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Peri-Operative Hemodynamic Changes and Anxiety in Patients Undergoing Surgical and LASER Assisted Periodontal Therapies- A Randomised Clinical Trial

NVS Sruthima Gottumukkala[1,a], KSV Ramesh[1,b*], M Satyanarayana Raju[2,c], Gadde Praveen[3,d], Gautami S Penmetsa[1,e]

[1] *Department of Periodontics and Implantology, Vishnu Dental College, Bhimavaram India*
[2] *Department of Prosthodontics and Implantology, Vishnu Dental College, Bhimavaram, India*
[3] *Public health Dentistry, Vishnu Dental College, Vishnupur, Bhimavaram, India*
**Corresponding author*

Research Article

History

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ABSTRACT

Objectives: Hemodynamic changes, such as changes in blood pressure, heart rate, and hypoxia, are observed during surgical procedures and may be related to pre-operative anxiety. As a result, the current study aims to compare the hemodynamic changes, hypoxia, and anxiety in LASER assisted periodontal therapy and surgical periodontal therapy for pocket reduction.

Methods: This single blinded randomized controlled observational clinical trial included 30 patients with Stage II, III and Grade B, C periodontitis randomly allocated to surgical periodontal therapy (SurPT) and LASER assisted periodontal therapy(LAPT) groups. The systolic blood pressure(SBP), diastolic blood pressure(DBP), Pulserate(PR), oxygen saturation (SpO2) were assessed before injection of local anaesthesia (LA), after LA, during and at the end of procedure. Pre-operative anxiety(POA) was assessed using Amsterdam pre-operative anxiety and information scale(APOAI) before starting the procedure. Statistical analysis was done using student t-test for intergroup and repeated measures of ANOVA for intragroup analysis.

Results: SBP and HR were significantly greater in SurPT group at all-time intervals compared to LAPT group (P<0.05). SpO2 levels reduced significantly in LAPT group at T2 (P-0.002) with no significant intergroup differences. POA especially anxiety scorewas significantly higher in SurPT(P-0.017) groupwith no difference in information scores (P-0.100).

Conclusions: Greater pre-operative anxiety was observed in SurPT group and significant increase in SBP, HR at all-time intervals compared to LAPT.

Key words: Blood pressure, dental anxiety, heart rate, laser, periodontitis, spO2.

a sruthima@gmail.com https://orcid.org/0000-0002-7126-5829
b rameshksv@vdc.edu.in https://orcid.org/0000-0001-7022-0023
c drsatya@doctor.com https://orcid.org/0000-0002-7952-8312
d sriyanthvarma@gmail.com https://orcid.org/0000-0002-5208-1522
e penmetsagautami@gmail.com https://orcid.org/0000-0002-8744-1452

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Introduction

Dental anxiety and dental fear are both severe negative emotions connected with dental treatments, and the terms are frequently used interchangeably in the dental literature.[1] Dental anxiety, according to Klingberg and Broberg, is the fear that something bad may happen as a result of dental therapy or certain components of dental treatment.[2] Patients' compliance may be hampered by their fear of dental treatment, resulting in worsening dental, periodontal, and overall health.

Dental anxiety is the fifth most common cause of anxiety, according to Agras *et al.*[3] It is an emotional state brought on by an unknown threatening stimulus. Dental anxiety and stress both cause physical, cognitive, emotional, and behavioural responses in people. Anxiety over surgery is widely acknowledged as a typical emotion in pre-operative patients. Waiting for surgery or invasive treatments is stressful, according to research, and anxiety aggravates and affects both physiological and psychological factors. Many factors, including previous dental experience, dental experience of friends or relatives, and congenital factors, influence dental patients' anxiety or fear of treatment.[4]

Periodontal pocket surgery/Surgical periodontal therapy (SurPT) is a time-consuming procedure that involves manipulating diseased tissues like gingiva and alveolar bone, which can cause changes in blood pressure and oxygen saturation.[5] Acute hypertension is a common complication of major surgical procedures. Blood pressure elevation raises the risk of intraoperative complications. As a result, to avoid complications, peri-operative blood pressure management is still required.[6,7] The negative impact of suboptimal blood pressure on outcomes is most likely determined not only by the magnitude of the abnormality but also by its duration.[8] Both a significant but brief change and a minor but ongoing change have the potential to be harmful.[9] Additionally, patients with medical conditions like cardiovascular disease are more likely to have periodontal disease.[10] As a result, there is a

growing need for routine periodontal therapy in hypertensive patients as well as for developing a safe protocol for managing periodontal pockets and lowering patient anxiety without affecting hemodynamics. The justification for routine and consistent BP monitoring in peri-operative care is crucial because BP can be extremely volatile, can cause unfavourable outcomes that are easily treatable, and can lead to complications that are difficult to treat.

Non-surgical periodontal therapy with LASER assistance is a commonly used and preferred minimally invasive procedure with reduced bleeding tendency and post-operative pain.[11] Many patients and professionals prefer LASER aided treatment techniques because they have less intraoperative and postoperative complications.[12,13] However, no studies have been conducted so far to assess the hemodynamic alterations caused on by LASER assisted periodontal therapy (LAPT). A treatment protocol is required to ensure that any postoperative problems brought on by perioperative hemodynamic alterations are kept to a minimum. Therefore, the current study was designed toevaluate and compare the variability in hemodynamics, Oxygen saturation and patient anxiety duringSurPT and LAPT.

Material and Methods

Study design and setting

This randomized controlled clinical trial was conducted in patients attending department of Periodontics and Implantology, Vishnu Dental College seeking treatment for moderate to severe periodontitis. Thirty subjects including 16 males and 14 females in the age range of 25-70years were included. A single calibrated (with intra-examiner correlation coefficient k-0.82) and blinded examiner performed the clinical assessments throughout the study period. The study was conducted in the Department of Periodontology at Vishnu Dental College, Bhimavaram from March 2019 to June 2019. The institutional ethics committee (ref.No. IECVDC/15/F01/PI/IVV/47) accepted the trial protocol. Before the trial began, all patients were told about the study's design and methodology, and signed informed permission was acquired.

Sample size and patient selection

Using G*Power software(version3.1.9.4), the required sample size was calculated to be 15 patients in both groups with a statistical power of 80, an alpha of 0.05, and effect sizes of and 0.42 considering blood pressure as the primary variable.

Selection Criteria

Patients diagnosed with periodontitis stage II and Stage III, Grade B and C (according to 2017 classification of periodontal diseases by world workshop of periodontal and peri-implant diseases) and in a good state of general health without any systemic disorder were included in the study.[14] Patients with systemic diseases that affects the heart rate and Blood pressure(BP),using medication that affects the heart rate and BP, on medication for anxiety and stress, Sensitive to LA, Bronchial asthma or any existing respiratory disorder, anemia, Severe uncontrolled pain, Pregnant and lactating women, with physical and mental disability and Patients with a known history of psychiatric illness were excluded.

Randomization, allocation concealment and blinding

All the selected participants underwent an initial examination and non surgical periodontal treatment was performed during the subsequent visits. The participants were explained about the study protocol, the advantages and disadvantages of both the techniques and written informed consent was obtained. 4 to 6 weeks after initial therapy the participants were re-assessed and eligible participants i.e., those with persistent probing pocket depths of ≥5mm and clinical attachment loss of ≥3mm in at least three teeth in a single quadrant were randomly assigned to the study groups. i.e., SurPT group (received surgical periodontal therapy for pocket reduction) and LAPT group (received LASER assisted non surgical periodontal therapy). Allocation concealment was done by using computer generated random numbering system which is sealed in opaque envelopes. All the hemodynamic changes were monitored by a single calibrated examiner (intra-examiner calibration was done) and a single investigator performed all the clinical procedures in both the groups.

Assessment of parameters

The hemodynamic changes including the monitoring of Systolic Blood Pressure(SBP), Diastolic Blood Pressure(DBP), Heart rate (HR) and Oxygen saturation (SpO2) was done at four different stages i.e., before injecting LA(TI1), after injecting LA(TI2), during the procedure(TI3), at the end of procedure(TI4). BP was monitored using sphygmomanometer and HR, SpO2 using digital finger pulse oxymeter. Pre-operative anxiety was assessed using Amsterdam Preoperative Anxiety and Information Scale (APAIS). The APAIS consists of six item questionnaire which is twofold consisting of anxiety and information scale. Each question has a five pointlikert scale ranging from 1 to 5.[15]

Treatment procedure

All the participants received upto two catridges of Local anesthesia containing 2% Lignocaine with 1:2,00,000 adrenaline. In the SurPT group intracrevicular incisions were given and full thickness mucoperiosteal flap was elevated after which thorough debridement and root surface planning was done. Regenerative procedures or osteoplasty were performed as required and the flaps were approximated using 4.0 resorbable suture material.

In the LAPT group, a diode laser (Denlase®, Pune, Maharashtra) with a wavelength of 810±10 nm and a power output of 2.5W was equipped with a probe tip, which was inserted at the depth of the pocket and moved circumferentially around the tooth in a continuous mode for 1 minute.

Statistical analysis

A sample size of 15 individuals was used in each group, with a 5% alpha error and an 80% power of the test to detect a significant difference. All collected data was tallied in Microsoft Excel (MS Office version 2010). SPSS 26.0 was used for statistical analysis of the results (IBM Inc.Chicago, IL, USA). The intergroup comparison of the data was done using the student t test and the intra group comparisons were performed using repeated measures of ANOVA.

Results

Demographic characteristics

A total of 30 participants were allocated to the intervention including 8 males and 7 females in each group. The mean age of the participants was 42.56±5.60 and 47.52±49 in SurPT and LAPT groups respectively with no significant difference in the distribution of participants in different age groups in both the protocols (P-0.904) (Table 1).

Hemodynamic changes and SpO2

A significant rise in the SBP was observed in both the groups after injection of LA with P value of 0.001 and 0.000 in the SurPT and LAPT groups respectively (Table 2, 3). Intergroup comparison of SBP showed significant difference at all time points with greater SBP in SurPT group except at TI2. No significant difference in DBP was observed in both the groups at any time point. Similarly intergroup comparison of DBP showed no considerable difference between the groups at any time point (Table 4).

Heart rate was highest at TI2 which reduced significantly towards TI4 in both the groups (P<0.000). In SurPT group the HR reduced from 81.40±3.22 (TI2) to 78.06± 3.32(TI4). Similarly in LAPT group HR reduced from 79.00±2.13(TI2) to 76.00±1.60(TI4).HR was considerably greater in SurPT group compared to LAPT group at all time points. Reduction in SpO2levels was observed in both the groups at TI2. HoweverLAPT group showed a statistically significant reduction (P-0.002) in SpO2 at TI2 which increased towards TI4. Intergroup comparison showed no difference in SpO2 levels at any time point (Tables 2-4).

Pre-operative anxiety

The APAIS was assessed before starting the treatment in both groups. The anxiety scale showed greater scores in SurPT group (6.8667±2.133) compared to LAPT group (5.0667±1.70) depicting greater anxiety in SurPT group (P-0.017). However, on information scale there was no significant difference (p-0.100) between both the groups. Overall anxiety scores were highest in SurPT group (12.40±3.35) compared to LAPT group (9.66±3.03) (Table 4).

Discussion

Hemodynamic changes are influenced by a number of variables, including the use of LA, patient-specific variables such age, gender, hypertension, anxiety, stress, prior dental treatment experience, and psychological response. Blood pressure changes with age and is found to be greater in males compared to females. The results show a equal distribution of gender in both the groups and all the patients included were in the age range of 30-50 years showing uniformity in the patient selection. Cardiovascular events during and after surgery are linked to intraoperative hemodynamic alterations. Even healthy patients are at serious risk from severe perioperative hypertension, especially if their blood pressure rises by more than 20% from preoperative levels.[7] Acute circulatory irregularities, bleeding, and uncontrollable haemorrhage are all effects of such pressure surges. As a result, monitoring hemodynamic changes while providing is critical to ensuring patient safety, identifying circumstances of elevated risk quickly, establishing an early diagnosis, preventing potential problems, and operating with enhanced safety. Although hemodynamic changes associated with dental treatment, surgical therapy and use of LA with vasoconstrictors has been well established no clinical trials evaluated the association of the same with LASER therapy.[16-19] Hence the current trial evaluated and compared the hemodynamic changes, HR and SpO2 variability in SurPT and LAPT.

In the present study SBPand HR increased after giving LA. This correlates with the study done by Matsumura *et al*. (1998) and Babak A *et al*. (2013), Matsumura et al found that administering LA (2% lidocaine) containing 1:80,000 epinephrine increased both blood pressure and pulse rate.[16,17] The authors also reported that middle-aged and older patients have a greater increase in blood pressure during dental surgery than younger patients, owing to differences in the regulation of the autonomic nervous system during dental surgery.[16] Similarly Babak A *et al.* reported a significant increase in SBP, DBP and HR after injection of LA (2% Lignocaine) containing 1:80,000 epinephrine. However, greater changes in SBP (137.84±1.729) and HR(101.14±1.590) after LA were reported by these authors which could be due to the higher concentration(1:80,000) of epinephrine in LA compared to our study(1:2,00,000).[17] The vasoconstrictor i.e., epinephrine used in the LA increases the potency and duration of anaesthesia, reduces the plasma concentrations of the anaesthetic, and improves local control of bleeding. However, use of epinephrine containing LA is found to induce hemodynamic changes during surgical procedures.In normotensive individuals, sympathetic activation during anaesthesia induction can cause blood pressure to rise by 20 to 30 mmHg and heart rate to rise by 15 to 20 beats per minute.[9] Contrary to the results of the current study Gedik RG *et al.* reported reduction in BP and HR after periodontal surgery.[5]

Shakeel AM *et al.* examined the cardiovascular effects of 2% lignocaine with two different adrenaline concentrations, 1:80,000 and 1:2,000,000. They reported a considerable increase in pulse rate immediately after LA with 1:80,000 adrenaline concentrations, which progressively decreased to the normal rate after 15 minutes, and no significant increase in pulse rate with a

1:2,00,000 adrenaline concentration.[20] However when compared to earlier studies the rise in hemodynamicswas slightly less in our study and the rise has reduced at a faster rate to pre-operative values, which may be due to the 1:2,00,000 concentration of epinephrine used which is a commonly used concentration in regular practice.[21] Another important factor in the hemodynamic changes associated with LA is the amount of LA injected, hence in the current study a standard amount of up to two cartridges was considered as inclusion criteria.

No significant variation in the SpO2 levels were observed during the different steps of periodontal therapy which is in accordance to an earlier study which evaluated the changes during surgical periodontal therapy.[17]

Intergroup comparison of the SBP and HR scores at different time intervals showed greater elevation in the values in SurPT group compared to LAPT group. And also individual anxiety scores and overall APAIS scores were significantly greater in SurPT group. These hemodynamic changes could be attributed to the anxiety of the patients towards surgery which results in a surge of adrenaline and rise in BP and HR. Anxiety caused by dental treatment can stimulate the release of endogenous catecholamines. In comparison to less invasive LASER therapy, the prospect of a planned surgical procedure causes a physiologic stress response in patients, manifesting as corticoid release, BP change, and hemodynamic and cardiovascular reactions. When this condition is paired with the use of local anaesthetics and vasoconstrictors, the negative effects on the cardiovascular system may be exacerbated. Furthermore, the anxiety associated with minor surgery and local anaesthetic injection may cause a catecholamine rush, which may raise myocardial oxygen demand and be arrhythmogenic.[22,23] Local anaesthetics' possible effect on cardiac rhythm has also been described in the literature.[22] Incomplete or inappropriate awareness regarding the treatment procedure can be considered as one of the factor for increased anxiety. However, the results of the current study dictate no difference in the information scale in patients in both the groups. The assessment of postoperative anxiety and patient reported outcomes was not within the confines of the current study, however may influence the postoperative hemodynamic changes. Hence, further studies may be necessary to prove the possible association between postoperative anxiety, patient reported outcomes and hemodynamic changes. Strategies for reduction of preoperative anxiety i.e., pharmacological and non-pharmacological may be necessary to prevent perioperative complications. Non pharmacological cognitive-behavioral therapy, music therapy, pre-op preparation video, aromatherapy, may be of potential benefit to reduce the pre-operative anxiety.

Table 1: Demographics of Study Participants

Characteristics	Category	SurPT	LAPT	P value
Gender	Male	8 (53.3%)	8 (53.3%)	1.000
	Female	7 (46.7%)	7 (46.7%)	
Age	< 35yrs	4 (26.7%)	5 (33.3%)	0.904
	35-60yrs	6 (40%)	5 (33.3%)	
	>60yrs	5 (33.3%)	5 (33.3%)	

Table 2: Comparison of Vitals at Different Time Intervals within SurPT group

Parameters	Time intervals	MEAN	SD	P VALUE
SBP	T1	129.6000	7.56684	0.001*
	T2	131.4667	8.12287	
	T3	129.6000	7.56684	
	T4	129.6000	7.56684	
DBP	T1	80.5333	2.55976	0. 234
	T2	80.9333	2.81493	
	T3	80.4000	2.29285	
	T4	80.2667	2.12020	
HR	T1	80.1333	3.44065	0.000*
	T2	81.4000	3.22490	
	T3	79.1333	3.56304	
	T4	78.0667	3.32666	
SPO2	T1	97.4000	1.24212	0.059
	T2	96.8667	1.59762	
	T3	97.4000	1.35225	
	T4	97.4000	1.35225	

*- p≤0.05 considered statistically significant

Table 3: Comparison of Vitals at Different Time Inetrvals Within LAPT

Parameters	Time intervals	MEAN	SD	P VALUE
SBP	T1	124.5333	5.57887	0.000*
	T2	126.2667	5.84889	
	T3	124.2667	4.89120	
	T4	122.6667	5.05211	
DBP	T1	79.0000	2.13809	0.243
	T2	79.7333	2.25093	
	T3	79.7333	2.25093	
	T4	79.7333	2.25093	
HR	T1	77.9333	2.25093	0.000*
	T2	79.0000	2.13809	
	T3	76.9333	2.34419	
	T4	76.0000	1.60357	
SPO2	T1	97.2000	1.14642	0.002*
	T2	96.3333	1.11270	
	T3	97.1333	1.30201	
	T4	97.4000	1.24212	

*- p≤0.05 considered statistically significant

Table 4: Comparıson of vıtals between the groups at dıfferent tıme ınetrvals

Parameters	Time intervals	Groups	MEAN	SD	P VALUE
SBP	T1	SurPT	129.6000	7.56684	.046*
		LAPT	124.5333	5.57887	
	T2	SurPT	131.4667	8.12287	.054
		LAPT	126.2667	5.84889	
	T3	SurPT	129.6000	7.56684	.030*
		LAPT	124.2667	4.89120	
	T4	SurPT	129.6000	7.56684	.006*
		LAPT	122.6667	5.05211	
DBP	T1	SurPT	80.5333	2.55976	.371
		LAPT	79.7333	2.25093	
	T2	SurPT	80.9333	2.81493	.208
		LAPT	79.7333	2.25093	
	T3	SurPT	80.4000	2.29285	.428
		LAPT	79.7333	2.25093	
	T4	SurPT	80.2667	2.12020	.510
		LAPT	79.7333	2.25093	
HR	T1	SurPT	80.1333	3.44065	.048*
		LAPT	77.9333	2.25093	
	T2	SurPT	81.4000	3.22490	.023*
		LAPT	79.0000	2.13809	
	T3	SurPT	79.1333	3.56304	.056
		LAPT	76.9333	2.34419	
	T4	SurPT	78.0667	3.32666	.039*
		LAPT	76.0000	1.60357	
SPO2	T1	SurPT	97.4000	1.24212	.650
		LAPT	97.2000	1.14642	
	T2	SurPT	96.8667	1.59762	.298
		LAPT	96.3333	1.11270	
	T3	SurPT	97.4000	1.35225	.587
		LAPT	97.1333	1.30201	
	T4	SurPT	97.4000	1.35225	1.000
		LAPT	97.4000	1.24212	
ANXIETY	Anxiety scale	SurPT	6.8667	2.13363	.017*
		LAPT	5.0667	1.70992	
	Info scale	SurPT	5.5333	1.50555	.100
		LAPT	4.6000	1.50238	
	Overall	SurPT	12.4000	3.35517	.027*
		LAPT	9.6667	3.03942	

*- p≤0.05 considered statistically significan

Future prospects

A methodology to assure safe periodontal practice may require further research in patients with compromised medical situations such hypertension and pre-existing cardiovascular disorders/abnormalities.

Conclusions

The hemodynamic alterations including SBP and HR were considerably greater during surgical periodontal therapy and in particular after injection of LA compared those induced by laser assisted periodontal therapy. The fluctuations in BP and HR, however, were normal ranges. Greater pre-operative anxiety brought on by surgical periodontal therapy may be a potential source of hemodynamic changes.

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Ethical Statement

The institutional ethics committee (ref.No. IECVDC/15/F01/PI/IVV/47) accepted the trial protocol. Before the trial began, all patients were told about the study's design and methodology, and signed informed permission was acquired.

Author contributions

NVSG, RSVK, carried out the research and collected the data. NVSG and KSVR designed and supervised the study, visualized and validated the data, acquired funding, and reviewed draft material. The data were organized, analyzed, and interpreted by NVSG, MSN, and GP.NVSG, RSVK and GSP reviewed the article. All authors were responsible for the content and similarity of the manuscript index and who have reviewed and critically approved the final draft.

Conflict of Interest

"This research did not receive any specific grant from funding agencies in the public, commercial, or notfor-profit sectors"

Informed Consent

All the participants were informed and a written consent was taken before their participation in the study.

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