

Triazolam Use in the General Dental Office

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In 1991 the American Dental Association (ADA) presented figures detailing that 12 million Americans are dental phobics, while another estimated 12 to 24 million suffer dental anxiety.¹

More than a decade later, these figures are even higher. About 30% of the population (85 million people) needs some form of anxiolysis or sedation to receive dental care and only 60% of these do well with nitrous oxide sedation alone. This means that 34 million phobic patients are currently avoiding routine dental visits.²

Whether or not a dentist provides various forms of sedation depends on their education, state regulations, costs of insurance, competency, and equipment. Intravenous sedation (IVS) is seldom used because of insurance costs, the need for costly postdoctoral education and, more recently, regulations in various states as to who can perform this technique. The cost and scarcity of training programs increases the problem. Typically these courses require 60 hours of training and 10 to 20 sedation patients and cost \$5,000 to \$7,000.

No one paid much attention to those of us using oral conscious sedation (OCS) until 2001 when there was a surge of dentists learning about and using OCS. Since that time, the ADA's Committee H suggested and the ADA House of Delegates passed guidelines that render most techniques unusable. These guidelines do not allow giving a second dose of sedative where a patient does not have adequate sedation. These guidelines limit the dose of a sedative that can be given. They state you may not give more than the "mrd." "Mrd" is an undefined term from Committee H derived from the Food and Drug Administration (FDA) term MRD, maximum recommended dose. MRD was developed for use of Halcion as a sleep-aid often for a patient who is elderly and lives alone.

Dental anesthesiologists and academics who teach in dental schools often claim they are pro-OCS, however, most believe those not trained in IVS should be limited by the ADA guidelines. This will cause a failure rate of close to 40%.

The American Association of Oral and Maxillofacial Surgeons (AAOMS) has sent letters to the licensing boards of every state sug-

gesting regulations for the states requiring any dentist who gives even one dose of an oral sedative be certified to do IVS. There are at least 6,000 dentists giving OCS. There are only 120 open positions in IVS courses each year. It will take more than 50 years to get all these dentists certified.

These regulations have been adopted by several states and are being considered by many other states. They will bring the end to the use of oral sedation. There has yet to be a death in a dental office using triazolam (Halcion[®]) as an oral sedative. It is estimated Halcion has been used successfully about 500,000 times. There are deaths every year in oral surgery offices using IVS and general anesthesia. If more rigid regulations are needed they should be instituted where there have been deaths.

The ADA guidelines and AAOMS regulations could eliminate the use of oral sedation from almost all offices and for almost all patients. If this loss is to be avoided, general dentists, even if they do not do oral sedation, need to make their concerns known to their licensing boards. If general dentists are not heard, we will lose. How long will it be before some specialty group goes to the licensing board with regulations that prevent general dentists from doing extractions, endodontic procedures, treating children or doing periodontal procedures?

Those of us doing oral sedation need to come up with some science if we are going to reverse this movement to outlaw oral sedation. It is close to impossible to do true double blind placebo controlled studies in clinical dental offices. Phobic patients simply will not agree to be treated with a, "sugar pill," placebo. However, we can do clinical studies where we carefully observe, monitor and record the effects of our drugs on our patients. While such studies do not have the power of a placebo-controlled study they are still science particularly if we have large numbers in our studies.

To that end I reviewed my records for the last 13 years. I selected patients over the age of 12 who were too fearful to treat with nitrous oxide sedation alone were eligible for this study. All were patients in my general dentistry practice.

This very important technique for general dentistry is about to be lost for political reasons.



Now is the time for general dentists to be heard.

Methods

All general dentistry patients over the age of 12 who were too fearful to treat with nitrous oxide sedation alone were eligible for this study.

All patients were treated with the oral drug triazolam.^{3,4,5} The goal of treatment was to create a 60-90 minute working time, and a recovery time of an additional 60 minutes, at which point the patient would be able to leave the office accompanied by a responsible adult. With their escort present, patients were instructed not to do anything the rest of the day that required any cognitive or coordination skills including cooking, driving or making legal decisions (marriage, house purchase, etc.). They were also instructed not to indulge in any other sedative use, including alcohol.

All patients had an initial examination to gather records and assess. A second appointment was used to describe the conditions of the patient's mouth, give treatment options, and to discuss sedation options and requirements. The third appointment was made one hour prior to the time dental treatment was to start. A signed informed consent was obtained, and monitoring was started. The initial dose was individualized according to the patient's weight (see Results page 52). Half the initial dose was given after 30 minutes if

there was no evidence of sedation as observed by the clinician or as reported by the patient.

A dental assistant visually monitored the patient at all times. The assistant took and recorded blood pressure pre-sedation and every 15 minutes thereafter. Hemoglobin oxygen saturation, SaO₂, and pulse rate as displayed by the pulse oximeter were also monitored and recorded. The dental assistant was required to talk to the patient to ensure the patient did not go to sleep. She was also required to call the dentist if the patient went to sleep or if the SaO₂ fell below 92%. The dentist evaluated the patient at 15-minute intervals.

The dental procedure began one hour after the initial administration of triazolam if an adequate level of anxiolysis or conscious sedation was achieved. Sedation could be augmented with nitrous oxide if required. If the patient was not relaxed enough to treat the appointment was canceled and they were referred for IVS.

During treatment, patients assessed and recorded their apprehension five times. The cardiovascular and respiratory parameters, blood pressure and percentage hemoglobin-oxygen saturation were recorded every 15 minutes. At the close of the appointment the clinician assessed and scored relaxation.

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Results

Since triazolam still does not have FDA approved guidelines for dosing in the dental setting, a dose-ranging run-in trial was necessary. Many authors have reported on the appropriate dosage of triazolam for sleep enhancement in the literature, suggesting dosages from 0.125mg to 0.5mg.^{3,7,8,9,10,11,12} It became obvious early on that some doses were ineffective for larger or the most fearful patients. It was decided that during the trial one-half the initial dose would be further administered after 30 minutes if there was no evidence of sedation. This practice is now outside of ADA guidelines.

The results from this initial run-in phase showed when the dose in milligrams and weight in pounds were compared with the practitioner's assessment of level of sedation, a trend emerged indicating that the appropriate initial dosage could be determined by the following equation:

Dose (mg) = (0.25mg) + (0.125mg for every 70 pound weight increment over 40 pounds), or 0.25 mg up to 110 pounds, 0.375 from 111 pounds to 180 pounds, 0.5 mg from 181 to 250 pounds, 0.625 above 251 pounds (Figs. 1-3).

One hundred fifty-three patients were seen for 235 appointments over a 13-year period. The mean age was 39.9 years, with a range of 12 to 71 years (Fig. 4). Average weight was 175 pounds (80 kg) with a range of 72-278 pounds (32-128 kg) (Fig. 5). All patients were ASA 1 or 2 with no history of recent illness.

Supplemental dosages were necessary for 16 of the 153 patients (10%). Another 31 patients (20%) required their sedation be augmented with nitrous oxide/oxygen mixtures of 30 to 50%. One patient was untreatable and another was treated but appeared to have no effect from the triazolam.

No patients were so relaxed they would not stay awake if spoken to. Two patients showed and reported no effect from the drug. The mean saturation of all patients varied from 96.5 to 95.8% with one minimum of 87% and maximum reading of 100% (Fig. 6). The patient who had the 87% saturation had a circulation problem with her hands, Raynaud's disease. While she read 87% saturation, she was completely conscious. Without sedation her normal was measured at 87%. The desaturation was the result of a circulatory problem in her hands and not related to sedation.

Cardiovascular parameters had minimal changes that were not deemed clinically significant. Self-reported apprehension levels fell from an initial mean of 2.99 (SD=1.86, afraid) to 1.833 (SD=1.6, tense) at 30 minutes, and to 1.33 (SD=1.52, a little nervous) after the procedure (Fig. 9). The largest drop in apprehension occurred in the first 30 minutes after the administration of triazolam.

All but one patient remembered the first symbol shown in the amnesia testing portion of the trial. Ninety patients (68%) remembered the symbol shown at 30 minutes; 98 patients (74%) remembered the 60-minute symbol; 66 patients (50%) remembered the symbol shown halfway through the appointment and 68 patients (52%) remembered the symbol shown at the conclusion of treatment (Fig. 10).

The narratives written by patients tended to agree with the amnesia test results. Only one patient recalled the whole appointment. Most remembered only small portions of it. The overall success rate was recorded as 151 positive outcomes out of a possible 153 or 98.7%.

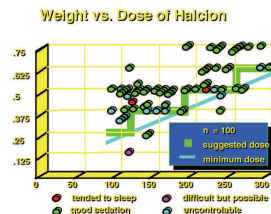


Figure 1
Dose vs. Weight with operator assessment of effect for the first 75 patients

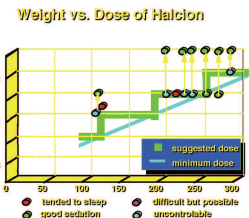


Figure 2
Cases that required an additional dose. 7 of the first 75 patients

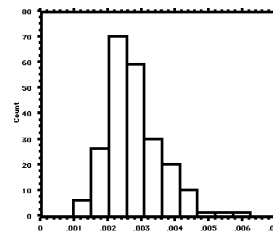


Figure 3
This is a histogram of the mg./lbs dose for patients

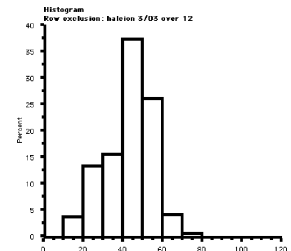


Figure 4
This is a histogram of ages. All patients were over 12 years old

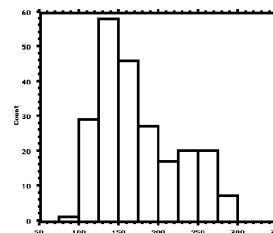


Figure 5
This is a histogram of the Patients' weight.

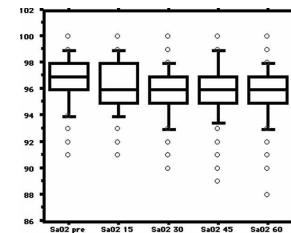


Figure 6
Oxygen saturation, SaO₂ pre treatment 15, 30, minutes after administering medication

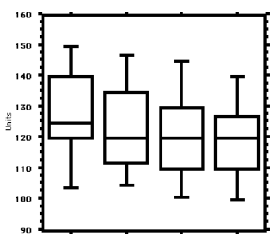


Figure 7
Systolic blood pressure pre-medication 15, 30, 45 and 60 minutes after medication

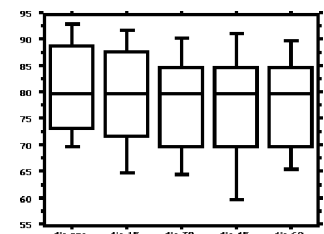


Figure 8
Diastolic blood pressure pre-medication, 15, 30, 45, and 60 minutes

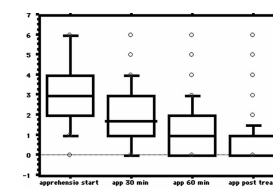


Figure 9
Patients' report of their level of apprehension

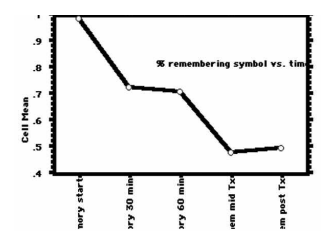


Figure 10
Patients' report of amnesia as determined by memory of symbols

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Discussion

When we first began using triazolam for OCS there were no published reports of its use as a dental sedative. Therefore, initial study doses consisted of FDA-approved triazolam doses to treat insomnia.¹³ The premise for choosing this dosing regimen was the logic that if the FDA had approved specific triazolam dosing recommendations for individuals to use in an unmonitored home setting, that dose of triazolam should be a safe start for a dental study. Even before this study began, effects of dosing triazolam at four to six times the maximum recommended dose had been studied, with no effect on either the respiratory or circulatory systems reported.¹⁴ Based on dosage range trials with other medications, a weight-based schema was determined to be the best way for us to achieve our OCS goals with these patients, and our results led us to the equation described above.

Over the next 13 years, 153 patients were dosed with triazolam at 235 appointments using this formula.

The pharmacological actions of triazolam required the insistence of an escort and very specific discharge instructions. None of the patients reported any adverse sequelae in the 24 hours following their appointment.

Constant respiratory and cardiovascular monitoring provided further evidence regarding the safety of this medication as there were no clinically significant changes throughout the course of each of the 235 appointments.

Reports of amnesia in the literature commencing about an hour after the drug was taken and lasting for several hours were exam-

ined, and recall percentages were recorded in this investigation using the symbol recognition methodology. Similar results were recorded as found by previous investigators.¹⁵

Conclusion

Determining the appropriate dosage of triazolam to achieve OCS early in the study was challenging. The literature suggests peak blood levels can take more than an hour to achieve, however, if a patient is going to be adequately sedated some signs of sedation will be evident at 30 minutes. All cardiovascular and respiratory parameters remained constant. Most patients had amnesia of the dental appointment. A supplemental dosage equal to half the initial dose was necessary in 10% of patients and was administered 30 minutes after the initial dose if there was no evidence of sedation. Another 20% required their sedation be augmented with nitrous oxide/oxygen mixtures of 30 to 50%. Effective OCS was achieved in 98.7% of all participants.

It should be emphasized that this study was conducted coincidentally to the patient's treatment in a private practice. The technique described and the parameters evaluated evolved with drug familiarity. As questions arose, the study was expanded to investigate these areas.

This very important technique for general dentistry is about to be lost for political reasons. Now is the time for general dentists to be heard.



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