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PATIENT SATISFACTION WITH SEDATION FOR PERIODONTAL SURGERY: A RANDOMIZED, CROSS-OVER CLINICAL STUDY

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PATIENT SATISFACTION WITH SEDATION FOR PERIODONTAL SURGERY:

A RANDOMIZED, CROSS-OVER CLINICAL STUDY

A thesis submitted in partial fulfillment of the requirements for the degree of Masters of Science in Dentistry at Virginia Commonwealth University.

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Abstract

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PURPOSE: To create a study designed to assess patient satisfaction and preference for oral versus intravenous sedation in conjunction with periodontal surgical procedures.

METHODS: Twenty-six patients who required at least two periodontal surgery procedures and requested sedation for treatment, participated in our study at VCU Department of Periodontics. This was a randomized, cross-over design with groups which received an intravenous sedative regimen with or without oral sedation premedication for one surgery and oral sedation medication alone for the other surgery. The primary outcome measurement was the type of sedation preferred by the subject.

RESULTS: 14/26 (53.8%) subjects indicated a preference for intravenous sedation, compared with 7/26 (26.9%) subjects who preferred oral sedation alone. 1/26 (3.8%) subject reported that they would prefer no sedation after experiencing both oral and oral/intravenous combination sedation methods. 4/26 (15.3%) of the subjects who completed the study reported “No Difference” with regards to their preference for either method of sedation.

CONCLUSION: More subjects preferred intravenous sedation and would consent to the sedation again for any future needed surgery. This study supports the need to offer intravenous sedation with periodontal surgery

INTRODUCTION

A large percentage of the population experience some degree of dental anxiety and a sizable minority of the population are so anxious that they avoid dental treatment altogether.[1] Some dentally anxious patients avoid dental treatment because of the fear of pain while others reported slightly more fear about reprimands for poor oral hygiene and shame for their dental anxiety. High dentally anxious subjects reported that they were reluctant to talk about their anxiety with the dentist.[2] Among the prominent historical causes of dental anxiety is the patient's perception of mismanagement by the dentist, greater sensitivity to pain, fear of an oral injection and the high-speed handpiece.[3] Despite these reasons, patient anxiety can be managed by using the appropriate stress reduction technique to improve patient cooperation and operator performance. Included in these techniques are oral and intravenous (IV) sedation.

Clinicians generally give oral premedication for oral sedation as a first consideration in the management of the mildly apprehensive dental patient. Since it is easier to administer, convenient and readily available at a reasonable cost, oral sedation is one of the most popular peri-operative sedation modalities. [4]

Advantages of oral medication

1) convenience and simplicity as most people are familiar with taking medications in pill form,

2) drugs are readily available by prescription,

3) there are no overhead costs to the dentist

4) drug reactions are generally less severe,

5) an oral route eliminates the need for premedication by intramuscular injection,

6) oral sedation requires only minimal training, and

7) the duration of action can extend into the post-treatment period.

Disadvantages of oral medication;

1) minimal and unpredictable effects in extremely apprehensive patients,

2) possibility of noncompliance,

3) response to oral medications is unpredictable regardless of level of pre-operative anxiety,

4) dosages are largely empirical, and

5) prescription costs can be high for only one or two doses.[5]

Results with oral sedation agents are not always predictable and can exhibit extremely variable responses. The onset of action is dependent upon the rate of absorption from the small intestine. A delay in the onset of action can also occur with a decrease in gastric motility which may be related to increased anxiety. Once oral agents have been absorbed, many will undergo a "first pass" metabolism through the liver which ultimately determines the concentration of a drug that is available for binding at receptor sites.[6] The dosages used for oral sedation are empirical and are usually based on body weight. While most patients will respond in the desired manner, some may receive little or no effect while others may become obtunded.[7] In some cases, oral sedation can be effective when combined with intravenous agents for the management of moderate to severe dental anxiety.

An alternative to oral sedation is IV sedation. Intravenous sedation was first recorded in a scientific journal in 1665 when Sir Christopher Wren published his experiments with injection of opium into a ligated vein of a dog using a quill and a

bladder as syringe.[8] He reported, “By making ligatures on the veins, and then opening them on the side of the ligature towards the heart, and by putting into them slender syringes or quills, fastened to bladders containing the matter to be injected; performing that operation upon pretty big and lean dogs, that the vessels might be large enough and easily accessible.” He then injected opium into the easily accessible large vessels of the hind legs of the dogs and reported, “the success was that opium, being soon circulated into the brain did within a short time stupify, though not kill the dog.” In the 1960s and 1970s, the Jorgensen technique used this technique with a medium acting barbiturate, pentobarbital, a narcotic, meperidine and scopolamine was a well established procedure for many dentists for the control of apprehension, fear, and the relief of stress.[9,10]

The advantages of intravenous administration of sedative drugs are well known; notably, the ability to titrate dosage incrementally to a clinical end point with reliable and less variable effect that can be obtained by the oral route. When administering drugs, the intravenous route has the major advantage of being more predictable. The peak drug plasma concentration is obtained nearly instantaneously because absorption delays are bypassed. Onset of action of drugs administered by the intravenous route is the most rapid of all the sedation techniques. Rapid onset of action is the principal advantage of this route as well as the greatest safety feature. It allows for the titration of drugs in small, incremental dosages until the clinical effects have been achieved. Maintenance of intravenous access affords for the opportunity to sustain suitable levels of sedation for longer procedures as additional sedative or analgesic drugs can be administered. In addition, intravenous access allows for administration of resuscitative drugs. Compared to a single oral dose, incremental dosing facilitates achievement of precise levels of

sedation, with less danger of oversedation.[11] The degree of control over the level of sedation afforded by the intravenous route allows for the optimal management of patients exhibiting moderate to severe anxiety or fear of the dental setting.

Multiple drugs have been used for sedation including benzodiazepines and narcotics. Benzodiazepines have a specific anxiolytic, anticonvulsant, sedative, and amnestic properties. Specific receptors for the benzodiazepines have been identified. The locations of these receptors parallel the locations of both the major inhibitory neurotransmitter in the brain, gamma-aminobutyric acid (GABA), and the major inhibitory neurotransmitter in the spinal cord, glycine. Benzodiazepines enhance GABA and glycine activity, thereby producing their therapeutic effects. Activation of the GABA receptor causes membrane chloride channels to open, increasing the influx of negative chloride ions through the cell membrane, thereby preventing depolarization of the neuron. Benzodiazepines appear to selectively suppress areas of the CNS, exerting their greatest inhibitory effects on the subcortical limbic system. The hippocampus and amygdala appear to play an important role in memory function. Disruption to these structures prevents conversion of information into long-term memory, although memory of prior events is not affected. Inhibition of these areas by benzodiazepines is responsible for the anterograde amnesia characteristically produced by these drugs.[12] The mechanism is selective and dose-related, acting on long-term memory and impairing the acquisition of new information. The rate of distribution of these agents depends on the lipid solubility. The elimination half-life for diazepam is from 20-100 hours. In addition, diazepam has two active metabolites, desmethyldiazepam and oxazepam. Both metabolites produce sedative effects. The sedative effects of the benzodiazepine

medications have very been useful in contemporary dental surgery and are applicable in both enteral and parenteral forms.

Lorazepam is a well established drug used for oral sedation that is a derivative of diazepam but differs from the other benzodiazepines structurally and pharmacokinetically. It has a central depressant effect in both oral and parenteral forms that is 5x as potent as the same dose of diazepam.[13] This drug also produces long-lasting anterograde amnesia.[14] Lorazepam has a delayed onset of action after oral administration with a peak at 90 minutes and a duration of approximately six hours. It has a much shorter half-life than diazepam and although some of the drug may be transformed to other metabolites, it is primarily conjugated to glucuronic acid and excreted in this inactive form.[13] Some have found lorazepam 2.5-5mg to be effective for sedation but not anxiolysis while prolonged drowsiness has been a significant side effect.[15,16] Occasionally, there are situations when a drug with a longer duration of action is indicated and night sedation with lorazepam followed by a repeat dose on the morning of the operation is beneficial for the pathologically anxious.[17]

For intravenous conscious sedation, a baseline level of sedation using a combination of short to medium duration drugs is used. Diazepam has high lipid solubility, rapidly crosses the blood-brain barrier, which results in a fast onset of action. However, it is also rapidly distributed to peripheral fat, resulting in a fairly short duration of action after a single dose, despite a prolonged elimination half-life and active metabolites with even longer duration. Diazepam was first synthesized in 1961 and was used principally as an orally administered tranquilizer and muscle relaxant. Chemically, diazepam is a benzodiazepine. It has a powerful sedative, amnestic and muscle relaxant

properties. Its main action is on the limbic system, the area of the brain concerned with emotions and emotional response to external stimuli. Because of the reported amnesia associated with the intravenous use of diazepam, a French dentist, Davidau[18], first used it for general dental procedures in 1965. Alternatively, midazolam is a potent imidobenzodiazepine with amnestic and anxiolytic properties. It is widely used for brief diagnostic procedures, conscious sedation and for inducing general anesthesia.[14]

Moderate doses of short-acting narcotics such as fentanyl or meperidine are frequently used in combination with benzodiazepines to potentiate the sedation while providing mild analgesia, euphoria and psychologic detachment.[11] Meperidine is one of the most commonly used opioids for moderate sedation and analgesia. It acts on the mu receptors found in the central nervous system as well as in the bowel. Its analgesic properties include inducing sedation and reducing reaction to painful stimuli and motor activity. Meperidine is primarily metabolized in the liver. Its side effects include hypotension, histamine release, nausea and vomiting and respiratory depression.[19] The combination of a sedative and analgesic (narcotic) has been shown to significantly reduce the amount of sedative needed to achieve the clinical end-point.[20]

With these characteristics in mind, these drugs can be used separately or in combination methods to achieve anxiety control. Combination techniques utilizing oral premedication followed by intravenous sedation were found to significantly reduce pre-treatment anxiety. However, the use of an oral premedication did not reduce the amount of intravenous drug required for sedation nor did it alter the time of discharge.[21]

Selection of the appropriate technique, whether oral sedation or IV sedation, is based on the degree of patient apprehension and should be individualized according to

the sedative effect required, the need for amnesia, the need for an elevated pain threshold and the duration of the dental procedure. The American Association of Periodontology has taken a stance that advanced education in conscious sedation is extremely important to periodontics, in which extensive and prolonged surgical procedures are commonplace.[29] Currently available sedative and analgesic drugs with conscious sedation techniques, used in conjunction with invasive periodontal therapy, results in patients having safe, non-traumatic treatment experiences.[22,23,24,25,26,27] This tends to enhance public perception of periodontal treatment.[28,29,30]

There have been several studies in the dental literature describing and comparing various sedation protocols with a variety of sedation medications. All of these comparative studies looked at the efficacy of either an intravenous narcotic or barbiturate in combination with intravenous diazepam or midazolam[31,32,33,34,35], a direct comparison of two intravenous benzodiazepines[36,37,38,39,40,41] or a direct comparison of an oral benzodiazepine versus an intravenous or oral benzodiazepine monotherapy[42,43,44,45]. All of these studies used the removal of 3rd molars as the test procedure. This procedure can be done very quickly in contrast to many periodontal procedures, which take significantly more time to complete. As such, a sedation protocol with more long acting agents must be utilized. The intravenous sedation protocol at the Virginia Commonwealth University Graduate Periodontics program includes the use of diazepam, midazolam and meperidine. For oral sedation, the drug of choice is lorazepam.

Thus, the aim was to create a study designed to assess patient satisfaction and preference for oral versus intravenous sedation in conjunction with periodontal surgical procedures.

METHODS & MATERIALS

Patient Population. A randomized, cross-over study was designed for healthy adult outpatients who required multiple periodontal surgeries to include: osseous surgery, extraction of teeth, guided bone regeneration, implant placement, and/or periodontal plastic surgery. The Institutional Review Board of Virginia Commonwealth University reviewed and approved this research protocol. Patients were recruited from the Virginia Commonwealth University School of Dentistry from July 2009-October 2010. 44 subjects were screened and written informed consent was obtained based on the inclusion criteria. Prior to consideration for sedation, each patient completed an extensive medical history form, and when judged necessary, medical consults were obtained. Particular attention was given to medications being taken by the patient. A baseline recording of vital signs, including blood pressure and pulse, was performed. Patients were included in the study if they: 1) 18 years of age and older; 2) required two or more periodontal surgeries with sedation; and 3) were ASA (American Society of Anesthesiologists) Class 1 or 2. Patients were excluded from the study if they: 1) were younger than 18 years of age; 2) were ASA Class 3 and 4; 3) were pregnant or lactating females; 4) had uncontrolled systemic conditions; 5) had contraindications to sedation medications; 6) had moderate to severe cognitive impairment; 7) take a benzodiazepine for a chronic condition or 8) had been determined poor candidates for sedation by their primary care physician. Consent was either in the form of a general consent for dental surgery or as a specific informed consent for intravenous sedation.

Procedure

General. All of the patients had paired or nearly identical operations that were performed at separate sittings. The randomization of the sedation protocol was by coin flip. One operation was conducted with oral conscious sedation medication by prescribing 1-2mg lorazepam 60 minutes prior to the appointment. The other surgery was performed with or without oral premedication with 1-2mg lorazepam followed by intravenous diazepam 5mg/ml, midazolam 1mg/ml and with or without meperidine 50mg/ml. The cross-over design of this study allowed for the subjects to be their own control. The procedures were performed by graduate periodontal residents at the Virginia Commonwealth University School of Dentistry Department of Periodontics.

Sedation. All patients were prescribed 1-2mg lorazepam to take 60 minutes prior to the scheduled oral sedation surgical appointment. Many of the oral sedation subjects, were prescribed to take an additional 1mg lorazepam prior to going to bed the night before the surgical appointment. In most cases but not all, patients scheduled for intravenous sedation procedures premedicated with 1-2mg lorazepam 60 minutes prior to their scheduled appointment.

All intravenous sedation procedures employed two titrated sedatives, either alone or in conjunction with a proportional dose of a narcotic similar to those recommended by Jorgensen. Sedatives used were diazepam and midazolam. The narcotic used was meperidine. Following venipuncture with a 20-gauge catheter and release of the tourniquet, a free inflow of 0.9% Sodium Chloride solution was established as surrounding tissues were carefully observed. If no signs of hematoma or subcutaneous

accumulation of fluids were noted, a test dose of no more than a few drops of diazepam was administered through the intravenous line. After waiting one full minute for signs of paradoxical reactions to the drugs, the diazepam was administered in small increments over 2-3 minutes until a titrated baseline was obtained based on Verrill's sign, ptosis, slurred speech and drowsiness. Diazepam was not used following initial baseline sedation. A proportional amount of meperidine was then slowly administered followed by 0.5mg of midazolam. Surgical sites were anesthetized with a combination of 2% lidocaine containing 1:100,000 epinephrine and/or 4% articaine 1:100,000 epinephrine and/or 0.5% bupivicaine 1:200,000 epinephrine by both nerve block and infiltration. Conventional periodontal surgical operations employing full thickness mucoperiosteal soft tissue flaps, osseous resection, tooth extractions with and without site preservation (guided bone regeneration), sinus augmentations, dental implant placement and periodontal plastic surgery were then accomplished. During the surgery, after oral local anesthesia was given, midazolam was introduced into the intravenous line at a dosage of 0.5mg/ml and was given in small 1ml increments approximately every 10-20 minutes throughout the surgery.

Post-sedation. At the conclusion of the surgery and sedation, an observational period began in which vital signs were measured until the patient scored at least an 8 Aldrete score[52] and vital signs were normal. At that time, the intravenous catheter was removed and both written and verbal post-operative instructions were given to both the patient and their escort. Patients were escorted to their car in a wheelchair by the resident surgeon or sedating resident.

Assessments

Anxiety. A pre-operative questionnaire assessing the patients' demographics and baseline anxiety was given at the pre-surgical appointment. The patients' pre-operative apprehension was assessed using both the Corah Dental Anxiety Scale[1] (DAS) and a Visual Analogue Scale (VAS). The DAS, through a short 4-item questionnaire consisting of multiple-choice questions with only one possible answer, assesses State anxiety and the degree of anticipatory anxiety generated by a dental treatment. State anxiety reflects a transitory emotional state or condition that is characterized by subjective, consciously perceived feelings of tension and apprehension, and heightened autonomic nervous system activity.[46] In other words, State anxiety is the transitory affective response to an anxiety-provoking situation which then ultimately retreats. A score of 9-12 indicates moderate anxiety whereas a score of 13-14 indicates high anxiety and a score of 15-20 indicates severe dental anxiety and/or phobia. The 100-mm VAS[47] where 0 denoted no anxiety about dental treatment and 100 denoted complete anxiety about dental treatment was used to corroborate the DAS and give more data about the subjects' baseline anxiety.

Amnesia. The patients completed a post-operative questionnaire immediately at the conclusion of each procedure, while still under the influence of the sedation medications, which included questions about their experience and his/her ability to recall events during the period from the beginning to the conclusion of the appointment.

Cardiovascular and Respiratory function. Heart rate, blood pressure, pulse oximetry, and EKG were continuously monitored and recorded on a sedation record

every 5 minutes throughout each procedure. The sedating dentist used a prechordial stethoscope to monitor breath sounds throughout the procedure as well.

Surgeon's ratings. In each immediate post-operative period, each surgeon recorded his/her impressions of the patients' behavior during the surgery assessed by the Modified Ramsay Sedation Score[48], the North Carolina Behavioral Score[49] and the Overall Effectiveness of Sedation Score[50].

The Modified Ramsay Sedation Score assesses patients from one to six based on their level of sedation. A score of one equals a patients who exhibits anxiety, agitation and restlessness score of two corresponds to a patient who is cooperative, oriented and tranquil; a score of three represents a patient who responds only to commands; a score of four demonstrates a brisk response to stimulus, while a score of five demonstrates a sluggish response to stimulus; and a score of six represents no response to forceful stimulus. An ideal score under sedation is two.

The North Carolina Behavior Rating Scale allows the practitioner to assess behavior at critical events of the procedure. Behavior ranging from quiet and cooperative (1) to wild and defiant (4) is scored using this scale. The North Carolina Behavior Rating Scale also allows for an overall effectiveness of sedation score, ranging from satisfactory (1) to unsuccessful (4).

The surgeons rated the subjects' depth of sedation with a classification of Minimal, Moderate or Deep[51]. Minimal Sedation is defined as a medically controlled state of depressed consciousness that allows protective reflexes to be maintained, retention of the patient's ability to maintain a patent airway independently, continuously permits appropriate response by the patient to physical stimulus or verbal command all

while ventilatory and cardiovascular functions are unaffected. Moderate Sedation is defined as a drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation while no interventions are required to maintain a patent airway and stable cardiovascular functions. Deep Sedation is defined as a medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused and may be accompanied by a partial loss of protective reflexes and inability to respond to physical stimulation or verbal commands.

An Aldrete score[52] was also recorded prior to release of the patient. The Aldrete Score is a post-anesthesia (sedation) recovery scoring system which assesses activity, respirations, circulation, consciousness, and oxygen saturation. Each category is scored from 0 to 2. Each patient was not discharged from the clinic until they achieved an Aldrete score of at least eight.

Patients' ratings. The author (JMS) called the patient 24 hours post-operative and asked the patient to complete a secondary post-operative questionnaire by phone which included similar questions as immediately post-operative in order to determine both amnesia and patient experience while not under the influence of the sedation medications as well as others to gauge the patients' preference of type of sedation and willingness to be sedated one way or the other for a future periodontal procedure if needed. Patients were asked if they experienced any nausea or vomiting during their sedation experience and during the post-operative period. Patients were also asked about their willingness to be sedated these ways for future periodontal procedures based on the

regular cost of sedation in the graduate program clinic($175) as well as the usual and customary cost of sedation in private practice ($350).

STATISTICAL ANALYSIS

The major goal of this report was to relate the preference of sedation method of the patient at the end of the study to age, race gender, and baseline anxiety. To evaluate this hypothesis analysis of variance was used. Secondary analyses included evaluating relationships between method of sedation and surgeon's evaluation of various aspects of patient's behavior during surgery. These relationships were evaluated with chi squared analysis due to the categorical nature of the outcome. Additional secondary analyses were done evaluating patients' recall of critical events immediately after and 24 hours after surgery.

RESULTS

A total of 26 subjects (TABLE I) completed the study (17 Female / 9 Male) with a mean age of 54±12.9 years and a mean weight of 82±16.9 kg. Patients were excluded or dropped from the study population due to a change in their treatment plan, which did not require two surgeries or a failure to accept the proposed treatment plan to address their periodontal disease or partial edentulism. The study population was predominantly Caucasian (50.0%) and African-American (46.2%) with one subject that was Asian (3.8%). Treatments included quadrants of osseous resective surgery, multiple extractions, guided bone regeneration, implant placement surgery and mucogingival surgery (Figure 2).

Sedation Procedure. Of all 52 surgeries, 20/52 (38.5%) surgical patients were premedicated the night prior to the periodontal surgery with lorazepam 1mg. Of the intravenous sedations, only 2/26 (7.7%) subjects did not have oral premedication of lorazepam 1-2mg.

Anxiety. Baseline anxiety measured by Corah's Dental Anxiety Scale (DAS) and Visual Analogue Scale (VAS) (TABLE II). Mean DAS score was 10.41±3.54 and 10.67±4.15 for females and males, respectively. Mean VAS measurements were 51.26±31.52 and 39.78±34.19 for females and males, respectively. Baseline anxiety and

DAS scores were not related in this sample of subjects' to race, gender, age and whether or not the individual had ever been sedated before. (ANOVA).

Amnesia. There was a significant difference in the amnesia between the two types of sedation methods. Immediately following surgery, patients being sedated with oral sedation medication alone reported 19.23% amnesia of local anesthetic administration, 50% amnesia of the initial incision/start of surgery, and 38.46% amnesia of suturing at the end of the procedure. When asked 24 hours later, this same group reported 19.23% amnesia of local anesthetic administration, 69.23% amnesia of the initial incision/start of surgery, and 38.46% amnesia of suturing at the end of the procedure. In addition, after 24 hours, this group showed 57.69% amnesia of the post-operative instructions given to them immediately following the surgery (TABLE III) (Figure 3).

In comparison, immediately following surgery, patients being sedated with a combination of oral and intravenous sedation reported 23.08% amnesia of local anesthetic administration, 69.23% amnesia of the initial incision/start of surgery, and 57.69% amnesia if suturing at the end of the procedure. When asked 24 hours later, this group reported 46.15% amnesia of local anesthetic administration, 84.62% amnesia of the initial incision/start of surgery, and 65.38% amnesia of suturing at the end of the procedure. In addition, after 24 hours, this group showed 73.07% amnesia of the post-operative instructions given to them immediately following the surgery (TABLE IV) (Figure 4).

When asked about the first thing they remembered after the surgery had been completed, a large majority of subjects recalled getting into a wheelchair as their first recalled event following surgery. Placing the patient into a wheelchair is standard

practice in this clinic following sedations, so it is not surprising that most subjects remembered this, but there were unpredictable results with regard to duration of amnesia. Some subjects didn't remember the ride home after remembering the wheelchair after surgery while other vividly remembered their ride home. These results seem to be unrelated to the method of sedation. Many subjects recalled the placement intravenous catheter or pre-sedation events such as getting into the dental chair or EKG monitor placement when they were asked about events they recalled during the surgery. Interestingly, many subjects recall remembering "everything" after being sedated with oral sedation medication alone.

Surgeon's Ratings. The surgeons' ratings using the Modified Ramsay Sedation Score (TABLE V) (Figure 5) indicated 3/26 (11.5%) of the subjects sedated with oral sedation medication alone still exhibited anxiety and agitation and restlessness during the procedure. These three patients exhibited a high to severe level of baseline anxiety. 12/26 (46.2%) of the subjects were cooperative, oriented and tranquil during the procedure. 5/26 (19.2%) of these subjects responded only to commands. 2/26 (7.7%) demonstrated a brisk response to a stimulus. 4/26 (15.4%) demonstrated a sluggish response to a stimulus. During sedation of the subjects with a combination of both oral and intravenous sedation medication, the surgeons' ratings with the Modified Ramsay Sedation Score indicated 0/26 (0%) of the subjects exhibited anxiety, agitation or restlessness. 7/26 (26.9%) of subjects were cooperative, oriented and tranquil during the procedure. 9/26 (34.6%) of these subjects responded only to commands. 1/26 (3.8%) demonstrated a brisk response to a stimulus while 9/26 (34.6%) demonstrated a sluggish response to a stimulus. No subject demonstrated a response only to forceful stimulus

when sedated with either method. There was no statistical relationship between baseline anxiety and how the subjects behaved during surgery. Also, the relationship between the type of sedation and the subjects' Modified Ramsay score was not significantly different between the methods (chi squared test).

Using the North Carolina Behavioral Rating Scale (NCBRS) (TABLE VI) (Figure 6), the surgeons rated the subjects as "Quiet" utilizing oral sedation medication alone 20/26 (76.9%) of the procedures while 5/26 (19.2%) were rated as "Annoyed" and 1/26 (3.8%) was "Upset". The five subjects who were rated as "Annoyed" (NCBRS-2) after oral sedation all were scored as having moderate to severe baseline anxiety via both the DAS and VAS. For subjects having oral/intravenous sedation, 24/26 (92.3%) were "Quiet", 1/26 (3.8%) was "Annoyed", and 1/26 (3.8) was "Wild". The "Wild" subject had a baseline anxiety score in the high range on the DAS and in the severe range on the VAS. The NCBRS was not different between the groups both by a continuous response and by a categorized response t-test and/or McNemar's test.

The surgeons' ratings of Overall Effectiveness of Sedation (TABLE VII) (Figure 7) resulted in 17/26 (65.4%) of oral sedation only procedures were deemed successful in that the patient slept throughout the procedure with minimal crying or movement at critical events (i.e. local anesthesia administration, initial incision, osseous resection and suturing). Only 9/26 (34.6%) of the oral sedations were deemed moderately successful in that the patient showed moderate amounts of crying and movement at times other than critical events, but behavior did not hinder the progress of sedation. When intravenous sedation was combined with oral sedation, 24/26 (92.3%) of the sedation were successful, 1/26 (3.8%) was moderately successful and 1/26 (3.8%) was unsuccessful as the patient

exhibited continuous crying and movement throughout the sedation and treatment was hindered and performed with difficulty. There was a significant difference between PO and IV sedation with regards to the relative success of the sedation, $p = 0.0035$, chi squared test.

Depth of sedation as measured by the surgeons via the Modified Ramsay Sedation Scale, the North Carolina Behavior Rating Scale and the Overall Effectiveness of Sedation Scale show that more subjects had remaining anxiety and agitation with the oral sedation medication alone compared to the intravenous sedation. In addition, fewer subjects taking oral sedation alone exhibited signs of depth of sedation that required more stimulatory action to rouse them whereas more intravenous sedation subjects required verbal, light tactile and strong tactile stimulation to respond to commands. Still, most of the subjects remained quiet or slightly annoyed during either method of sedation and most of the surgeries were deemed successful or moderately successful by the operating surgeons.

As seen by the surgeons, 17/26 (65.38%) of those sedated with oral medication alone resulted in minimal sedation while 9/26 (34.62%) were judged to be moderately sedated. After combination oral/intravenous sedation, as seen by the surgeons, 6/26 (23.08%) subjects were judged to minimally sedated, 19/26 (73.08%) were judged to be moderately sedated and 1/26 (3.85%) resulted in deep sedation (TABLE VIII). There was a significantly different depth of sedation between PO and IV($p = 0.0025$).

No subject was discharged without an Aldrete score of at least 8. All patients were stable at discharge with Aldrete scores of 10.

Patient Ratings. All subjects except one reported feeling comfortable during the surgery both immediately following each procedure as well as 24 hours later. All subjects except two reported feeling sleepy during the procedure immediately following each procedure. When asked 24 hours later, 4/26 subjects reported not feeling sleepy during the procedure utilizing oral sedation alone. When asked about how the subjects spent the rest of their day following the procedure, 14 subjects and 16 subjects reported sleeping for much of the day following oral sedation and oral/intravenous sedation, respectively. Six oral sedation alone patients reported feeling groggy for the rest of the day while eight of the oral/intravenous sedation subjects reported this same feeling. Six oral sedation alone subjects reported being awake in the 24 hours following the surgery while only two oral/intravenous sedation subjects reported being awake in the 24 hours following the surgery.

After both procedures had been completed, 25/26 (96.2%) of subjects reported that they would recommend this the oral/intravenous combination method of sedation to someone else needing periodontal surgery, while 23/26 (88.5%) would recommend the lorazepam by mouth alone method of sedation for periodontal surgery. The same percentages would agree to consent again in the future for these methods of sedation based on their experiences (Figure 8). Interestingly, after the 1st surgery, every subject recommended sedation to someone else needing periodontal surgery, would consent to be sedated that way again in the future and cost of sedation did not affect consenting for sedation in the future. The majority of subjects (24/26) agreed when asked if they would consent to be sedated in the future based on the cost of the sedation method ($65 for oral sedation monitoring and $175 for oral/intravenous combination sedation and monitoring)

(Figure 9). Interestingly, a greater percentage of subjects (9/26) declined to consent for future sedations in conjunction with periodontal surgery based on the increased usual and customary fee of $350 for sedation monitoring (Figure 10). This indicates that a small percentage of subjects will feel that cost for sedation is not worth the benefit whereas most subjects prefer to be sedated for periodontal surgery regardless of cost.

Subjects showed greater satisfaction with the oral/intravenous sedation than oral sedation alone (TABLE IX). Of the 26 subjects who completed the study, 14 (53.8%) indicated a preference for "Intravenous" sedation, compared with 7/26 (26.9%) who preferred "Oral" sedation alone. 1/26 (3.8%) reported that they would prefer no sedation at all after experiencing both oral and oral/intravenous combination sedation methods. 4/26 (15.3%) of the subjects who completed the study reported "No Difference" with regards to their preference for either method of sedation. Table IX illustrates that the anxiety scores of those who had no preference for method of sedation were significantly different from those who preferred oral sedation ($p = 0.05$) (ANOVA and Tukey's test for multiple comparisons).

DISCUSSION

Preference. The primary outcome measure of this study showed that more subjects preferred intravenous sedation in conjunction with periodontal surgery to oral sedation alone. Seeing a significant difference in depth of sedation between the two methods combined with the primary outcome can be interpreted as more subjects preferred the moderate sedation experience and would consent for it again. Interestingly though, some subjects preferred to be minimally sedated or did not like the feeling of being moderately sedated, which made a small number of subjects feel out of control, and

therefore preferred the oral sedation alone. Still, some subjects found no difference in their sedation experiences between the two methods and only one subject preferred to have any future surgery completed with no sedation. The interpretation of these findings highlight the fact that there remains significant variability in the responses to these two methods of sedation. Even though more periodontal surgery subjects in this study preferred the more moderate sedation of the intravenous methods during their procedures in this study, likely due to its titratability, approximately one-third of the subjects felt that the intravenous sedation was worse than expected and had a better experience with oral medication alone. If the population of this study represents the anxiety, behavior and attitudes of most adult patients, then it is reasonable to conclude sedation should at least be offered to periodontal surgery patients.

Anxiety. A subject may have scored in the high anxiety category in one scale and the low or moderate anxiety in the other scale. These scores could be related between the four subjects who had no preference for sedation method and the seven subjects who preferred oral sedation. With this as the only significant connection between baseline anxiety level and sedation method preference, it was difficult to predict which method will be more satisfactory to an anxious patient desiring sedation in conjunction with periodontal surgery. This interpretation is in agreement with Corah et al. who found that there appears to be no relationship between the assessment of satisfaction and any of the measures of anxiety.[1] Previous reviews have discussed oral sedation use with patients who have minimal dental anxiety whereas patients with more severe anxiety would benefit from intravenous sedation.[5,11] The present study cannot confirm this statement

and further cannot confirm that baseline anxiety level is predictive of how a patient will react to a certain sedation method.

Amnesia. When subjects were sedated with intravenous medications they showed more amnesia of critical events during the surgery than those sedated with oral medication alone. Although studies comparing the relative amnesia of oral lorazepam and intravenous diazepam are few[53,54], there are studies that measure relative amnesia between other oral sedation medications and intravenous diazepam[43,44,45,55,56] as well as relative amnesia between intravenous diazepam and intravenous midazolam. Several of these studies found that intravenous midazolam produced more profound and longer lasting anterograde amnesia compared to intravenous diazepam.[36,37,38,39,40,41] Relating the results of all of these studies can show that intravenous and oral midazolam is a more potent amnestic agent than oral lorazepam which is about as potent an amnestic agent than intravenous diazepam but takes longer for onset. Results of O'Boyle et al.[44] indicated that 15mg of midazolam PO is superior, in some respects, to a 10mg dose of IV diazepam for conscious sedation in association with oral surgery. So therefore, importance of midazolam use in sedation has been elucidated by these studies to be the major inducer of anterograde amnesia during oral and periodontal surgery. The amnestic properties of diazepam are weaker relative to midazolam and the oral sedation medications used in the present study. This is apparent when looking at the results of the present study, which show significantly more amnesia of local anesthetic administration, initial incisions, suturing and post-operative instructions following intravenous sedation as compared to oral sedation alone and slightly more amnesia of the procedure 24 hours after surgery as compared to immediately following surgery. Inevitably, it is what the

patient subsequently remembers of the procedure that is important, not what is recalled in the post-operative period.

Satisfaction. Subjects in the present study would overwhelmingly consent again for sedation for a future periodontal surgery procedure based on their experience with sedation of both methods. In addition, knowing that the cost of the sedation and monitoring was waived for this study (the subjects were informed both at the per-operative appointment as well as at the 24 hour post-operative questionnaire that the cost for the sedation and monitoring was $65 for oral sedation alone and $175 for intravenous sedation), the subjects still would consent again for sedation in conjunction with a future periodontal surgery based on the cost of sedation. Interestingly, many of the subjects, when informed of the cost of intravenous sedation in a private practice setting (approximately $300-$350), declined future consent for intravenous sedation in conjunction with periodontal surgery after accepting to consent both based on their experience and the cost of sedation at the Virginia Commonwealth University Department of Periodontics. This an interesting finding as 9/26 subjects thought that being sedated for surgery was not worth the extra cost in a private practice setting while only 2/26 subjects found that the cost of sedation in the school setting was not worth the cost. This finding may be related to the current economic climate in the United States, which may be resulting in many patients declining treatment options for periodontal disease. Interestingly, many other subjects would rather be sedated for periodontal surgery regardless of the cost.

Limitations. A total of twenty-six subjects completed this study out of forty-four that originally were accepted and consented to participate. All of the subjects who were

dropped from the study failed to schedule their surgical appointments due to personal or financial reasons and chose to delay or not accept treatment. The limited number of subjects completing this study may result in limited statistical power. Also, the variation in surgery type, experience of the surgeon and type and dosages of both sedation medications and local anesthetic agents brings significant confounders to this study. In this study the surgeons and patients were not blinded in any way as compared to previous studies of this topic. If this study were to be duplicated, addition of blinding characteristics may be beneficial. Also, some of the questions in the questionnaires used in this study have been previously tested and validated while many other questions in these questionnaires have not. As it pertains to amnesia, it was not possible to correlate the subjects' perception of time for the duration of the procedure as compared to the actual time elapsed for the completion of the procedure due to the type of question asked in the subject questionnaire. A visual analogue scale from one to 3 hours would have been a better choice than multiple choice questions to assess the subjects' perception elapsed time.

CONCLUSIONS

In conclusion, in this study more patients preferred to have periodontal surgery while being intravenously sedated as compared to orally sedated. The clinical significance of this finding is that, at minimum, patients should be at least be offered intravenous sedation with periodontal surgery because many of them will be more satisfied with the surgical experience. These patients may have been subject to selection

bias as they may have had higher baseline anxiety than patients who do not require periodontal surgery. Though, this population likely represents typical periodontal surgery patients in that they may be more anxious than other dental patients with regards to periodontal treatment. In many cases, this may be apparent as this population required periodontal surgery for disease developed over many years lacking in professional dental care. These dental patients may very well illustrate the tremendous amount of anxiety still pervasive in our society.

Additionally, baseline anxiety cannot be very accurately correlated to preferred method of sedation. High baseline anxiety is no guarantee that intravenous sedation will be successful and low to moderate baseline anxiety is no guarantee that oral sedation will be successful. Sedation using either technique still remains highly variable between patients. Amnesia was more profound after intravenous sedation compared to oral sedation. Due to this finding, post-operative instructions must be given in writing as most sedated subjects will not remember specific instructions 24hrs later. The surgeons found that intravenous sedation typically resulted in moderate sedation and oral sedation typically resulted in minimal sedation. The majority of subjects were quiet and well-behaved for both surgeries with both methods resulting in successful sedations. The patients mostly had good experiences and appreciated the low cost while many of the patients would opt not to be sedated in private practice due to higher costs.

Future studies in this subject should measure anxiety both pre-op and post-op, vital signs at each critical event, relative success of surgery (i.e. 100% root coverage during mucogingival surgery or adequate pocket reduction during osseous resective surgery, etc.), and amnesia by using photos or objects shown to patients during surgery.

As technology advances, new sedation medications are developed and the mechanisms of action of the benzodiazepines becomes more clear, future studies need to be completed to understand the effect of these medications on the patient experience during periodontal surgery, stability of cardiovascular and respiratory function and anterograde amnesia of critical events during periodontal surgery.

TABLE I. Subject Demographics

		N	
Gender			
	Male	9	34.6%
	Female	17	65.4%
Age (yrs)		26	Mean 54±12.9
Weight (kg)		26	Mean 82±16.9
Race			
	Asian	1	3.8%
	African American	12	46.2%
	Caucasian	13	50.0%

TABLE II. Baseline Anxiety

	DAS			Anxiety (VAS)		
Gender	**N**	**Mean**	**Std Dev**	**N**	**Mean**	**Std Dev**
Female	17.00	10.41	3.54	17.00	51.26	31.52
Male	9.00	10.67	4.15	9.00	39.78	34.19

TABLE III. Patients' ability to recall events during surgery (PO only)

Surgical event	Day of Surgery			24 hrs Post-op	
	Yes	% amnesia		Yes	% amnesia
Administration of Local Anesthesia	21	19.23		21	19.23
Initial Incision	13	50.00		8	69.23
Suturing	16	38.46		16	38.46
Do you remember the post-op instructions given to you after the surgery?	N/A	N/A		11	57.69

TABLE IV. Patients' ability to recall events during surgery (PO/IV)

Surgical event	Day of Surgery			24 hrs Post-op	
	Yes	% amnesia		Yes	% amnesia
Administration of Local Anesthesia	20	23.08		14	46.15
Initial Incision	8	69.23		4	84.62
Suturing	11	57.69		9	65.38
Do you remember the post-op instructions given to you after the surgery?	N/A	N/A		7	73.07

TABLE V. Modified Ramsay Sedation Score

	PO	%	IV	%
1	3	11.5	0	0.0
2	12	46.2	7	26.9
3	5	19.2	9	34.6
4	2	7.7	1	3.8
5	4	15.4	9	34.6
6	0	0.0	0	0.0

1 - patient who exhibits anxiety, agitation and restlessness
2 - patient who is cooperative, oriented and tranquil
3 - patient who responds only to commands
4 - patient who demonstrates a brisk response to a stimulus
5 - patient who demonstrates a sluggish response to stimulus
6 - patient who does not demonstrate a response to a forceful stimulus

TABLE VI. North Carolina Behavioral Rating Score

	PO	%	IV	%
1	20	76.9	24	92.3
2	5	19.2	1	3.8
3	1	3.8	0	0.0
4	0	0.0	1	3.8

1 - Quiet: patient quiet or sleeping with only extraneous, inconsequential movements
2 - Annoyed: patient cooperative for treatment but with 1 or 2 of the undesirable behaviors
3 - Upset: patient noticeably disturbed, with 2-3 undesirable behaviors present, making treatment difficult but possible
4 - Wild: patient extremely defiant with presence of all undesirable behaviors, making treatment extremely difficult

TABLE VII. Overall Effectiveness of Sedation Scale

	PO	%	IV	%
1	17	65.4	24	92.3
2	9	34.6	1	3.8
3	0	0.0	0	0.0
4	0	0.0	1	3.8

1 Successful: patient slept throughout procedure with minimal crying or movement at critical events*
2 Moderately successful: successful sedation with moderate amounts of crying and movement at times other than critical events,* but behavior did not hinder progress of sedation
3 Mildly successful: treatment was accomplished as planned, but because of screaming or combative movements throughout the sedation the progression of portions of the treatment was hindered
4 Unsuccessful: continuous crying or movement throughout sedation; treatment was performed with difficulty; the progression of all treatment was hindered

***** Critical events include topical placement, penetration of the needle, initial incision, initial activation of bur during osseous resection and suturing.

TABLE VIII. Subject depth of sedation

	PO	%	IV	%
Minimal	17	65.38	6	23.08
Moderate	9	34.62	19	73.08
Deep	0	0.00	1	3.85

Minimal Sedation
A medically controlled state of depressed consciousness that allows protective reflexes to be maintained, retains the patient's ability to maintain a patent airway independently and continuously permits appropriate response by the patient to physical stimulation or verbal command, e.g. “open your eyes.” Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation
A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep sedation
A medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused. It may be accompanied by a partial loss of protective reflexes, and includes the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

TABLE IX. Preference for Sedation Method

		Age(yrs)		DAS		Anxiety (VAS)	
Preferred method	**N**	**Mean**	**Std Dev**	**Mean**	**Std Dev**	**Mean**	**Std Dev**
Intravenous	14	52.79	13.87	11.50	3.84	49.43	32.10
No Difference	4	53.25	17.00	12.25	2.50	81.50	12.34
No Sedation	1	69.00	.	4.00	.	0.00	.
Oral	7	54.86	9.77	8.43	2.23	30.21	22.93

Figure 1.

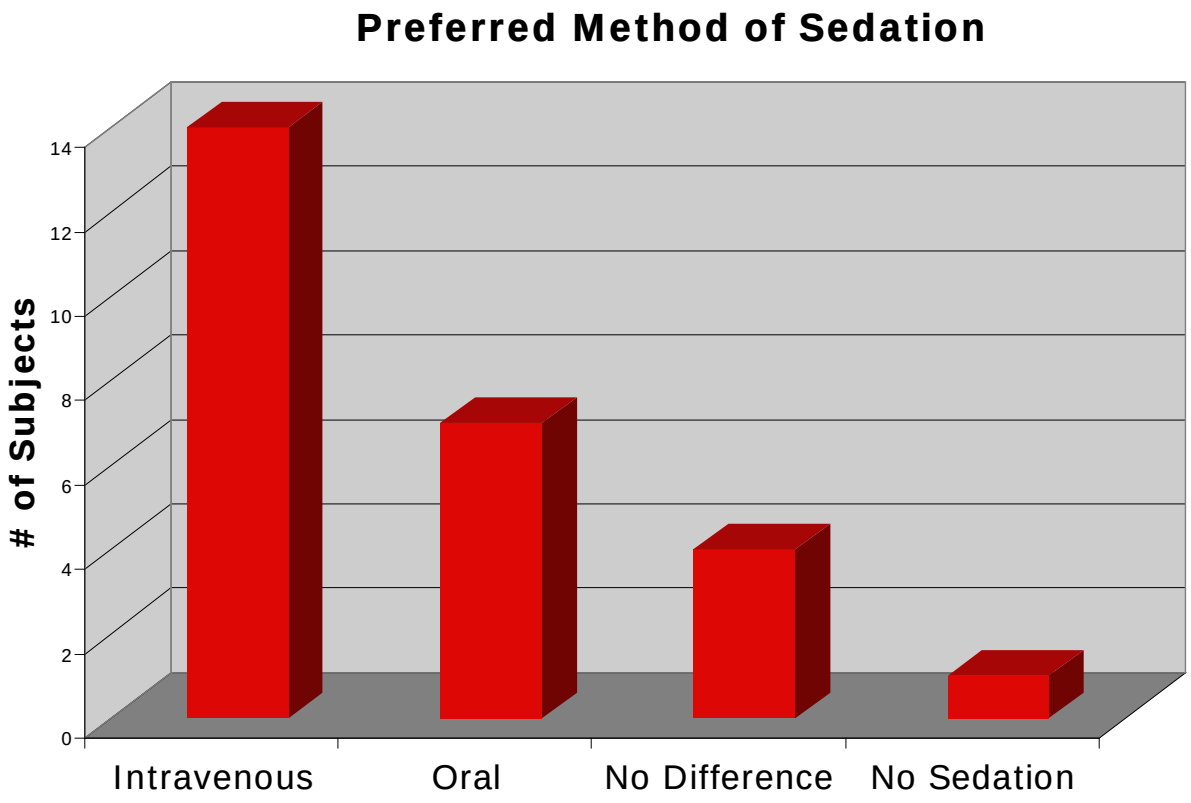

Preferred Method of Sedation
# of Subjects
0
2
4
6
8
10
12
14
Intravenous
Oral
No Difference
No Sedation

Figure 2.

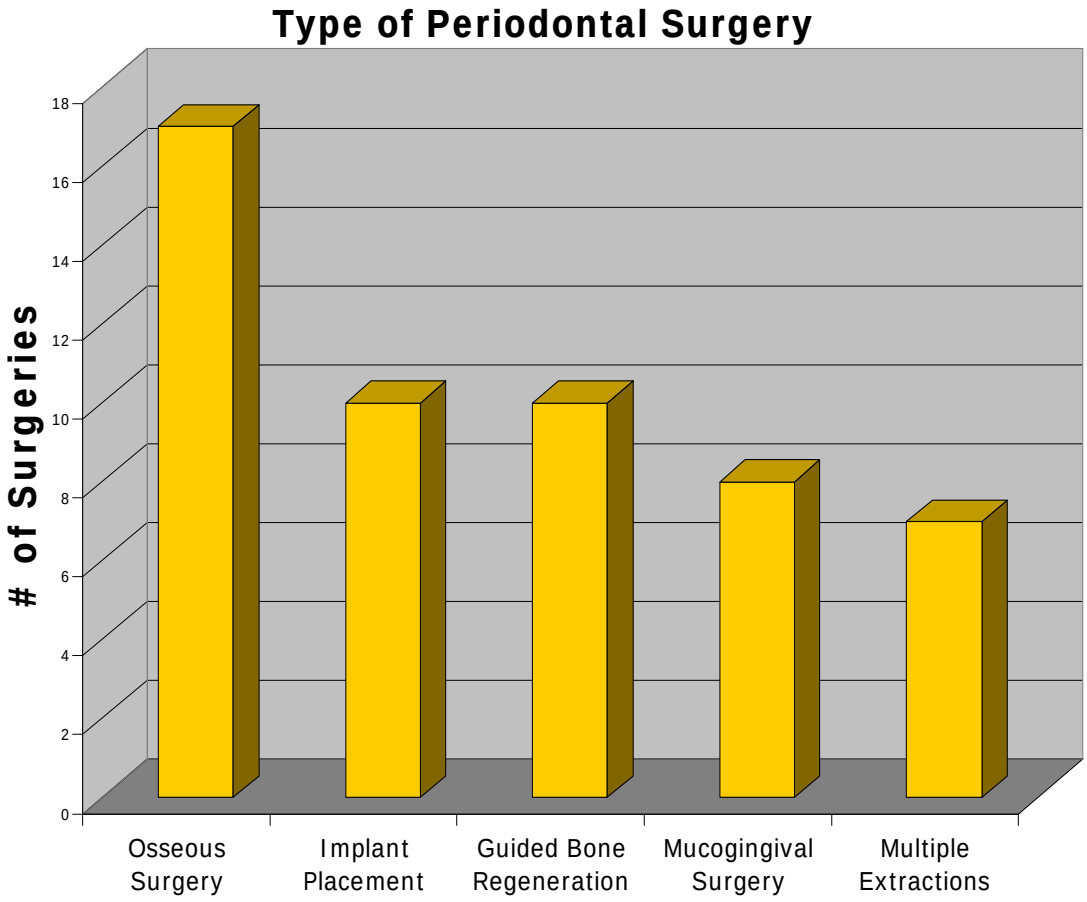

Type of Periodontal Surgery
# of Surgeries
0
2
4
6
8
10
12
14
16
18
Osseous Surgery
Implant Placement
Guided Bone Regeneration
Mucogingival Surgery
Multiple Extractions

Figure 3.

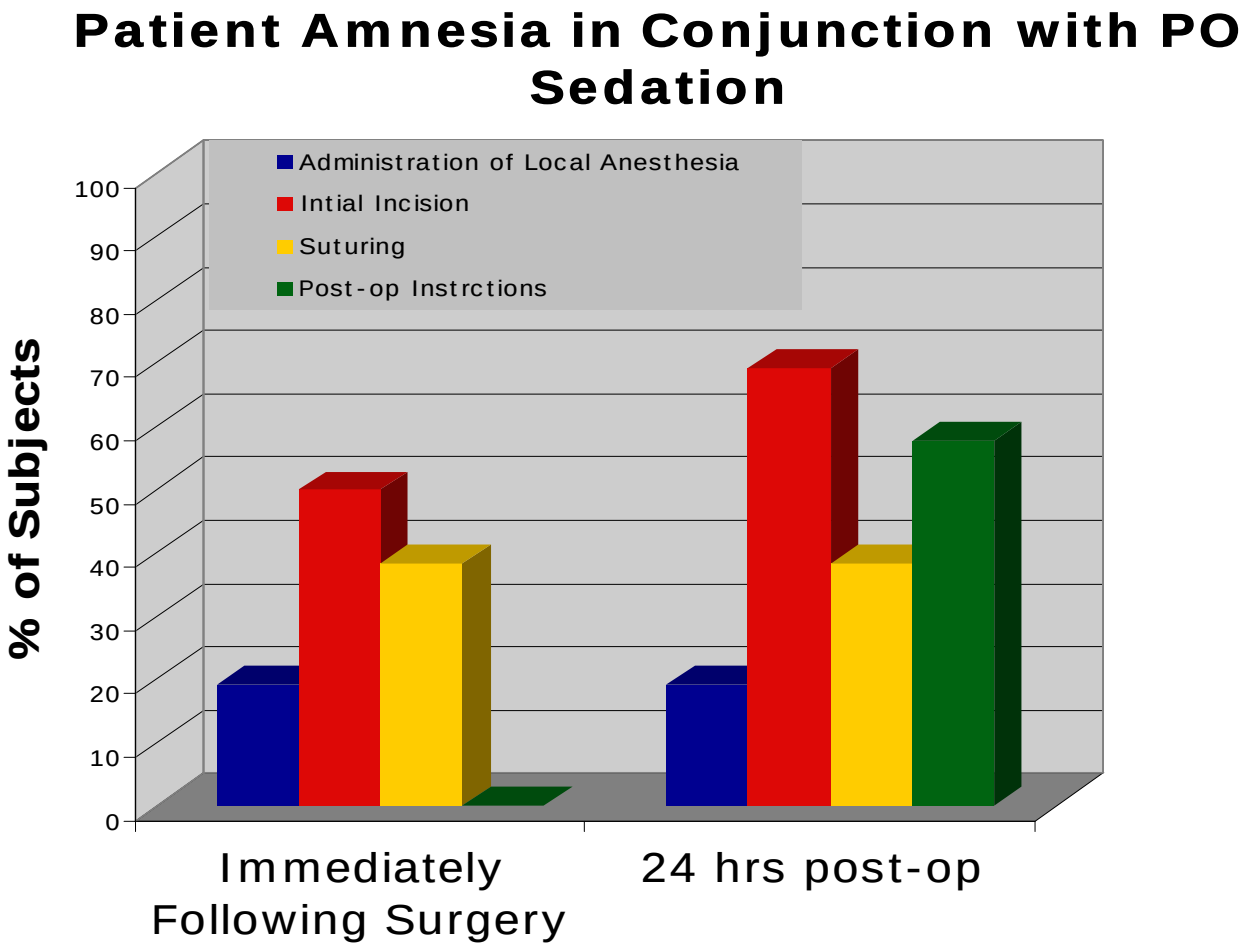

Patient Amnesia in Conjunction with PO Sedation
% of Subjects
100
90
80
70
60
50
40
30
20
10
0
Administration of Local Anesthesia
Intial Incision
Suturing
Post-op Instrctions
Immediately Following Surgery
24 hrs post-op

Figure 4.

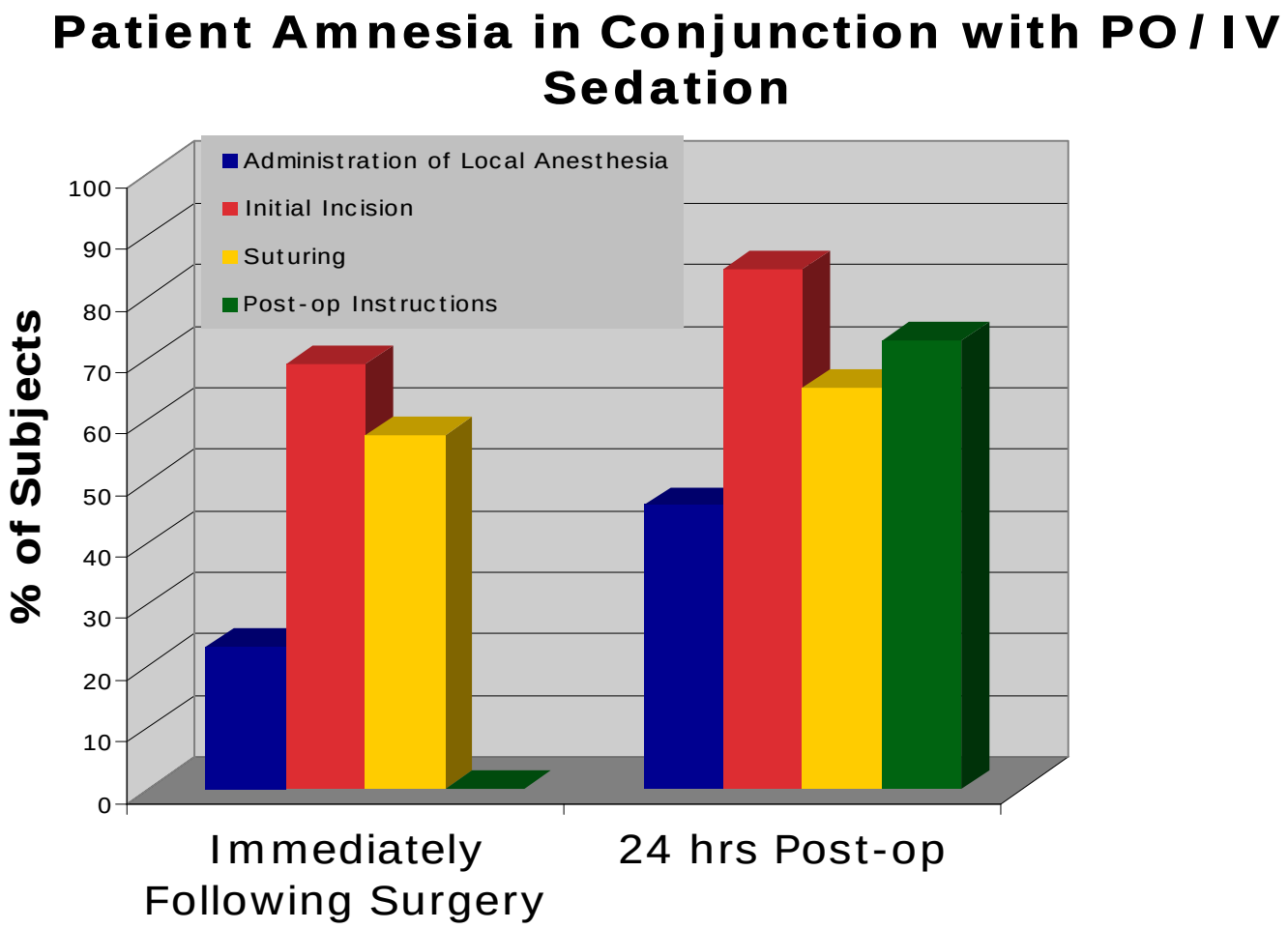

Patient Amnesia in Conjunction with PO/IV Sedation
Administration of Local Anesthesia
Initial Incision
Suturing
Post-op Instructions
% of Subjects
100
90
80
70
60
50
40
30
20
10
0
Immediately Following Surgery
24 hrs Post-op

Figure 5.

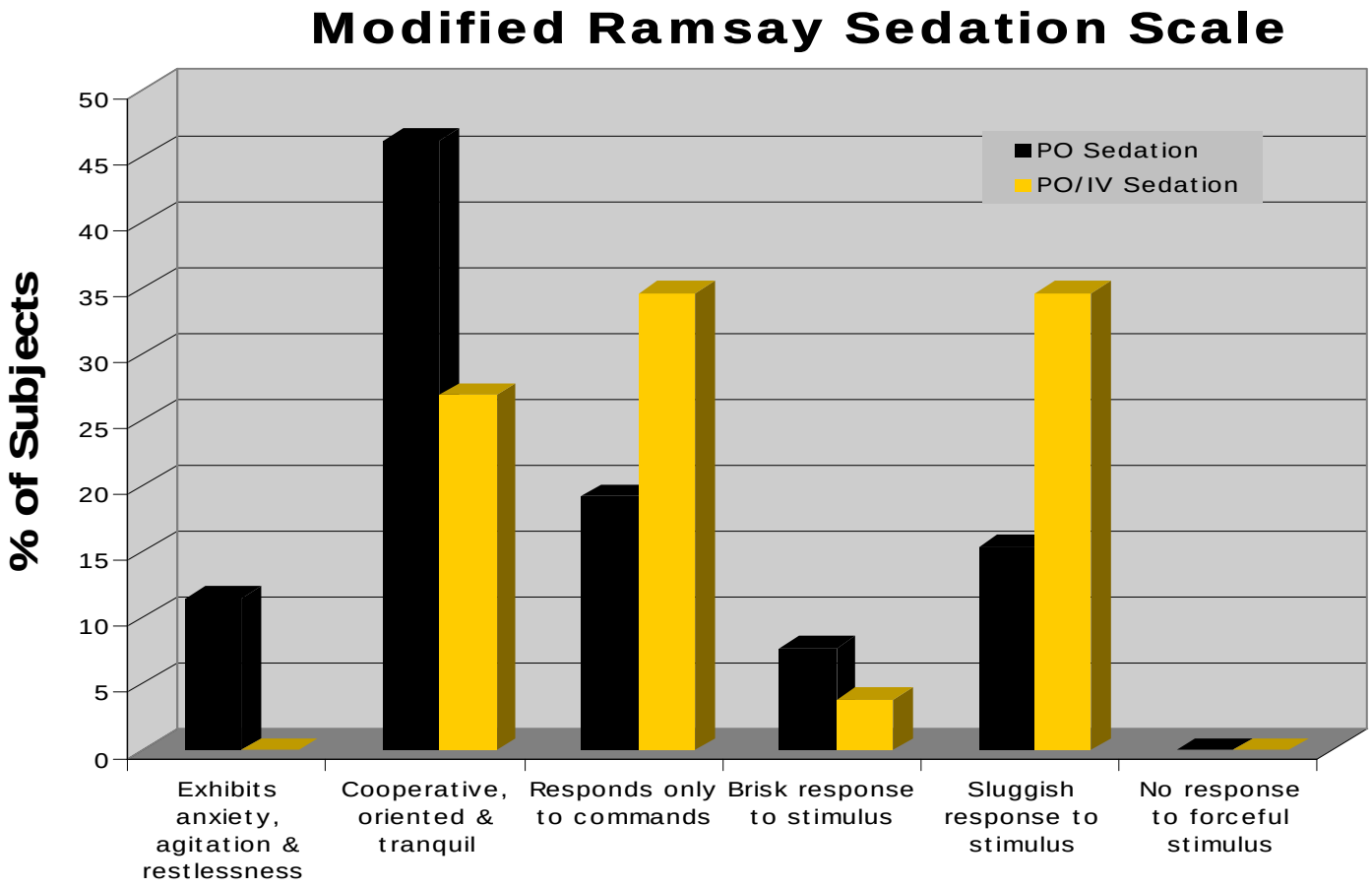

Modified Ramsay Sedation Scale
% of Subjects
50
45
40
35
30
25
20
15
10
5
0
PO Sedation
PO/IV Sedation
Exhibits anxiety, agitation & restlessness
Cooperative, oriented & tranquil
Responds only to commands
Brisk response to stimulus
Sluggish response to stimulus
No response to forceful stimulus

Figure 6.

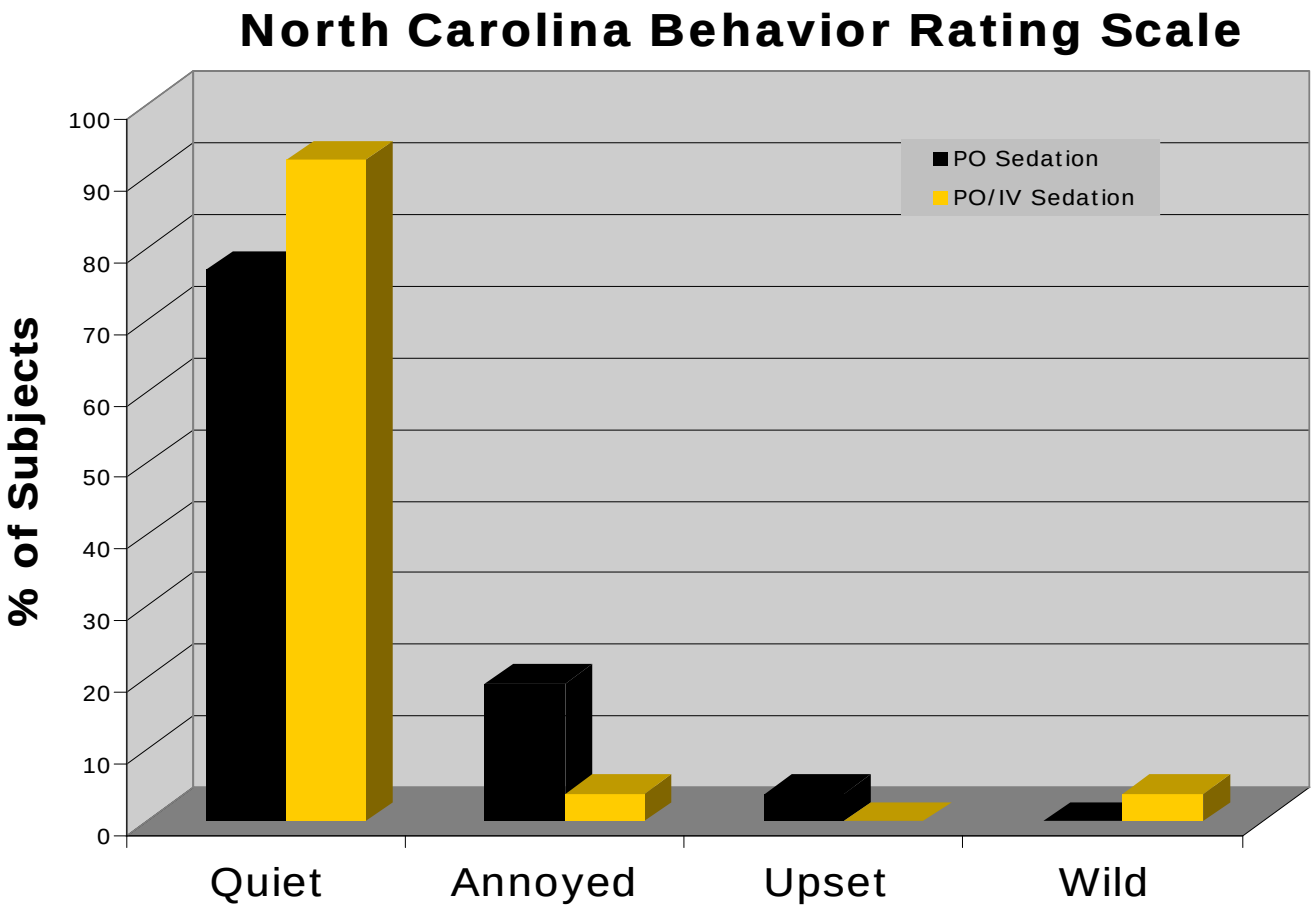

North Carolina Behavior Rating Scale
% of Subjects
100
90
80
70
60
50
40
30
20
10
0
PO Sedation
PO/IV Sedation
Quiet
Annoyed
Upset
Wild

Figure 7.

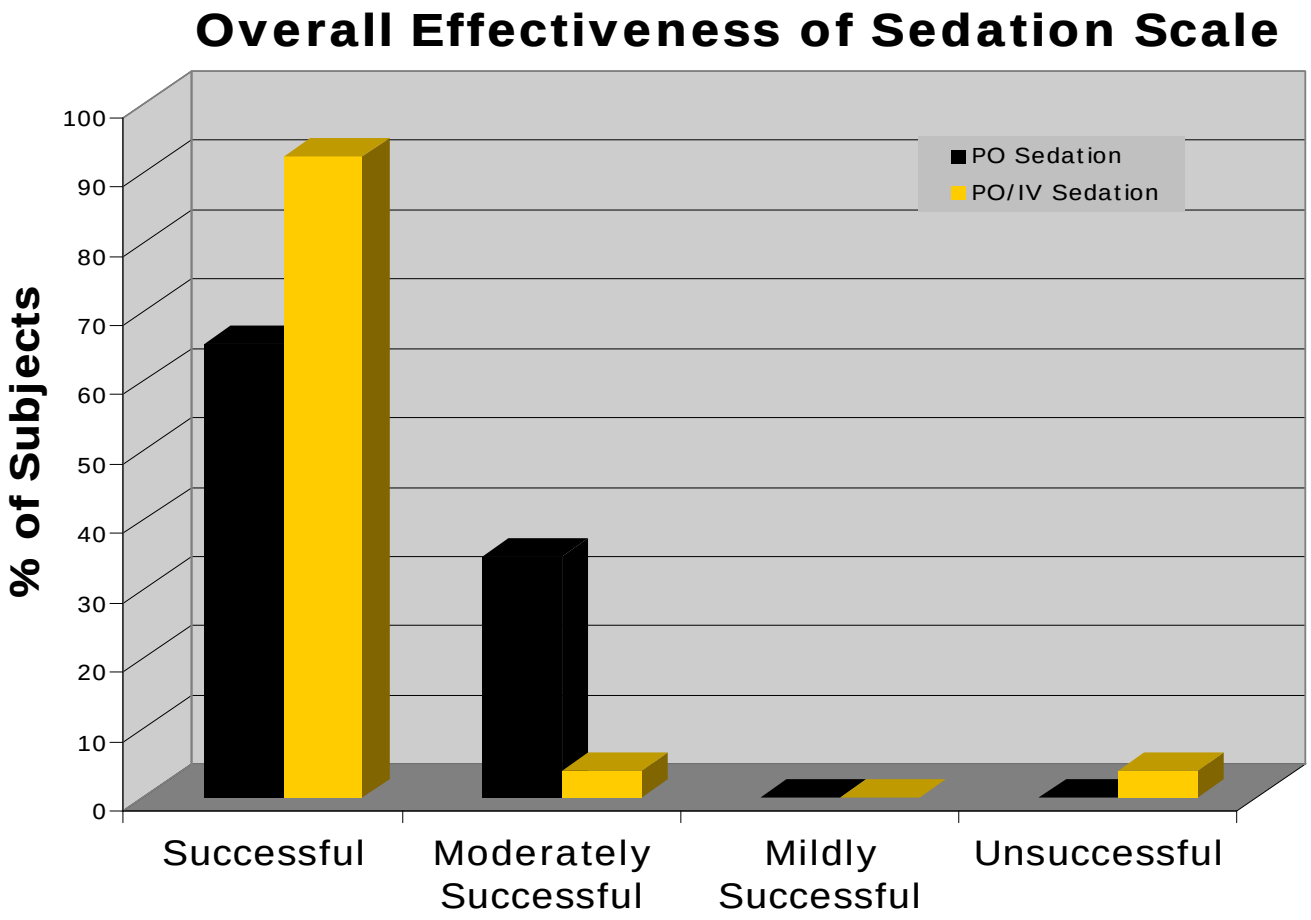

Overall Effectiveness of Sedation Scale
% of Subjects
100
90
80
70
60
50
40
30
20
10
0
PO Sedation
PO/IV Sedation
Successful
Moderately Successful
Mildly Successful
Unsuccessful

Figure 8.

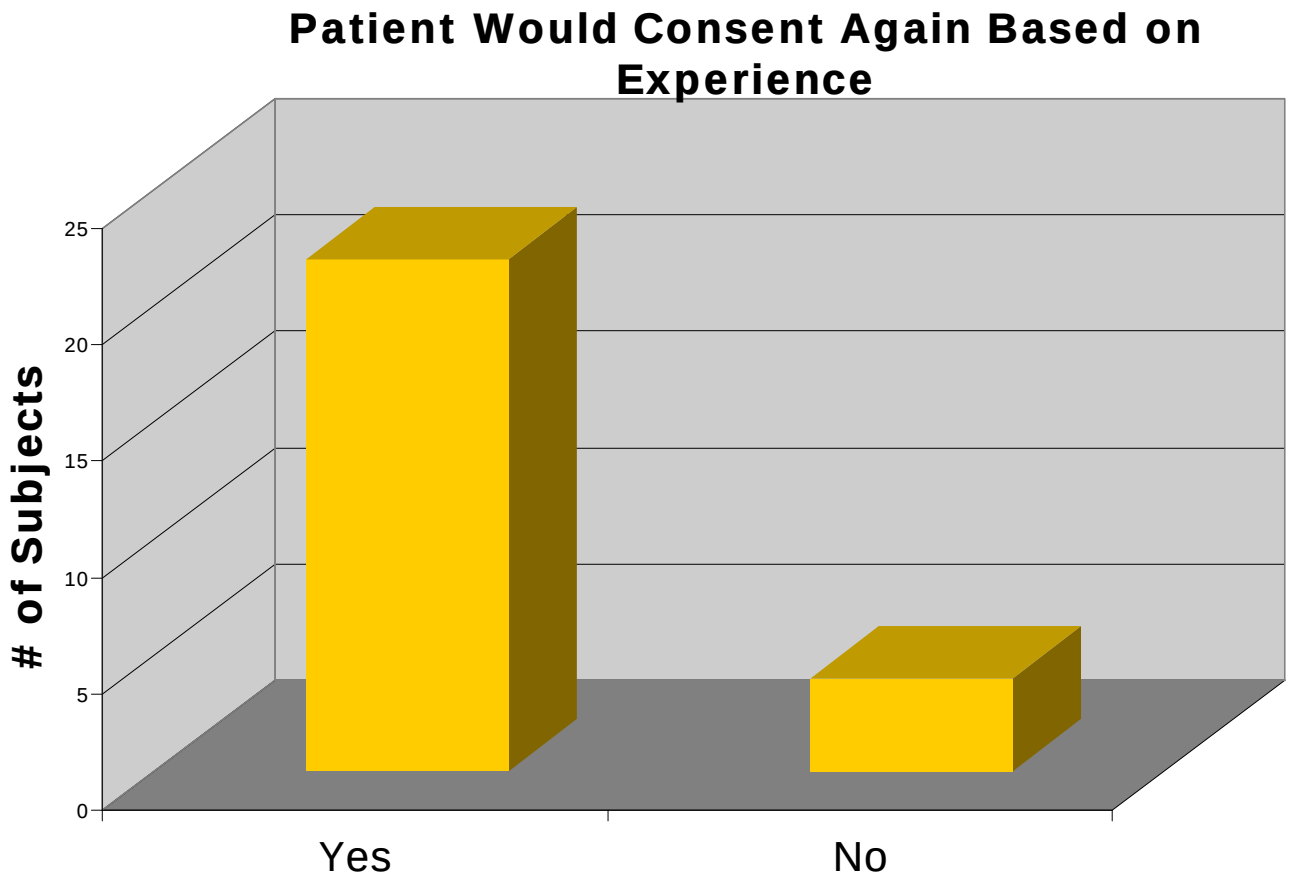

Patient Would Consent Again Based on Experience
# of Subjects
25
20
15
10
5
0
Yes
No

Figure 9.

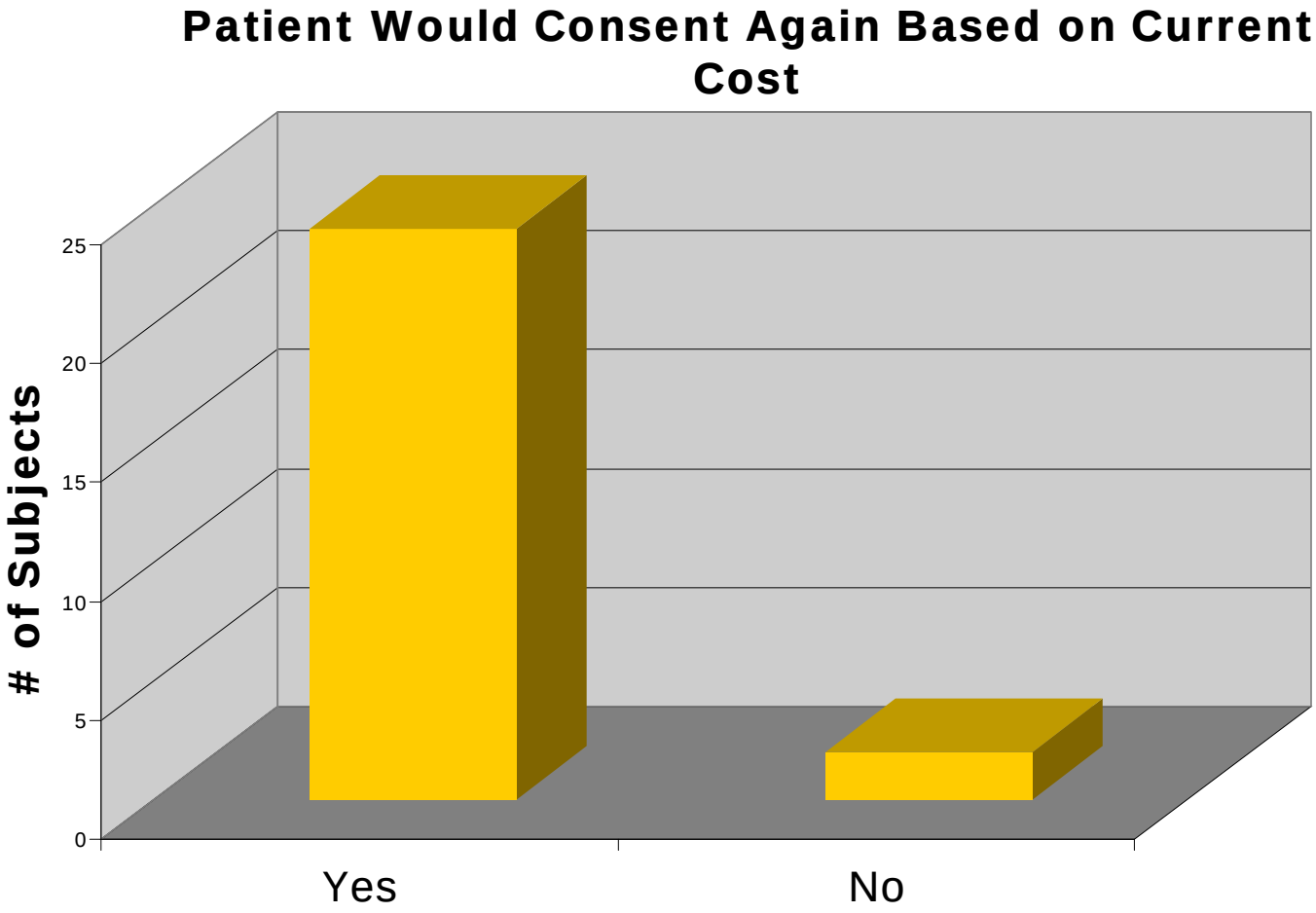
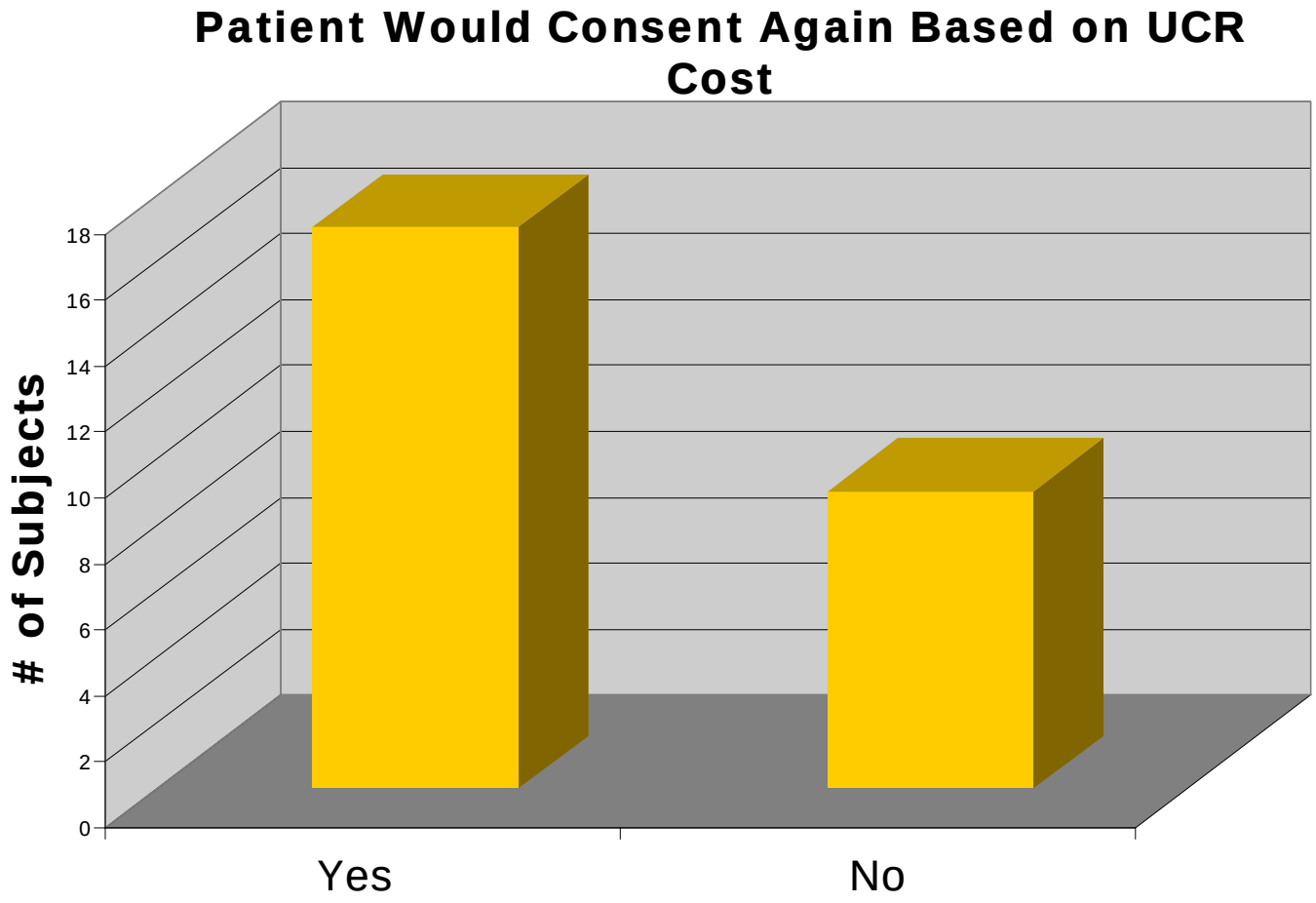

Patient Would Consent Again Based on Current Cost
# of Subjects
25
20
15
10
5
0
Yes
No

Figure 10.


Patient Would Consent Again Based on UCR Cost
# of Subjects
0
2
4
6
8
10
12
14
16
18
Yes
No

APPENDIX

Appointment before the 1st sedation

Patient ID: _____ Surgeon ID: _____

Instructions: Please circle and/or write in your answer on this form. For those questions requiring additional information, please write in your answer on this form in the space provided.

Please write in Today's Date: _____ (mm/dd/yyyy)
Please write in Age of Patient: _____years
Please write in Patient Date of Birth: _____ (mm/dd/yyyy)

1. Gender: a) Male b) Female
2. Race:
    a) Asian or Pacific Islander: Persons having origins in any of the peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, Japan, Korea, the Philippine Islands and Samoa.
    b) African American (not of Hispanic origin): Person having origins in any of the black ethnic groups.
    c) Hispanic: Persons having origins in any of the Mexican, Puerto Rican, Cuban, Central or South American or other Spanish Cultures, regardless of ethnicity.
    d) Native American or Alaskan Native: Persons having origins in any of the original peoples of North America, and who maintain cultural identification through tribal affiliation or community recognition.
    e) Caucasian (not of Hispanic origin): Persons having origins in any of the original peoples of Europe, North Africa or the Middle East.

3. Tobacco smoking: a)Yes b) No
If yes please write in, Number of ____ pks/day Number of _____ years smoking

4. If you had to go to the dentist tomorrow, how would you feel about it?
a) I would look forward to it as a reasonably enjoyable experience.
b) I wouldn't care one way or the other.
c) I would be a little uneasy about it.
d) I would be afraid that it would be unpleasant and painful.
e) I would be very frightened of what the dentist might do.

5. When you are waiting in the dentist's office for your turn in the chair, how do you feel?
a) Relaxed.
b) A little uneasy.
c) Tense.
d) Anxious.
e) So anxious that I sometimes break out in a sweat or almost feel physically sick.

6. When you are in the dentist's chair waiting while he/she gets his/her drill ready to begin working on your teeth, how do you feel?
a) Relaxed.
b) A little uneasy.
c) Tense.
d) Anxious.
e) So anxious that I sometimes break out in a sweat or almost feel physically sick.

7. You are in the dentist's chair to have your teeth cleaned. While you are waiting and the dentist is getting out the instruments which he/she will use to scrape your teeth around the gums, how do you feel?
a) Relaxed.
b) A little uneasy.
c) Tense.
d) Anxious.
e) So anxious that I sometimes break out in a sweat or almost feel physically sick.

8. Have you been sedated for any type of medical or dental procedure in the past?
a) Yes b) No

If no, skip to question 12.

By which form were you sedated and did you have a good or bad experience?
If you have never been sedated by the method listed please answer "Never".
9. By mouth (pill) a) Never b) Good Experience c) Neutral d) Bad Experience
Please Describe why you had a bad experience:

10. Laughing gas (Nitrous Oxide)a) Never b) Good Experience c) Neutral d) Bad Experience
Please Describe why you had a bad experience:

11. Intravenous (IV) a) Never b) Good Experience c) Neutral d) Bad Experience
Please Describe why you had a bad experience:

12. Have you been prescribed a sedative or tranquilizer by your medical doctor for regular use? a) Yes b) No
If yes, please write in which medication and what dosage?

13.
Please mark your current level of anxiety or nervousness with a vertical line on the dotted line.
0……..50…….……..…100
(100mm)

THANK YOU FOR PARTICIPATING IN OUR RESEARCH STUDY
VCU DEPARTMENT OF PERIODONTICS

Immediately after the 1st and 2nd surgeries

Patient ID: _____ Surgeon ID:_____

Instructions: Please circle and/or write in your answer on this form. For those questions requiring additional information, please write in your answer on this form in the space provided.

Today's Date:_____ (mm/dd/yyyy)

1. Were you comfortable during the surgery?
a) Yes b) No

2. Did you feel sleepy during the surgery?
a) Yes b) No

3. How long do you think the surgery lasted?
a) 15 minutes
b) 30 minutes
c) 1 hour
d) 3 hours
e) Unsure

4. What events during the surgery do you remember? (Fill in all that apply)
a) Local Anesthetic administration
b) Initial incision
c) Suturing
d) Other
If Other, please write in:

5. What was your comfort level at the Local Anesthetic administration? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

6. What was your comfort level at the initial incision? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

7. What was your comfort level at suturing? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

8. What was your comfort level at any other portion of the surgery that you remember?
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

9. Was the sedation experience what you expected?
a) Yes b) No
If No, please write why?

Survey for Surgeon following 1st and 2nd surgery

Surgeon ID: _____ Patient ID: _____

Instructions: Please circle and/or write in your answers on this form in the additional space provided.

1. What was the Modified Ramsey Sedation score for the patient?(choose one answer)

_____

1 - patient who exhibits anxiety, agitation and restlessness
2 - patient who is cooperative, oriented and tranquil
3 - patient who responds only to commands
4 - patient who demonstrates a brisk response to a stimulus
5 - patient who demonstrates a sluggish response to stimulus
6 - patient who does not demonstrate a response to a forceful stimulus

2. What was the North Carolina Behavioral score for the patient? (Please circle one)

1 - Quiet: patient quiet or sleeping with only extraneous, inconsequential movements

2 - Annoyed: patient cooperative for treatment but with 1 or 2 of the undesirable behaviors

3 - Upset: patient noticeably disturbed, with 2-3 undesirable behaviors present, making treatment difficult but possible

4 - Wild: patient extremely defiant with presence of all undesirable behaviors, making treatment extremely difficult

3. How did the patient's behavior affect the progression of treatment? (Please circle one)

1 Successful: patient slept throughout procedure with minimal crying or movement at critical events*

2 Moderately successful: successful sedation with moderate amounts of crying and movement at times other than critical events,* but behavior did not hinder progress of sedation

3 Mildly successful: treatment was accomplished as planned, but because of screaming or combative movements throughout the sedation the progression of portions of the treatment was hindered

4 Unsuccessful: continuous crying or movement throughout sedation; treatment was performed with difficulty; the progression of all treatment was hindered

4. Do you feel that these indices (Questions 1-3) are adequate for the accurate assessment of the success of your sedation? Yes or No

5. What level of sedation did the patient achieve? (Please circle) Minimal Moderate Deep

6. What was the Aldrete recovery score for the patient as they left the appointment? (Circle applicable scores at right)

ACTIVITY
Able to move 4 extremities voluntarily or on command = 2
Able to move 2 extremities voluntarily or on command = 1
Able to move 0 extremities voluntarily or on command = 0
RESPIRATION
Able to deep breathe and cough freely = 2
Dyspnea or limited breathing = 1
Apneic = 0

CIRCULATION
BP" 20% of Preanesthetic level = 2
BP" 20-50% of Preanesthetic level = 1
BP" 50% of Preanesthetic level = 0
LEVEL OF CONSCIOUSNESS
Fully Awake = 2
Arousable on calling = 1
Not responding = 0
SKIN COLOR
Pink = 2
Pale, dusky blotchy, jaundiced, other = 1
Cyanotic = 0

24 hrs post-operative after 1st surgery

Patient ID: 001
Called by:
Time & Date:_____ am/pm _____ (mm/dd/yyyy)

Instructions: Please circle and/or write in your answer on this form. For those questions requiring additional information, please write in your answer on this form in the space provided.

1. Were you comfortable during the surgery?
a) Yes b) No

2. Did you feel sleepy during the surgery?
a) Yes b) No

3. How long do you think the surgery lasted?
a) 15 minutes
b) 30 minutes
c) 1 hour
d) 3 hours
e) Unsure

4. What events during the surgery do you remember? (circle all that apply)
a) Local Anesthetic administration
b) Initial incision
c) Suturing
d) Other
If Other, please write in:

5. What was your comfort level at the Local Anesthetic administration? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

6. What was your comfort level at the initial incision? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

7. What was your comfort level at suturing? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

8. What was your comfort level at any other portion of the surgery that you remember?
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

9. Was the sedation experience what you expected?
a) Yes b) No
If No, please write why?

10. Do you remember the post-operative instructions given to you after the surgery?
a) Yes b) No c) Some

11. What is the first thing you remember after the procedure? Please write in:

12. Did you experience any nausea/vomiting after the surgery?
a) Yes b) No

13. Did you take your pain medication as directed?
a) Yes b) No

14. How did you spend the rest of your day after the surgery?
a) Awake
b) Groggy
c) Asleep

15. Would you recommend this type of sedation to someone else needing Periodontal surgery? a) Yes b) No

16. Would you consent to be sedated this way again for future Periodontal procedures based on your experience? a) Yes b) No

17. Would you consent to be sedated this way again for future Periodontal procedures based on the cost of the sedation? a) Yes b) No

<u>24 hrs post-operative after 2nd surgery</u>
Patient ID: _____
Called by:
Time & Date: _____ am/pm _____(mm/dd/yyyy)

Instructions: Please circle and/or write in your answer on this form. For those questions requiring additional information, please write in your answer on this form in the space provided.

1. Were you comfortable during the surgery?
a) Yes b) No

2. Did you feel sleepy during the surgery?
a) Yes b) No

3. How long do you think the surgery lasted?
a) 15 minutes
b) 30 minutes
c) 1 hour
d) 3 hours
e) Unsure

4. What events during the surgery do you remember? (circle all that apply)
a) Local Anesthetic administration
b) Initial incision
c) Suturing
d) Other
If Other, please write in:

5. What was your comfort level at the Local Anesthetic administration? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

6. What was your comfort level at the initial incision? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

7. What was your comfort level at suturing? (select unsure if you don't remember)
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

8. What was your comfort level at any other portion of the surgery that you remember?
a) Very comfortable
b) Somewhat comfortable
c) Unsure
d) Somewhat uncomfortable
e) Very uncomfortable

9. Was the sedation experience what you expected?
a) Yes b) No
If No, please write why?

10. Do you remember the post-operative instructions given to you after the surgery?
a) Yes b) No c)Some

11. What is the first thing you remember after the procedure? Please write in answer.

12. Did you experience any nausea/vomiting after the surgery?
a) Yes b) No

13. Did you take your pain medication as directed?
a) Yes b) No

14. How did you spend the rest of your day after the surgery?
a) Awake
b) Groggy
c) Asleep

15. Would you recommend this type of sedation to someone else needing Periodontal surgery? a) Yes b) No

16. Would you consent to be sedated this way again for future Periodontal procedures based on your experience? a) Yes b) No

17. Would you consent to be sedated this way again for future Periodontal procedures based on the current fee of 150 for IV? $35 for Oral? a) Yes b) No

18. What is your preferred method of sedation?
a) Oral (pill form) b)IV (intravenous) c) No Sedation

19. The usual and customary cost for conscious sedation in private practice is roughly $350. Knowing this, would you be willing to pay this amount for the sedation experience in conjunction with your periodontal surgery if needed in the future? a) Yes b) No

VITA

Jason Michael Streem was born on November 5th, 1977 in Cleveland, Ohio. He graduated from Beachwood High School, Beachwood, OH in 1996. Dr. Streem attended Columbia University in the City of New York earning a Bachelor of Arts degree in political science with a concentration in pre-medical sciences. Upon graduation, he entered the University of Michigan School of Dentistry and was commissioned as an Ensign in the United States Navy Dental Corps in February 2002. After receiving his Doctor of Dental Surgery Degree in 2005, he completed a General Practice Residency in Hospital Dentistry at National Naval Medical Center in Bethesda, MD. In July 2006, he reported to U.S. Naval Mobile Construction FIVE (NMCB-5) in Port Hueneme, CA. He served as an Battalion Dental Officer and Dental Department Head, completing a six-month deployment to both to Camp Arifjan, Kuwait in support of Operation Iraqi Freedom and to Camp Shields, Okinawa, Japan.

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