Int. J. Odontostomat.,
17(4):451-456, 2023.

Evaluation of Cardiovascular Parameters of ASA I and ASA II Patients Undergoing Dental Implant Surgery Under Intravenous Sedation with Midazolam: A Retrospective Analysis

Evaluación de Parámetros Cardiovasculares de Pacientes ASA I y ASA II Sometidos a Cirugía de Implantes Dentales Bajo Sedación Intravenosa con Midazolam: Un Análisis Retrospectivo

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ORCINA, B. F.; OLIVEIRA, E.; FEDELI JÚNIOR, A.; STUKER, H. & MOREIRA, R. S. Evaluation of cardiovascular parameters of ASA I and ASA II patients undergoing dental implant surgery under intravenous sedation with Midazolam: a retrospective analysis. *Int. J. Odontostomat., 17(4)*:451-456, 2023.

ABSTRACT: The purpose of this research was to compare the vital signs of ASA II patients undergoing dental implant surgery under intravenous anesthesia to those of ASA I patients. From a specialist course in Implant Dentistry, 41 medical records (22 ASA I and 19 ASA II patients) were analyzed. Age, gender, ASA classification, blood pressure, heart rate, and oxygen saturation were all measured. Pre-surgery, following the onset of local anesthetic, at the end of the initial implant insertion, and at the end of surgery were all used to collect vital signs. Student's t-test (p<0.05) was used to determine inter- and intra-group data associations. The crossing of operative moments pre-surgical and installation of the first implant in both systolic (p<=0.01) and diastolic (p<=0.03) pressure was statistically significant in ASA I patients. In contrast, there was only a statistical difference in the verification of peripheral oxygen saturation data at preoperative and local anesthesia times in ASA II patients (p<=0.04). When comparing the time of installation of the first implant (p<=0.03) and at the end of surgery (p<=0.02), with respect to systolic pressure, ASA II presented statistically higher, while variable oxygen saturation at the beginning of local anesthesia in ASA I was statistically higher (p<=0.04). It is proposed that intravenous sedation acts in a compensatory manner in patients with systemic disease, leading both groups' behavior to be similar.

KEY WORDS: midazolam, surgery, oral, dental implantation, comorbidity, conscious sedation.

INTRODUCTION

Pain control and anxiety management are required in the dental office because some procedures, such as dental implants, are invasive and cause discomfort in patients (McCrea, 2015). In addition to these factors, the epidemiological transition of the twentieth century was accompanied by a decrease in deaths from disabling communicable diseases and an increase in chronic noncommunicable diseases (NCDs). Cardiovascular diseases are the leading cause of death and morbidity worldwide (Omran, 1971; GBD 2015 DALYs and HALE Collaborators, 2016; GBD 2015 Mortality and Causes of Death Collaborators, 2016; GBD 2015 Mortality and Causes of Death Collaborators, 2016).

The presence of hypertensive patients who have their blood pressure (BP) controlled by medication is common in the dental routine. These are the people who are more likely to present a hypertensive crisis in front of the dentist (Egan, 2013; Southerland *et al*., 2016). Furthermore, several factors in dental care may cause cardiovascular effects in patients, particularly during dental extractions or oral surgeries due to the use of local anesthetics containing vasoconstrictor

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Received: 2023-07-31 Accepted:2023-09-27

drugs, i.e., exogenous catecholamines (Ogunlewe *et al*., 2011; Silvestre *et al*., 2011). In this sense, these drugs associated with endogenous catecholamines, which are released by the patient's anxiety prior to the dental surgeon, cause cardiovascular changes such as increased blood pressure and heart rate (HR) (Ogunlewe *et al*., 2011; Silvestre *et al*., 2011; Uzeda *et al*., 2014; Agani *et al*., 2015).

Intravenous sedation is a parenteral, moderate sedation that causes a drug-induced reduction in the patient's level of consciousness while the patient responds to verbal commands and light tactile stimuli. Another advantage of this method is the absence of interventions to preserve the upper airway because adequate and spontaneous ventilation, as well as cardiovascular function, are maintained (Southerland & Brown, 2016; AHA, 2019).

The purpose of this study was to compare the vital signs (blood pressure, heart rate, and oxygen saturation) of ASA I and ASA II patients throughout the transoperative period of dental implant insertion procedures performed under intravenous sedation with midazolam.

MATERIAL AND METHOD

This primary, observational, and retrospective study was characterized by the collection of data from the medical records of patients who sought the services of a Specialization Course in Implant Dentistry between 2013 and 2015 and subsequently underwent procedures for the installation of dental implants using venous sedation in the same course's surgical center.

The convenience sample was created by reviewing all medical records of patients seen under intravenous sedation during the course, 22 ASA I and 19 ASA II. The following comorbidities were listed in the anamnesis of each record for the ASA II patients: arterial hypertension, diabetes mellitus, fibromyalgia, intestinal metaplasia, smoking, asthma, gastroesophageal reflux, and cardiac ischemia.

In general, the patients received total implant-supported rehabilitation in the maxilla and/or mandible, as well as surgery for autogenous bone grafting. According to the specialization course protocol, these patients in rehabilitation were given endovenous sedation and local anesthesia. Midazolam, fentanyl, and flumazenil were used in these patients, and associations with specific medications such as cephalexin (antibiotic), dexamethasone (corticoid), plasil (antiemetic), and dipyrone (analgesic) could occur, according to the criteria of the anesthesiologist in charge of sedation administration and maintenance. The dental surgeon used anesthetic Mepiadre 2 % with epinephrine 1:100,000 (DFL, Taquara, Brazil) for local anesthesia.

Venous sedation was administered while the patient was properly positioned and comfortably accommodated in the dental chair. The anesthesiologist started sedation by puncturing the patient's left hand, and then sensors for cardiac monitoring, AP, and non-invasive oximetry (monitored every 5 minutes) were placed in the patient. Following this, the nasal catheter was inserted to administer oxygen to the patient throughout the sedation procedure. Following completion of these procedures, the anesthesiologist administered an initial dose of 1.5 mg or more, depending on the patient's anxiety level, and observed the patient's response to this dose, increasing it incrementally until the appropriate level of sedation was reached. Starting the dental procedure, the dental surgeon begins the local anesthesia required for the type of surgical procedure and anatomical location of the area to be operated on.

The specialization had already used a form to collect some cardiovascular parameters during the trans-operative period for uniform registration and monitoring. Both anesthesiologists and post-graduate implant dentistry students were instructed to complete the form at pre-determined times. This form contained data that was tabulated in an Excel software (Microsoft, version 15.0, Albuquerque, New Mexico, USA) spreadsheet, such as: sex; age; general health conditions, according to the American Society of Anesthesiologists (2019, 2020), where the patient was classified as ASA I when healthy and ASA II when there was some mild systemic disease without functional limitation; blood pressure (systolic and diastolic), heart rate, and peripheral oxygen saturation (SpO2) (oxygen saturation of the blood) (ASA, 2020). The collections were made in four moments to evaluate these last three parameters during the pre, trans, and immediate postoperative periods:

T1 - When the patient is sitting in the dental chair but before undergoing venous sedation;
T2 - At the time of the initial local anesthesia;
T3 - During the first implant installation;
T4 - Following the last suture at the end of surgery.

The BP classification followed the American Heart Association (2023) values. Based on this, blood pressure is considered normal when it is less than 120/80 mmHg; elevated when systole values range between 120-129 mmHg and diastole < 80 mmHg; stage 1 hypertension systole 130-139 mmHg and diastole 80-89 mmHg; stage 2 hypertension 140 mmHg or more systole and diastole 90 mmHg or more; and finally hypertensive crisis systole >180 mmHg and diastole > 120 mmHg (AHA, 2023).

According to Coulthard & Craig (1997), the sedation criteria can be based on the Ramsay scale, which is used in Intensive Care Units (ICU), where level 1 (mild sedation) the patient is tranquil and responds when requested; level 2 (moderate sedation) the patient is drowsy and responds to a touch on the forehead; level 3 (deep sedation) the patient is asleep and responds little to stimuli; and level 4 (general an The dose of midazolam was continuously adjusted during the surgical procedure to maintain adequate sedation of the patient between Ramsay grades 1 and 2 (Coulthard & Craig, 1997).

Statistical analysis was performed using the Jamovi® (Sydney, Australia) software individually in each group at the four points of each clinical parameter (comparing the means for systolic and diastolic BP, HR, and SpO2). The Student's t test (p<0.05) was used to determine whether there were statistical differences between the means of the initial moment (T1) of each clinical parameter and the remaining three (T2, T3, T4), as well as between the two groups, ASA I x ASA II.

The Ethics and Research in Human Beings Committee approved this study (CAAE: 21937913.5.0000.0120). In addition, the study followed the STROBE checklist for observational studies.

RESULTS

A total of 41 medical records were analyzed for this study, with 22 (54 %) of patients classified as ASA I and 19 (46 %) classified as ASA II (Table I).

Table II displays the mean, standard deviation, and maximum and minimum values of systolic and diastolic blood pressure, heart rate, and oxygen saturation in ASA I patients at surgical times 1, 2, 3, and 4. Table III shows the same values for the same surgical times for ASA II patients.

Table I. Demographic and clinical data of both groups of patients: ASA I and ASA II.

	ASA I (n=22)	ASA II (n=19)
Age (mean)	48.6 years	58.6 years
Male/Female (n)	7/15	6/13
Presence of comorbidities (% of patients)	-	57,8

When the Student's t-test was used to compare the systolic AP of individuals in the ASA I group at different surgical times, times 1 and 3 were statistically different from each other (p<=0.01), and a statistical difference was repeated when the diastolic pressure of the same group was analyzed (p<=0.03).

When the systolic and diastolic blood pressures of the ASA II patients were measured, there were no statistical differences between the different surgical times. Systolic blood pressure remained stable throughout the measurements, with the lowest mean absolute value of 137.4 mmHg recorded at time 2. Furthermore, the diastolic blood pressure was lowest at times 2 and 3 (79.7 mmHg) and highest at time 1(86.7 mmHg).

In terms of HR, neither ASA I nor ASA II patients showed statistically significant differences in intragroup comparisons. The same thing happened with oxygen saturation, which showed no statistical differences in intragroup comparison in both groups of patients studied.

The Student's t-test (p< <0.05) was used to compare the groups ASA I and ASA II. In the analysis of BP behavior (systolic and diastolic), this test revealed statistically higher differences in the ASA II group at times 3 (p<=0.03) and 4 (p<=0.02), while there were no statistical differences in diastolic BP. For oxygen saturation, only surgical time 2 had mean values that were statistically higher in ASA I than in ASA II (p<=0.04). In the HR topic, however, no statistically significant differences were found (Table IV).

DISCUSSION

In this study, ASA I patients had statistically significant intragroup differences in the clinical parameter AP (p<=0.01) between times T1 and T3. T1 represents the beginning of the appointment, when the patient sits in the dental chair and is not yet sedated,

Table II. Values of systolic (S), diastolic (D) pressure, heart rate (HR) and peripheral oxygen saturation (SPO) in surgical times 1,2,3 and 4 of ASA I patients.

	Age	SI	S2	S3	S4	D1	D2	D3	D4	HR1	HR2	HR3	HR4	SPO1	SPO2	SPO3	SPO4
N	22	22	20	20	19	22	20	20	19	22	20	20	19	22	20	20	19
Mean	48.7	140	131	126	130	87.5	82.9	80.8	83.6	82.6	86.3	83.5	86.1	97.4	96.5	97.0	96.9
Standard Deviation	14.2	19.0	14.7	11.9	12.9	10.7	9.37	9.69	7.57	16.1	19.6	20.1	19.1	1.87	1.93	2.24	1.35
Minimum	0	110	108	109	107	68	67	60	67	64	65	59	64	92	91	92	95
Maximum	64	177	155	149	157	114	105	99	98	140	150	151	147	100	99	99	100

Table III. Values of systolic (S), diastolic (D) pressure, heart rate (HR) and peripheral oxygen saturation (SPO) in surgical times 1,2,3 and 4 of ASA II patients.

	Age	S1	S2	S3	S4	D1	D2	D3	D4	HR1	HR2	HR3	HR4	SPO1	SPO2	SPO3	SPO4
N	20	21	21	21	21	21	21	21	21	20	20	20	20	21	21	21	21
Mean	59.3	145	137	140	142	86.7	79.7	79.7	82.6	83.0	80.7	78.7	76.8	96.7	94.9	95.8	96.5
Standard Deviation	8.85	22.2	20.8	25.1	20.2	27.2	10.1	24.2	13.3	12.5	11.7	13.3	10.7	2.59	3.05	2.57	1.72
Minimum	40	117	104	105	100	10	64	50	52	60	62	56	57	90	89	89	94
Maximum	75	190	180	197	180	161	100	170	105	105	102	103	94	100	100	100	100

Table IV. Results of the Student's t test on the parameters systolic pressure (S), diastolic pressure (D), heart rate (HR) and peripheral oxygen saturation (SPO) in surgical times 1,2,3 and 4 between ASA I and ASA II groups.

	S1	S2	S3	S4	D1	D2	D3	D4	HR1	HR2	HR3	HR4	SPO1	SPO2	SPO3	SPO4
Results*	0.360	0.260	0.0300	0.0200	0.900	0.300	0.840	0.760	0.940	0.290	0.370	0.0700	0.290	0.0400	0.120	0.390

* Student's t test

whereas T3, when the first implant is installed, the patient is hemodynamically stabilized by sedation. As a result, the mean value at T1 corresponds to the American Heart Association's classification of stage 2 hypertension, whereas at T3 this parameter already falls to more acceptable levels, which is explained by the fact that the increase in systolic pressure occurs in the face of psychological stress, such as the dental surgical procedure, and its proportionality is determined by the patient's age and baseline BP values (Tsuchihashi *et al*., 1996; AHA, 2023).

Furthermore, while T1 is a clinical moment in which the patient is not sedated, it also shows the absence of the vasoconstrictor action of local anesthesia. Exogenous catecholamines linked to stress and anxiety can cause cardiovascular and hemodynamic changes, such as an increase in blood pressure and heart rate (Ogunlewe *et al*., 2011; Silvestre *et al*., 2011). Although T3 is a clinical moment in which the patient is anxious and under the influence of an adrenergic vasoconstrictor, it was statistically lower in relation to diastolic BP than the initial moment (P=0.03). Midazolam has sedative, anxiolytic, and short-acting properties that may cause anterograde amnesia, as well as being considered by the Standing Committee on Sedation in Dentistry (SCSD) as a standard drug of choice for patients over the age of 12 who wish to provide greater comfort in dental treatments (Aulakh *et al*., 2018; Intercollegiate Advisory Committee for Sedation in Dentistry, 2020).

There were no statistical differences in all criteria examined before the predetermined times when the hemodynamic parameters of ASA II patients were evaluated, even though this group of individuals had comorbidities, including arterial hypertension. In this sense, approximately 50 % of patients are anxious when they require dental treatment, and this feeling may be accompanied by an increase in BP and HR (DiAngelis & Luepker, 1983; Stouthard & Hoogstraten, 1990; Brand & Abraham-Inpijn, 1996). Furthermore, being in these psychological conditions associated with the stress of a treatment, such as implant surgery, causes the adrenal medulla to produce endogenous adrenaline, which has a direct impact on the patient's hemodynamic patterns

(Guyton & Hall, 2017). Thus, during these patients' surgeries, systolic blood pressure values remained variable between hypertension stages 1 and 2, and diastolic blood pressure values alternated between hypertension stages 1 and high, but without statistically significant differences. The criteria for HR and peripheral oxygen saturation remained satisfactory, leading us to believe that the low oscillations in cardiovascular parameters were obtained through intravenous sedation (AHA, 2023).

There were statistical differences in systolic blood pressure between groups ASA I and ASA II at moments 3 (p<=0.03) and 4 (p<=0.02). The ASA I group had 126 mmHg for high blood pressure at moment 3, while the other had 140 mmHg for stage 2 hypertension. According to dental surgery manuals, blood pressure levels in hypertensive patients should be kept between normal and high. This should be prioritized with the goal of preventing cardiovascular complications during dental implant surgery; additionally, fear and anxiety before surgery can be reduced with conscious sedation or the continued use of the antihypertensive agent (Kimura *et al*., 2015). There were statistical differences in systolic blood pressure between groups ASA I and ASA II at moments 3 (p<=0.03) and 4 (p<=0.02). The ASA I group had 126 mmHg for high blood pressure at moment 3, while the other had 140 mmHg for stage 2 hypertension. According to dental surgery manuals, blood pressure levels in hypertensive patients should be kept between normal and high. This should be prioritized with the goal of preventing cardiovascular complications during dental implant surgery; additionally, fear and anxiety before surgery can be reduced with conscious sedation or the continued use of the antihypertensive agent (Kimura *et al*., 2015). At time 2, the parameter peripheral oxygen saturation (SpO2) showed statistical differences (p<=0.04) between the two groups. As previously stated, ASA 2 patients had high mean values of systole in the trans-surgery, which may have contributed to a deeper initial sedation, given that the dose of the sedative is applied "sensing" the patient's level of sedation and that independent respiratory capacity may be impaired in this type of sedation (Southerland & Brown, 2016). Despite statistical differences, SpO2 levels remained within the recommended range (Mason *et al*., 2012).

Finally, even if the behavior of the groups was similar across the parameters evaluated, the interpretation of the results must be approached with caution due to the convenience sample. Furthermore, the ASA II patients had a limited number of comorbidities, which could lead to different outcomes when approaching patients with other systemic pathologies. Similarly, the type of surgery performed, with its anatomical difficulties, implies different surgical times, which may result in another interpretation bias. As a result, the need for new studies with a larger sample size and comorbidity heterogeneity should be encouraged.

CONCLUSION

Thus, intravenous sedation appears to be a good option for patients who require dental implant surgery and have anxiety, fear, or medical conditions that characterize them as ASA II which may interfere with the progress of the surgery, affecting their safety and comfort. In these ASA II patients, a better preoperative control of their fears and anxieties is required. The intravenous sedation reproduces acceptable hemodynamic values in the transoperative period reducing the risk of cardiovascular accidents.

ACKNOWLEDGMENTS. This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Brazil (Finance Code 001).

ORCINA, B. F.; OLIVEIRA, E.; FEDELI JÚNIOR, A.; STUKER, H. & MOREIRA, R. S. Evaluación de parámetros cardiovasculares de pacientes ASA I y ASA II sometidos a cirugía de implantes dentales bajo sedación intravenosa con Midazolam: un análisis retrospectivo. *Int. J. Odontostomat., 17(4):*451-456, 2023.

RESUMEN: El propósito de esta investigación fue comparar los signos vitales de pacientes ASA II sometidos a cirugía de implante dental bajo anestesia intravenosa con los de pacientes ASA I. Se analizaron 41 historias clínicas de un curso de especialista en Implantología (22 pacientes ASA I y 19 ASA II). Se midieron la edad, el sexo, la clasificación ASA, la presión arterial, la frecuencia cardíaca y la saturación de oxígeno. Se tomarn los signos vitales antes de la cirugía, después del inicio de la anestesia local, al final de la inserción inicial del implante y al final de la cirugía. Se utilizó la prueba t de Student (p<0,05) para determinar las asociaciones de datos entre e intragrupos. El cruce de los momentos operatorios prequirúrgicos y de instalación del primer implante tanto en la presión sistólica (p<=0,01) como en la diastólica (p<=0,03) fue estadísticamente significativo en los pacientes ASA I. En contraste, solo hubo diferencia estadística en la verificación de los datos de saturación

periférica de oxígeno en el momento preoperatorio y de anestesia local en los pacientes ASA II (p<=0,04). Al comparar el tiempo de instalación del primer implante (p<=0,03) y al final de la cirugía (p<=0,02), con respecto a la presión sistólica, el ASA II se presentó estadísticamente mayor, mientras que la variable saturación de oxígeno al inicio de la anestesia local en El ASA I fue estadísticamente mayor (p<0,4). Se propone que la sedación intravenosa actúa de forma compensatoria en pacientes con enfermedad sistémica, lo que hace que el comportamiento de ambos grupos sea similar.

PALABRAS CLAVE: midazolam, cirugía oral, implantación dental, comorbilidad, sedación consciente.

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