

Comparing efficacy and safety of four intravenous sedation regimens in dental out patients.

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Background. Management of patients' fear and anxiety during dental treatment is a primary concern of dental practitioners. Pharmacological strategies used in outpatient dental settings must be both safe and effective. Regimens of intravenously administered sedative drugs were evaluated in a collaborative, multicenter study of outpatients undergoing removal of impacted third molars.

Methods. A total of 997 patients randomly received one of five treatments: placebo; midazolam administered to a clinical endpoint of conscious sedation (mean dose, 8.6 milligrams); midazolam plus additional midazolam as needed during the procedure (mean total dose, 12.2 mg); fentanyl (1.4 micrograms/kilogram) plus midazolam to achieve the same endpoint of conscious sedation (mean dose, 5.7 mg); or fentanyl (1.4 $\mu\text{g}/\text{kg}$), midazolam (mean dose, 5.8 mg) and methohexital as needed during the procedure (mean dose, 61.0 mg).

Results. Each drug regimen reduced anxiety during surgery in comparison with placebo, with the combination of midazolam, fentanyl and methohexital resulting in significantly less anxiety in comparison with the other treatment groups. Pain reports by patients during surgery also were reduced significantly by the combination of fentanyl, midazolam and methohexital. Patients' global evaluations of the efficacy of sedation ranked midazolam with supplemental midazolam and the combination of fentanyl, midazolam and methohexital as significantly more efficacious than the other two drug regimens. The authors noted transient respiratory depression in patients in the two opioid-treated groups, but no other physiological changes were detected.

Conclusions. These data provide evidence that the drugs and doses evaluated resulted in therapeutic benefit to dental outpatients, with minimal incidence of potentially serious adverse effects.

Clinical Implications. The results of this large-scale study provide assurance to both the public and the dental profession of the safety of parenteral sedation with these drugs and combinations of these drugs when titrated slowly in the recommended doses by appropriately trained dentists.