TITLE

Efficacy and Feasibility of Oral

Midazolam Premedication in Pediatric

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Introduction: A recent study of oral Midazolam (M) premedication in children noted improved sedation/separation at induction of anesthesia as the dose of M was increased. However, parental separation was rated as excellent in less than 10% of children. Therefore we sought to improve the quality of separation and the feasibility of a higher dose of oral M in children scheduled for short day surgery cases, averaging less than 45 min.

Methods: This randomized, double blind, placebo controlled study was approved by the Institutional Review Board and written parental consent was obtained. Forty unmedicated children (ASA I or II, ages 1-6 yr) scheduled for minor general or dental surgery lasting less than 90 min. were studied. Children were randomized to 1 of 4 groups (n=10 per group) and received a premedication diluted in 3-5cc of chocolate-cherry syrup. Group 1 received syrup alone (placebo); Group II received M 0.5 mg/kg; Group III received M 0.75 mg/kg; Group IV received M 1 mg/kg. Once the premedication was given, a blinded observer assessed the children for sedation and anxiety for 30 min. prior to surgery and noted the quality of parental separation and mask acceptance. Anesthesia was induced by mask with 70% N2O and halothane. The inspired maintenance halothane concentration was titrated to the minimum required for hemodynamic stability. Postoperatively, patient sedation and anxiety levels were measured every 5 min for 15 min and then every 15 min for the remainder of 1 hr. Parametric data were analysed using one-way ANOVA and the Newman-Keuls test. Non-parametric data were analysed using the Fischer exact test and Wilcoxon Rank Sum test. p<0.05 was accepted.

Results: Patient groups did not differ in age, weight or length of

surgery. Two children (5%) refused to swallow the medication entirely; one received M 1mg/kg and the other the placebo. Average sedation and anxiolysis increased with both time and dose although not always achieving statistical significance. In addition, sedation, anxiolysis at 30 min and quality of separation were significantly better in the 0.75 or 1 mg/kg M groups compared to the placebo group. Furthermore, the sedative effect at 15 min in patients receiving 0.75 mg/kg M was already statistically greater than the placebo group. Parental separation and patient mask acceptance was rated excellent in 80% of the children receiving 0.75 or 1 mg/kg compared to 40% in the placebo group (p<.05). Postoperatively, time to eye opening and suitability for discharge were not different among the four groups. Three children, however, experienced paradoxical dysphoric reactions, two after 0.75 mg/kg and one after 1 mg/kg. These reactions were seen as increased irritability and rapid changes in mood. In follow up calls, 95% of parents with children receiving M stated that they would request the same premedication the next time.

Discussion: M in doses of 0.75 and 1.0 mg/kg appears to be equally effective in ensuring sedation and anxiolysis, with an onset time as brief as 15 min. However, these higher doses of M may be associated with transient dysphoric reactions. These findings suggest that the time course of action of oral M premedication in children is appropriate for surgical procedures of brief duration and is compatible with the need for expedient discharge following ambulatory surgery.

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References: 1. Anesthesiology 73:841-834, 1990.

A28

TITLE:

EFFECTS OF PROPOFOL SEDATION FOR

OPHTHALMIC NERVE BLOCKS.

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Introduction. Ophthalmic surgery is often performed under local anesthetic nerve blocks and monitored anesthesia care (MAC). The anesthesiologist's goal is to provide a state of sedation and analgesia while maintaining patient responsiveness. Propofol, a unique, ultra-short acting sedative/hypnotic agent, may be especially helpful in this setting. In addition to its novel pharmacokinetic profile, propofol lowers intraocular pressure, and unlike the barbiturates, may possess intrinsic analgesic properties. We studied the cardiopulmonary and cognitive effects of adding propofol to a sedation regimen of alfentanil administered by bolus and infusion.

Methods. This study was conducted in accordance with Human Subject Protection Committee guidelines. Two groups of unpremedicated ASA I-III patients undergoing ophthalmic surgery under MAC were studied (A=alfentanil alone, AP=alfentanil+propofol). Both groups received i.v. alfentanil by bolus (3-5 µg/kg) followed by infusion (0.75-1.0 µg/kg/min). Group AP patients additionally received i.v. propofol by bolus (0.24-0.4 mg/kg) and infusion (60-80 µg/kg/min). The sedation regimens were begun 2 minutes before the nerve blocks and continued until the completion of the blocks. Vital signs (MAP, HR, and O2SAT) were recorded each minute for ten minutes following the boluses. After return to baseline mental status, the patients' subjective recall of the blocks was assessed. Statistical testing included ANOVA for repeated measures, Bonferroni t-test and Pearson Chisquare; p<0.05 was considered significant.

Results. Data from 45 patients aged 36-95 was collected. There was no loss of consciousness observed during the study and all patients remained responsive and cooperative. The alfentanil dose was 430+19 µg (6.4 µg/kg) for both groups. The propofol dose was 35±3 mg (0.52 mg/kg) for group AP. O₂SATs started at 98+0.4% and remained stable in Group A throughout the study period. Group AP's O2SATs were significantly lower than those of Group A at 4, 5 and 7 minutes, although the actual difference was never more than 3% (Fig). Preop MAPs were similar: 109±2 and 105±4 torr for groups A and AP respectively, and remained unchanged (Fig). Preop HRs were also similar: 71+3 and 69+2 bpm and likewise did not change with time. A significant difference was found between the two group's pain scores (p<0.01), with Group AP patients reporting less recall of blocks (Table).

Discussion. This study examined the effect of adding a sedative dose of propofol to alfentanil administered by bolus and infusion during the placement of ophthalmic nerve blocks. The addition of propofol had no effect on MAP or HR. O₂SAT decreased in the propofol group, however the magnitude of the decrease was small and of questionable clinical import. Patients who received propofol had significantly less recall of the nerve blocks than did patients receiving alfentanil alone. Of those patients with recall, the incidence of pain or discomfort was virtually identical for the two groups. Our data showed that propofol at this dosage had a profound amnestic effect and did not share the antianalgesic properties of the barbiturates. The addition of propofol to the sedation regimen was a safe and effective means of rapidly achieving a brief state of profound amnesia for the placement of local anesthetic blocks in MAC cases.

Pt Asses.	No Recall	Painless	Discomfort	Painful
Grp A	3	11	9	0
Grp AP	15	4	3	0

