(weight) of mixed salivary secretions. Administration of diazepam significantly suppressed uptake and elimination of $99m(TcO_4^-)$ by and from the parotid glands and submandibular glands. The amount of mixed salivary secretions was also significantly suppressed by adminis-

tration of diazepam in both the subjects at rest and the subjects stimulated on the tongue with 10% citric acid. The results of the study revealed that diazepam affects human salivary gland function and suppresses secretion of saliva.

Pediatric Sedation with Intramuscular and Intravenous Midazolam

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Narcotic agonists have traditionally been employed as first-line agents in the management of pediatric patients requiring behavioral modification through the administration of drugs. Although the administration of agents such as meperidine (pethidine), alphaprodine, and morphine have proven to be quite effective in patient management, there have also been reported numerous occasions on which serious adverse responses have occurred.

The narcotic agonists possess potent CNS depressant properties, which provide for the effective analgesia and sedation that is observed with their administration. In addition, these agents are potent depressants of respiration, and it appears that it is this property that has led to the majority of negative reactions. Other potentially negative actions of the narcotic agonists are their addiction potential and the tendency to induce nausea and vomiting—an effect noted more often in ambulatory patients (i.e., dental outpatients).

In the late 1960s and early 1970s the search for agents with narcotic agonist properties but without the negative actions produced the first of the narcotic agonist-antagonists, pentazocine (Talwin). In the 1980s butorphanol and nalbuphine were added to this list. Pentazocine has fallen into disfavor as the newer agents have entered into clinical usage. These newer agents appear to provide analgesia and sedation equal to the agonists, but possess a ceiling effect on respiratory depression (whereas respiratory depression with the agonists is dose-related until apnea develops). At this time, however, there is not enough clinical evidence as to the effectiveness of these

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agents as intramuscular (IM) or intravenous (IV) agents for pediatric sedation.

The water-soluble benzodiazepine, midazolam, was recently approved for clinical use in the United States. Its solubility in water makes the agent suitable for IM administration as well as via the IV route.

The aim of this study was to determine if midazolam maleate would be an effective substitute for the narcotic agonists in the management of children with severe behavioral problems associated with dental treatment.

METHODS

Patients were determined as being in need of parenteral sedation following difficulty or failure at treatment with nondrug techniques or with oral sedation. Informed consent was obtained from the patient's parent or guardian, and a complete medical evaluation was obtained. All patients included in this study were determined to be ASA I medical risks.

Immediately before the start of treatment the patient was asked to void and then weighed. The patient and a parent were brought into a "quiet room" and seated on a sofa where an intramuscular dose of 0.15 mg/kg of midazolam was administered into the anterior-lateral aspect of the thigh. Lighting in this room is kept subdued throughout the sedative procedure to enhance the quiet effect. A pulse oximeter probe is placed on the patient's toe or finger immediately following the IM injection. The patient and the parent are then left alone for 10 minutes, and the oximeter is monitored continuously by the dental staff in an adjacent area.

At 10 minutes the patient is placed in the dental chair. Nitrous oxide (50%)-oxygen (50%) is added via nasal

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Table 1. Criteria for Discharge

A. Movement
2—able to move all extremities
1—able to move two extremities
0—unable to move any extremity
B. Respiration
2-able to breathe deeply and cough
1—limited respiratory effort
0—no spontaneous respirations
C. Circulation
2—systolic BP $+/-20\%$ of baseline
1—systolic BP $+/-40\%$ of baseline
0—systolic BP $+/-40\%$ of baseline
D. Consciousness
2—fully alert, answers questions appropriately
1—aroused when called by name
0—unresponsive to auditory stimulation
E. Color
2—normal skin color and appearance
1—any alteration in skin color
0—frank cyanosis or extremely pale

hood and physical restraints (papoose board/pediwrap) applied. A continuous IV infusion is then started (DSW, pediatric infusion set (60 drops = 1 mL) and midazolam at a dose of 0.5 to 1.0 mg is administered IV as needed for the duration of the procedure.

Intravenous meperidine is administered IV if necessary.

In addition to direct visual monitoring, monitoring during the procedure consists of pulse oximetry, pretracheal stethoscope, ECG, and automatic BP/heart rate monitoring (every 5 min).

The treatment team consisted of: a pediatric dental resident (dentistry); a dental assistant (assist pediatric resident); an IV sedation doctor (in charge of sedation); an IV sedation assistant doctor (assists IV sedation doctor) someone from the pediatric dentistry faculty; and someone from the IV sedation faculty.

Recovery from sedation and ability to be discharged in the custody of the parent was based upon the following criteria given in Table 1. The patient must achieve a score of 10 in order to be considered for discharge.

RESULTS

Of thirty-one cases using this procedure, 30 were successful. A case was considered successful if the doctor was able to complete the planned dental procedure without difficulty. In the one unsuccessful case we were unable to start an IV infusion, and the IM medication was inadequate to permit proceeding with the treatment. The patient was referred for dental care under general anesthesia.

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Patients ranged in age from 19 months to 11 years and had a weight range ranging from 17 to 40 kg. Of the 31 patients, 17 were female and 14 male. IM doses of midazolam ranged from 2.5 mg to 5 mg, and IV doses ranged from 1 mg to 8 mg. IV doses of midazolam were initially administered as needed (i.e., patient movement or verbalization), but early in the study it was determined that the administration of 0.5 mg to 1.0 mg midazolam IV every 10 to 15 minutes would be more effective, as it would minimize the interruption of dental treatment necessitated by the original protocol. Dental treatment time ranged from 75 minutes to 135 minutes.

Fourteen cases (45%) required the IV administration of meperidine (pethidine). Doses ranged from 5 mg to 50 mg and were always administered in 5 to 10-mg increments. The primary indication for the administration of the narcotic agonist was in situations where the midazolam and N_2O - O_2 combination was ineffective in providing adequate conditions for treatment.

Recovery from the sedation procedure was prompt following completion of the dental procedure in all but one patient (below). As the dental procedure neared completion, we attempted to discontinue the use of IV medications, relying on N_2O/O_2 and effective pain control to maintain the patient. With this protocol virtually all patients met recovery criteria within 30 minutes after completion of the dental procedure.

All patients were contacted that same evening by either the pediatric dental resident or the IV sedation doctor to ascertain the degree of recovery. No complications were noted during these communications.

In four of the cases (12.9%) pulse oximeter measurements fell to 90% or below. In all cases dental treatment had to do with mandibular teeth. Management consisted of support of the patient's mandible by the IV doctor during the remainder of mandibular care. Tachycardias in the range of 140 or above were noted on six occasions (19.4%). The most often observed cause was inadequate pain control. The administration of additional local anesthesia terminated the rapid heart rate. Delayed recovery was observed in one patient (3.2%). Oxygen was administered to the patient, and the patient was monitored and observed for 80 minutes following the completion of the dental treatment.

DISCUSSION

The combined IM and IV administration of the watersoluble benzodiazepine, midazolam maleate, has proven to be a highly successful method of managing the behaviorally disruptive pediatric patient in need of dental care. The vast majority (96.8%) of patients were successfully managed using this combination with N_2O/O_2 alone or with the addition of the narcotic agonist, meperidine. The ability to titrate these agents via the IV route greatly adds to their safety in the pediatric patient. The value of continuous monitoring, especially of the respiration with

Outpatient Intravenous Sedation

pidemiologic investigations carried out in the 1960s indicate that at least 6% of the American population avoids dental care due to anxiety.

Unfortunately, similar data for Italy are not available. But our personal experience and that of our colleagues suggests that anxiety deeply affects dental care in Italy, too.

The fear of the dentist, the drill, local anesthesia, and the pain affects also subjects that do not suffer psychological problems for other reasons.

To evaluate situational dental anxiety, subjective methods have been used, as for example a particular questionnaire to be filled in by patients before, during, and after the dental treatment. Not every researcher agrees on the reliability of the subjective scales, but it now a common opinion that they can be very valuable.

Different sedation techniques, inhalatory or intravenous, have been proposed as particular treatments for this kind of patient.

The authors present their experience with the clinical use of a combination of a benzodiazepine with an analgesic-narcotic drug administered IV.

METHODS

Thirty patients with considerable anxiety problems were treated. All these patients refused to be treated with the normal dental procedures.

All the patients had had an empty stomach for at least three hours. After the amnestic, clinical, and laboratory tests evaluation, the anxiety level of each patient was estimated using a self-report anxiety scale: the Interval Scale of Anxiety Response. The anxiety levels were pretracheal stethoscope and pulse oximetry, cannot be overemphasized.

Midazolam maleate has been demonstrated to be a highly effective agent for the management of the recalcitrant pediatric dental patient.

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measured before the intervention, then every 30 minutes until 30 minutes after the same intervention. At the same intervals heart rate and blood pressure were simultaneously controlled.

The sedation was administered with an initial oral dose of 0.18 mg/kg of diazepam and 250 mg of suprofen, followed by IV micro-doses of fentanyl to a maximum total dose of 0.005 mg within the time of the dental procedure. The local analgesia (lidocaine + epinephrine by infiltration) was given 30 minutes after the oral sedation administration.

RESULTS

The results were satisfying for all 30 cases. Each case had an average duration of four hours and 20 minutes, with no difficulties in carrying out the complete scheduled program. The stomatological interventions consisted of all kinds of performance: surgical, conservative, and prosthetic.

The patients never hampered or slowed the different operators' maneuvers.

The changes of anxiety level confirm the efficacy of the sedation technique. The average scale value before the treatment was 14, 4 at 30 minutes from the sedation, and 2 during the dental intervention.

Sometimes we were witness to an abnormal reaction that demonstrated the considerable mental detachment of the patient. On two occasions, some jerking of the patient, misunderstood to be a reaction to pain, turned out to be something else entirely: the patient declared that in fact "he was laughing"! In a third case, the patient began to croon. These reactions always occurred after some hours of intervention.

All the patients declared at the end of the intervention that they were completely satisfied with the treatment.

All the patients were dismissed 30 to 45 minutes after the dental treatment and were accompanied home, as we

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