89	0.51–1.56	0.684
Retching or vomiting						
2 h	11.9	19.2	38.1	0.57	0.26–1.24	0.153
6 h	41.6	33.3	–24.1	1.42	0.80–2.53	0.228
24 h	29.7	21.2	–40.0	1.57	0.82–2.98	0.168

P-values refer to χ^2 tests.

OR, odds ratio; CI, confidence interval.

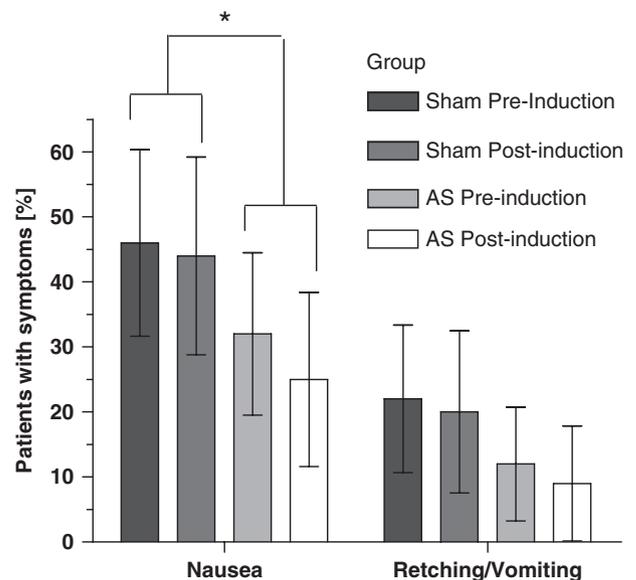


Fig. 2. Effect of acustimulation on nausea and retching/vomiting after 2 h. Data are presented as mean ± 95% confidence interval; AS, acustimulation; *P < 0.05.

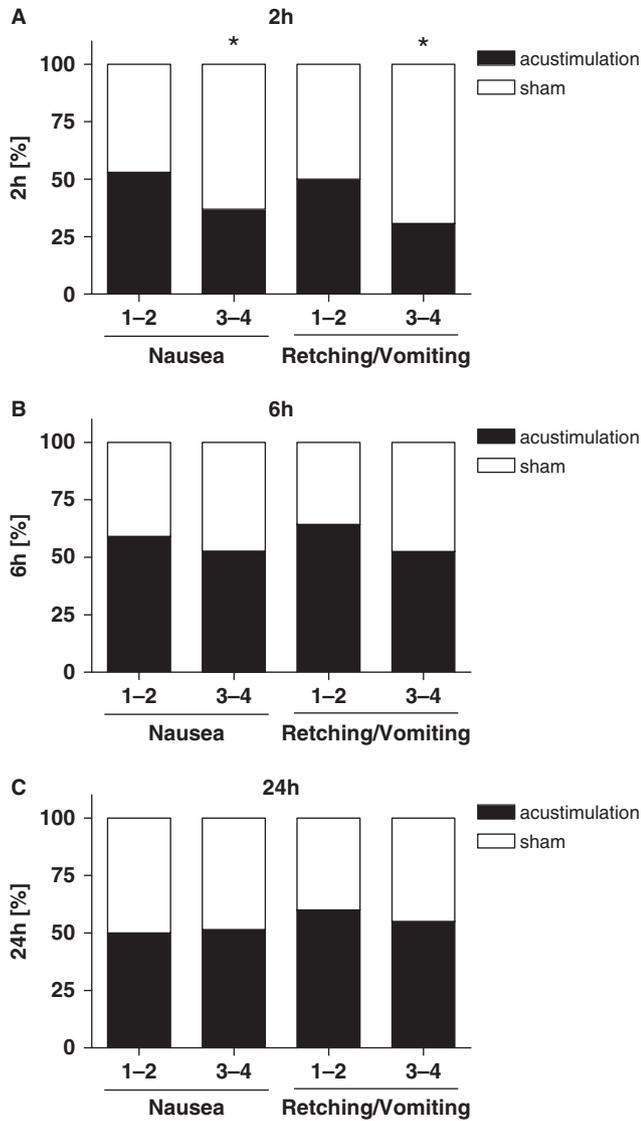


Fig.3. Effect on the development of post-operative nausea and retching/vomiting of risk factors and acustimulation. Risk factors were defined as female gender, non-smoking, history of post-operative nausea and vomiting or motion sickness, and post-operative morphine requirement. Percentages refer to all patients experiencing symptoms in that specific subgroup. *P < 0.05.

ervation could be either lack of effectiveness in patients who are not at a high risk or because the lower incidence and/or the limited sample size did not provide sufficient power to detect such an effect, if present.

In our study, we used and continued acustimulation for 24 h after surgery. However, PONV reduction was observed only in the early post-operative period. Although data from the literature supports the notion that acustimulation shows the best PONV-reducing effect in the early post-operative period,^{8,9} our former study in patients under-

going vaginal hysterectomy showed a PONV-reducing effect over the whole observational period of 24 h.⁷

As the study protocol between these two studies differed only in the type of operation (laparoscopic cholecystectomy vs. vaginal hysterectomy), the specific surgical procedure as well as the number of risk factors could provide an explanation for the observed discrepancies. Women in the hysterectomy study already had two of four possible risk factors for developing PONV (female gender and post-operative morphine usage). In this context, using a multivariable binary regression analysis using all potential risk factors for developing PONV, we could now show that female gender was independently associated with a more than twofold risk for developing PONV, being the strongest predictor for the post-operative incidence of PONV. Moreover, it has been shown that patients undergoing hysterectomy have an increased risk for developing PONV.²⁰ Thus, in retrospect, it is not too surprising that in the present study acustimulation shows smaller effects in a population at less risk for PONV. Conversely, it shows that acustimulation indeed decreases the risk of PONV regardless of the specific surgical procedure.

In a multivariable analysis with each risk factor for PONV investigated separately, acustimulation was independently associated with a reduction of early PONV by up to 50% when PONV is classified as at least one episode of nausea, retching, or vomiting. We could also show that besides acustimulation, male gender and no history of PONV showed the largest effect on the development of PONV. Because all patients received morphine post-operatively, we could not analyse this factor as a predictor for PONV. However, smoking was not found to be independently associated with the incidence of PONV in our study. Therefore, one should keep in mind that the risk stratification score is only a simplified system and that each risk factor might have a different weight in influencing the predictability of development of PONV.

Study limitations should be discussed, too. These include blinding in that patients receiving the active ReliefBand[®] devices preinduction are more likely to be able to detect a tingling sensation potentially evoked at the P6 acupoint, and, therefore, a patient bias may have contributed to the greater antiemetic efficacy of acustimulation vs. sham. However, all patients were told that the ReliefBands[®] can evoke a sensation that they 'might or might not feel' and this unavoidable

methodological problem in awake patients is common to many clinical studies addressing the use of non-pharmacologic antiemetic therapies and has been reported previously.^{6,21} However, because there was no difference in the effect of pre- vs. post-induction acustimulation, patient bias is unlikely to have played an important role. Furthermore, different results might be obtained with other types of surgery or with other anaesthetic regimens.

In conclusion, acustimulation by the ReliefBand[®] decreases early post-operative nausea and vomiting in patients undergoing a laparoscopic cholecystectomy, with the best effects on nausea and in patients with three or more risk factors for PONV.

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