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COMPARISON OF TWO VASOCONSTRICTORS ON GLYCEMIC LEVELS IN DIABETIC PATIENTS

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DANIELA MENESES SANTOS

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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.

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SUMÁRIO

1. ARTIGO SUBMETIDO

1.1.1. Folha de identificação

Title of the Paper: **Comparison of two vasoconstrictor on glycemic levels in diabetic patients.**

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Running title:Vasoconstrictor and glycemic level.

1.2. ABSTRACT

We evaluated glycemic levels in diabetic patients before, during, and after exodontia using 2% lidocaine with 1:100,000 epinephrine (Lido/Epi) and 3% prilocaine with 0.03 IU/mL felypressin (Prilo/Fely). A double-blind, randomized clinical study was conducted to evaluate changes in body parameters and glycemic levels in diabetic patients undergoing two anesthetic protocols during dental extractions. During surgery, we evaluated hemodynamic parameters such as blood pressure (BP), heart rate (HR), saturation (SpO2), and capillary glycemic levels (Gly), which were measured at different surgical moments: basal, 30 min after medication, incision, alveolus removal, suture, and 30 and 60 min after anesthesia. The data analysis showed no statistically significant differences (*t* test) between the groups inage, weight, and time of surgery. In the Lido/Epi group, increased systolic BP and decreased diastolic BP were observed. No significant difference was observed in the Prilo/Fely group among the surgical moments or between the groups regarding BP. No significant difference was observed in HR, SpO2, and Gly between the groups at any surgical moment ($P > 0.05$). In anxiety level evaluation, there was no difference between the different surgical moments. Thus, both Lido/Epi and Prilo/Fely (maximum 3.6 mL) can be safely used in controlled diabetic patients.

KEYWORDS: Dental extraction; epinephrine; felypressin; glycemic levels; lidocaine; prilocaine.

1.3. INTRODUCTION

Diabetes mellitus (DM) is defined as a group of metabolic diseases characterized by hyperglycemia caused by defects in insulin secretion, insulin-signaling action, or both[1].It can be classified as Type 1or Type 2. Type 1 DM (DM1) is an autoimmune disease resulting in destruction of pancreatic β cells, leading to poor insulin production[2].Type 2 DM (DM2) has multifactorial causes and affects β-cell function and insulin tissue sensitivity[3].

Patients with diabetes usually present with oral cavity manifestations such as dental caries, periodontal disease, dental mobility, and dental extractions[4]. In a study carried out in France, it was observed that the prevalence of dental extractions in the diabetic population was around two times higher than that in non-diabetic individuals[5]. It is well-known that oral surgery requires special care, including the use of a safe and effective anesthetic solution[6].

Local anesthetics are associated with vasoconstrictors whose function is to decrease blood flow at the site of administration, reduce the toxicity risk, increase the duration of local anesthetic's action, and decrease blood loss at the surgical field[7]. Vasoconstrictors may belong to agroup of sympathomimetic amines, such as adrenaline and norepinephrine. Felypressin, an analogous of vasopressin hormone, is also used as a vasoconstrictor[8].

Some authors have reported an increase in blood glucose levels after administration of local anesthetics containing adrenaline as a vasoconstrictor[9,10,11]. Indeed, the use of vasoconstrictors in non-controlled diabetic patients should be avoided[12,13].The recommended anesthetics in these patients may be 3% mepivacaine without vasoconstrictor or 3% prilocaine with 0.03 IU/mL felypressin[14]. Felypressinis indicated in non-controlled diabetic patients because it does not activate α- and β-adrenergic receptors[15]. However, it presents some disadvantages, such as deficient hemostasis control and short pulpal anesthesia[7].

The present study evaluates glycemic levels in diabetic patients before, during, and after extraction using 2% lidocaine with 1:100,000 epinephrine and 3% prilocaine with 0.03 IU/mL felypressin.

1.4. MATERIALS AND METHODS

1.4.1. Ethics review

The Committee on Ethics in Human Research of the Federal University of Sergipe approved the study on the protocol number nº 43.134915.8.0000.5546. The present study was also registered in the Brazilian clinical trials (Trial: RBR-2HX7P2). All patients who participated in the study signed the informed consent agreement.

1.4.2. Selection and eligibility of participants

This double-blind, parallel, controlled trial was conducted to evaluate changes in physical parameters and glycemic levels in diabetic patients undergoing two anesthetic protocols during exodontia. The study was conducted in the Dentistry School at the Federal University of Sergipe, Aracaju-Sergipe, Brazil.

Forty adult subjects participated in this study. All patients were diabetic controlled by medication (oral hypoglycemic agents and insulin). Inclusion criteria were as follows: patients over 18 years of age, DM controlled by medication, requiring tooth extraction in the mandible, and tooth with similar position and surgical difficulty. Exclusion criteria were as follows: patients younger than 18 years of age, any general health problem (besides DM),

using any medication (anti-inflammatories, sedatives) in the past 15 days, history of hypersensitivity to local anesthetics, pregnantor lactating, and anatomical location of the tooth unfavorable to the inferior alveolar and buccal nerve block.

1.4.3. Study design

The participants were randomly divided into two groups: group Lido/Epi (20 patients), who were anesthetized with 2% lidocaine with 1:100,000 epinephrine (Alphacaine 100; NOVA DFL); and group Prilo/Fely (20 patients), who were anesthetized with 3% prilocaine with 0.03 IU/mL felypressin (Prilonest; NOVA DFL).

The present study was conducted in three phases. In phase I, the degree of anxiety was assessed in all participants before the surgical procedure by applying the Corah Dental Anxiety Scale. Subsequently, the basal physical parameters, such as systolic (SBP) and diastolic (DBP) blood pressure, heart rate (HR), blood oxygen saturation (SpO_2), and glycemic levels by capillarity were evaluated. Glycemic levels were determined by using a glucometer (Accu-Chek® Active; Roche Diagnostics Brazil Ltda. SP).

In phase II, the baseline physical parameters were measured and antibiotic prophylaxis (amoxicillin 2g, 1 h before the surgical procedure) was administered to all patients. In both groups, patients received a *Passiflora incarnata* capsule (500 mg orally, 1 h before the start of the surgical procedure). The physical parameters were measured 30 min after the administration of *P.incarnata*. At the time of surgery, 3.6 mL of Lido/Epi or Prilo/Fely were administered by an inferior and buccal alveolar nerve block. At this point, the timer was triggered up to 60 min after the anesthesia. Physical parameters were measured at different surgical moments: during incision, during tooth removal, during suture, and 30 and

60 min after anesthesia. In addition, the degree of anxiety was evaluated by the investigator and the operator responsible for the surgery, who were stimulated to respond to the same questionnaire at the end of each surgical procedure. In the postoperative period, sodium dipyrone 500mg (Magnopyrol®, Farmasa business corporation, São Paulo, Brasil) every 6 h for 48 h was prescribed.

In phase III performed 8 days after the tooth extraction and during suture removal, the side-effects resulting from the medication used in this study were evaluated using a questionnaire.

1.4.4. Statistical analysis

Differences between the two groups regarding patients' age and weight were assessed by non-paired *t* test. The same test was used to observe the total time of surgery. Sex and anxiety levels were observed by Qui-square or Fisher's exact tests.

Variation on all physical parameters along the surgical moments induced by both groups was observed by Friedman's test. Mann-Whitney test was used to compare the local anesthetics at each surgical moment.

For all tests, the level of significance was set at 5%.GraphPad 7.0 and BioEstat 5.0 were used to perform the analysis.

1.5. RESULTS

1.5.1. Evaluation of physical parameters

No statistically significant differences were observed between the groups in age, weight, and time of surgery (Table 1). In addition, neither group differed in gender, surgery sides, and the initial anxiety level. The majority of the sample was low-anxiety level patients (Table 1).

Figures 1 and 2 show the variation in blood pressure, heart rate, and SpO_2 in the periods observed, considering the two local anesthetics. The use of Lido/Epi induced a significant increase in SBP during "incision" period in relation to "basal", "anesthesia," and "60 min after anesthesia" periods. The last period showed lower SBP than that in the "tooth removal" period. No statistically significant differences were found in the other periods. Prilo/Fely caused increased SBP during "suture" when compared with "basal", "30 min after anesthesia," and "60 min after anesthesia" periods. Markedly, when lidocaine was used, SBP peaks greater than 160 mmHg were observed in eight(40%) patients during the incision, six(30%) during tooth removal, five(25%) during suturing, four(20%) after 30 min of anesthesia, and three(15%) at the end of the procedure. None of the patients presented these peaks at the baseline.

When Prilo/Fely was used, these peaks were observed in two(10%) patients during the baseline, eight(40%) during the incision, nine(45%) during tooth removal, nine(45%) during suturing, six(30%) after 30 min of anesthesia, and three(15%) at the end of the procedure. No statistically significant differences among the periods were observed considering SpO_2 for both Lido/Epi (p= 0.94) and Prilo/Fely (p = 0.91). Levels of HR did not

show statistically significant differences ($p > 0.05$) between basal values and those obtained in other periods for both local anesthetics despite the sporadic fluctuations.

Figure 3 shows the variation in glycaemia over time. It also shows a marked reduction in blood glucose caused by Lido/Epi, from 30 min of *P. incarnate* administration until the last period when compared to the baseline value. Although less pronounced, Prilo/Fely also significantly decreased glucose, starting at the "tooth removal" period until the last period when compared to the baseline. Six episodes of increased blood glucose above the initial measurements (5.0% of 120 measurements) were observed when Lido/Epi was used. Prilo/Fely caused 28 (23.3%) episodes. However, none significant differences were observed between the two local anesthetics ($p > 0.05$) in any of the systemic parameters studied.

1.5.2.Assessment of anxiety level

Table 2 shows the perception of the patients of their own anxiety on the day of surgery compared with the anxiety initially declared. It also shows that, in general, no significant improvement or worsening was observed between the initial anxiety and the anxiety reported onthe day of surgery. The perception of the patient, operator, and researcher in relation to the basal anxiety is shown in Table 3. In general, no significant difference between the perception of operator and researcher was observed in relation to the anxiety declared by the patient. Table 4 shows the cumulative frequency of the perception of the researcher and the operator in relation to signs of anxiety and the moment of anxiety.

The most common anxiety signals observed by both the researcher and operator were the increased heart rate. The most frequent moments when anxiety occurred were during local

anesthesia and the surgery itself. In general, no significant differences were observed between the two local anesthetics in relation to the signs of anxiety and the evaluated moments.

1.5.3. Perceptions of patients after the surgery

Table 5 reveals the perceptions of patients regarding the moments they remembered after the surgery. Table 5 shows that no statistically significant differences between the two local anesthetics were observed ($p > 0.05$). The undesirable effects (cumulative frequency) observed 24 h after administration of the local anesthetics are shown in Table 6. There were no statistically significant differences between the local anesthetics ($p > 0.05$) in relation to the cumulative number of undesirable effects.

1.6. DISCUSSION

In the present study, changes in blood glucose levels in controlled diabetic patients, as well as pressure, heart rate, saturation, and the level of anxiety of these patients were evaluated. Patients underwent simple dental extraction procedures and were anesthetized with 2% lidocaine with 1:100,000 epinephrine or 3% prilocaine with 0.03IU/mL felypressin.

It is known that epinephrine activates the α-adrenergic receptors, which are responsible for peripheral vasoconstriction. It also activates the β-adrenergic receptors, leading to increased heart rate[16].The results of the present investigation indicated that the Lido/Epi induced an increase in SBP in the period immediately after the injection of the anesthetic during the “incision” period. In a study performed in patients who underwent dental extraction after being anesthetized with lidocaine 2% with epinephrine 1:80,000,

increased SBP during surgery was also observed[17]. Lidocaine 2% with 1:80,000 epinephrine resulted in a decrease in DBP[18]. This result can be observed in the present study when decreased DBP was seen in the period "60 min after anesthesia" when lidocaine 2% with epinephrine 1:100,000 was used.

Felypressin does not interact with adrenergic receptors presenting a lower incidence of side-effects on the hemodynamic response[19]. Felypressin binds to vasopressin V_{1A} receptors contracting vascular smooth muscle and capillaries[20]. In the present study, the Prilo/Fely group presented an increase in SBP only in the "suture" period. The increase in SBP can be justified in the Prilo/Fely group by the release of endogenous catecholamines. It is known that the dental surgery procedure causes anxiety and stress[21]. In the present study, there was no difference between the two anesthetic protocols in the assessment of SBP and DBP. Additionally, no significant difference in HR and SpO_2 was observed between the two groups evaluated.

The use of epinephrine in diabetic patients in dentistry has been contraindicated since it sactionis opposed to that of insulin[22]. It is known that epinephrine, due to its α-adrenergic effect, stimulates gluconeogenesis and hepatic glycogenolysis, leading to hyperglycemia[23,24]. A study performed with diabetic and healthy patients who used lidocaine without vasoconstrictor and lidocaine with 1:80,000 adrenaline showed alterations in the glycemic levels in both groups[10]. A similar study observed that pre- and postoperative blood glucose levels did not present a significant difference between the groups. In addition, the difference was observed only within the diabetic group between patients who had taken hypoglycemic agents and those who did not[25]. Khawaja et al.[12] comparing healthy and diabetic patients who used 2% lidocaine with 1:80,000 adrenaline also did not observe a

significant difference before and after administration of adrenaline in healthy patients and in those who used hypoglycemia medication.

A prospective randomized study of 70 patients with DM2 who underwent exodontia and were anesthetized with 5.4 mL of 2% lidocaine or 5.4 mL of 2% lidocaine with 1:100,000 epinephrine observed that there was no difference in the blood glucose levels between the groups with pharmacologically controlled diabetes[6]. These results are consistent with those of the present study with regard to the glycemic level in the Lido/Epi group as long as all patients are pharmacologically controlled.

In a double-blind study conducted with healthy patients receiving 2% lidocaine containing 1:80,000 adrenaline and 3% prilocaine with 0.03 IU/mL felypressin, both groups received 4.4 mL of solution. In the present study, blood glucose increased 30 min after the injection of Lido/Epi, whereas in the group receiving prilocaine, no significant difference was observed[15]. A randomized, crossover, clinical study that evaluated the effects of 2% lidocaine with 1:100,000 epinephrine and 3% prilocaine with 0.03 IU/mL felypressin on the glycemic levels of diabetic patients submitted to two sessions of periodontal instrumentation in three moments: before procedure, 10 min after anesthesia, and 20 min after anesthesia. The study observed no significant difference between the two protocols[26]. In the present study, controlled diabetic patients of both groups who underwent dental extraction and used 3.6 mL of Lido/Epi or Prilo/Fely observed a reduction in blood glucose levels over time. Paul et al.[6] also observed a significant decrease in glucose levels over time in diabetic patients receiving lidocaine with or without epinephrine.

A study was conducted on 110 patients who needed exodontia and were divided into three groups: 50 patients without diabetes, 30 patients who were medicated, and 30 patients who were non-medicated. Their glycemic levels were assessed before local anesthesia, after

anesthesia, and after extraction. An increase in glycemic levels after exodontia was observed only in non-medicated diabetic patients[27]. In a study with 150 diabetic patients and 150 non-diabetic patients who underwent minor oral surgery and received 1.8 mL of 2% lidocaine with 1:000,000 adrenaline, the glycemic levels were evaluated and compared in the preoperative period and one hour after the post operative period. However, no significant difference in glycemic levels was observed post operatively between the two groups[24]. Santos-Paul et al.[6] suggested that the divergences found in the literature can be attributed to different patient characteristics and methods used.

This study evaluated the anxiety level of patients using the Corah anxiety scale[28]. It is known that in diabetic patients, anxiety level should be controlled[29]. In the present study, we used *P.incarnata*to control anxiety. Akhondzadehet al.[30] suggest a possible anxiolytic effect of *P.incarnata.* In the present study, no significant difference was observed between the initial anxiety level and the anxiety level on the day of surgery, as well as in the anxiety levels in relation to the signs of anxiety at the evaluated moments.

1.7. CONCLUSION

Lido/Epi and Prilo/Fely slightly affected some of the physical parameters, but they did not differ each other. Thus, both local anesthetics are safe for controlled diabetic patients.

1.8. ACKNOWLEDGMENT

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The authors declare no conflict of interest in the publication of this work.

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FIGURE LEGENDS

Figure 1. Median (± interquartile deviation) of systolic blood pressure (SBP) and diastolic blood pressure (DBP) over time.Lido/Epi = 2% Lidocaine with 1:100,000 epinephrine; Prilo/Feli = 3% Prilocaine with 0.03 IU felypressin. A = basal; B = 30 min after medication; C = incision; D = tooth removal; E = suture; F = 30 min after anesthesia; G = 60 min after anesthesia.

Figure 2. Median (± interquartile deviation) of heart rate and SpO_2 over time. Lido/Epi = 2% Lidocaine with 1:100,000 epinephrine; Prilo/Feli = 3% Prilocaine with 0.03 IU felypressin. A = basal; B = 30 min after medication; C = incision; D = tooth removal; E = suture; F = 30 min after anesthesia; G = 60 min after anesthesia.

Figure 3. Median (± interquartile deviation) of blood sugar over time. Lido/Epi = 2% Lidocaine with 1:100,000 epinephrine; Prilo/Feli = 3% Prilocaine with 0.03 IU felypressin. A = basal; B = 30 min after medication; C = incision; D = tooth removal; E = suture; F = 30 min after anesthesia; G = 60 min after anesthesia.

FIGURES

Figure 1:

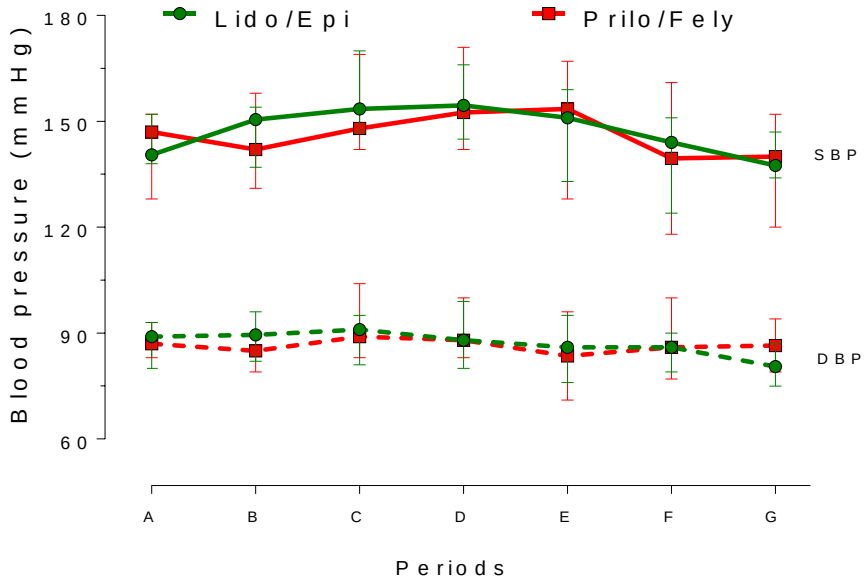


Figure 2:

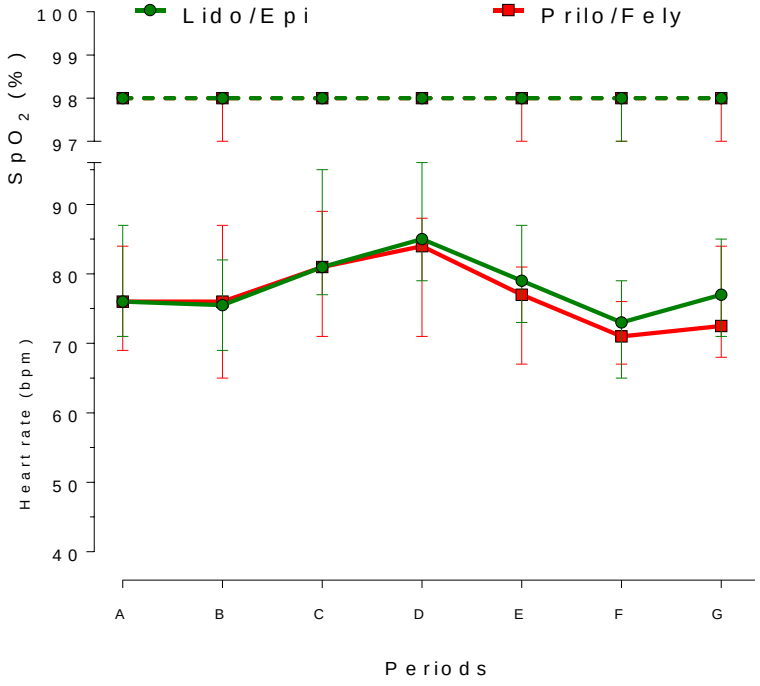
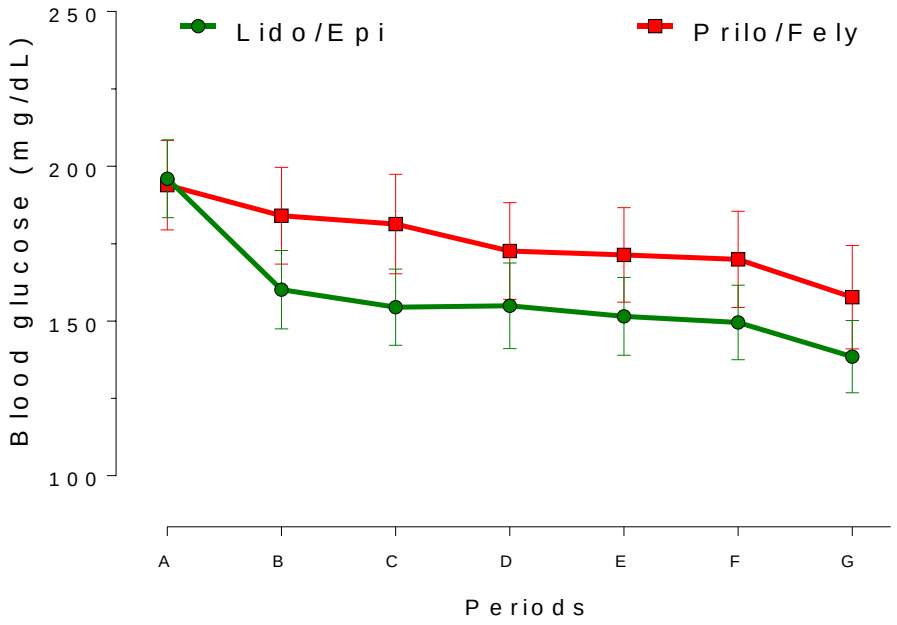


Figure 3:


Lido/Epi
Prilo/Fely
Blood glucose (mg/dL)
250
200
150
100
A
B
C
D
E
F
G
Periods

TABLES:

Table 1. Shows the characteristics of the study subjects according to the groups.

Factors		**Lido/Epi**	**Prilo/Fely**	**p**
Age in years	Mean (±standard error)	60.6 (±3)	60.1 (±2)	0.83
Weight in kg		82.3 (±3.3)	74.9 (±3.3)	0.12
Surgery time in min		22.8 (±1.8)	27.8 (±2.7)	0.13
Sex	Female n (%)	11 (55%)	10 (50%)	0.75
	Male n (%)	9 (45%)	10 (50%)	
Surgery side	Right	11 (55%)	11 (55%)	1
	Left	9 (45%)	9 (45%)	
Initial anxiety level*	Very little anxious	11 (55%)	10 (50%)	0.75
	Slightly anxious	8 (40%)	7 (35%)	
	Mildly anxious	1 (5%)	3 (15%)	
	Extremely anxious	-	-	

*-Between "Very anxious" and the sum of the others. Lido/Epi = 2% Lidocaine with 1:100,000 epinephrine; Prilo/Feli = 3% Prilocaine with 0.03 IU felypressin.

Table 2. The perception of the patients on the day of surgery of their own anxiety in comparison with the anxiety initially declared.

		Basal anxiety level			
Group	***At the surgery day***	**Tranquil**	**Slightly**	**Moderately**	**Extremely**
Lido/Epi	***Tranquil***	9 (45%)	2 (10%)	1 (5%)	-
	Slightly	2 (10%)	5 (25%)		-
	Moderately		1 (5%)		-
	Extremely	-	-	-	-
Prilo/Fely	***Tranquil***	8 (40%)	5 (25%)	-	-
	Slightly	1 (5%)	2 (10%)	2 (10%)	-
	Moderately	1 (5%)	-	1 (5%)	-
	Extremely	-	-	-	-

Table3. The perception of the patient, operator, and researcher in relation to the basal anxiety.

		Lido/Epi	**Prilo/Fely**
Patient on the day of surgery	***Tranquil***	12 (60%)	13 (65%)
	Slightly	7 (35%)	5 (25%)
	Moderately	-	-
	Extremely	1 (5%)	2 (10%)
Patient according to the researcher	***Tranquil***	13 (65%)	11 (55%)
	Slightly	-	-
	Moderately	7 (35%)	9 (45%)
	Extremely	-	-
Patient according to the operator	***Tranquil***	14 (70%)	13 (65%)
	Slightly	-	-
	Moderately	6 (30%)	7 (35%)
	Extremely	-	-

Table 4. Shows the cumulative frequency of the perception of the researcher and the operator in relation to signs of anxiety and the moment of anxiety occurred.

		According to researcher		**According to operator**	
		Lido/Epi	**Prilo/Fely**	**Lido/Epi**	**Prilo/Fely**
Signs	**Increased FC**	9 (45%)	5 (18.5%)	6 (30%)	4 (16.7%)
	Restlessness	4 (20%)	5 (18.5%)	1 (5%)	3 (12.5%)
	Increased respiratory rate	1 (5%)	1 (3.7%)	1 (5%)	3 (12.5%)
	Pallor	-	1 (3.7%)	-	1 (4.2%)
	Perspiration	1 (5%)	2 (7.4%)	-	-
	Other	-	3 (11.1%)	6 (30%)	3 (12.5%)
	None	5 (25%)	10 (37%)	6 (30%)	10 (41.7%)
Moment of anxiety	**When entering the surgical center**	1 (4.8%)	-	-	2 (8%)
	Antisepsis	1 (4.8%)	5 (22.7%)	-	3 (12%)
	Local anesthesia	6 (28.6%)	4 (18.2%)	7 (33.3%)	8 (32%)
	During the surgery	7 (33.3%)	6 (27.3%)	5 (23.8%)	3 (12%)
	At theend	-	-	-	1 (4%)
	None	6 (28.6%)	7 (31.8%)	9 (42.9%)	8 (32%)

Table 5. Reveals the perceptions of patients regarding the moments they remembered after the surgery.

Memory of the surgery events	**Lido/Epi**	**Prilo/Fely**
Absolutely nothing	-	1 (5%)
Some facts	4 (20%)	3 (15%)
Most of thefacts	3 (15%)	8 (40%)
Everything	13 (65%)	8 (40%)

Table 6. The undesirable effects (cumulative frequency) observed 24 hours after administration of the local anesthetics.

	Lido/Epi	**Prilo/Fely**
Muscle relaxation	4 (17.4%)	1 (5%)
Itching	-	1 (5%)
Gastrointestinal problems	1 (4.3%)	-
Drowsiness	4 (17.4%)	6 (30%)
Others	6 (26.1%)	-
None	8 (34.8%)	12 (60%)

2. NORMAS DE PUBLICAÇÃO DA ANESTHESIA PROGRESS

Information for Authors

STATEMENT OF PURPOSE

Anesthesia Progress is the official publication of the American Dental Society of Anesthesiology. It is also the official publication of the American Society of Dentist Anesthesiologists, the Canadian Academy of Dental Anaesthesiology, the European Federation for the Advancement of Anaesthesia in Dentistry, the International Federation of Dental Anesthesiology Societies, and the Japanese Dental Society of Anesthesiology. The journal invites submission of scientific articles, review articles, reports on clinical techniques, case reports, conference summaries, and articles of opinion pertinent to the control of pain and anxiety in dentistry. Articles are considered for publication with the understanding that they have not been previously published and that they are not being submitted to another journal. Authors are responsible for all statements made in the article and the veracity of the references cited.

SUBMISSION OF MANUSCRIPTS

Manuscripts should be submitted online at http://www.editorialmanager.com/anesthesiaprog/. The corresponding author will be notified of receipt of the manuscript, which will then be sent to two outside reviewers for an anonymous critique. Following this review, the authors will be notified of either acceptance, rejection, or the need to revise the manuscript prior to final acceptance. The editor reserves the right to edit all manuscripts and correspondence to ensure conciseness and clarity. The corresponding author will receive proofs and a copy of the edited manuscript prior to publication and is responsible for proofreading for errors. No editorial changes are permitted at the proof stage.

The author(s) acknowledge that the publisher reserves the right to charge authors for excessive alterations made to their page proofs. Authors are also responsible for all reprint charges associated with their article. Reprints may be withheld if authors fail to fulfill these obligations.

DEPARTMENTS

Scientific Articles. The journal will publish the results of controlled clinical trials of drugs and devices relevant to pain control, sedation and anesthesiology in dentistry, including reports on analgesics, local and general anesthetics, anti-anxiety agents, adjunctive drugs for anesthesia, and medications used to manage chronic orofacial pain. Studies should incorporate comparison of the experimental treatment to either a standard treatment or placebo, random allocation of treatments, double-blind procedures when quantifying subjective reports, and appropriate parametric or nonparametric statistical analysis of data.

Review Articles. The journal welcomes reviews of clinical and scientific topics relevant to any aspect of anesthesiology in dentistry or areas of medicine/pharmacology related to anesthetic practice. These articles should critically review the scientific literature on the subject and present either a summary or synthesis of the field based on the literature cited. Summary tables and figures should be used where applicable. These articles may also be used for the Continuing Education section.

Case Reports. Brief reports of unusual or instructive cases are welcome if well documented and illustrated. Of particular interest are cases illustrating unexpected outcomes, the management of medical emergencies or idiosyncratic responses to treatment.

Continuing Education Articles. The journal welcomes comprehensive reviews of any aspect of anesthesiology in dentistry or areas of medicine/pharmacology related to anesthetic practice with a focus on how the topic relates to clinical practice. The article should be referenced appropriately and utilize liberal use of tables and figures to condense and enhance the submission. A total of four multiple choice or true/false questions related to the manuscript should be included.

Clinical Techniques. Succinct reports of new techniques or variations of traditional clinical techniques as well as case series that may suggest a clinical hypothesis are invited for this section. Since the value of this kind of communication rests with the ability of the reader

to understand the method being presented, it is essential that manuscripts be well illustrated with either photographs or figures. Case series should be summarized with tables and descriptive statistics.

Brief Communications from The Japanese Dental Society of Anesthesiology. The Japanese Dental Society of Anesthesiology, a professional society consisting of dental anesthesiologists from Japan, publishes a non-PubMed listed high-quality journal that includes many articles of interest to the international audience of *Anesthesia Progress*. As a Society that recognizes *Anesthesia Progress* as another "Official Journal," Brief Communications are accepted for wider dissemination to the readers of *Anesthesia Progress*. A Brief Communication reports a concise summary of a study from the Journal of JDSA. The original title should be used and all authors should be included. The university affiliation should be listed but ranks and titles should not be included. Brief Communications begin with a brief unreferenced abstract (maximum 5 sentences, no more than 100 words), which will appear on PubMed. The main text should not exceed 500 words maximum (not including references and figures/tables) and contains no headings. Brief Communications normally have no more than a total of 2 figures or tables. References are limited to key articles only (ideally no more than 5, maximum 10 in special circumstances). After the main body of text, a sentence should state: "This research was originally published in the Journal of the Japanese Dental Society of Anesthesiology (include the appropriate citation from J-JDSA within these parenthesis)." All Checklist items MUST be fulfilled as for other submissions. See below.

Commentaries. The journal will consider for publication manuscripts based on personal opinion, treatment philosophies, therapeutic or professional controversies, and medicolegal issues. References should be used to illustrate or support the opinions expressed in the article.

Meeting Summaries. Brief summaries of individual scientific presentations, conference reports, or deliberations of society meetings related to pain control are welcome.

Correspondents are encouraged to contact the editor prior to preparing summaries for specific guidelines or to review formats previously published in the journal.

Correspondence. All readers are invited to address inquires to the editor in response to any articles published in the journal or to invite a dialogue on a topic relevant to pain control in dentistry. Correspondence must conform to the guidelines listed for manuscripts with regard to typing references and author affiliation. Correspondence is published at the discretion of the Editor.

Correspondence and editorial inquiries should be addressed to:
Steven Ganzberg, DMD, MS
Editor-in-Chief, *Anesthesia Progress*
sganzberg@ucla.edu

Continuing Education Calendar. The journal will attempt to publish notices of all state, regional, national, and international meetings related to pain control, as well as announcements of continuing education courses. All announcements should be submitted to the editor three months before the cover date of the issue in which it is to appear.

REPRINTS

Anesthesia Progress now uses EzReprint, a user-friendly, automated online system for purchasing article reprints. Prior to publication of the issue, you will receive an e-mail with a unique URL (SmartLink) and information about the reprint order process. Clicking on the SmartLink will take you directly to a web portal where you may place your reprint order. The email will be sent to you from EzReprint@yurchak.com. You may want to add this to your "safe senders" list to ensure that you receive the message. Reprint orders no longer have to be received in advance. Reprints can be ordered up to six months after the issue is published. If you have questions concerning your reprint order, please contact EzReprint@yurchak.com.

Editing & Translation Services

Submissions from authors whose first language is not English are strongly advised to have native English speakers review manuscripts before submission to ensure proper wording and

about the resolution, figure size, fonts, and color mode of the files.

References

___References are indicated in text by consecutive superscript numerals.
___Numbered reference list contains names of all authors and abbreviated journal title (per Index Medicus). Volume number, inclusive pages, and year of publication (examples below) should all be provided.
___Unpublished observations, personal communications, and articles in preparation do not appear in the reference list but parenthetically in text.

Examples for References:

McGrath PA, Sharav Y, Dubner R, Gracely RH. Masseter inhibitory periods and sensations evolved by electrical tooth pulp stimulation. *Pain*. 1981;10:1 –17.

Stoelting RK, Dierdorf SF, McCammon RL. *Anesthesia and Co-Existing Disease*. 2nd ed. New York: Churchill Livingstone; 1988.

Chapman CR, Chen AC, Harkins SW. Brain evoked potentials as correlates of laboratory pain: a review and perspective. In: Bonica JJ, Liebeskind JC, Alber-Fessard DG, eds. *Advances in Pain Research and Therapy*. New York, NY: Raven Press; 1979:791–803.

3. COMPROVANTE DE SUBMISSÃO

Submission Confirmation for Comparison of two vasoconstrictor on glycemic levels in diabetic patients.

Anesthesia Progress <em@editorialmanager.com>

Para Daniela Meneses santos

Fev 8 em 11:03 PM

Dear Mrs santos,

Your submission entitled "Comparison of two vasoconstrictor on glycemic levels in diabetic patients." has been received by journal Anesthesia Progress

You will be able to check on the progress of your paper by logging on to http://anesthesiaprog.edmgr.com/.

Your manuscript will be given a reference number once an Editor has been assigned.

Thank you for submitting your work to this journal.

Kind regards,

Anesthesia Progress

APÊNDICE A

UNIVERSIDADE FEDERAL DE SERGIPE
CENTRO DE CIÊNCIAS BIOLÓGICAS E DA SAÚDE
CAMPUS DA SAÚDE PROFº JOÃO CARDOSO NASCIMENTO JUNIOR
DEPARTAMENTO DE ODONTOLOGIA
Rua Claudio Batista, s/n, Bairro Cidade Nova, Aracaju-Sergipe

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

1- Título do trabalho: Comparação dos efeitos das soluções de lidocaína 2% com adrenalina 1: 100.000 e prilocaína 3% com felipressina 0,03 UI / ml nas concentrações de glicose sanguínea durante exodontia.

2- Objetivos: Este trabalho visa Comparar o efeito de duas soluções anestésicas (lidocaína 2% com adrenalina 1: 100.000 e prilocaína 3% com felipressina 0,03 UI / ml) nas concentrações de glicose sanguínea durante exodontia.

3- Justificativa: Pacientes diabéticos precisam de uma atenção redobrada no momento de cirurgias exodônticas, devido à utilização de anestésico locais, sobretudo os anestésicos locais associados vasoconstrictores. Os vasoconstrictores servem como hemostático, reduzindo o sangramento durante o procedimento cirúrgico e são úteis na redução da quantidade da anestesia local. A utilização de anestésicos locais associados a vasoconstritores para tratamento odontológico de rotina de pacientes diabéticos ainda gera controvérsia, em razão do risco de efeitos adversos. Contudo a literatura científica carece de bibliografia e protocolos que estabeleçam a melhor escolha anestésica para exodontia de pacientes diabéticos. Sendo assim, este trabalho é de extrema relevância no sentido que visa averiguar as possíveis alterações sofridas com administração destes anestésicos em pacientes diabéticos na clínica odontológica e estabelecer um protocolo para seu uso.

4- Procedimentos da pesquisa: O experimento será realizado no Departamento de Odontologia da Universidade Federal de Sergipe - UFS, que apresenta toda a infra- estrutura necessária para sua execução, sob a responsabilidade de cirurgião buco-maxilo-facial com grande experiência neste tipo de intervenção.

5- Desconforto e riscos possíveis e benefícios esperados: Após cessar os efeitos da anestesia local, é possível que se manifeste um certo grau de dor e inchaço da região operada, decorrente da resposta inflamatória ao trauma cirúrgico. Em função disso, estaremos empregando a *dexametasona 8mg*, que possui uma ação analgésica e antiinflamatória comprovadas, para o controle da dor e inchaço. Além destes medicamentos, você irá empregar uma solução aquosa de um anti-séptico (*digluconato de clorexidina 0,12%*) para prevenir a infecção da ferida cirúrgica e receberá três comprimidos de *paracetamol 750mg* para analgesia durante o pós-operatório. É pouco provável que os medicamentos que serão empregados nesta pesquisa promovam algum tipo de reação adversa, principalmente pelo fato de serem empregados por tempo restrito. Entretanto, é sabido que o uso de anestésico local com vasoconstritor poderá levar o aumento dos níveis sanguíneo. Contudo esta condição por si é critério de

exclusão desses pacientes do trabalho em questão. Além disso, a quantidade de tubetes esta restrita a no máximo dois por sessão, ou seja, (0,04 mg) de sal anestésico com vasoconstritor. A utilização da *Passiflora incarnata* 100 mg trará como benefício o controle da ansiedade pré-operatória por métodos fitoterápicos reduzindo o stress cirúrgico e propiciando procedimentos exodônticos mais tranquilos.

6- Forma de acompanhamento e assistência: Você terá um acompanhamento direto por parte dos pesquisadores, durante todo o período da pesquisa, com a garantia de receber respostas a qualquer esclarecimento ou dúvida acerca dos procedimentos, riscos, benefícios do tratamento, bem como informações atualizadas obtidas durante o estudo, ainda que esta possa afetar sua vontade em continuar participando dele.

7- Garantia de sigilo: Comprometem-se os pesquisadores de resguardar todas as informações individuais acerca da pesquisa, tratando-as com impessoalidade e não revelando a identidade do sujeito que as originou.

8- Divulgação dos resultados, propriedade de informações geradas e destino dos materiais e/ou dados coletados na pesquisa: Os resultados obtidos na pesquisa, as informações geradas e os dados coletados serão divulgados em periódico especializado e congressos sem nenhuma restrição, assim que seja concluída a pesquisa, tornando as informações de uso e caráter público.

9- Formas de ressarcimento de despesas e de indenização: Não estão previstas despesas ou indenizações aos indivíduos nesta pesquisa, porém caso ocorram, ficam responsáveis os pesquisadores em ressarci-las.

10- Retirada do consentimento: O voluntário tem o direito de se retirar do estudo, a qualquer momento, conforme estabelecido pela Resolução 466/2012 do Conselho Nacional de Ética em Pesquisa/Ministério da Saúde, sem sofrer qualquer tipo de prejuízo.

11- Consentimento ATENÇÃO: SUA PARTICIPAÇÃO EM QUALQUER TIPO DE PESQUISA É VOLUNTÁRIA

Eu,_____, certifico ter lido todas as informações acima citadas e estar suficientemente esclarecido de todos os itens pela Prof[a]. Dr[a]. Liane Maciel de Almeida Souza e pelas graduanda Daniela Meneses Santos. Estou plenamente de acordo e autorizo a minha participação neste experimento e dispenso o recebimento de qualquer auxílio financeiro.

Telefone para contato: (079) 9814-2384

Aracaju,_____de_____de_____

Nome:_____

Assinatura: _____

_____

Dr[a]. Liane Maciel de Almeida Souza

APÊNDICE B

FASE I (BASAL): Classificação quanto ao grau de ansiedade

Nome ..... Nº: …….
Idade..... Peso..... Raça ..... PA...../..... mmHg FC..... bpm Níveis de glicose …….mg/dL So2 …….

A. Se você tiver que se submeter a uma cirurgia bucal amanhã, como se sentiria?
1 – tudo bem, não me importaria
2 – ficaria ligeiramente preocupado
3 – sentiria um maior desconforto– estaria com medo do que poderá acontecer
5– ficaria muito apreensivo, não iria nem dormir direito

B. Quando você se encontra na sala de espera, esperando ser chamado pelo dentista, como se sente?
1 – tranqüilo, relaxado
2 – um pouco desconfortável
3 – tenso
4 – ansioso ou com medo
5 – tão ansioso ou com medo que começo a suar e me sentir mal

C. Quando você já se encontra na cadeira do dentista, aguardando que ele comece a fazer a anestesia local, como se sente?

1 – tranqüilo, relaxado
2 – um pouco desconfortável
3 – tenso
4 – ansioso ou com medo
5 – tão ansioso ou com medo que começo a suar e me sentir mal

D. Você já se encontra anestesiado. Enquanto aguarda o dentista pegar os instrumentos para começar a cirurgia, como se sente ?

1 – tranqüilo, relaxado
2 – um pouco desconfortável
3 – tenso
4 – ansioso ou com medo
5 – tão ansioso ou com medo que começo a suar e me sentir mal
Pontuação: _____

Na avaliação dos resultados, a pontuação obtida neste questionário será assim interpretada:
Até 5 pontos = muito pouco ansioso
De 6 a 10 pontos = levemente ansioso
De 11 a 15 pontos = moderadamente ansioso
De 16 a 20 pontos = extremamente ansioso

Classificação : _____

APÊNDICE C

FASE II (dia da intervenção)

Paciente Nº ____

Protocolo empregado: ( )1 ( )2

Lado operado: ( )direito ( )esquerdo Tempo de cirurgia: ……

Retorno agendado para o dia / /

	PA	FC	Níveis de Glicose	So2
30 min após medicação				
Anestesia local (30 min após)				
Anestesia local (60 min após)				
Incisão				
Remoção do dente				
Sutura				

Pesquisador:

1. Qual sua avaliação quanto ao comportamento geral do paciente?
( ) tranqüilo, relaxado ( ) moderadamente ansioso ( ) muito ansioso.

2. O paciente apresentou ou relatou algum destes sinais?
( ) inquietação/ agitação/ tiques nervosos
( ) palidez da pele
( ) transpiração excessiva
( ) sensação de formigamento das mãos, pés ou lábios
( ) alteração na profundidade ou ritmo respiratório
( ) alteração da freqüência cardíaca
( ) Outros _____

3. No caso do paciente ter apresentado sinais de ansiedade, qual o momento em que isto ocorreu?
( ) quando foi convidado a entrar no centro cirúrgico
( ) durante os procedimentos de anti-sepsia
( ) durante a anestesia local
( ) durante a cirurgia propriamente dita
( ) após o término do atendimento
( ) a pergunta não se aplica

Operador:

1. Qual sua avaliação quanto ao comportamento geral do paciente?
( ) tranqüilo, relaxado ( ) moderadamente ansioso ( ) muito ansioso.

2. O paciente apresentou ou relatou algum destes sinais?
( ) inquietação/ agitação/ tiques nervosos
( ) palidez da pele
( ) transpiração excessiva
( ) sensação de formigamento das mãos, pés ou lábios
( ) alteração na profundidade ou ritmo respiratório
( ) alteração da freqüência cardíaca
( ) Outros _____

3. No caso do paciente ter apresentado sinais de ansiedade, qual o momento em que isto ocorreu?
( ) quando foi convidado a entrar no centro cirúrgico
( ) durante os procedimentos de anti-sepsia
( ) durante a anestesia local
( ) durante a cirurgia propriamente dita
( ) após o término do atendimento
( ) a pergunta não se aplica

APÊNDICE D

FASE III (consulta de retorno)

Paciente N^{O}.....
Lado operado: ( )direito ( )esquerdo
Protocolo empregado: ( )1 ( )2

No dia de amanhã, responder a este questionário, nos devolvendo por ocasião da consulta de retorno, marcada para o dia ...../...../.....

A. No dia desta cirurgia, desde sua chegada ao consultório até o término da intervenção, quando foi dispensado, como você se sentiu?
( ) tranqüilo, relaxado
( ) um pouco ansioso
( ) muito ansioso ou com medo
( ) tão ansioso que comecei a me sentir mal

B.Com relação ao período da cirurgia, do que você se lembra?
( ) de tudo
( ) da maioria dos acontecimentos
( ) de algum fato ou acontecimento específico
( ) de quase nada
( ) de absolutamente nada

C. Nas primeiras 24 horas após as cirurgias, você notou ou sentiu alguma das seguintes reações ?
( ) Sonolência
( )tontura
( )relaxamento muscular
( )problemas gastrintestinais (desconforto estomacal, náuseas, vômito, etc.)
( )sinais de alergia (urticária, coceira)
( )outras: _____

ANEXO A

APROVAÇÃO DO COMITÊ DE ÉTICA

ANEXO B

APROVAÇÃO NO REGISTRO BRASILEIRO DE ENSAIOS CLÍNICOS

Trial: **RBR-2hx7p2** Comparação dos efeitos de dois protocolos anestésicos sobre os níveis glicêmicos de pacientes submetidos à extração.

ANEXO C

CERTIFICADO DE REVISÃO DO INGLÊS

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CERTIFICATE OF EDITING

This is to certify that the paper titled **Comparison of two vasoconstrictor on glycemic levels in diabetic patients.** commissioned to us by **Daniela Menesessantos (Universidade Federal de Sergipe)** has been edited for English language, grammar, punctuation, and spelling by Enago, the editing brand of Crimson Interactive Inc. under Normal Editing.

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