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Assessment of True and Surrogate End Points After Periodontal Flap Surgery

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ABSTRACT: Patient centered outcomes are particularly important in periodontal treatment as they facilitate clinical decision making to provide a more focused patient centered care. **Aim:** The purpose of this study was to compare patient-centered outcomes, based on a self-reported questionnaire before and after periodontal flap surgery.

Methods and material: The study included 40 patients between the age group of 20 years-60 years diagnosed with chronic periodontitis. Patients were informed about the study and consent was taken. The clinical parameters were measured using a UNC – 15 probe, clinical and radiographic evaluation was performed at baseline before periodontal surgery and 9 months post operatively. Questionnaire regarding patient centered outcomes was similar to OHIP-14 and was constructed as an opinion statement using Liekert scale. Information was recorded 9 months following periodontal flap surgery.

Statistical analysis: Data was assessed using SPSS V22. Paired t-test and the chi-square test were applied based on the nature of distribution.

Results: There was a statistically ($P<0.01$) significant improvement in all the assessed parameters excluding psychological disability and handicap. There was no variation in pronunciation post treatment. There was a statistically ($P<0.01$) significant improvement in clinical and radiographic parameters following treatment.

Conclusion: Patient centered outcomes like patient satisfaction and quality of life are more relevant to patients. They also add value to periodontal clinical practice and research.

KEYWORDS: True end points, patient centered outcomes, quality of life, periodontal flap surgery, tangible outcomes.

I. INTRODUCTION

Therapeutic success after periodontal flap surgery is traditionally measured using objective measures such as gingival inflammation, bleeding on probing, probing pocket depths, and clinical attachment level which provides important information on disease status or treatment outcomes. However, traditional surrogate markers give little insight into the impact of the treatment on the patient.

Evidence-based dentistry involves four different parameters that include patient values, scientific evidence, clinical knowledge and experience and judgment, which help in decision making, planning of the treatment, as well as for future research.[1] Of these parameters, patient values are more critical since the patient is the primary beneficiary of the treatment and there is a need to recognize and value the patient's perception of change in response to treatment. Patients' opinion is therefore a fundamental measure of therapeutic success along with various traditional markers.

Tangible outcomes of the patient are those outcomes that directly measure the patient's perception about the treatment which are referred to as true endpoints, or clinically relevant endpoints.[2]According to World Health Organization (WHO 1948), evaluation of the health of subjects requires the assessment of their physical, psychological, and emotional well being, not merely confirmation of disease absence.[3] It was suggested that subjective oral health-related quality of life measurements should be considered true endpoints to assess periodontal treatment efficiency (Hujoel 2004).[4]

Surgical intervention is often indicated after initial therapy in the treatment of moderate to advanced periodontitis. Treatment of deep pockets with open flap debridement helps in the reduction of probing pocket depth and gain in clinical attachment levels. However, periodontal surgery can also cause certain post-operative discomforts

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such as pain, swelling, or tooth sensitivity. The importance of assessing changes in patients' perception in other fields of dentistry has been shown (Cunningham et al 2000, McGrath et al 2003, Lee et al 2008).[5,6,7] It is also important to note that patients differ in the degree of impact of periodontal treatment when the outcome is evaluated in terms of patient perception. Periodontal therapy was suggested to have a positive impact on the quality of life of patients. However, the evidence is still limited regarding the effect of periodontal therapy on quality of life.[8,9]

Thus, measurement of the impact of periodontal flap surgery on patient centered outcomes is an important part of the assessment of an individual's health needs.

The present study assessed and compared changes in clinical outcomes before and after surgery, and change in patient-centered outcomes in dimensions such as functional limitation, physical pain, and discomfort, psychological disability, social disability, and handicap based on Lockers theoretical model of oral health.[10]

II. MATERIALS AND METHODS

(1). Study population: A total of 40 subjects between the age group of 20 – 60 yrs with moderate to severe periodontitis indicated for periodontal flap surgery were chosen from the outpatient Department of Periodontics and Oral Implantology, GITAM Dental College and Hospital, Visakhapatnam. Patients were informed and consent was taken. The sample size was measured by using the formula

$$n \geq \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{[\delta_{\text{Difference}} / \sigma_{\text{Difference}}]^2} + \frac{Z_{1-\alpha/2}^2}{2}$$

Where n = Required sample size; Z = Standard normal variate, α= Aipha, β=Beta

δ_{Diff} = Mean of difference, σ_{Diff} = Standard deviation of difference.

To compare two means (Paired/ Before-After), minimum paired sample n =7 at
α =0.05 for a two sided test, β =0.2 would have a power of 80%. Our study included n=40 subjects.

Inclusion criteria: Patients demonstrating a probing depth of ≥ 5 mm and clinical attachment loss ≥ 7mm, showing radiographic evidence of bone loss, without any systemic disease that could affect the treatment result and with no history of drug intake known to affect the periodontium, were included in the study.

Exclusion criteria: Patients unable to do regular oral hygiene practices, current and former smokers, pregnant and lactating women, patients on long term steroidal or antibiotic therapy and medically compromised patients were excluded from the study.

(2). Procedure:

Clinical parameters – Papillary bleeding index, probing pocket depth using UNC -15 periodontal probe, clinical attachment level were recorded at baseline, and 9 months. Radiographic evaluation by long cone paralleling technique was done at baseline and 9 months for mean defect depth or amount of defect fill.

Patient-centered outcome - The main questionnaire used to determine the expectation of periodontal treatment and level of satisfaction was similar to OHIP-14 and was composed of 16 items. Each question was constructed as an opinion statement using the Likert scale and administered with a 5 point response format (Always, constantly, sometimes, rarely, never). Items were rated from always (scored 5) to never (scored 0).[11] The 16 questions were sub scaled into 7 dimensions according to Locker's conceptual model of oral health as a functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap.[10]The internal consistency of the questionnaire measured by Cronbach's alpha reliability coefficient for each dimension ranged from 0.52 to 0.88.

(3). Statistical analysis:

Data is entered in MS- Excel and analyzed by using SPSS V22. Normality is checked by using Kolmogorosvmirnov test. Descriptive statistics were represented with percentages, mean with SD. Paired t-test, the chi-square test were applied based on the nature of the distribution. P< 0.05 is considered as statistically significant.

III. RESULTS

Effect of periodontal therapy on clinical parameters:

Periodontal flap surgery resulted in a statistically significant improvement in all periodontal parameters as shown in (Table 1). At baseline, the mean full-mouth papillary bleeding index was 2.05±0.72mm, at nine months the mean papillary bleeding index score reduced to 0.79±0.50mm (P<0.01). Pocket depth was measured at baseline and nine months, there was a significant reduction in probing depth from baseline to nine months. The mean probing depth at baseline was 5.74±1.73 mm which reduced to 2.22±0.83mm (P<0.01) at 9 months. There was a significant increase in mean CAL from baseline to nine months. At baseline, the level of attachment

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was 5.97 ± 1.71mm; at nine months it was 2.42±0.88mm with a gain of 3.55±0.83mm from baseline (P <0.01).Radiographic parameters: The mean defect depth (distance from CEJ – the base of the defect) at baseline was 5.21±1.64; at nine months the defect depth reduced to 4.49±1.56 mm, which was statistically significant (P <0.01).

Periodontal parameters	Baseline		9 Months		P-value
	Mean	SD	Mean	SD	
Papillary bleeding	2.05	0.72	0.79	0.5	<0.01*
Probing pocket depth	5.74	1.73	2.22	0.83	<0.01*
Clinical attachment level	5.97	1.71	2.42	0.88	<0.01*
Radiographic parameters	5.21	1.64	4.49	1.56	<0.01*

*p≤0.05 statistically significant,† SD-Standard deviation

Table 1.Periodontal parameters at baseline and 9 months.

Effect of periodontal flap surgery on patient-centered outcomes:

The changes in responses before and after treatment to the questionnaire items which are divided into seven dimensions are shown in the Table 2. The mean total score at post-treatment showed a statistically significant improvement from the baseline score (Table 2).Significant improvement in scores were seen in most dimensions except for psychological disability, handicap, and in pronunciation.

Functional limitation dimension consisted of two questions:

Question 1 regarding the ability to chew food without difficulty showed that most of the patients were able to chew food without difficulty both before and after treatment.

Question 2 regarding the change in food habits demonstrated a higher satisfaction in patient's food habits post-treatment.

The second dimension included physical pain; results showed that there was a significant decrease in pain post-treatment.

The third dimension regarding physical discomfort showed a statistically decreased physical discomfort post-treatment, there was no significant variation in pronunciation pre and post treatment.

The fourth dimension regarding physical disability showed improvement post-treatment.

The fifth dimension of psychological disability showed that most of the patients had no irritability or difficulty with concentration both pre and post treatment. However, there was significant stress due to toothache pre-treatment compared to post-treatment.

Social disability - the sixth dimension demonstrated significant reduction post-treatment.

The seventh dimension – Handicap did not show a significant change post-treatment.

Dimension	Question	Time	Mean	SD	P-Value
Functional limitations	1. Are you able to chew your food without difficulty?	Pre Post	3.30 3.75	1.02 0.71	<0.01*
	2. Were you required to change your food habits?	Pre Post	1.08 0.13	1.21 0.65	<0.01*

Physical pain	3. Do you have any unprovoked tooth pain?	Pre Post	0.98 0.10	1.14 0.30	<0.01*
	4. Do you have pain in your gums?	Pre Post	1.45 0.05	1.26 0.32	<0.01*
	5. Do you feel sensitivity when you eat or drink anything cold ?	Pre Post	1.78 0.28	1.46 0.51	<0.01*
Physical discomfort	6. Any trouble pronouncing words?	Pre Post	0.25 0.18	0.59 0.64	0.43
	7. Do your gums bleed?	Pre Post	1.88 0.05	1.22 0.32	<0.01*
	8. Do you have any problem due to food being trapped in between teeth?	Pre Post	2.05 0.68	1.26 0.73	<0.01*
Physical disability	9. Unable to eat desired foods?	Pre Post	0.88 0.05	0.99 0.22	<0.01*
	10. Had to interrupt meals due to discomfort and pain?	Pre Post	0.68 0.15	0.94 0.58	<0.01*
Psychological disability	11. Does tooth ache cause stress in you?	Pre Post	1.65 0.13	1.42 0.46	<0.01*
	12. Irritable?	Pre Post	1.00 0.00	1.28 0.00	-
	13. Difficulty with concentration?	Pre Post	0.38 0.00	0.74 0.00	-
Social disability	14. Have your teeth caused you any embarrassment?	Pre Post	1.13 0.18	1.28 0.68	<0.01*
	15. Do you have bad breath?	Pre Post	2.33 0.10	1.46 0.38	<0.01*
Handicap	16.Totally unable to function	Pre Post	0.08 0.00	0.47 0.00	-

*p≤0.05 statistically significant,† SD-Standard deviation.

Table 2. Patient centered outcomes pre and post surgery.

IV. DISCUSSION

The primary goal of our study was to gain basic information about patient-centered outcomes in patients who underwent periodontal surgery. There was a statistically significant improvement from baseline in clinical parameters and patient-centered outcomes after receiving surgical periodontal surgery.

Patient-based outcomes refer to patients' self-evaluation of the perception of the disease, its impact upon their quality of life, and an evaluation of treatment as measured through questionnaires and scales.[12]Periodontal disease symptoms such as swollen gums, painful and receding gums, drifting teeth, and halitosis may deeply affect the patient's physical, social, and psychological aspects. According to Needleman I individuals affected by periodontitis reported that the disease and it's symptoms had an impact on patients' function, comfort, appearance, and self-confidence.[13]Measuring the patient-centered outcomes is important as it enhances screening and monitoring for psychological problems in the individual patient case, provides outcome measures in health services or evaluation research. Brauchle F et al reported that patients with severe periodontal disease showed better improvement in the quality of life after therapy when compared to those with mild to moderate disease.[14]

Patients' self-report is a simple, convenient, and less expensive mechanism for getting primary information related to therapeutic success. Patient-based outcomes were identified as a research priority in the 2003 World Workshop on Emerging Science in Periodontology according to Newman M.G. et al.[15]However, these measures are highly influenced by patients' personal beliefs, cultural backgrounds, social, educational and environmental factors.[16] In our study, patient satisfaction increased significantly after treatment compared to pre-treatment. However, it was noticed that there was increased satisfaction in dimensions such as physical pain, physical disability, and social disability than other dimensions.

Limitations: Administering the questionnaire 9 months post surgery could lead patients to partly forget the pre treatment discomfort.However, most of the patients were satisfied with the treatment outcome and could easily recall pre-treatment suffering.

V.CONCLUSION

Patient-related outcomes play an important role in periodontal therapeutic research. Studies have shown patient-centered outcomes like treatment satisfaction and quality of life are more relevant to patients' perception than clinical changes in probing depths and clinical attachment levels.

Patients based outcomes provide an important opportunity to complement clinical data with the views of the patient. Together, they help in assessing physical, psychological, and social well being and not just the absence/ presence of disease, thereby allowing better clinical decision making and facilitate comparisons.

List of abbreviations

None

Ethical consideration

Written informed consent from all participants were taken.

Consent for publication

Written informed consent for publication of participants clinical images was obtained from all patients.

Availability of data and materials

The datasets used and /or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

No competing interests.

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