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ANDREA GOMES DELLOVO

EFFECTS OF AURICULOTHERAPY AND MIDAZOLAM IN THE ANXIETY CONTROL OF PATIENTS SUBMITTED TO THIRD-MOLAR EXTRACTIONS

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Trabalho de conclusão de curso apresentado ao Departamento de Odontologia, da Universidade Federal de Sergipe, como requisito parcial à obtenção do grau de bacharel em Odontologia.

Orientador: Prof. Dr. Jeison Saturnino de Oliveira

Co-orientador: Profa. Dra. Liane Maciel de Almeida Souza

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Dellovo, Andrea Gomes

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Effects of auriculotherapy and midazolam in the anxiety control of patients submitted to third-molar extractions

Anxiety control: auriculotherapy x midazolam

Andrea Gomes Dellovo[1]; Jeison Saturnino de Oliveira[2]; Liane Maciel de Almeida Souza[2]

[1]DDS, Federal University of Sergipe, Aracaju, Sergipe, Brasil
[2]PhD, Federal University of Sergipe, Aracaju, Sergipe, Brasil

Andrea Gomes Dellovo
Rua Maye Bell Taylor, 150,
Luzia, Aracaju -SE 49045-030;
deadellovo@hotmail.com;
+55 (079) 99930-5302

Summary

Objectives: Anxiety is common and it still represents a barrier to appropriate professional care for patients requiring dental treatment. The aim of this study was to compare the effects of auriculotherapy and midazolam in the anxiety control of patients submitted to third molar extractions.

Study design: In a randomized, double-blind, controlled, crossover, clinical trial, 30 healthy volunteers received midazolam 15mg/V.O. and sham-auriculotherapy during one session. In the other session, a placebo tablet/V.O. and auriculotherapy was performed. The sessions were randomized. Anxiety level was assessed through questionnaires and physical parameters, such as blood pressure (BP), heart rate (HR) and oxygen saturation (SpO2) in three periods: baseline, at the day of surgery, and during patient return.

Results: No significant differences between the protocols were observed for BP and SpO2. Auriculotherapy induced lower HR than midazolam during some periods. Auriculotherapy induced more events remembered after surgery ($p < 0.0001$) than midazolam. More undesirable effects ($p < 0.0001$) were observed with midazolam. However, the preference for auriculotherapy (53.3%) was not higher than patient´s preference for midazolam (46.7%).

Conclusions: Auriculotherapy showed an anxiolytic effect equivalent to the midazolam effect, without the undesirable effects usually attributed to the benzodiazepine.

Key-words: Anxiety. Auriculotherapy. Exodotics. Midazolam.

Introdution

Fear and anxiety are common in dental patients, representing one of the biggest barriers to adequate professional dental care (1,2). Fear is a primitive, basic emotion tied to the fight-or-flight response, activated during an imminent and specific threat, while anxiety is a conditioned response characterized by anticipation of a potential or future threat (3). The intensity of dental anxiety is varies according to the patient, being clearly affected by the type of procedure.

Behavioral observation and recognition of signs such as pupil dilation, paleness, excessive sweating, tremors, increased blood pressure and heart rate, dizziness, dry mouth, weakness, respiratory distress contribute to the identification of anxiety in patients seeking care dental practice (1).

Midazolam is a benzodiazepine widely used in sedation for dental procedures. It effectively reduces anxiety without producing cardiorespiratory instability. Midazolam is the usual choice due to its rapid onset, great anxiolytic potency, water solubility, low toxicity, rapid elimination, and short anxiolytic effect (30 to 40 minutes). However, it can cause respiratory depression in predisposed patients, and its variable oral absorption could cause unexpected sedation levels (4).

Complementary therapies are often sought in order to overcome altered emotional states. Nowadays, emotional imbalance is common, and complementary therapies have gained scientific credibility, increasing the use of traditional practices (5,6).

Auriculotherapy is used to treat physical and mental illnesses through stimuli of points located in the auricular pavilion. It is originated in China between the 2000 BC and 100 BC (6), and based in a set of anatomical maps superimposed on ear. Each ear has reflex points that correspond to the organs and functions of the body. Auricular points may be stimulated with needles, seeds, percutaneous electrical nerve stimulation, or laser (7).

Auriculotherapy can be associated with phytotherapy, in order to stimulate certain acupuncture points with medicinal seeds (8,9). Mustard seed (*Brassica juncea*) is widely used in imbalances of the lung, stomach and liver and cold. It is also widely used in bronchitis, congestion, headache, pharyngitis, flu, paralysis, pneumonia, common cold, rheumatism, and cough. It has analgesic, antiseptic, disinfectant, diuretic, emetic, stimulant, expectorant properties (9- 14). Auriculotherapy associated with phytotherapy showed low risk of collateral effects and addiction (15).

The present study aimed to compare the effects of auriculotherapy (associated mustard seed) with midazolam to control anxiety in patients submitted to third molar extractions.

Material and Methods

The study was approved by the University Hospital Research Ethics Committee of the Federal University of Sergipe (protocols CEP 080889/2015 and CAAE 48361115.7.0000.5546). REBEC: RBR-67xf25 and UTN number: U111111883570.

In a randomized, double-blind, crossover study, 30 patients from the Department of Dentistry of the Federal University of Sergipe (DOD/UFS) were selected. The third molars had diagnosis and indication for bilateral extraction. They were asymptomatic with similar position and surgical difficulty level (according to panoramic radiographs), being classified in position 2B of Pell & Gregory (16). All participants were informed of both risks and benefits of the study, and signed an informed consent. Exclusion criteria were patients under the age of 18, ASA III or ASA IV, use of any medication within 15 days before the beginning of the research, hypersensitivity to the drugs, substances or materials used in this experiment, pregnancy or lactation, previous or actual history of pericoronitis.

Group 1 consisted of participants receiving both 15 mg of midazolam (one tablet, administered orally 30 minutes before the surgery started) associated with sham auriculotherapy (coverage of ear points with a tape, which were placed five days before surgery). Group 2 received a placebo medication (one tablet, administered orally 30 minutes before the surgery started) associated with auriculotherapy (started at five days before surgery) in the auricle points indicated in Fig. 1. Mustard seeds covered with tape were used in the auriculotherapy. The extraction side (right or left) and the groups (midazolam or auriculotherapy) were randomly assigned at the first day. All surgeries were performed by the same operator, as well as auriculotherapy. Surgical procedures were performed in 2 sessions, one for each side of the mandible. The minimum interval between the first and second surgery was 15 days. Both protocols were only identified at the end of the experiment. Randomization was performed by the Random Number Generator Pro 2.15 software.

In order to avoid the pain and post-surgical edema, a single dose of intramuscular dexamethasone (8 mg) was administered 30 minutes before surgery. Oral antisepsis was performed by vigorous rinsing, for one minute, with an aqueous solution of 0.12% chlorhexidine digluconate. An alcoholic solution of 10% polyvinylpyrrolidoneiodine (PVP-I) was used in the extra-oral antisepsis.

Local anesthesia was injected slowly after negative aspiration using in an inferior and lingual alveolar nerve block with 1.8 mL of 2% lidocaine with 1: 100,000 epinephrine. The buccal nerve was anesthetized with 0.9 ml of 4% articaine with 1: 100,000 epinephrine. Patients were instructed for local hemostatic care, feeding, cleaning the operated region, restriction of physical exertion, and other routine recommendations. Suture was removed on the seventh day after surgery. The patients were advised to take one tablet of paracetamol 750 mg, every 6 hours for 3 days, only in case of

pain.

The assessment of the subjects' anxiety level was conducted through questionnaires and physical parameters. It was divided into three periods: 1st) baseline, 2nd) day of surgery, and 3rd) patient´s return visit.

Baseline was the initial session, one week before the day for the first surgery. The Corah Dental Anxiety Scale (17) was used to classify participants according to their degree of anxiety. After patients rested for 5 minutes, arterial blood pressure (BP), heart rate (HR), and blood oxygen saturation (SpO_2) were measured by a single operator.

At the 2nd period, both researcher and the surgeon related their perception regarding the anxiety level of each patient by answering a questionnaire at the end of each surgery. They classified the patients as "not anxious", "mild anxious", "moderate anxious", or "severe anxious". For moderate or severe anxious patients, both researcher and surgeon related the moment of the occurrence of the anxious behavior during the surgery. In addition, in all patients, BP, HR, and SpO_2 were measured after: 1) 30 minutes of drug administration; 2) local anesthesia; 3) incision; 4) tooth removal; and 4) suture.

In the 3rd period, patients returned the self-assessment form answered 24h after the surgery, asking about the treatment experience, the occurrence of anterograde amnesia, collateral effects, and their preference for the protocol used in the first or the second surgery.

Data were analyzed by chi-square test, non-paired t-test, Wilcoxon test, Friedman test, Mann-Whitney test, and Fisher's exact test, according to data characteristics. All tests were performed considering a significance level of 5%. Power calculation was performed *a priori*. Considering 80% of sedation effectiveness (when the previous anxiety level was decreased) for midazolam and only 40% for auriculotherapy, 23 patients would be necessary per group to provide 80% power with a 5% significance level. Larger differences in the effectiveness could be significant with fewer individuals and very small differences indicated that the two treatments could be interchangeable in terms of effect, since even with a large number of patients there would be no statistically significant differences between the treatments.

Results

No statistically significant differences (non-paired t-test, $p=0.22$) were observed between ages

of male (34.7±6.1 years) and female (28.0±2.7 years) subjects. Body weight also did not differed (Mann-Whitney test, p=0.075) between male (76.0±6.1 kg) and female (61.8±2.1 kg) subjects.

Figures 2 and 3 show the variation in blood pressure, heart rate and SpO_2 during the periods considering the two treatments.

Systolic blood pressure significantly decreased (Friedman test) after 30 minutes of treatments, remaining lower than the initial level until the last period (suture), for both midazolam ($p < 0.0001$) and auriculotherapy ($p = 0.0004$). Comparison of the two treatments in each period separately (Wilcoxon test) revealed no statistically significant differences between them in any of the periods. Diastolic blood pressure showed the same profile, but it started to decrease in the "local anesthesia" period, remaining stable until the suture.

No statistically significant differences were verified among the periods (Friedman test) for both midazolam (p=0.25) and auriculotherapy (p=0.06) considering SpO_2 levels. The comparison between the two treatments in each period (Wilcoxon test) showed no statistically significant differences between them in any period.

Despite the punctual fluctuations, no significant differences (Friedman test, $p > 0.05$) were observed between the baseline heart-rate and HR values obtained in other periods in the midazolam group. However, a significant decrease in HR was observed after 30 minutes of auriculotherapy and during suture, when both periods were compared to the HR-baseline. Auriculotherapy induced lower HR than midazolam during the periods "30 minutes" (p=0.0314), "tooth removal" (p=0.0402) and "suture" (p=0.0032).

The self-perception of the patients about anxiety in both baseline and in the day of surgery periods is shown in Table 1.

Reduction of anxiety was verified in 86.7% of the patients using auriculotherapy and in 83.3% with midazolam. Only two patients, one using auriculotherapy (3.3%) and the other using midazolam, presented increased anxiety than the anxiety initially related. No significant differences (chi-square test, p=0.74) were observed between the treatments considering the reduction on anxiety.

The perception of anxiety by the patient (self-perception), operator, and researcher showed no significant differences ($p>0.05$) among them, irrespectively of the treatments.

Table 2 shows the cumulative frequency of the perception of the researcher and the operator in relation to the signs and the moment of anxiety.

Most of the patients did not present any signs of anxiety in any of the evaluated moments. When observing anxiety, the most frequent signals related by both researcher and operator were agitation and increased respiratory rate. The most related anxiety moment was during local anesthesia and the tooth removal. None significant differences were observed between the two treatments.

Table 3 shows the events during the surgery that were remembered by patients after the surgery, and reveals that the patients using auriculotherapy significantly remembered more events (Fisher exact test, $p < 0.0001$) during surgery than when they used midazolam.

The cumulative frequency of undesirable effects observed 24 hours after the treatments is shown in Table 4. The number of undesirable effects was significantly bigger (Fisher exact test, $p < 0.0001$) when midazolam was used. Interestingly, the undesirable effects appeared to not interfere in the patients' preference, since auriculotherapy was preferred by 53.3% of the patients while 46.7% preferred midazolam.

Discussion

Dental anxiety, or the fear of dental procedures, is a relatively common problem. (1-4), Despite the improvements in the modern dentistry, dental anxiety scores have remained stable since the mid-1900s (18). Dental anxiety is associated with postponement or avoidance of dental treatment and, hence, poorer oral health and oral health-related quality of life (3).

In medicine and dentistry, the efficacy of midazolam in anxiety control appears to be well established, based on well-conducted, placebo-controlled clinical trials. The incidence of undesirable side effects with midazolam (eg, paradoxical effects, hallucinations/fantasies, and anterograde amnesia) may restrict its use. Some of these effects were, in fact, observed in the present study.

Other clinical trials have evaluated the amnesic effect of anxiolytic agents. Among 30 children aged 2 to 4 years undergoing dental treatment, 66.7% of those sedated with intranasal midazolam did not remember a figure presented during the procedure (19). Coincidently, in our study 66.7% of the patients related they remembered absolutely nothing or almost nothing during surgery.

Two studies comparing auriculotherapy with midazolam were previously performed (20,21).

However, they used needles in auriculotherapy procedure, while here we used a less invasive, and probably more acceptable, approach. The experimental model used in the present study, in a crossing-over design using bilateral extraction of the third molars, was also another differential from those previous studies. Our study also used a sham auriculotherapy, which was not possible in the other designs. Besides, auriculotherapy using needles could influence the anxiety (6,20,21).

In the present study, the physiological parameters measured (blood pressure, SpO2, HR) remained into acceptable biological levels during all periods and they did not differ between groups. This fact indicates that both treatments are safe regarding those parameters.

The intensity of anxiety decreased in most of the patients, irrespectively of the treatments, being both interchangeable. These results corroborate with other showing reduction of anxiety with auriculotherapy (3,6,20-22). However, patients using auriculotherapy significantly remembered more events during surgery than when they used midazolam, confirming the retrograde amnesia effect of midazolam (1,4,23). Besides, undesirable effects were more present with midazolam, since only 10% of patients showed no undesirable effects with midazolam.

The reasons by the preference for one or another treatment, which was related by the patients, are not completely clear. Despite the lower number of undesirable effects for midazolam, it did not reflect in the preferences. It is possible that anterograde amnesia could be responsible for the preference regarding the treatments. Some patients stated that they do not like to remember the events during the surgery and others stated the opposite.

The anxiolytic effect of both treatments was comparable, and it could be considerate interchangeable. Therefore, we concluded that auriculotherapy presents a safe and effective alternative to midazolam for conscious sedation in adult patients undergoing mandibular third molars surgery.

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Table 1. Level of anxiety at baseline and the day of surgery, according to the treatments.

		Baseline				
Treatments	***At the day of surgery***	***Not anxious***	***Mild anxious***	***Moderate anxious***	***Severe anxious***	**Total**
Auriculotherapy	***Not anxious***	2 (6.7%)	8 (26.7%)	9 (30%)	1 (3.3%)	20 (66.7%)
	Mild anxious	-	1 (3.3%)	6 (20%)	1 (3.3%)	8 (26.7%)
	Moderate anxious	-	-	-	1 (3.3%)	1 (3.3%)
	Severe anxious	-	-	1 (3.3%)	-	1 (3.3%)
Midazolam	***Not anxious***	1 (3.3%)	7 (23.3%)	8 (26.7%)	2 (6.7%)	18 (60%)
	Mild anxious	1 (3.3%)	2 (6.7%)	7 (23.3%)	-	10 (33.3%)
	Moderate anxious	-	-	1 (3.3%)	1 (3.3%)	2 (6.7%)
	Severe anxious	-	-	-	-	-

Table 2. Signs of anxiety and the moment it was present, according to the treatments and researcher/surgeon.

		According to researcher		According to surgeon	
		Auriculotherapy	**Midazolam**	**Auriculotherapy**	**Midazolam**
Signs	**Increased HR**	2 (6.7%)	1 (3.3%)	1 (3.3%)	-
	Agitation	7 (23.3%)	7 (23.3%)	7 (23.3%)	7 (23.3%)
	Increased respiratory rate	1 (3.3%)	2 (6.7%)	2 (6.7%)	4 (13.3%)
	Pallor	-	2 (6.7%)	1 (3.3%)	-
	Perspiration	2 (6.7%)	-	1 (3.3%)	1 (3.3%)
	Other	1 (3.3%)	-	-	-
	None	20 (66.7%)	19 (63.3%)	22 (73.3%)	20 (66.7%)
Moment of anxiety	**Entering the surgery**	1 (3.3%)	3 (10%)	1 (3.3%)	1 (3.3%)
	Antisepsis	1 (3.3%)	1 (3.3%)	-	-
	Local anesthesia	4 (13.3%)	5 (16.7%)	6 (20%)	9 (30%)
	Tooth removal	6 (20%)	3 (10%)	3 (10%)	2 (6.7%)
	None	19 (63.3%)	20 (66.7%)	21 (70%)	20 (66.7%)

Table 3. Events the patients remembered after surgery, according to the treatments.

Events remembered after surgery	Auriculotherapy	Midazolam	Total
Absolutely nothing	-	8 (26.7%)	8 (26.7%)
Almost nothing	-	12 (40%)	12 (40%)
Some facts	-	4 (13.3%)	4 (13.3%)
Most of the facts	4 (13.3%)	3 (10%)	7 (23.3%)
All facts	26 (86.7%)	3 (10%)	29 (96.7%)

Table 4. Undesirable effects reported by patients after surgery, according to the treatments.

Undesirable effects	Auriculotherapy	Midazolam	Total
Restlessness	1 (3.3%)	27 (90%)	28 (93.3%)
Muscle relaxation	1 (3.3%)	11 (36.7%)	12 (40%)
Dizziness	2 (6.7%)	17 (56.7%)	19 (63.3%)
Gastrointestinal problems		3 (10%)	3 (10%)
None	26 (86.7%)	3 (10%)	29 (96.7%)

1. *Shen Men*
2. Kidney
3. Sympathic
4. Anxiety
5. Neurasthenia
6. Heart
7. Liver
8. Occipital

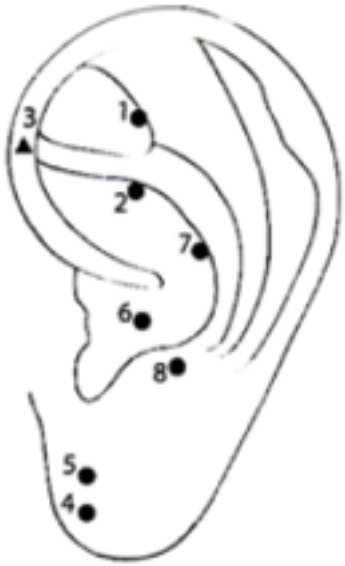

Figure 1. Auricle Protocol for anxiety control.

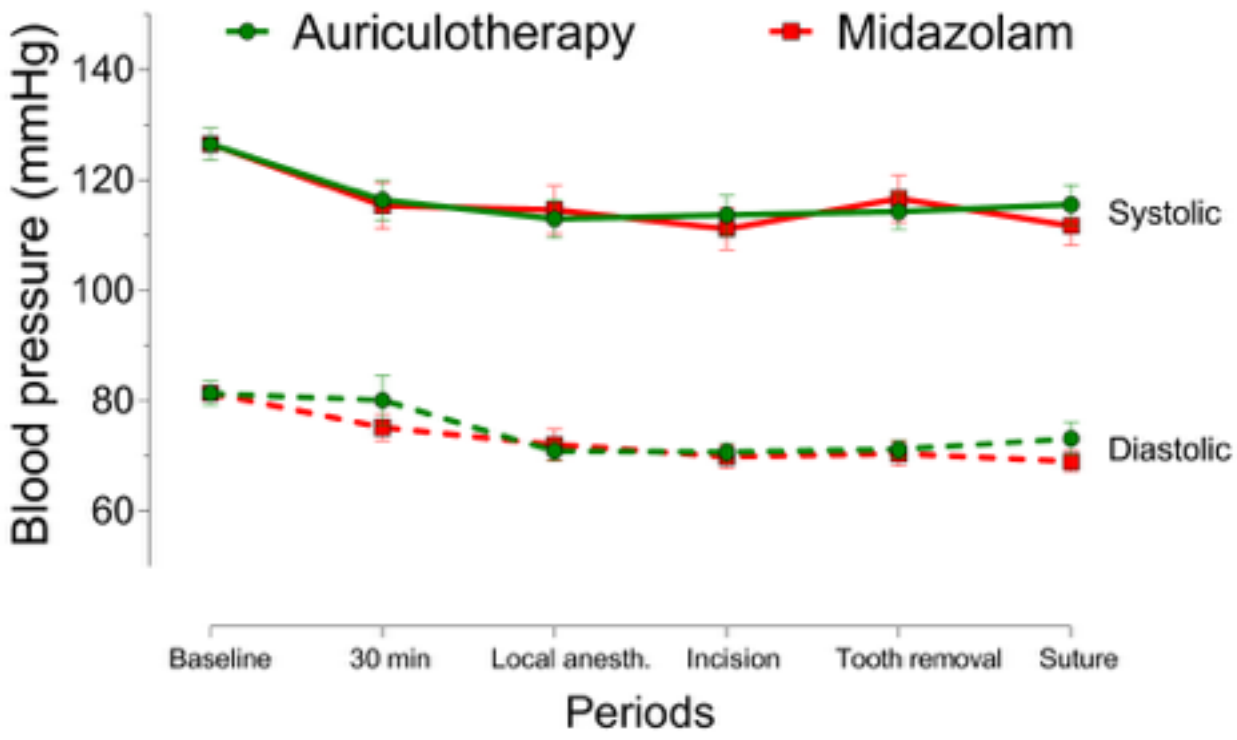

Figure 2. Sytolic and diastolic blood pressure (mean±standard error) during the evaluated periods for both treatments.

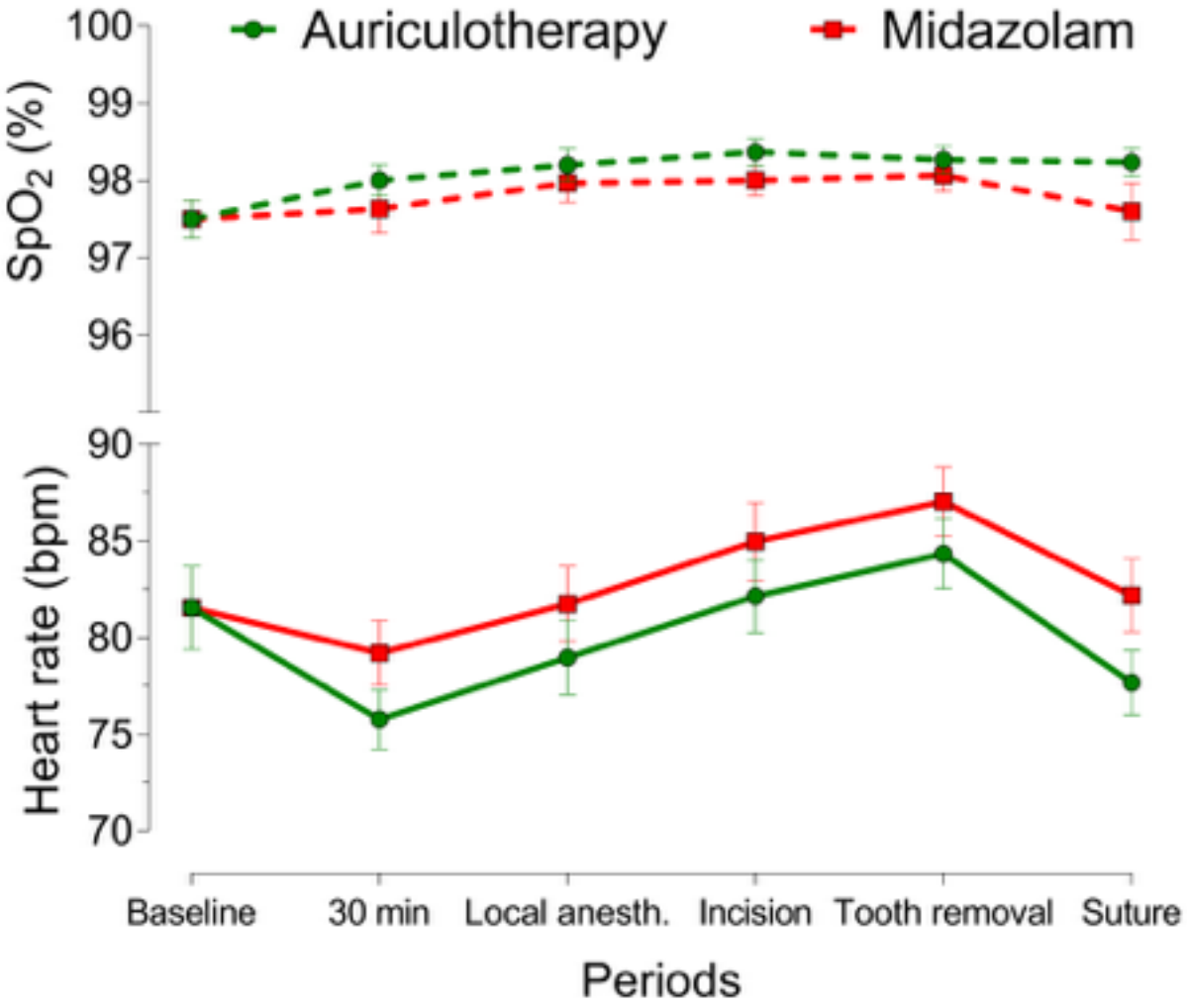

Figure 3. Heart rate and SpO_2 (mean±standard error) during the evaluated periods for both treatments.

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