September 1996
Volume 85, Number 3A
ISSN 0003-3022


Anesthesiology
The Journal of the American Society of Anesthesiologists, Inc.

SUPPLEMENT

# Abstracts of Scientific Papers 1996 Annual Meeting

# AMBULATORY ANESTHESIA II

## A21

TITLE: ORAL RS-25259 PREVENTS POSTOPERATIVE NAUSEA AND VOMITING FOLLOWING LAPAROSCOPIC SURGERY

AUTHORS: J Chelly MD*, T Melson MD#, J Pollock MD^, C Hantler MD@

AFFILIATIONS: University of Texas, Houston* and San Antonio@, TX; Helen Keller Memorial Hosp#, Sheffield, AL; Mason Clinic^, Seattle, WA

Introduction: RS-25259 is a new highly specific 5-HT3-receptor antagonist being developed for the prevention and treatment of postoperative nausea and vomiting (PONV). This study was designed to evaluate the efficacy and safety of RS-25259 administrated orally for PONV in patients undergoing laparoscopic procedure with a balanced anesthesia.

Methods: This randomized double-blind multicenter placebo controlled dose ranging efficacy and safety study included 0three hundred fifty-one patients (308 women, and 43 men). After institution review board approval and written informed consent were obtained, these patients ASA I and II, 19-75 years old scheduled for elective laparoscopic surgery were enrolled to randomly receive oral RS-25259 (0.3, 1, 3, 10.0 and 30 μg/kg) or placebo. Exclusion criteria included: women of child bearing potential who did not practice an effective method of birth control, and patients with known hypersensitivity to HT3 blockers. Patients received the study medication 1 to 2 hours prior surgery. The primary efficacy variable was defined as the proportion of patients who did not develop an emetic episode and did not require antiemetic medication for 24 hours after recovery from anesthesia and surgery (complete responders; CR). Secondary variables included the severity of nausea using visual analog scale, the frequency and time course of nausea and vomiting episodes. The safety evaluation was based on the adverse events documented during the 24-hour postoperative observation period. Data were analyzed using the Cochran-Mantel-Haenszel test. $P<0.05$ was considered significant.

Results: Compared to the placebo, RS-25259 increased significantly the percentage of patients who elicited CR (37%, 58%, 52%, 59% and 53% vs 33%). RS-25259 therapeutic effectiveness reached a plateau at a dose of 1 μg/kg. Except for 0.3 μg/kg, RS-25259 induced a significant reduction in the frequency of severe nausea episodes as compared to placebo. There was no significant difference between the adverse reactions reported in the placebo vs RS-25259 groups (52.4% vs 57.3%). In this respect, headache was the most frequent adverse reaction reported by the patients receiving the study medication.

Conclusions: This data demonstrates that a minimum dose of 1 μg/kg RS-25259 orally administrated is an effective and safe treatment for the prevention of PONV in patients undergoing laparoscopy surgery.

## A22

TITLE: **THE ANALGESIC SPARING EFFECTS OF MUSIC: A NOVEL WAY TO CONTAIN COSTS**

AUTHORS: ME. Koch, MD; ZN. Kain, MD; C. Ayoub, MD; SA. Rosenbaum MD

AFFILIATION: Departments of Anesthesiology, Surgery, Medicine, and Pediatrics Yale University School of Medicine, New Haven, CT, 06510

**Introduction:**

Music is often used in every day life to help us relax. It provides an auditory distraction from emotional, psychological and physical stressors. The purpose of this study was to determine if music is a potent enough distractant to lessen the amount of analgesia required for patients undergoing lithotripsy whose primary anesthetic was a patient controlled analgesia pump (PCAP).

**Methods:**

Informed consent was obtained from all participants. Unpremedicated ASA I or II patients undergoing lithotripsy with the Dornier 3 or Dornier 4 lithotripter were randomized into either a music (n=21) or a control (n=22) group and instructed on use of a PCAP system. Next, baseline vital signs were recorded and situational and baseline anxiety were noted using Spielberger's self-report state and trait anxiety inventory (STAI). Subjects also had baseline pain and sedation scores noted using a self-report visual analog scale (VAS). Baseline level of sedation was determined by assessing responsiveness, speech, facial expression, and eye signs (SLOS). Next, intravenous midazolam 20 μ/kg, metoclopramide 10 mg, and alfentanil 10 μ/kg bolus were administered to all subjects and the subjects were attached to an intravenous PCAP set to deliver 10 μ/kg of alfentanil with a lockout period of 2 minutes. The music group had occlusive headphones applied and the control group listened to the ambient noise present in the lithotriptor suite. Blood pressure, heart rate, $SPO_2$, self-report VAS pain and sedation scores, and SLOS scores were recorded every 15 minutes as was the average power and frequency of the lithotriptor shock-wave generator. Postoperatively, total PACU time and episodes of emesis were noted.

**Results:**

Patients in the control and study group were similar in age, gender, weight, state and trait anxiety scores. They were also similar with respect to hemodynamic and respiratory baseline and intraoperative values, case length, and lithotriptor stimulus power and frequency. Patients who listened to music had an average 50% reduction in alfentanil requirements (study 1.6 μ/kg/min vs. control 0.8 μ/kg/min, $p<.002$) and spent an average of 25% less time in the PACU (study 98±55 min vs. control 73±21 min, $p=0.05$). The pre and mean intraoperative pain and sedation scores were similar as were the rate of adverse respiratory depression (31% vs. 28%, p=NS) and post operative nausea and emesis (28% vs. 27%, p=NS). All patients with respiratory depression responded to verbal stimulation with immediate increases in $SpO_2$.

**Conclusion:**

Using music results in less alfentanil needed to achieve the same level of patient controlled analgesia, with less PACU time needed before discharge. This decreased utilization of hospital resources could provide for substantial savings for both hospitals and patients. The relatively high incidence of respiratory depression, nausea, and emesis leaves room for future investigation and refinement.