A study of effectiveness of midazolam sedation for prevention of myocardial arrhythmias in endosseous implant placement

The association of dental treatment with fear and anxiety may provoke physiological, behavioral, motor and cognitive responses in the patient. Although such responses are known and have been intensely studied by a variety of authors, their variability makes it difficult to determine the degree of risks that these may cause, especially because the individual factor is very hard to evaluate in a precise manner.

Acute stress during dental procedures triggers a mechanism characterized by a marked increase in sympathetic nervous system activity. Healthy patients are able to adapt well to such an increase, but in patients with cardiovascular diseases, an increase in sympathetic activity may be dangerous. The degree and significance of such alterations have been studied during different types of clinical dental procedures using a variety of methods. Electrocardiographic assessments have been used to study hemodynamic alterations (arterial pressure and heart rate), the concentration of catecholamines and their derivatives in blood plasma and alterations in the heart’s electrical activity.

Although expressive controversy exists concerning the issue of the clinical significance of arrhythmias observed during dental procedures, such alterations may represent serious risks. In surgical procedures involving a high emotional stress level, the release of endogenous catecholamines in response to neurohumoral stimulus, when associated with the use of local anesthetics with sympathomimetic vasoconstrictors, could cause an increase in the plasmatic concentration of catecholamines and lead to alterations in the cardiovascular system, representing risks to patients, especially to those with systemic diseases (Goldstein et al. 1982; Papadimitriou et al. 1986; Meyer 1987; Abraham-Inpijn et al. 1998; Wong 1998; Dijkstra et al. 1996; Cusick et al. 2001; Antunes et al. 2002).
Table 1. Summary statistics and P-value of comparison tests between moments (stages) for each group and between groups for each moment

<table>
<thead>
<tr>
<th>Stage</th>
<th>Median (IQR)</th>
<th>Control group</th>
<th>Treatment group</th>
<th>P-value (groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Basal</td>
<td>Amp P (mV)</td>
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<td></td>
<td></td>
<td></td>
<td>Initial</td>
<td>0.0925 (0.065; 0.1267)</td>
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<td></td>
<td></td>
<td></td>
<td>Basal</td>
<td>0.11 (0.0738; 0.1363)</td>
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<td></td>
<td></td>
<td></td>
<td>Anesthesia</td>
<td>0.126 (0.086; 0.14)</td>
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<td></td>
<td></td>
<td></td>
<td>Incision</td>
<td>0.105 (0.0782; 0.1225)</td>
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<td></td>
<td></td>
<td></td>
<td>Drilling</td>
<td>0.1067 (0.09; 0.1214)</td>
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<td></td>
<td></td>
<td></td>
<td>Suturing</td>
<td>0.0975 (0.08; 0.12)</td>
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<td></td>
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<td>Initial</td>
<td>0.092 (0.0788; 0.1214)</td>
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<td></td>
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<td>Amp P (mV)</td>
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<td></td>
<td></td>
<td></td>
<td>Initial</td>
<td>0.04 (0.02; 0.045)</td>
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<td></td>
<td></td>
<td></td>
<td>Basal</td>
<td>0.728 (0.6192; 0.884)</td>
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<td></td>
<td></td>
<td></td>
<td>Anesthesia</td>
<td>0.712 (0.5525; 0.918)</td>
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<td></td>
<td></td>
<td></td>
<td>Incision</td>
<td>0.69 (0.58; 0.926)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Drilling</td>
<td>0.7378 (0.564; 0.9)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Suturing</td>
<td>0.75 (0.5533; 0.9167)</td>
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<td></td>
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<td>Final</td>
<td>0.728 (0.5363; 0.9286)</td>
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<td>Amp P (mV)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Initial</td>
<td>105.83 (97.67; 111.14)</td>
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<td></td>
<td></td>
<td></td>
<td>Basal</td>
<td>0.69 (0.54; 0.9617)</td>
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<td>Anesthesia</td>
<td>0.712 (0.5525; 0.918)</td>
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<td>Final</td>
<td>0.728 (0.5363; 0.9286)</td>
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<td>Pr (ms)</td>
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<td></td>
<td></td>
<td></td>
<td>Initial</td>
<td>149.22 (140.57; 159.14)</td>
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<td></td>
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<td>Basal</td>
<td>138.89 (133; 153.5)</td>
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<td></td>
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<td>Incision</td>
<td>144.2 (137.6; 159.6)</td>
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<td></td>
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<td></td>
<td>Drilling</td>
<td>149.25 (135.83; 157.46)</td>
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<td></td>
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<td>Suturing</td>
<td>145.13 (135.5; 158)</td>
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<td>Final</td>
<td>152.25 (138.38; 166.5)</td>
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<td>Pr (ms)</td>
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<td>Initial</td>
<td>807.1 (737.5; 919.83)</td>
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<td>Basal</td>
<td>384.17 (357.25; 409.14)</td>
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<td>Anesthesia</td>
<td>377.33 (369.17; 395)</td>
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<td>Incision</td>
<td>371 (350.67; 394.5)</td>
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<td>Drilling</td>
<td>373.86 (359.64; 398.89)</td>
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<td></td>
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<td>Suturing</td>
<td>383 (366.33; 400.14)</td>
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<td>Final</td>
<td>385.75 (365; 398.3)</td>
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<td>RR (ms)</td>
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ASA I patients during osseointegrated implant
alterations in myocardial electrical activity in
This study aimed to assess the incidence of
Purpose
premedication, analyzing its efficacy for the pre-
this study was to evaluate the use of anxiolytic
surgical procedures, such as the placement of
implants. The main objective of
Material and methods
The present study obtained prior approval by the
Research Ethics Committee of the School of
Dentistry of the University of São Paulo (proto-
col 230/03). The study consisted of 20 ASA I
patients, aged 21–50 years old, requiring bilateral
dental implants in the lower jaw, who had
not used any medication for 30 days before the
surgery. A total of 15 patients concluded all of the
routine of the experiment. Five patients were
excluded because the surgical time was higher
than the exclusion criteria. With the purpose of
surgical injuries controlling, the surgeries were all
performed by the same expert surgeon, with
similar difficulties and no longer than 30 min.
The patient’s ECG was obtained by recording 12
static leads every 2 min, while D2 derivations
were recorded continuously during the surgical
procedure. The following morphological aspects
of the ECG waves were registered: heart rate, the
duration of PR, RR, QT and QTc intervals.
The basal values of the ECG parameters were
obtained during a separate 30 min evaluation,
before the surgical intervention procedures. Each
patient was observed while using placebo
during implant placement surgery on one side
(control group) and [15 mg] midazolam on the
contralateral side [treatment group], chosen at
random and with 30-day intervals between sur-
geries. Both the midazolam and the placebo were
administered orally 1 h before the surgical proce-
dure using a double-blind distribution, with the
medication sealed in a yellow amber envelope.
The dosage was standardized by the indication of
oral midazolam in 70 kg patients with no history
of severe fear. The dental fear was measured and
standardized through Corah fear scales, and se-
vere fear patient was excluded. The procedures
were conducted under local anesthesia using
3.6 ml of 2% lidocaine chlorhydrate with
1:100,000 epinephrine, and the surgical proce-
dure was made with no pain, without additional
anesthesia. The patient who needed anesthesia
complement, let the research down. The proce-
dure was made with no pain, without additional
anesthesia. The patient who needed anesthesia
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anesthesia. The patient who needed anesthesia
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complement, let the research down. The proce-

& Lytle 1991; Brand et al. 1995; Montebugnoli
et al. 2004; Romano et al. 2009)

Psychological and physiological responses that
can be affected by anxiety could be minimized by
prophylactic measures, such as psychological
maneuvers and the use of sedative or anxiolytic
medication, especially diazepines (De Jong &
Heavner 1981; Baker et al. 1984; Abraham-In-
pijn et al. 2004; Romano et al. 2009).

The importance of benzodiazepine agents as
anxiolytics for the control and prevention of
adverse effects on the central nervous and cardi-
vascular systems has been extensively studied
by different authors [De Jong & Heavner 1981;
Cox et al. 2006].

Thus, diminishing stressful responses could
offer greater comfort and safety to patients during
surgical procedures, such as the placement of
osseointegrated implants. The main objective of
this study was to evaluate the use of anxiolytic
premedication, analyzing its efficacy for the pre-
vention of cardiovascular signs and symptoms.

Purpose
This study aimed to assess the incidence of
alterations in myocardial electrical activity in
ASA I patients during osseointegrated implant
placement surgeries, using local anesthetics and
midazolam as an anxiolytic premedication.

<table>
<thead>
<tr>
<th>Table 1. Continued</th>
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<tbody>
<tr>
<td><strong>Stage</strong></td>
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<tr>
<td>QRS (ms)</td>
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<tr>
<td><strong>P-value (stages) Friedman’s test</strong></td>
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<td>QTc (ms)</td>
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<tr>
<td><strong>P-value (stages) Friedman’s test</strong></td>
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<td>Heart rate</td>
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<tr>
<td><strong>P-value (stages) Friedman’s test</strong></td>
</tr>
</tbody>
</table>

IQR, interquartile range.
preliminary analysis, nonparametric tests were performed to compare the values between the stages (Friedman’s test) and between groups (Wilcoxon’s test). When significant statistically differences were found \( P\)-value<0.05 \) a nonparametric analysis of ordered data in designs with longitudinal observations and small sample sizes [Brunner & Langer 2000] was applied to evaluate the effects of group, stage and interaction between group and stage. The contrasts were evaluated applying Bonferroni’s correction [Siegel & Castellan 1988].

**Results**

The values determined for the patients under midazolam were called treatment group and under the placebo, were called the control group. Descriptive statistics and the comparison of the results obtained for the two groups and for the eight stages are presented on Table 1. The results of Brunner and Langer nonparametric analysis did not yield statistically significant effects of group and interaction [Table 2] that showed similar behavior in both groups and the differences among the stages occurred independently the groups.

When analyzing the behavior of the electrocardiographic parameters at the different stages of the surgical procedures, statistically significant differences were observed for P-wave amplitude, the duration of the PR, QT, QTc and RR intervals and heart rate following aspects.

The P-wave amplitude increased until it reached its peak value at the incision stage and then decreased until the final stage, where values were similar to the basal value (Fig. 1). The incision stage showed significantly higher values than the basal, initial, suturing and final stages (Table 2).

The PR [ms] decreased until it reached its peak value at the drilling stage. The drilling stage values showed significantly lower than basal and final stages (Fig. 2 and Table 2). The duration of the RR interval were significantly different until incision stage and after drilling stage increased until the final stage. The final stage values were similar to the basal and initial stages (Fig. 3 and Table 2).

The duration of the QT interval showed a significant increase from the incision stage until implant stage reaching its peak value (Fig. 4) and maintaining a similar value until the final stage (Table 2).

The duration of the QTc interval showed a similar behavior pattern in both groups, especially in the final stages (Fig. 5). The drilling stage showed significantly higher values than the initial, suturing and final stages.

The heart rate variable increased during the initial stage up to the incision stage, where the highest values were obtained (Fig. 6). After the drilling stage, the heart rate decreased until the suturing stage, registering values that were similar to the final and basal values (Table 2).

Regarding the incidence of arrhythmias, the patients showed similar alterations under midazolam and placebo. Alterations were observed in eight patients (33.3%) during the experiment; arrhythmias were observed in 17 (43.3%) out of the total of 30 surgical interventions.

The alterations identified were: sinus tachycardia and bradycardia, sinus arrhythmia, ventricular and supraventricular extrasystoles and blocked atrial extrasystole. Ventricular extrasystoles and sinus tachycardia were the most frequent findings.

**Discussion**

Cardiovascular reactions are common in surgical situations and could be related to cardiac vagal response to the activation of \( \alpha \) and \( \beta \)-adrenergic receptors, resulting in an increase in cardiac chronotropism and inotropism, as well as an increase in peripheral vascular resistance and an eventual increase in arterial pressure and heart rate.

However, such hemodynamic alterations may vary according to each patient’s reaction to conflicting situations. While some individuals react with an intense increase in cardiac output, others show a more intense reaction in the regulation of peripheral vascular resistance. It is possible that this difference corresponds to the individual variability in sympatoadrenal activation, causing the release of either more epinephrine or more norepinephrine during a stressful situation.

The control and prevention of adverse effects on the central nervous and cardiovascular systems by benzodiazepine agents as anxiolytics has been studied by different authors. Midazolam was chosen because it shows faster effects and shorter duration than the others even in oral administration. Although IV administration could be better in controlling the correct dosage for each patient, the midazolam given orally as premedication is acceptable, effective and safe [Cox et al. 2006].

When evaluating the behavior of electrocardiographic parameters between the different stages of this study, statistically significant differences were only obtained in the treatment group, for P-wave amplitude, the duration of the PR, QT, QTc and RR intervals and heart rate.

Regarding P-wave amplitude, generally it does not go above 0.3 mV at any given derivation or

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**Table 2. Results of Brunner and Langer nonparametric analysis and P-values of multiple comparisons that showed significant differences**

<table>
<thead>
<tr>
<th>Effect</th>
<th>P-value</th>
<th>Amp P (mV)</th>
<th>ST (mV)</th>
<th>Amp R (mV)</th>
<th>P (ms)</th>
<th>PR (ms)</th>
<th>RR (ms)</th>
<th>QT (ms)</th>
<th>QRS (ms)</th>
<th>QTc (ms)</th>
<th>Heart rate</th>
</tr>
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</tr>
<tr>
<td>Stage</td>
<td></td>
<td>0.7322</td>
<td>0.5274</td>
<td>1</td>
<td>0.9756</td>
<td>0.9045</td>
<td>0.7566</td>
<td>0.9012</td>
<td>0.8821</td>
<td>0.7730</td>
<td>0.6620</td>
</tr>
<tr>
<td>Interaction (group × stage)</td>
<td></td>
<td>0.0001</td>
<td>0.6675</td>
<td>0.3543</td>
<td>0.6016</td>
<td>0.0024</td>
<td>0.0001</td>
<td>0.0222</td>
<td>0.4707</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
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<td>Pair-wise Comparisons*</td>
<td></td>
<td>0.3197</td>
<td>0.4236</td>
<td>0.4672</td>
<td>0.1245</td>
<td>0.0561</td>
<td>0.6055</td>
<td>0.8104</td>
<td>0.7191</td>
<td>0.5943</td>
<td>0.7734</td>
</tr>
<tr>
<td>Anesthesia vs. initial</td>
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<td>–</td>
<td>–</td>
<td>&lt;0.001</td>
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<tr>
<td>Incision vs. basal</td>
<td></td>
<td>0.028</td>
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<tr>
<td>Incision vs. initial</td>
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<td>&lt;0.001</td>
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<td>&lt;0.001</td>
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<tr>
<td>Drilling vs. basal</td>
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<td>–</td>
<td>&lt;0.001</td>
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<td>&lt;0.001</td>
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<tr>
<td>Drilling vs. initial</td>
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<tr>
<td>Implant vs. incision</td>
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<td>&lt;0.001</td>
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<td>–</td>
<td>&lt;0.001</td>
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<tr>
<td>Suturing vs. incision</td>
<td></td>
<td>&lt;0.001</td>
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<td>&lt;0.001</td>
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<td>–</td>
<td>–</td>
<td>0.028</td>
<td>–</td>
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<tr>
<td>Final vs. incision</td>
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<td>&lt;0.001</td>
<td>–</td>
<td>&lt;0.001</td>
<td>0.028</td>
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<td>–</td>
<td>&lt;0.001</td>
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<tr>
<td>Implant vs. drilling</td>
<td></td>
<td>–</td>
<td>–</td>
<td>&lt;0.001</td>
<td>–</td>
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<td>–</td>
<td>0.028</td>
<td>0.028</td>
<td>–</td>
</tr>
<tr>
<td>Suturing vs. drilling</td>
<td></td>
<td>&lt;0.001</td>
<td>–</td>
<td>&lt;0.001</td>
<td>0.028</td>
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<tr>
<td>Final vs. drilling</td>
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<td>0.028</td>
<td>&lt;0.001</td>
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*Applied Bonferroni’s correction.
Measurements above 0.3 mV suggest an overload of the right or left atrium, during which the wave could be discontinuous and blurred, with an irregular contour [Moffa 2001]. The values obtained never exceeded 0.3 mV in either of the experimental groups.

The increase in the QTc interval could indicate a disturbance in ventricular conduction, either during depolarization or repolarization, and could suggest a greater incidence of cardiac arrhythmias [Moffa 2001].

Statistically significant alterations were observed only for the treatment group between the incision and the basal and initial stages, with the highest values at the incision stage, demonstrating a possible correlation with stress induced during the experiment.

Studies evaluating cardiac rhythm during different types of dental procedures reported an increase in heart rate during treatment [Ryder 1970; Hasse et al. 1986; Abraham-Inpijn et al. 1988; Vanderheyden et al. 1989; Blinder et al. 1998, 1996; Romano et al. 2009].

In the treatment group, heart rate values were significantly different ($P < 0.01$) between the incision stage and the basal, initial, implant placement, suture and final stages. In the control group, significantly higher heart rate values were obtained during the incision stage than the basal and final stages.

This pattern of results is similar to that reported by Romano et al. (2009) although the author identified higher values for the bone drilling stage. These results could be more directly related to an increase in cardiovascular demand due to the stressful situation at the onset of surgery (incision) than related to the action of the epinephrine in the local anesthetic, since the incision stage occurred more than 5 min after local anesthesia. Given that epinephrine is readily metabolized, cardiovascular responses rarely take more than 5 min [Cox et al. 2006]. This hypothesis could also be applied to variables that showed the same behavior, such as: P-wave amplitude, the duration of the RR segment and the duration of the RR, QT and corrected QT intervals. In their study using sedation, Salonen et al. (1989) reported the possibility of an exogenous origin of plasmatic catecholamines and although conflicting results have been reported, part of the literature reviewed agrees with this possibility.

In the present study, the use of sedation yielded results similar to those reported in the literature; i.e., higher heart rate values compared with the use of the placebo, showing an adaptation that is pertinent to the decrease in arterial pressure observed with the use of benzodiazepines [Moffa 2001]. On the other hand, this could represent proof of a decrease in stress. This second hypoth-
esis is based on the diminished response during the bone drilling stage, which is considered to be the most stressful stage of the procedure. No statistically significant differences were observed for this stage compared with the other stages of the study, as observed by Romano et al. (2009) thus the values obtained during the incision stage could be related to the influence of epinephrine contained in the local anesthetic.

The majority of the reports in the literature studied surgical procedures of tooth extraction and observed an increase in heart rate after local anesthesia, which lasted throughout the entire procedure (Goldstein et al. 1982; Abraham-Inpijn et al. 1988; Blinder et al. 1998, 1996; Romano et al. 2009). In some studies where the effect of sedation was evaluated, an increase in heart rate associated with its use was identified (Moffa 2001). Other authors, including Wilson et al. (2002), observed no statistically significant differences between the sedation and placebo groups. In the present study, the values obtained for the sedation group were slightly higher than in the placebo group, although not statistically significant.

Higher values obtained during the incision and bone drilling stages, for both groups, can be justified by the use of local anesthetics containing epinephrine and the use of rotary drills that cause noise, vibration, discomfort and possibly elevated levels of stress in the patients during surgical procedures of dental implants. The results obtained in this study were similar to those reported by Romano et al. (2009) who evaluated heart rate during the placement of implants and observed a higher rate during all stages of the procedure compared with the basal and final stages, although the highest values in his study were obtained during the bone drilling stage.

In relation to cardiac arrhythmias, the results are in agreement with those reported in literature (Hughes et al. 1966; Hassel et al. 1986; Abraham-Inpijn et al. 1988; Vanderheiden et al. 1989; Rodrigo et al. 1990; Blinder et al. 1998, 1996; Romano et al. 2009). Although Blinder et al. (1998), Rodrigo et al. (1990) and Roelofse & Bijl (1994) observed an increase in the incidence of arrhythmias with the use of sedation, Salonen et al. (1989) observed no differences. Among the alterations detected in the present research, six occurred in the control group and seven occurred in the treatment group. Although the sedation group presented more alterations, the differences between the two groups were not significant. However, of the eight patients that presented arrhythmias, three presented them while under sedation, one occurred while using the placebo and four patients presented them in both surgical situations.
In the present study, only patients with no systemic disturbances were included and a greater incidence of arrhythmias occurred compared with the studies by Hughes et al. [1966], in which 39% of the patients presented arrhythmia, Rodrigo et al. [1990], in which 35.6% presented arrhythmia and Blinder et al. [1996], in which 37.5% presented arrhythmia and it was similar to Romano et al. [2009] in which 60% presented arrhythmia.

The incidence of arrhythmias was also greater than that determined in experiments where patients with cardiovascular disease were not excluded, such as the study by Hasse et al. [1986], who reported an incidence of 37%. However, the types of arrhythmia described in these studies were of greater severity, such as atrial fibrillation, multifocal ventricular extrasystoles, severe S–T segment deviation and atrioventricular disconnections, among others.

Although benzodiazepines may represent a safe alternative for controlling anxiety and stress in these patients, when evaluating the results obtained, the use of midazolam showed no significant advantages.

Even when procedures are not extremely invasive, those that involve stressful situations, such as anesthesia and the use of burs and drills, during the placement of dental implants, should be considered procedures of risk. Cardiovascular reactions in response to the emotional stress associated with the use of local anesthetics with sympathomimetic vasoconstrictors could increase the risk of cardiovascular complications in the patient.

Conclusions

According to the sample and results presented in this study, it is possible to conclude that:

- Although dental implant placement surgeries induced electrocardiographic alterations in 53.3% of patients, the clinical significance of these arrhythmias may not represent serious risks.
- The use of 15 mg of midazolam did not show advantage in the incidence of arrhythmias. The anxiolytic premedication does not prevent myocardial arrhythmias in endosseous implant placement.
- The incision stage demonstrated the highest values of heart rate and P-wave amplitude and lowest values of the duration of PR, RR and QT intervals.

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References


