Oral Conscious Sedation
Too big to swallow?
By Matt Schlossberg

Even its most ardent critics must admit that there is a lot to like about enteral conscious sedation (ECS), on both sides of the dental chair. For dentists, ECS is simple to administer, doesn't require much training compared to IV and other types of sedation, and often doesn't affect malpractice premiums. For the large population terrified of the dental office, swallowing a pill is the only alternative to the needle.

But ECS has caused controversy within the profession. Some dentists and dental associations have raised questions about the quality of its continuing education, as well as the safety and efficacy of the procedure itself. Dentistry seems divided on whether or not the bulk of ECS continuing education centers on the dentist's bottom line rather than the safety and comfort of patients; critics say that most seminars and courses amount to nothing more than marketing seminars pitched by unqualified instructors. "It is unclear whether the individuals teaching these courses have been appropriately trained. In fact, these courses seem more entrepreneurial than scientifically based," said Robert M. Peskin, DDS, chair of the American Dental Association (ADA) Committee on Anesthesiology, in a November 2002 interview with the ADA.

Advocates say the quality of education is present; there simply aren't enough courses to meet the demand. They add that marketing is a small but essential component to the education. How else can they access a population too afraid to step into the dental office?

Most dentists argue that GPs should be able to administer ECS. Those skeptical about ECS in practice are worried about methods, especially incremental dosing, or titration. Critics say titration runs the risk of an untrained and ill-prepared dentist inducing deep sedation in a patient.

The ADA in 2002, voted to add language to its anesthesia guidelines critical of titration, citing concerns for patient safety. The documents, *Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry* (Guidelines for Teaching) and *Guidelines for Use of Conscious Sedation, Deep Sedation and General Anesthesia in Dentistry* (Guidelines for Dentists), were created by the ADA in the 1970s to develop a framework for teaching and administering sedation techniques. Many state dental boards use these guidelines to develop their own regulations and requirements.

Many dentists and organizations, including the Academy of General Dentistry, supported the new language added to the guidelines. Others, however, said the ADA passed language that had no scientific basis, and left ECS dentists wide open to lawsuits.

"When I first heard about [the language] I was very surprised," said Michael D. Silverman, DDS, president and founder of the Dental Organization for Conscious Sedation (DOCS), and member of the AGD. "The trial lawyer associations are rubbing their hands together because we've left a huge opening for dentists. Give [patients] a second dose of medication and we [the lawyers] can attack them."

Resolved?
After defining the term titration as "the administration of small incremental doses of a drug until a desired clinical effect is observed," the resolution reads: "In accord with this particular definition, titration of oral medication for the purposes of sedation is unpredictable. Repeated dosing of

orally administered sedative agents may result in an alteration in the state of consciousness beyond the intent of the practitioner. Except in unusual circumstances, the Maximum Recommended Dose (MRD) of an oral medication should not be exceeded." (In 2003, the ADA voted to lowercase MRD and dropped the acronym.)

"In the last several years, there has been a proliferation of [continuing education] courses where the technique being touted calls into question good anesthetic principles with regard to use of these medications," Dr. Peskin said. "What apparently is being taught is that following the initial administration of a certain medication, if in the practitioner's judgment the desired effect has not been attained, additional doses are added. In recommending changes to the guidelines, it was the committee's [ADA Committee on Anesthesiology] opinion that orally administered drugs cannot be titrated safely in that manner." According to the AGD Council on Dental Care, the AGD is supportive of the ADA resolution. But some Academy members are divided on the issue.

In February 2003, David Apsey, DDS, a Fraser, Mich.-dentist who practices oral conscious sedation, wrote to the AGD Council on Legislative & Governmental Affairs: "Arbitrary restrictions on a safe practice may be inappropriate. The maximum recommended dosage of most drugs is established during the FDA application for marketing. The MRD is thereby established for the intended purposes of the drug at the time of application. Federal law also protects the right of professionals to establish new accepted uses for drugs, which are already marketed. These new uses, commonly known as off-label applications, are published in professional scientific journals. Any restriction on the development of off-label uses for drugs arbitrarily imposed by a professional organization is inappropriate and may result in large numbers of frivolous lawsuits and the loss of additional drug applications from the practitioner's armamentarium. This change of policy by the ADA is apparently arbitrary and inappropriate."

Dr. Silverman points to studies that show that exceeding the maximum recommended dosage of triazolam, the drug of choice for ECS, did not adversely affect subjects. He also argues that incremental administration is safer than a single large dose.

While some questioned the scientific validity of the language, the ADA maintains that it was looking out for the safety of patients. "The ADA feels that the safety of dental patients is of the utmost importance. There was a concern that patients who received multiple doses of oral sedative drugs may be at risk of being sedated at a level deeper than a dentist intended," says Robert Weaver, DDS, a spokesperson on oral conscious sedation for the ADA.

The language he says is historically consistent with the ADA's treatment of anesthesia. At one time dentists could administer anesthesia without any training. The ADA published its anesthesia guidelines in 1971, he says, to "increase the margin of safety."

He notes that some state dental boards, such as Ohio's, state that dentists without a permit in general anesthesia or IV conscious sedation may not titrate. If the initial dose given on the day of the appointment is not sufficient, another appointment to increase the dose must be made for another day. Essentially, the guidelines are recommendations to state dental boards to develop appropriate education and practice standards of several kinds of sedation, most recently oral conscious sedation.

Dr. Weaver says that the ADA is not anti-ECS. "[The ADA] strongly supports the right of appropriately trained dentists to use sedation to manage patients in the dental office," he says. "Ensuring the safe and effective use and training of this sedation, the ADA is certainly in favor of dentists doing this for their patients, but they have guidelines they feel need to be followed."

Rumor vs. science

After the vote that revised the ADA anesthesia guidelines, Dr. Silverman spent a great deal of

time delivering presentations on ECS, hoping to convince the skeptics that the practice was safe and effective, and the educational standards were high quality.

He founded DOCS fours years ago, and slowly developed its programs, hiring educators and building its membership. With in six months of its inception, DOCS hosted its first seminar. Today, DOCS counts more than 1,900 dentists as members, 22 employees, and offers 10 courses from an equal number of lecturers and clinicians. This year, he hopes to add another course. Dr. Silverman says he founded DOCS to provide conscious sedation education to dentists.

In his nine years as an ECS practitioner, Dr. Silverman has handled more than 2,500 sedation cases. His ambitions for ECS are far from modest. Dr. Silverman believes oral conscious sedation is a vital instrument in breaking down a barrier of fear that keeps millions of people from regular dental visits. He spends a great deal of time defending DOCS and ECS from rumors. A few tall tales include the adult patient who overdosed and died before a group of horrified GPs during a DOCS educational seminar and the DOCS employee who encouraged a dentist on an Internet listserv to feed a patient 25 milligrams of triazolam to ensure sedation.

Other accusations are that DOCS teaches deep sedation and pediatric sedation. He says DOCS teaches only conscious sedation in adults. Dr. Silverman admits to using the term “sleep dentistry” for what his organization teaches and advocates, but today dismisses a semantic stumble made by a new company just getting off the ground. “There was a mistake made in 2000 where the term sleep dentistry was tossed around as viable terminology for oral conscious sedation. It’s not a good term [for what we do.] Since then we’ve withdrawn it from all materials, and have emphatically told dentists not to use that term. Our organization has never taught deep sedation,” he says. Yet Dr. Silverman feels DOCS continues to live down that instance of poor phrasing.

Why ECS?

Enteral conscious sedation is primarily used to curb anxiety and fear in a patient without rendering them unconscious. Dr. Apsey uses ECS in 10 percent of his patients, in procedures ranging from prophylaxis to fillings and surgeries. Though he was trained in IV sedation, he has yet to use it in his practice. He says the malpractice insurance was too high. With ECS, his premiums remain steady. He also is a DOCS member.

Several polls and surveys suggest that fear of the dentist remains pervasive despite advancements in pain management, improved patient comfort techniques and various public-awareness campaigns. Ironically, sedation via a needle is a chief concern of more than half of all patients afraid of dental visits. According to a clinical article in the February 1998 issue of the *Journal of the American Dental Association*, one survey found that “25 percent of adults expressed a fear of injections, with one in 20 respondents indicating that they avoided, canceled or did not appear for dental appointments because of fear.”

Many of these fearful patients don’t actually see a dentist until an oral problem becomes too large to ignore, when the pain finally outweighs the fear of injections. Dr. Silverman and ECS dentists believe this “cycle of fear” can be halted and, in fact, reversed, with a pill.

Prior to the 1960s, alcohol and barbiturates were used to relax patients. Once benzodiazepines hit the market, they became the drugs of choice for dentists. Triazolam is the benzodiazepine most commonly used by dentists because of its rapid onset, reported high margin of safety, and the availability of the antagonist flumazenil. Triazolam’s popularity with dentists also stems from the drug’s short half-life and duration. Peak plasma concentration of .25 mg to .50 mg occurs in about one hour. The elimination half-time is 1.7 hours. “The combination of probable amnesia and somnolence has brought triazolam into the forefront as a preferred sedative among dentists who use oral sedation in their practice,” according to a 2002 study in The Dental Clinics of North

America, titled “Inhalation and enteral conscious sedation for the adult dental patient.”

The challenge, according to some studies, is the timing of administration and variables in absorption. Dr. Apsey works on a one-dose system, and rarely has to adjust the level of sedation through titration. Titration “is very time consuming, and takes approximately 30 to 40 minutes between doses. If the desired level of sedation isn’t achieved after the second dose, we just terminate the appointment.”

Education

Myron J. Bromberg, DDS, chair of the AGD Council on Dental Care, says he is not for or against the practice of oral education. His concern lies in the educational standards and the competence of the dentist. ECS is appropriate only “if the education is handled according to [state dental board] guidelines,” he said. “If it does not conform, then the education needs to be examined more closely.” His other concern is if an overdose or some other emergency were to occur the dentist is comfortable and competent enough to administer an IV. “Even if the [GP] feels confident enough to respond accordingly in an emergency, what if they haven’t administered an IV before or haven’t done on in a long time? How comfortable are they going to be doing one now?”

Dr. Silverman doesn’t dispute that there is a lack of continuing education for ECS. For the most part, DOCS is the only show in town when it comes to ECS. Many state boards that have placed specific education requirements on dentists seeking to practice ECS are looking toward IV sedation, which, according to Dr. Silverman, in a given year there are little more than 100 slots available. The problem with that, according to Dr. David Apsey, is that many IV courses don’t teach ECS and permits to practice IV sedation usually means an increase in malpractice insurance. Dr. Apsey has used oral conscious sedation for 15 years. The reasons he uses enteral conscious sedation over IV sedation primarily has to do with methods. Back in the 1980s insurance premiums to practice IV sedation went up. Oral sedation, at least in Michigan, requires no permit process and doesn’t increase insurance premiums.

“There’s not enough [education] for all the people who might want it,” Dr. Apsey says. Dr. Silverman says marketing does play a role, but a small—and necessary—one. “The controversy surrounding oral conscious sedation came out not from providing a service but the marketing,” he says. “Doing it quietly in the dental office never would have created such a storm.” The marketing aspect of DOCS has since been outsourced to the Royal Dental Society, but some associations are not convinced that the quality is there.

The New York AGD hasn’t supported the DOCS program primarily over concerns with the quality of its continuing education. “The reason we didn’t sponsor DOCS was because we were concerned about the commercialism of the organization and had questions about the actual quality of continuing education begin presented,” said past-president Phil Epstein, DDS.

Dr. Apsey says the marketing component has gotten a bad rap. “Marketing is not in itself bad. You’re selling whatever service you have. We all do it. Marketing is not a bad word or bad concept,” he says. The amount of training required of dentists is considerably less than that of GPs seeking to fulfill requirements for general sedation or parenteral sedation. “Perhaps the most favorable characteristic of this administration route is the ease of administering the agents to most adult populations. Oral drug administration is not technically difficult and does not require special instrumentation to deliver the sedatives. Most states permit dentists to prescribe and administer single enteral agents without additional training or credentialing beyond their undergraduate dental school curriculum, according to the clinical article in a 2002 issue of *Dental Clinics of North America*.

The ADA Guidelines for Dentists recommends that dentists who administer ECS and/or combination enteral/inhalation sedation maintain proficiency in basic life support. The ADA also

recommends that dentists either complete training consistent with Part I and Part III of the Guidelines for Teaching or complete an accredited post-doctoral training program. This includes 18 hours of instruction and 20 clinically oriented experiences; and emergency airway management training. The guidelines also recommend that office staff be certified in basic life-support and learn how to properly monitor a patient. The guidelines also suggest that dentists develop an emergency office protocol. Dr. Silverman says that all of his company's speakers have at least three years experience in ECS, were trained in IV sedation and are certified in advanced cardiac life support. He also says his courses hew closely to what the ADA guidelines recommend.

Safety

Dr. Silverman says DOCS educates dentists to judge if ECS may be appropriate for a patient, teaching them to include critical variables such as age, health history, and drug interactions to make an assessment. DOCS also stresses the importance of constant monitoring, of never leaving a patient alone and using equipment such as a pulse oximeter.

Even with that training, some dentists believe that ECS is too unpredictable, especially with incremental dosing. Whereas the effects of IV or inhalation sedation can be observed within minutes, oral medication can take up to two hours to absorb. The scenario many opposed to ECS paint is a patient swallowing a pill and the dentist, not seeing the effects of the drug an hour or two later, delivers a second pill. Meanwhile, the first pill is being absorbed and the patient has ingested twice the amount he or she needs.

Additionally, some dentists question the effectiveness of the drug's antagonist flumazenil. "There is no scientific evidence that flumazenil would be effective to immediately reverse the effects of triazolam by any other route than when administered intravenously. The dentist is naïve to expect that he or she could quickly start an IV to give flumazenil when starting an IV is not part of their training or experience in order to save a patient's life," Dr. Weaver said.

Dr. Weaver says IV or inhalation sedation is more ideally suited to titration because the effect upon the patient is immediate. "It gets into body quickly. The dentists can measure the effect and give more if necessary. With oral conscious sedation the effect would take an hour or two. It might take all day to titrate appropriately." The slow absorption, he says, makes it more difficult for dentists to assess whether or not they over-sedated the patient.

"The major drawback of oral sedation is that absorption rates are highly variable," Dr. Weaver says. "Nitrous oxide goes right to the lungs. IV is delivered straight into the bloodstream—it doesn't have to go thorough a process."

The absorption process for ECS can vary depending on the amount of food in the patient's stomach and the other medication they are taking. "For a drugs like triazolam the absorption time is one to two hours. I have to wait for the body to absorb the drug before I can determine that is safe to give additional doses. Titrating a patient might take six to eight hours," Dr. Weaver says.

The jury is still out on the safety of this practice. Many dental journals are publishing examinations and studies of ECS. Dr. Silverman expects that as more education courses are made available, the number of dentists who introduce ECS into their practices will grow.

Matt Schlossberg is Senior Staff Writer of AGD Impact. He can be reached at matts@agd.org.

Types of sedation administration

- **Enteral:** Any technique of administration in which the agent is absorbed through the

gastrointestinal tract or oral mucosa (i.e., oral, rectal, and sublingual).

- **Parenteral:** A technique of administration in which the drug bypasses the gastrointestinal tract (i.e., intramuscular, intravenous, intranasal, submucosal, subcutaneous, and intraocular).
- **Transdermal/transmucosal:** A technique of administration in which the drug is administered by patch or iontophoresis.
- **Inhalation:** A technique of administration in which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.
- *Source: ADA Guidelines for the Use of Conscious Sedation, Deep Sedation, and General Anesthesia for Dentists (2002)*

Dental anxiety not always controlled with drugs

Drugs are a helpful way to reduce dental anxiety, but dentists also are exploring other methods to reduce fear of the dental office in hopes of overcoming this serious access problem. Numbers vary, but many experts believe as many as 25 million people refuse to schedule and keep dental appointments because of fear. Many GPs are gearing office designs to produce a calming effect in their patients and playing soft music.

Some dentists are looking inward and to see how they can improve their chair-side habits to induce calm in their patients. According to research conducted by Arthur A. Weiner, DMD, FAGD, professor of general and behavioral dentistry at Tufts University School of Dental Medicine in Boston, communication and behavior are keys to success. Dentists who take a moment to explain procedures, answer questions, and promptly address any of the patient's concerns are likely to find a more relaxed patient.

"If you don't know how to communicate with a patient, if you don't take the time to build a relationship with a patient, then all the fancy equipment, and all the techniques you have are useless," he says. A friendly, helpful staff front office also plays an important role in patient comfort. This combination has done much to reduce dental anxiety in the population. "Dentistry is not what it used to be because of the approach we take," says Manuel Cordero, DDS, MAGD, and a member of the Academy of General Dentistry's Public Information Council. "Our approach is much more humane, much more concerned about patients' feelings. As opposed to just getting the tooth taken care of, we take care of the patient."

AGD Impact, January, Volume 32, Number 1