

# Utility of Bispectral Index Monitoring During Intravenous Sedation in the Dental Office

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**Purpose:** This research sought to compare two different systems to monitor sedated patients undergoing implant surgery in the dental office: the bispectral index (BIS) and the Ramsay scale. This information was used to establish an optimal BIS range for surgery in these patients and to calculate differences in drug consumption in both groups. **Materials and Methods:** Consecutive patients undergoing implant surgery were studied and randomly assigned to two groups. Patients were sedated using intravenous propofol, fentanyl, and midazolam. The sedation level in group A was measured using the Ramsay scale. In group B, the Ramsay scale and the BIS were used together. Heart rate, blood pressure, and peripheral oxygen saturation were monitored in all patients. The levels of anxiety, satisfaction, and drug consumption were compared between groups. **Results:** Forty-three patients were included; 20 were placed in group A and 23 were included in group B. There were no differences in the hemodynamic and respiratory parameters monitored or in anxiety or satisfaction levels in both groups. In group B patients, the BIS values stabilized around 85; the Ramsay scale stabilized around 3 in both groups and remained at these levels until the end of the procedure. Drug consumption was significantly lower in the BIS group. **Conclusion:** The optimal BIS value during intravenous sedation in sedated ambulatory patients in dental surgery should be within the 80 to 85 range. BIS monitoring allows for reduced consumption of propofol, fentanyl, and midazolam. *INT J ORAL MAXILLOFAC IMPLANTS* 2012;27:375–382

**Key words:** bispectral index, deep sedation, dental office, oral surgery

In recent years, the number of oral surgical procedures performed in the dental office has increased.<sup>1–4</sup> Perhaps the most important reason for this is the use of new technologies, increasingly less invasive surgeries, and the ability to include an anesthesiologist in this setting. Intravenous sedation techniques offer the patient greater comfort and less anxiety during operative procedures.<sup>5,6</sup>

The use of the bispectral index (BIS) as a parameter for neurophysiologic monitoring has gained considerable popularity in anesthetic practice in recent years. It is calculated via a complex mathematical analysis of the electroencephalogram and is directly related to cortical activity. To determine the BIS, the first step is to obtain the electroencephalogram signal by means of three electrodes placed on the cutaneous surface of the frontotemporal region, which allows adequate

electrical contact and low impedance. The analog signal obtained is digitized and then undergoes an artifact recognition process (use of an electric scalpel, blinking, etc) and subsequent filtering. Then the signal is mathematically processed using the Fourier analysis method, based on Fourier's theorem (which states that any complex wavelike form that varies arbitrarily over time can be broken down into the sum of simple sine or cosine waves) and with bispectral analysis.<sup>7,8</sup> The BIS number is the combined sum of the parameters analyzed (latency, amplitude, bicoherence)<sup>9,10</sup> and can range from 0 to 100 to provide a measure of the patient's level of consciousness. A number under 60 would indicate levels of consciousness characteristic of general anesthesia; between 60 and 70, deep sedation; between 70 and 80, moderate sedation; between 80 and 95, mild sedation; values close to 100 would reflect a fully conscious patient. Use of the BIS has been linked to lower dosages of anesthetic drugs (and hence lower costs), reductions in postoperative nausea and vomiting, and faster recovery for patients.<sup>11–15</sup> The small size and weight of a BIS monitor makes it easy to use and move. Therefore, the use of this monitoring technique in any location outside an operating room does not pose any difficulty. In fact, it is frequently used during transport and evacuation of patients by both ground and air.<sup>16</sup>

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In-office oral surgery, and more specifically implant placement, typically requires an anesthetic technique that maintains the patient in a state of conscious sedation. In this state, full swallowing and airway protective reflexes are retained and it is possible for the dentist to communicate with the patient, allowing the patient to respond to orders, help keep the mouth open, and maintain proper head position to facilitate surgery.

The scale most commonly used as an indicator of the depth of sedation is the one described by Ramsay in 1974.<sup>17</sup> It evaluates visually identifiable aspects: anxiety, agitation, eyes open or shut, and the patient's response to commands and light or auditory stimuli (Table 1). This scale cannot be used with disabled patients who are incapable of responding or listening. It is subject to fatigue, both of the evaluator and the person evaluated, and provides information that is subjective.<sup>18,19</sup>

Therefore, the hypothesis of the present study is that BIS can be an adequate method of evaluating the level of consciousness during sedation in the dental office, and its utilization can reduce the consumption of drugs used to sedate these patients. The main aims of the study were (1) to compare sedation monitored using BIS with that monitored using the Ramsay scale; (2) to establish an ideal BIS range for these patients and this type of surgery (ie, implant placement with or without adjunctive procedures); and (3) to calculate drug consumption in both groups. Specifically, the authors sought to: (1) measure the depth of sedation using the Ramsay scale (control group [group A]); (2) measure the depth of sedation using the Ramsay scale and the BIS together (group B); (3) compare the two groups to determine the usefulness of the BIS in this type of operation; (4) compare drug consumption in both groups; and (5) establish ideal BIS levels for these patients and this type of surgery.

## MATERIAL AND METHODS

Written informed consent was obtained from all participating patients. The ethics committee of the Hospital Universitario San Carlos (Universidad Complutense, Madrid) granted approval for the study. A randomized prospective study was performed with consecutive patients scheduled for in-office dental implant surgery (either implant placement or preimplantation surgery) during a single month.

The criteria for inclusion were: age greater than 18 and less than 80, American Society of Anesthesiologist (ASA) status of I or II, weight of at least 50 kg, and Body Mass Index less than or equal to 30. Potential subjects with an ASA status above II; a potentially difficult airway (eg, Mallampati IV, thyromental distance of less than 6 cm, other anatomical abnormalities); and/or

intellectual or serious hearing impairment were excluded. Patients with sleep apnea syndrome were also excluded, because in these patients the depressive effects of the drugs used for sedation cause a relaxation of the airway, making collapse a possibility and altering the ability to wake up as a result of hypoxic and hypercarbic stimuli. Also, in patients with this syndrome, the supine position may compromise respiration.

The demographic data recorded were sex, age, and weight. The patients' ASA status was also recorded, as well as the duration of each procedure.

The patients did not receive any premedication and were randomly allocated into two groups: group A (control group) and group B. Once a patient was seated in the dental chair, the heart rate, blood pressure (bloodless method), and peripheral oxygen saturation were monitored. In addition, group B patients received BIS monitoring by means of an Aspect A-2000 XP monitor and Quatro sensor for adults (Aspect Medical Systems). This sensor is made up of four silver/silver chloride electrodes. It is placed on the patient's forehead and the temporal region above the zygomatic arch using Zipprep self-adhesive. Monitoring was performed as recommended by the manufacturer. After the skin has been cleaned, the BIS Quatro sensor is placed, with the surgeon pressing lightly on the skin for 5 seconds to ensure adhesive contact between the skin and the conductive gel to obtain good signal quality. Once the sensor is in place and connected to the monitor, the electrical activity generated by the neurons in the cerebral cortex is detected in real time. The dimensions of the Aspect A-2000 XP monitor are 17 × 17 × 10 cm and its weight is 1.4 kg. (Data provided appear in Table 2.)

For all patients, a venous access line was inserted in the back of the hand using a 22-G catheter. After 500 mL of saline solution were connected to the line, administration of the sedatives began 5 to 10 minutes before the end branches of the maxillary nerves were blocked with local anesthetic (4% articaine + 1% adrenaline). The decision of which nerve branches would be blocked depended on where the implants were to be placed and how many were planned. Dosage of the local anesthetic was limited to the maximum recommendation to avoid possible toxic effects. Patients remained in a half-seated position during the operation when the surgery was in the mandible, and they were nearly supine when the implants were placed in the maxilla.

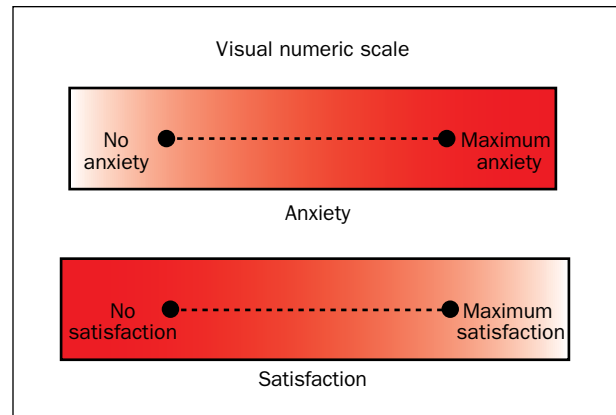
The sedation protocol consisted of a continuous intravenous infusion of propofol using a volumetric pump at a rate of 2 to 4 mg/kg/h, as well as an initial bolus of midazolam and fentanyl at 0.02 to 0.04 mg/kg and 1 µg/kg, respectively. Every 5 minutes, beginning at the start of sedation, the Ramsay scale score was assessed and recorded for patients in both groups.

**Table 1 Ramsay Sedation Scale**

Score	Description
1	Anxious, restless, or both
2	Cooperative, orientated, and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

**Table 2 Data Provided by Aspect A-2000 Monitor**

1	BIS value: 0–100
2	Suppression ratio: Percentage of time with isoelectric EEG
3	Signal quality index: Quality of the EEG signal
4	Electromyograph: Muscular activity index
5	Electroencephalogram: EEG wave

**Fig 1** VAS used to assess patients' levels of anxiety and satisfaction.

Heart rate, blood pressure, and peripheral oxygen saturation values were also noted. For group B subjects, the BIS values were also collected every 5 minutes. If the patient was experiencing some degree of discomfort caused by anxiety or a surgical stimulus (movement, complaint, or increased heart rate and/or blood pressure), if the Ramsay Scale score reached 2, or if the BIS reached 90, additional boluses of midazolam and fentanyl were administered at a rate of 0.01 to 0.02 mg/kg and 0.5 µg/kg, respectively. Likewise, when the Ramsay Scale reached 5, the BIS dropped to 75, or peripheral oxygen saturation fell below 90%, the continuous infusion of propofol was interrupted. Any unexpected events, such as a need for ventilation support, supplemental oxygen, or reversal using flumazenil or naloxone, were reported.

Between 10 and 15 minutes before the end of the surgery, the administration of drugs was stopped, but monitoring continued until 10 minutes after the operation was completed. All patients were kept under observation for 30 to 45 minutes after surgery. They were then discharged in accordance with the usual criteria for major ambulatory surgery anesthesia: stable vital signs; ability to stand; tolerance of intestinal fluids; no bleeding, nausea, and/or vomiting; and no moderate or severe pain. Before discharge (45 minutes after surgery), patients were asked to rate the level of anxiety and degree of satisfaction they had experienced during

the procedure. A visual analog and numeric scale (VAS) was used, where 0 = no anxiety/no satisfaction and 10 = maximum anxiety/maximum satisfaction (Fig 1).

Statistical analysis was performed using the SPSS 15 program. All data were evaluated for normality of distribution. The Student *t* test was used for analyses of the data. Relationships between the variables within each group were analyzed using the Pearson correlation coefficient. *P* values less than .05 were considered significant.

## RESULTS

The number of implants placed per patient ranged from 0 (preimplantation bone augmentation surgery and postimplantation soft tissue surgical management) to 12. Table 3 shows the different implant and preimplantation surgical procedures that were performed in the present patient population under intravenous sedation.

Figures 2 to 7 are intraoperative images of surgical bone augmentation and soft tissue management during implantation and postimplantation surgery. Tables 4 and 5 show the demographic data and ASA classification of the patients in the study, respectively. No differences were observed between group A and group B. There were also no differences in the duration of the procedures between groups (Table 6).

**Table 3 Surgical Procedures Performed Under Intravenous Sedation**

Case	Sex	Surgical procedure	Arch	Implants
<b>Group A</b>				
1	F	Mandibular bone block graft	Mandibular	0
2	M	Sinus floor augmentation	Maxillary	3
3	F	Implants	Mandibular	8
4	F	Implants	Maxillary	6
5	M	Implants and GTR	Maxillary	4
6	F	Implants	Mandibular	8
7	F	Implants	Maxillary	8
8	M	Free gingival graft	Mandibular	0
9	M	Implants	Mandibular	8
10	F	Mandibular bone block graft	Maxillary	3
11	M	Bilateral sinus lift	Maxillary	6
12	M	Implants and Kazanjian vestibuloplasty	Mandibular	4
13	M	Implants	Maxillary	6
14	M	Sinus floor augmentation	Maxillary	2
15	M	Implants	Maxillary	6
16	M	Implants and GTR	Maxillary	4
17	F	Mandibular bone block graft	Mandibular	0
18	M	Implants	Maxillary	6
19	F	Mandibular bone block graft	Mandibular	0
20	F	Mandibular bone block graft	Maxillary	0
Total implants				82
<b>Group B</b>				
1	M	Sinus floor augmentation	Maxillary	3
2	M	Sinus floor augmentation	Maxillary	2
3	F	Implants	Mandibular	4
4	F	Implants	Maxillary	6
5	F	Mandibular bone block graft	Mandibular	0
6	F	Implants	Maxillary and Mandibular	12
7	M	Sinus floor augmentation	Maxillary	3
8	F	Implants	Maxillary	6
9	M	Mandibular bone block graft	Mandibular	0
10	M	Implants and Kazanjian vestibuloplasty	Mandibular	4
11	F	Implants and pedicled palatal flap	Maxillary	4
12	F	Mandibular bone block graft	Mandibular	0
13	M	Implants and Kazanjian vestibuloplasty	Mandibular	4
14	M	Implants	Mandibular	8
15	F	Sinus lift and buccal bone block graft	Maxillary	3
16	F	Bilateral sinus lift	Maxillary	6
17	M	Free gingival graft	Mandibular	0
18	F	Sinus floor augmentation	Maxillary	3
19	F	Implants and Kazanjian vestibuloplasty	Mandibular	4
20	M	Sinus floor augmentation	Maxillary	4
21	F	Implants and Kazanjian vestibuloplasty	Mandibular	4
22	F	Implants	Maxillary	6
23	M	Mandibular bone block graft	Mandibular	0
Total implants				86

Hemodynamic and respiratory parameters (heart rate, average blood pressure, and peripheral oxygen saturation) were similar in both groups, with no statistically significant differences (Figs 8 to 10). The same was true of the Ramsay scale score, which leveled out around 3 for both groups (Fig 11).

Figure 12 compares the BIS and Ramsay scale scores in the group B patients. Both parameters stabilized 5 minutes after the start of sedation at around 85 for the BIS and around 3 for the Ramsay Scale and remained at these levels until the end of the operation.





**Fig 2** Mandibular bone block graft from the retromolar region (ramus) for anterior mandibular augmentation (patient 1, group A).



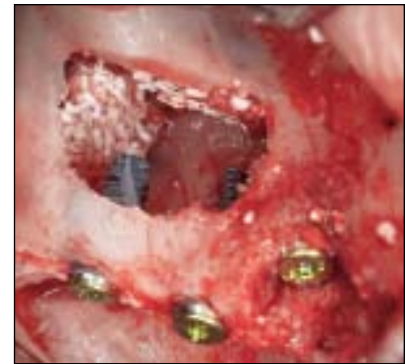
**Fig 3** Kazanjian vestibuloplasty (patient 12, group A).



**Fig 4** Mandibular bone block graft from the chin area (symphysis) for augmentation of the anterior maxilla (patient 20, group A).



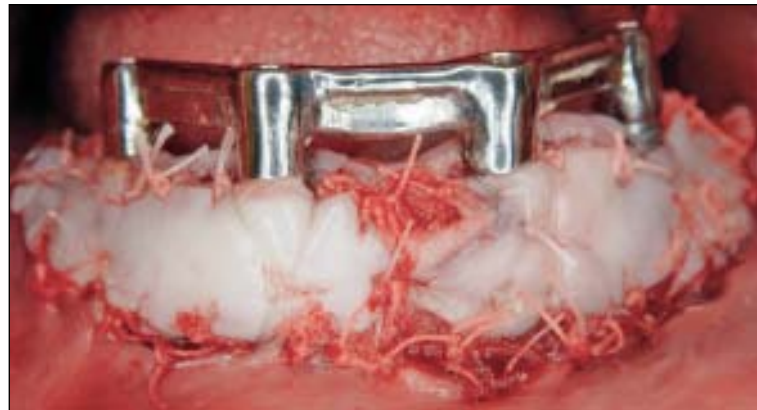
**Fig 5** Tunnel technique for mandibular bone block graft from the retromolar region (ramus) to augment the posterior mandible (patient 5, group B).



**Fig 6** Sinus floor augmentation (patient 7, group B).



**Fig 7a** Donor site, free gingival graft from the palate (patient 17, group B).



**Fig 7b** Recipient site, free gingival graft from palate (patient 17, group B).

Drug consumption, standardized by weight and time, was lower in group B: 30.09% for propofol, 33.33% for fentanyl, and 33.52% for midazolam. The differences versus drug consumption in group A were statistically significant ( $P < .05$ ) (Table 7).

One unexpected event was recorded in a 66-year-old patient in group B weighing 62 kg. In minute 5 of the procedure, coinciding with the administration of a 0.5-mg bolus of midazolam, there was a desaturation episode to 85%, a drop in the BIS to 55, and an increase in the Ramsay Scale score to 6. At that point, the

**Table 4 Patient Demographic Data**

Group	Sex	Mean age (y) (range)	Mean weight (kg) (range)
A	M 11 (55%)/ F 9 (45%)	49.9 ± 0.6 (28–71)	75.4 ± 13.6 (50–100)
B	M 10 (43%)/ F 13 (57%)	55.3 ± 14.3 (35–79)	73.6 ± 15.3 (52–98)

**Table 5 ASA Scores**

Group	Score	
	I	II
A	11 (55%)	9 (45%)
B	11 (47.8%)	12 (52.2%)

**Table 6 Duration of Procedures (in Minutes)**

Group	Mean duration	Range
A	101 ± 17.55	60–120
B	100 ± 21.42	50–120

patient had received a total of 2 mg of midazolam, 60 µg of fentanyl, and a continuous infusion of propofol at a rate of 3 mg/kg/h. A 0.2-mg bolus of flumazenil was administered and the continuous infusion of propofol was stopped. These maneuvers, together with verbal and moderate physical stimuli, were enough to return the patient's oxygen saturation to normal. No ventilation support or supplemental oxygen was required. After this, the procedure was continued, with dosage of the drugs administered at the lower end of the protocol range. No other problems were recorded.

The anxiety and satisfaction perceived by the patients were recorded at the end of the operation. Mean anxiety scores were 1.35 and 1.26 for groups A and B, respectively, indicating low levels of anxiety; mean satisfaction scores were 8.8 and 8.68 for groups A and B, respectively, indicating good satisfaction with the procedures. There were no significant differences between the two groups for either measure.

## DISCUSSION

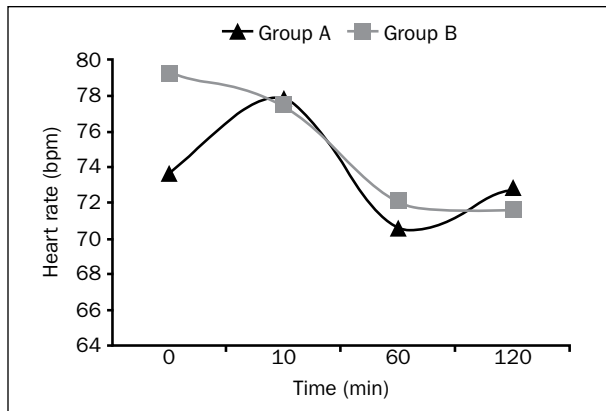
The use of sedation in the dental office for oral surgery procedures has increased significantly in recent years. The possibility of safely monitoring patients with more manageable tools and the experience of a specialist in the intravenous use of short half-life drugs have facilitated the proliferation of this technique.

Analysis of the BIS has shown it to be useful in sedation as an indirect measure of drug action employed in subanesthetic doses as an indicator of the patient's response and as a very sensitive predictor of the loss of consciousness.<sup>20,21</sup> A few studies have been carried out on sedated patients, verifying that the BIS correlates to the sedation level clinically observed in these patients.<sup>22,23</sup>

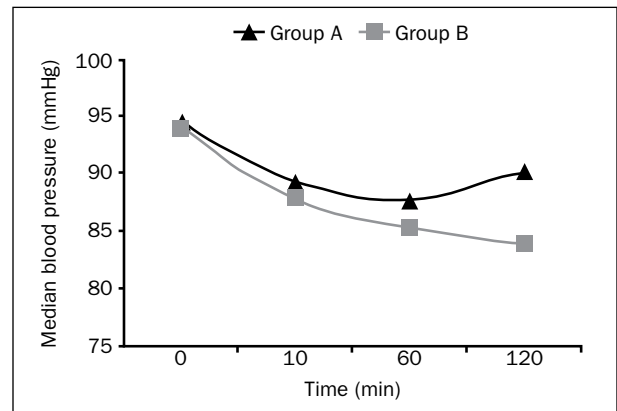
Of the two scales most commonly used to clinically assess sedation level, in this study the Ramsay Sedation Scale was used rather than the Modified Observer's Assessment of Alertness/Sedation (MOAA/S).<sup>24</sup> The Ramsay scale is more suitable for patients under the moderate sedation administered in the present study. In addition, it has more items that are applicable to this sedation status than the MOAA/S, which is used more commonly in procedures where the level of consciousness reaches a deeper degree (eg, interventional radiology, digestive endoscopy).

If the BIS sensor is placed on the forehead, close to the site of the dental implant surgery, and the patient under sedation has not received any neuromuscular-blocking drug, the BIS might frequently be subject to artifact interference from input secondary to muscular activity (patients do not receive any muscle relaxant) or high-frequency electrical artifacts, distorting the measurement. In this sense, the findings of Matsuzaki and Tanaka<sup>25</sup> are conclusive. They compared the BIS measurements under general anesthesia and intravenous sedation in patients undergoing oral surgery or dental treatments. The findings suggest that BIS monitoring is also effective in sedated patients, with no appearance of interference.<sup>25</sup> Additionally, improvements in the most recent generation of monitors have made it possible to eliminate the majority of artifacts, including those resulting from muscular activity.<sup>26</sup> However, more studies should be carried out on this subject to obtain definitive data.

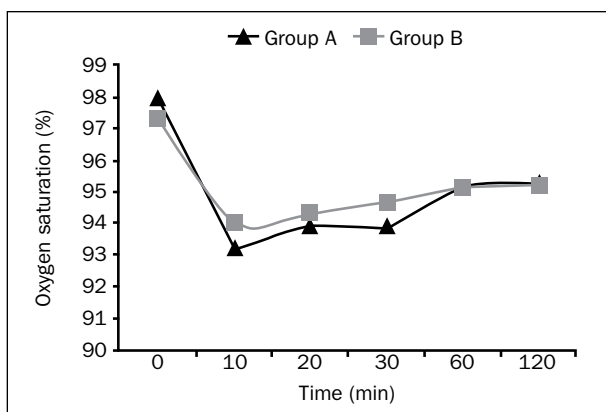
The present study showed homogeneity between the two groups in age, sex, weight, ASA status, and duration of surgery (Tables 4 to 6). No significant differences were observed between the two groups in terms of blood pressure, heart rate, and peripheral oxygen saturation, although average blood pressure values were slightly lower in group B (Figs 8 to 10). This finding is noteworthy, as drug consumption in this group was significantly less, a fact that should have been reflected more obviously in the hemodynamic parameters. The size of the sample and the different duration times for the operations may also have influenced this result. Additionally, the Ramsay scale scores did not differ between the two groups. A similar development of scores was achieved, characterized by stabilization at around a value of 3 within 10 minutes of the start of sedation (Fig 11).



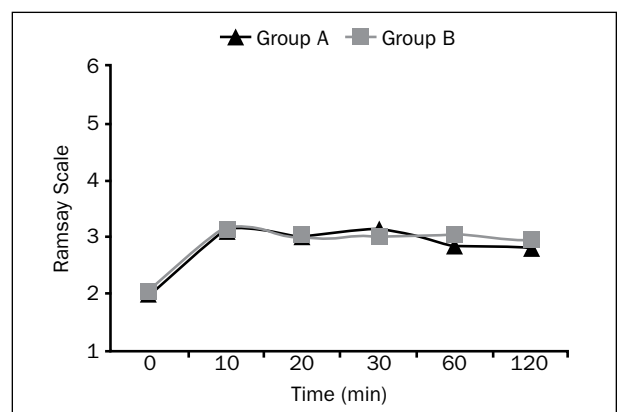
**Fig 8** Changes in heart rate (beats per minute) during surgery.



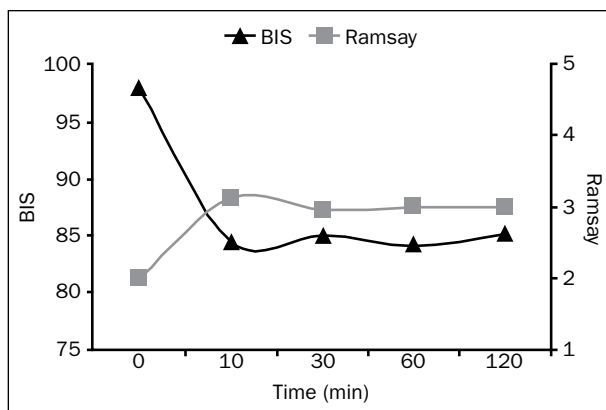
**Fig 9** Changes in median blood pressure during surgery.



**Fig 10** Changes in oxygen saturation during surgery.



**Fig 11** Changes in the Ramsay Sedation Scale during surgery.



**Fig 12 (Left)** Comparison of changes in BIS and Ramsay Sedation Scale in group B over time.

Group	Propofol (mg/kg/h)	Fentanyl (µg/kg/h)	Midazolam (µg/kg/h)
A (n = 20)	0.113	0.051	1.602
B (n = 23)	0.079*	0.034*	1.065*

\*P < .05.

In group B, the BIS measurements showed an evolution that could be superimposed over that of the Ramsay scale score in terms of time—although logically they are inversely proportional—achieving a value of close to 85, which held steady until surgery was completed (see Fig 12). It is possible to assert that this range would be an adequate target for BIS in this type of surgery, and it coincides with other authors' findings.<sup>21,27</sup>

Standardized consumption of all the drugs used for sedation was clearly lower in group B (Table 7). This difference was statistically significant and in agreement with other studies.<sup>12,14,27,28</sup> This overall decrease in dosage in group B decreases the probability of side effects, as well as recovery time and overall costs. Although these aspects of surgery were not evaluated in this study, similar observations have been made by others.<sup>11,12,14,28</sup>

The feeling of anxiety experienced by the patients in both groups during the operation was very low, with an average slightly below 1.5 on the VAS. The average level of satisfaction described by all patients was very high (averages close to 9 on a scale of 0 to 10). The fact that prior to carrying out the study, abundant experience had been acquired in intravenous sedation for this type of surgery without the BIS may bias the results associated with all measured parameters.

## CONCLUSIONS

No differences were detected in patient hemodynamic and respiratory parameters when the Ramsay Sedation Scale and the bispectral index (BIS) were used to monitor patients. All patients experienced a low level of anxiety and high satisfaction. A value of 3 on the Ramsay scale seems to be an optimum indicator of the level of consciousness, coinciding with a BIS value ranging from 80 to 85. Therefore, the optimum BIS value during intravenous sedation of these patients should be within the 80 to 85 range, or very close to these values. Patients monitored with the BIS required about 30% less intravenous medication (propofol, midazolam, and fentanyl), decreasing the probability of adverse pharmacological effects, shortening recovery time, and lowering the cost of the procedure. The BIS should be included in monitoring standards when an intravenous sedation technique is used in any location outside the operating room, including the dental office. The inclusion of BIS monitoring as a regular work tool to control patients' level of consciousness will increase anesthetic efficiency level and improve patient safety.

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