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Safety of Oral Conscious Sedation with Midazolam in Oral Surgery, Implantology and Periodontics

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Abstract

Objectives: Determine the efficacy and safety of Conscious Oral Sedation with Midazolam for treatments of Oral Surgery, Periodontics and Implantology in phobic or anxious adult patients.

Material and Methods: 60 non-cooperative phobic patients were treated through Oral Surgery procedures, 30 of them through Local Anaesthesia with Articaine, and another 30 through Local Anaesthesia with Articaine associated with Conscious Oral Sedation with Midazolam. Heart Rate, Systolic and Diastolic Blood Pressure, Partial Oxygen Saturation, Respiratory Rate, Forced Vital Capacity, Expiry Volume per Second and Maximum Expiration Flow were recorded.

Results: Sedation was recorded in small oscillations in the parameters, always within the safety margin, with Normocardia prevailing in the heart rate, the Normotension with some oscillations in Systolic Blood Pressure, the Normotension in the Diastolic Blood Pressure, a decrease in the Partial Oxygen Saturation within the safety margin, with Normopnea in the Respiratory Rate and with decreases in the respiratory records of Forced Vital Capacity, the Expiratory Volume per second and the Maximum Expired Flow.

Conclusion: Conscious Oral Sedation with Midazolam for procedures of Oral Surgery, Implantology and Periodontics is a safe and effective method to obtain the patient's collaboration, thus avoiding procedures of greater morbidity such as General Anaesthesia. However, the statistically significant reduction of both Partial Oxygen Saturation and Respiratory Volume, caution against certain conditions of the patient, and be very cautious if Midazolam is associated with other sedatives that can cause respiratory depression.

Keywords: Conscious Sedation; Midazolam; Local Anaesthesia; Oral Surgery

Introduction

Dental phobia or anxiety is widespread, and control of anxiety for medical treatments is both a right for the patient and a duty for the professional. Different studies have shown that the prevalence of dental anxiety ranges between 5% and 24% worldwide [1,2]. Dental Fear or Anxiety related to dental procedures, together with hypersensitivity to pain, have been recognized as barriers or obstacles to get an adequate dental treatment, thus preventing a quality dental treatment [3]. In fact, when both the prevalence and the clinical consequences of untreated caries and their relation to fear or dental phobia have been studied, they have shown that patients with a lot of fear had a 2.05 times greater risk of having cavities than those who they were not afraid [4].

When treating these patients through sedation procedures, it has been established that the patient can evolve from one sedative level to another and that the professional must be prepared to increase monitoring and supervision properly [5]. Thus, a sufficiently large level of security must be preserved to avoid an unforeseen loss of consciousness [6]. The safety and proper administration of sedative and analgesic drugs can transform uncontrollable situations into tolerable ones, with which Conscious Sedation is a safe and effective tool to improve patient tolerance and acceptance of Oral Surgery procedures. General Anaesthesia, although it is the most common procedure to treat non-cooperative patients [7], however, the morbidity and mortality associated with this technique is much greater than that of Conscious Sedation [8], and it has much higher costs [9].

Conscious Oral Sedation through Benzodiazepines such as Midazolam, provides the necessary anxiolysis, hypnosis/sedation, musculoskeletal relaxation, anterograde amnesia, respiratory depression and anticonvulsant effect [10], but without analgesic

properties. Benzodiazepines have a wide margin of safety between therapeutic and toxic doses. The absorption of Midazolam occurs in the small intestine and the stomach, with high lipid solubility so they have a rapid effect although it has a short time of action, but it is considered as the BDZ of choice in dentistry [11], besides being four times more powerful than Diazepam. When the effectiveness of Midazolam administered orally has been studied, great efficiency has been observed in the modification of the patient's behaviour, and that the physiological changes produced by Oxygen Saturation, Blood Pressure, Heart and Respiratory Rate, were never outside the limits normal [12]. The changes of these parameters when using Midazolam are minimal [13] and they do not cause problems. In the literature, however, there are conflicting results about whether or not Midazolam affects blood pressure, although there is a consensus that it causes a slight respiratory depression [13-16], by acting directly on the Central Nervous System. In light of these considerations, the objective of this study is to investigate Cardiac and Respiratory alterations in patients treated with Conscious Oral Sedation with Midazolam to determine the safety of the procedure.

Material and Methods

Volunteers

60 non-cooperative phobic patients separated into two groups without significant differences in age, sex (Figures 1 and 2), smoking habits, Cardiac Pathologies or Respiratory Diseases (Table 1) were treated by advanced procedures of Oral Surgery, Periodontics or Implantology such as Sinus Lift, Periodontal Surgeries and Implant Surgeries, 30 of them through Local Anaesthesia with Articaine (Ultracain®), and 30 others associated Local Anaesthesia to Conscious Oral Sedation with Midazolam (Dormicum®). They were treated at the Dental Clinic of the College of Dentists of León by personnel trained in Basic Life Support and Reanimation Techniques. This study was carried out in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of the University of León with the project number ETICA-ULE-011-2016. The inclusion criteria were to be phobic patients determined through the STAI Questionnaire to determine the degree of Phobia or Dental Anxiety, not having contraindications to be anesthetized or sedated, and to present an acceptable state of health (ASA I and ASA II). They were given a prior consent both of the procedures to be performed and of the anaesthesia and sedation procedure before being randomly assigned to each of the groups. After being assigned and before being anesthetized and / or sedated, they were verbally informed of the details concerning the procedure. A complete health questionnaire was filled in and partial oxygen saturation (SpO2), Respiratory Frequency, Respiratory Volume in the form of Forced Vital Capacity (FVC), Forced Expiration Volume (FEV) and Maximum Expiratory Flow (PEF) were taken as respiratory records, and as cardiac registers the Cardiac Frequency, and the Systolic and Diastolic Blood Pressure. The records were taken before starting the procedure and repeated every 5 minutes during and until the end of the procedure, except for CVF, FEV and PEF that were only recorded at the beginning and at the end. The authors do not declare any conflict of interest about the publication of this article.

Variable	Category	Sample (N=60)	Groups (n=30)			Chi cuadrado Test
			A. Local	AL + Midaz.	Value	P-Sig
Smoking	Smoker/ Foresmoker.	70.0% (63)	76.7% (23)	66.7% (20)	0.95 NS	.621
	Never Smoked	30.0% (27)	23.% (7)	33.3% (10)		
Cardiac Pathol.	Yes	41.1% (37)	40.0% (12)	36.7% (11)	0.64 NS	.725
	No	58.9% (53)	60.0% (18)	63.3% (19)		
Respiratory. Pathol	Yes	36.7% (33)	46.7% (14)	30.0% (9)	2.01 NS	.366
	No	63.3% (57)	53.3% (16)	70.0% (21)		

N.S. = NON significative al 5% (p>.05)

Table 1: Descriptive analysis. Clinical characteristics of the sample and comparison between groups

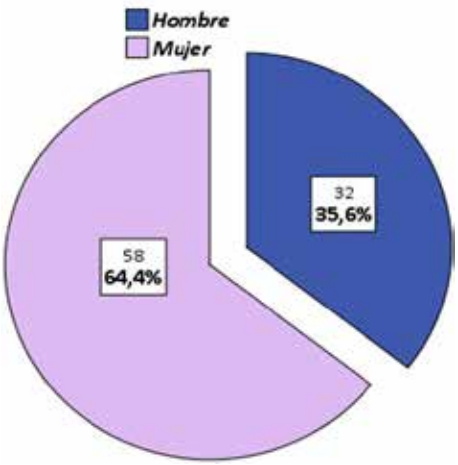


Figure 1: Sectors diagrams. Composition of the sample according to gender

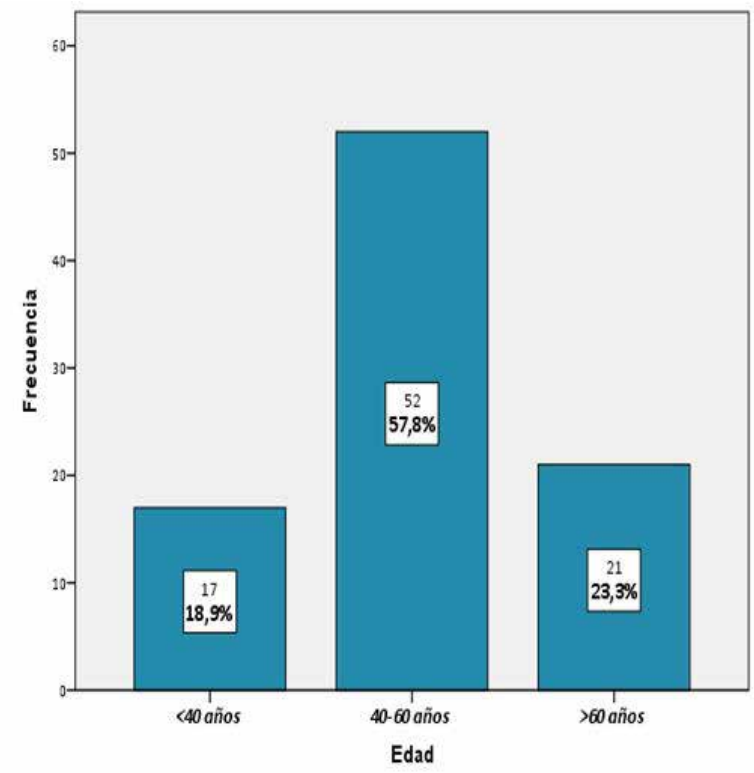


Figure 2: Bar chart. Composition of the sample according to age

Instrumental

The instruments include a Digital Pulsioximeter (Aerocare and NellCore ® Puritan Bennett Inc N-550-B), an Spirometer (Contec SP10 Spirometer, Contec medical Systems Co., Ltd) and a Digital Blood Pressure Monitor (Automatic Blood Pressure Monitor, H.Life Model). These parameters were recorded and the recorded data was saved and safeguarded.

Statistical analysis

For the statistical analysis the computer application used was: IBM-SPSS-22 (ref: IBM Corp. Rel 2013. IBM SPSS Statistics v 22.0 for Windows, Armonk, NY. USA). The statistical techniques and tests used have been in qualitative variables (nominal) the distribution of frequencies and percentages, and in quantitative variables the data exploration was performed with Q–Q graph of adjustment to normal, histogram, asymmetry coefficients and kurtosis / height together to the Kolmogorov-Smirnov goodness of fit test and description with the usual tools of centrality (mean, median) and variability (standard deviation, range and interquartile range). The Chi-square Test of independence was used in the intergroup analysis.

Results

Group treated with Local Anaesthesia (Al)

The variations in the heart frequency show an absence of Bradycardia, a number of patients in Normocardia that go to Tachycardia and then return to Normocardia. These alterations have statistical significance. Regarding Systolic Blood Pressure, uncontrolled variations are observed. In the Diastolic Blood Pressure there are uncontrolled variations but predominance of Normotension, and punctual peaks in the HTA.

Regarding Partial Oxygen Saturation, the collected data present minimal variations. The general line that is appreciated is that from the 30 min (7^{th}) increase the cases with low saturation.

Regarding the Respiratory Rate per minute there was no bradypnea at any time and they all started in tachypnea. Regarding the FVC, FEV and PEF, they present similar results. There is a change of 33.3% of patients who have normal FVC in the initial situation and in the final one have low FVC. The cited change has turned out to be highly significant ($p < .01$).

Group treated with Al and Sedation with Midazolam

The variations in the heart frequency indicate a total absence of bradycardia throughout the surgery, a constant Normocardia that is complemented exclusively by a small tachycardia, but in the Test of the Signs of the Heart Frequency it is evident that none of the variations is statistically significant, since the predominant Normocardia does not suffer alterations that reach significance.

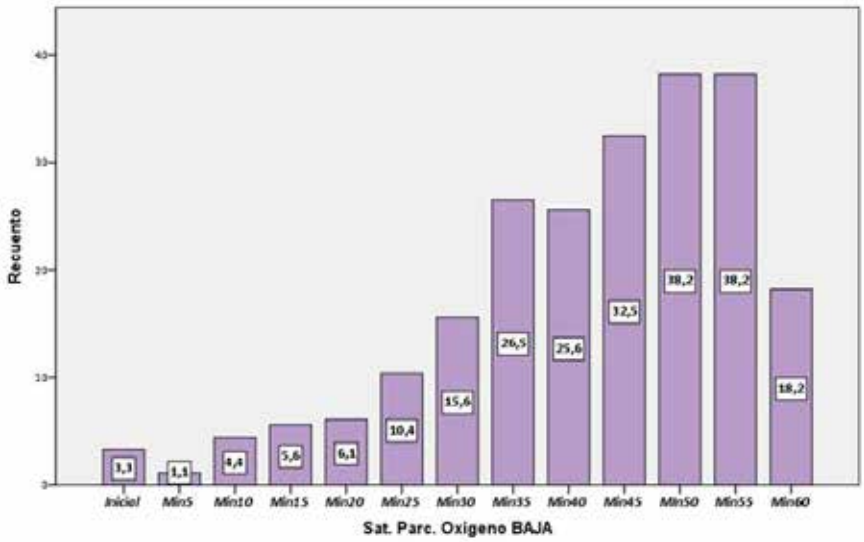
As for the Systolic Blood Pressure, the High Blood Pressure and the Grade II Hypertension predominate. The Normotension is residual. The Diastolic Blood Pressure presents, in contrast to the Systolic, more Normotension. The remarkable thing is that both Grade I and Grade II Diastolic Arterial Hypertension start at not too low values that rapidly descend and constantly undergo discrete variations.

In Partial Oxygen Saturation, it stands out that Normal Saturation predominates at the beginning, but then gradually reduces with statistical significance (Table 2) (Figure 3).

Measure	2ª	3ª	4ª	5ª	6ª	7ª	8ª	9ª	10ª	11ª	12ª	13ª
1ª Initial	1^{NS}	$.500^{NS}$	$.312^{NS}$	$.312^{NS}$	$.063^{NS}$	**.035***	**.035***	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$	$.500^{NS}$
2ª		$.500^{NS}$	$.250^{NS}$	$.250^{NS}$	.031*	**.016***	**.016***	**.031***	**.03***	**.031***	**.031***	$.500^{NS}$
3ª			$.500^{NS}$	$.500^{NS}$	$.063^{NS}$	**.031***	**.031***	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$	$.999^{NS}$
4ª (15min)				$.750^{NS}$	$.188^{NS}$	$.063^{NS}$	$.063^{NS}$	$.125^{NS}$	$.125^{NS}$	$.125^{NS}$	$.125^{NS}$	$.999^{NS}$
5ª					$.125^{NS}$	$.063^{NS}$	**.031***	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$	$.063^{NS}$
6ª						$.500^{NS}$	$.063^{NS}$	$.188^{NS}$	$.188^{NS}$	$.188^{NS}$	$.188^{NS}$	$.999^{NS}$
7ª (30min)							$.125^{NS}$	$.312^{NS}$	$.312^{NS}$	$.312^{NS}$	$.312^{NS}$	$.999^{NS}$
8ª								$.500^{NS}$	$.500^{NS}$	$.500^{NS}$	$.500^{NS}$	$.999^{NS}$
9ª									1^{NS}	1^{NS}	1^{NS}	$.999^{NS}$
10ª (45min)										1^{NS}	1^{NS}	$.999^{NS}$
11ª											1^{NS}	$.999^{NS}$
12ª												$.999^{NS}$
13ª (60min)												

N.S. = NON significative at 5% (p>.05) * = Significative at 5% (p<.05) ** = highly significative at 1% (p<.01)

Table 2: Test of the Signs of the significance of the change. Patients with AL + Midazolam: Partial oxygen saturation



Recuento means count. Sat Parc. Ox BAJA means LOW partial oxygen saturation

Figure 3: Bar chart. Evolution of Partial Oxygen Saturation LOW from the initial measurement to the measurement 1 hour after

In the Respiratory Rate per minute, it is very remarkable that no case presented Bradipnea, which in an immense majority began with Tachypnea. This indicates that the respiratory depressant effect of Midazolam occurs at the level of Oxygen Saturation (Table 2), and not of the Respiratory Rate (Table 3).

Measure	N valid	Bradipnea		Normopnea		Tachypnea	
		% observed	Change	% observed	Change	% observed	Change
1ª Initial	30	--	--	--	--	100% (30)	--
2ª	30	--	--	3.3% (1)	+3.3%	96.7% (29)	-3.3%
3ª	30	--	--	3.3% (1)	--	96.7% (29)	--
4ª (15min)	30	--	--	10.0% (3)	+6.7%	90.0% (27)	-6.7%
5ª	28	--	--	17.9% (5)	+7.9%	82.1% (23)	-7.9%
6ª	28	--	--	28.6% (8)	+11.3%	71.4% (20)	-11.3%
7ª (30min)	28	--	--	28.6% (8)	--	71.4% (20)	--
8ª	18	--	--	47.1% (8)	+18.5%	52.9% (9)	-18.5%
9ª	16	--	--	62.5% (10)	+15.4%	37.5% (6)	-15.4%

Measure	N valid	Bradipnea		Normopnea		Tachypnea	
		% observed	Change	% observed	Change	% observed	Change
10ª (45min)	16	--	--	75.0% (12)	+12.5%	25.0% (4)	-12.5%
11ª	16	--	--	75.0% (12)	--	25.0% (4)	--
12ª	16	--	--	75.0% (12)	--	25.0% (4)	--
13ª (60min)	10	--	--	70.0% (7)	-5.0%	30.0% (3)	+5.0%

Table 3: Longitudinal variation intra group. Patients with AL + Midazolam: Respiratory frequency per minute

Regarding Forced Vital Capacity (VFC), it should be noted that there is a statistical significance (p <.01) of a decrease in FVC with the use of Midazolam (Table 4).

		Final		Test of Signs
		Low 14 (46.7%)	**Normal** 16 (53.3%)	**p-value**
Initial	**Low** 5 (16.7%)	16.7% (5)	--	.002**
	Normal 25 (83.3%)	30.0% (9)	53.3% (16)	

**= Highly significative at 1% (p<.01)

Table 4: Test of the Signs of the significance of the change. Patients with AL + Midazolam: Forced vital capacity. (N = 30)

Regarding the Volume of Forced Expiration by Second (FEV) and Maximum Expiratory Flow (PEF), a lower change is observed than in the FVC, presenting an statistical significance of lower power, in this case p <.05. There is therefore a statistical significance (p<.05) of a decrease in FEV with the use of Midazolam.

Comparative, Al vs. Al and Sedation with Midazolam

In both groups there were several statistically significant tachycardic growth peaks, of greater intensity in Local Anesthtics where patients were not sedated, although they were reversible almost immediately and were within safety margins.

In the group where patients were sedated with Midazolam, the results present more oscillations of pressure, which are always lower and less frequent than in group of local anesthetics (Table 5). The presence of tension peaks related to the most demanding surgical activities is evident.

Measure	Category FC	Sample	Groups		Chi cuadrado Test	
			A. Local	AL + Midaz.	Value	P-Sig
1ª Inicial	**Normocardia**	91.1% (82)	93.3% (28)	96.7% (29)	3.57NS	.168
	Tachycardia	8.9% (8)	6.7% (2)	3.3% (1)		
2ª	**Normocardia**	85.6% (77)	86.7% (26)	93.3% (28)	3.42NS	.181
	Tachyicardia	14.4% (13)	13.3% (4)	6.7% (2)		
3ª	**Normocardia**	87.8% (79)	90.0% (27)	93.3% (28)	2.69NS	.260
	Tachycardia	12.2% (11)	10.0% (3)	6.7% (2)		
4ª (15min)	**Braiycardia**	1.1% (1)	--	--	2.93NS	.569
	Normocardia	84.3% (75)	83.3% (25)	90.0% (27)		
	Tachycardia	14.6% (13)	16.7% (5)	10.0% (3)		
5ª	**Bradycardia**	1.2% (1)	--	--	7.58*	.023
	Normocardia	72.3% (60)	59.3% (16)	**82.1% (23)**		
	Tachycardia	26.5% (22)	**40.7% (11)**	17.9% (5)		
6ª	**Bradycardia**	1.3% (1)	--	--	7.58*	.023
	Normocardia	79.2% (61)	68.0% (17)	**96.4% (27)**		
	Tachycardia	19.5% (15)	**32.0% (8)**	3.6% (1)		
7ª (30min)	**Bradycardia**	1.3% (1)	--	--	2.65NS	.266
	Normocardia	88.3% (68)	88.0% (22)	96.4% (27)		
	Tachycardia	10.4% (8)	12.0% (3)	3.6% (1)		
8ª	**Bradycardia**	6.1% (3)	--	--	14.00**	.007
	Normocardia	87.8% (43)	83.3% (15)	**100% (18)**		
	Tachycardia	6.1% (3)	**16.7% (3)**	--		

Measure	Category FC	Sample	Groups		Chi cuadrado Test	
			A. Local	AL + Midaz.	Value	P-Sig
9[a]	**Bradycardia**	4.7% (2)	--	--	12.13*	.016
	Normocardia	88.4% (38)	83.3% (15)	**100% (16)**		
	Tachycardia	7.0 (3)	**16.7% (3)**	--		
10[a] (45min)	**Bradycardia**	5.0% (2)	--	--	15.29**	.004
	Normocardia	85.0% (34)	83.3% (15)	**100% (16)**		
	Tachycardia	10.0% (4)	16.7% (3)	--		
11[a]	**Normocardia**	97.1% (33)	94.4% (17)	100% (16)	--	--
	Tachycardia	2.9% (1)	5.6% (1)	--		
12[a]	**Normocardia**	100% (34)	100% (18)	100% (16)	--	--
13[a] (60min)	**Normocardia**	100% (11)	100% (1)	100% (10)	--	--

N.S. = NO significative at 5% (p>.05) *= Significative at 5% (p<.05) **= Highly significative at 1% (p<.01)

In **bold**, categories whith signification (residuous=>2)

Table 5: Intergroup comparative analysis. Heart rate (arterial pulse). All sizes

In both cases, as the procedure progresses, there are a higher percentage of cases with low oxygen saturation, although always within the safety margin.

In the group ol local anesthetics there is a predominance of tachypnea, although at the end when the procedure is running out, it also tends to normopnea.

The maximum expiratory flow in both groups shows similar results with around 30% reduction (Table 6).

Measure	Category MEF	Sample	Groups			Chi cuadrado Test
			A. Local	AL + Midaz.	Value	P-Sign
Initial	**Low**	42.2% (38)	50.0% (15)	16.7% (5)	12.66**	.002
	Normal	57.8% (52)	50.0% (15)	**83.3% (25)**		
Final	**Low**	67.8% (61)	80.0% (24)	33.3% (10)	25.13**	.000
	Normal	32.2% (29)	20.0% (6)	**66.7% (20)**		

**= Highly significative at 1% (p<.01)

In **bold**, categories whith signification (residuous=>2)

Table 6: Intergroup comparative analysis. Maximum expiratory flow per minute. Both measures

In the group of Al and Midazolam, the reduction in the expiration volume was 17% compared to more than 27% of the AL group (Table 7).

Measure	Category FEV	Sample	Groups			Chi cuadrado Test
			A. Local	AL + Midaz.	Value	P-Sig
Initial	**Low**	41.1% (37)	50.0% (15)	16.7% (5)	11.38**	.003
	Normal	58.9% (53)	50.0% (15)	**83.3% (25)**		
Final	**Low**	66.7% (60)	76.7% (23)	33.3% (10)	23.70**	.000
	Normal	33.3% (30)	23.3% (7)	**66.7% (20)**		

**= Highly significative at 1% (p<.01)

In **bold**, categories whith signification (residuous=>2)

Table 7: Intergroup comparative analysis. Forced expiration volume per second. Both measures

In the group of Midazolam, the reduction in forced vital capacity was 30% compared to 33% in group of Local anesthetics (Table 8).

Measure	Category VFC	Sample	Groups			Chi cuadrado Test
			A. Local	AL + Midaz.	Value	P-Sig
Initial	**Low**	37.8% (34)	40.0% (12)	16.7% (5)	10.30**	.006
	Normal	62.2% (56)	60.0% (18)	**83.3% (25)**		
Final	**Low**	68.9% (62)	73.3% (22)	46.7% (14)	11.61**	.003
	Normal	31.1% (28)	26.7% (8)	**53.3% (16)**		

**= Highly significative at 1% (p<.01)

In bold, categories with signification (residuous=>2)

Table 8: Intergroup comparative analysis. Forced vital capacity Both measures

Discussion

In the literature, in studies of patients treated for dental procedures using Local Anaesthetics with Vasoconstrictor, there are always significant variations in physiological parameters, "more related to innate stress to the dental procedure than to the anaesthetic used" [17]. This is explained by the fact that the anticipation of future pain or a stress situation causes more vascular alterations than those that arise due to anaesthetics or vasoconstrictors. Even systematic reviews highlight the fact that in decompensated or uncontrolled patients, the effect of local anaesthesia with adrenaline is minimal [17]. It has been demonstrated that surgical stress releases many catecholamines whose autosomal response generates symptoms such as arrhythmias. Epinephrine released endogenously by the procedure occurs in much greater quantities than the one injected [18]. In fact, higher vascular parameters are always recorded just before the anaesthetic injection, and even in normal-stressed patients, no significant variations in blood pressure were observed even when the anaesthetic was injected intravascularly [18]. Studies to assess Local Anaesthesia with Epinephrine determine that both the heart rate and blood pressure do not suffer alterations when injecting Lidocaine with or without Vasoconstrictor [19]. Sanattkar concludes that the presence of vasoconstrictor not only does not constitute a danger, but helps to reduce the systemic toxicity of the anaesthetic, prevents blood loss during the procedure and helps control pain, eventually reducing the presence of catecholamines [20].

In the present study, patients treated by LA show evidence of a total absence of Bradycardia in Cardiac Frequency, a predominance of Normocardia, as endorsed by the literature, with punctual peaks of Tachycardia related to the procedure. With regard to Systolic Blood Pressure, uncontrolled variations are seen with a predominance of High Blood Pressure and Grade 2 Hypertension. Regarding Diastolic Blood Pressure, there is a predominance of Normotension, as described by Godzieba, *et al.* [18], who co-exists with uncontrolled variations and peaks in the HTA more related to the procedures performed than with the anaesthetic method.

Regarding Partial Oxygen Saturation the collected data present minimal variations, and the general line that is appreciated is that from the 30th minute of the procedure duration (7th measurement) the number of cases with low saturation increases. Regarding Forced Vital Capacity, Forced Expiration Volume per Second and Maximum Expiratory Flow per minute present similar results. There is a change of 33.3% of patients who have normal FVC in the initial situation and in the final one have low FVC. The literature does not present studies with which to compare these results at the respiratory level.

In short, the results of this study coincide with Tortaman, *et al.* when finding, fundamentally in the parameters of Cardiac Frequency and Blood Pressure, identical non-significant variations in the physiological parameters, "more related to the innate stress to the dental procedure than to the anesthetic used" [17]. The respiratory values of Saturation and Lung Capacity tend to be reduced by increasing the time of the procedure, without being worrisome.

In the literature, in the studies on patients treated for dental procedures by Local Anesthetics with Vasoconstrictor associated with Midazolam, the findings in the Cardiac Frequency refers to a slight rise in it [21,22]. Even when its effects are compared with those of a powerful anaesthetic such as Propofol, it can be seen that Midazolam causes an increase in heart rate of 7.4% while Propofol did not alter it, and that Midazolam did not modify more variables apart from the heart rate [21]. In the same way, there is a decrease in the systolic and diastolic blood pressure in the literature, and in the Tidal Respiratory Volume when using Midazolam, accompanied by an increase in the compensatory Respiratory Rate [23].

The findings of this study in patients treated with AL and Midazolam, report absence of statistical significance in the records of Heart Rate. Regarding Systolic Blood Pressure, Elevated Arterial Tension and Grade II Hypertension share the limelight, with Normotension totally residual. This contrast with the Gazal, who obtained records of Normotension that were also descending away from Hypertension as the procedure progressed [23]. About Diastolic Blood Pressure, unlike the Systolic in this group but coinciding with the literature [23], there is a predominance of Normotension, although it is true that Grade I Arterial Hypertension as Grade II begin in values not too much low that quickly descend and constantly suffer discrete inconspicuous variations.

In the Respiratory Rate, they started with Tachypnea, which remained very high in the first three registers to gradually decrease and quickly to leave the preponderance to the Normopnea. The literature does not show studies with which to compare these results. In the values in which statistical significance was recorded was in Partial Oxygen Saturation, it should be noted that Normal Saturation predominates from the beginning and then decreases. Probably the effects of respiratory depression of Midazolam cause this effect that is statistically significant, although when it reaches significance the sample has been reduced by almost half so that statistical significance loses power. This indicates that in this study the respiratory depressant effect of Midazolam occurs at the level of Oxygen Saturation, and not Respiratory Rate, since the Bradypnea was not registered in any case (Figure 3).

Regarding Forced Vital Capacity, there is a statistical significance ($p < .01$) of a decrease in FVC with the use of Midazolam. Regarding the Volume of Forced Expiration, there is a statistical relevance ($p < .05$) of a decrease in the FEV with the use of Midazolam. Regarding the Maximum Expiratory Flow, there is a statistical significance ($p < .05$) of a decrease in the PEF with the use of Midazolam.

It therefore coincides with the literature on the significant decrease in Partial Oxygen Saturation and Pulmonary Capacity, but disagrees with other values, since literature refers to an increase in heart rate and respiratory rate, not found in this [23,24].

Conclusions

The findings of this Clinical Trial determine that the Cardiac and Respiratory alterations in the phobic patients treated of Oral Surgery procedures by means of Conscious Oral Sedation with Midazolam are within the margins of safety.

Oral Conscious Sedation with Midazolam for Oral Surgery procedures, Implantology and Periodontics in phobic patients is a safe and effective method. However, the statistically significant reduction of both Partial Oxygen Saturation and Respiratory Volume, caution against certain preconditions of the patient and if Midazolam is going to be associated with other sedatives that may cause respiratory depression.

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