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RESEARCH ARTICLE

COMPARISON OF TWO NON-SURGICAL PERIODONTAL TECHNIQUES AND PROPOSAL OF NEW PATIENT REPORTED OUTCOME TOOL

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Abstract

Background: Non-surgical periodontal therapy determines the future course of periodontal disease progression and its management; hence, remains the corner-stone of periodontal therapy. Recent evidence suggests that patient-centered outcomes and patient satisfaction should be an integral part of treatment planning. However, limited evidence exists in the literature regarding patient-related outcome measures among chronic periodontitis patients treated with non-surgical periodontal therapy.

Material and Methods: 103 patients with chronic periodontitis were treated with non-surgical periodontal therapy. 54 were treated with full-mouth disinfection (test) and 49 were treated with scaling and root planing per quadrant (control). The primary outcome was measured using the Modified Dental Anxiety Score (MDAS) and Dental Fear Survey (DFS) while the plaque index, gingival index, periodontal pocket depth and clinical attachment loss were recorded as secondary outcomes.

Results: There was a significant improvement in clinical parameters in both the groups. All the participants in both the groups reported mild discomfort and pain with no significant difference between the groups.

Conclusions: Patient related outcomes are often neglected during NSPT and there are no specific tools to assess PROMs. The PROMs tool for NSPT assessment suggested in the study could fill in this knowledge gap.

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Introduction:-

Recently, the criteria for successful treatment have largely shifted from procedure centered to patient centered with an increased focus on placing patients at the core of the health care delivery.[1]A **patient-reported outcome** is a report of a patient's health condition directly from the patient, without interpretation by a clinician or anyone else.[1,2] It reflects the patient's perspective on their symptoms, overall mental state, or the effects of a disease or condition on their functioning. These measures come directly from the patient without added interpretation by healthcare

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workers.[2] Thus, the role of PROMs in determining the success of treatment is largely based on patient satisfaction with the overall treatment experience and not solely on clinical parameters.[1-3] As patient satisfaction is closely linked to improved health outcomes, treatment adherence and resource utilization by actively measuring and addressing patient satisfaction, healthcare providers can enhance the overall quality of care they deliver.[4]

The importance of PROMs is even more in procedures which involve instrumentation by the clinician either during surgical or non-surgical procedures.[5] Dental procedures especially periodontal procedures involve increased levels of fear and anxiety among the patients undergoing treatment due to various reasons associated with these procedures.[6-10]

As in medical field, efforts have been made in dentistry to record patient's responses to various dental procedures and emphasis is on assessing and addressing factors responsible for improved PROMs.[11-14] Previous work on PROMs is mainly relied upon predesigned questionnaires assessing patient's response to various clinical procedures.[15-18] Moreover, it is also evident that there is no specific questionnaire designed to assess PROMs associated with non-surgical periodontal therapy[19](NSPT), which in fact is the corner stone of periodontal disease management.[20] Conventional scaling and root planing is the most common form of NSPT which involves multiple patient visits and use of manual and ultrasonic instruments. Full mouth disinfection is also a form of NSPT prescribed by Quirynen [21] in order to reduce the number of visits while increasing the effectiveness of NSPT utilizing chemical plaque control agents.[22] Therefore, the purpose of this article was to assess and compare treatment outcomes of conventional scaling and root planing and full mouth disinfection with a special emphasis on PROMs. An attempt will also be made to assess the most commonly used questionnaires for recording PROMs in periodontal patients and propose a new tool specifically designed for periodontal patients to assess patient satisfaction with NSPT.

Focused question:
Does PROMs questionnaire well coordinates with NSPT also?

Material and Method:-

Study design and population

This randomized control trial was conducted in a tertiary care level educational institute from Sept 2022 till Oct 2023. The study protocol was approved by the Institutional Ethical Committee [No:(HFW[GDC]B [12]50/2015)3348] and the study was conducted in accordance with the Helsinki Declaration as revised in 2013. All patients were fully informed about the proposed study and duly signed the informed consent form.

Patients were selected based on specified inclusion and exclusion criteria mentioned below:

Inclusion criteria

1. Patients who consented to participate in study.
2. Patients more than 18 years of age.
3. Diagnosis of mild to moderate chronic periodontitis in at least 18 natural teeth.
4. Compliant patients willing to follow oral hygiene instructions.

Exclusion criteria

1. Patients not willing to participate in study.
2. Patients with history of sensitivity to chlorohexidine.
3. Patients currently undergoing periodontal therapy.
4. Patients who had undergone NSPT within 12 months.
5. Patients with uncontrolled diabetes mellitus.
6. Pregnant or lactating females.
7. Medically compromised patients.
8. Smokers.

Sample size

The sample size was calculated with a power of 80% and 5% significance level. A minimum of 49 patients per group was determined to detect a significant difference between the groups effect ranging from 12% to 18% (α = 95%). Considering 20% attrition 120 patients (60 each group) were finally enrolled for the study.

Study procedure

120 patients were randomly divided into test (FMD) and control (SRP) groups using closed envelope method.[23] Objective clinical parameters included plaque index (PI), gingival index (GI), periodontal pocket depth (PPD) and clinical attachment loss (CAL). The data was taken at baseline i.e. day 0 and at 3 months post operatively.

Patient satisfaction was measured utilizing certain subjective criteria based on the questionnaires i.e. modified dental anxiety scale (MDAS)[24] and dental fear survey (DFS).[25] The questionnaires were given to all the patients at baseline and at the end of the study. Visual Analog Scale (VAS)[26] was used to record the pain experienced by the patients immediately after the completion of the treatment. VAS was applied in a standard manner with an initial explanation to the patients, clarifying that 0 means no pain and discomfort, while 10 represents extremely intense pain and discomfort. Participants were encouraged to give their opinions and suggestions freely about their experience with the treatment process and how it can be improved.

Data Analysis

Statistical analysis was performed with the help of IBM SPSS[M] Statistics Software[¶]. Mean and standard deviation were calculated in both test and control groups for all the parameters. Intragroup and intergroup variation was calculated using 'paired t test' and 'unpaired t test' respectively, for parametric variables. All values of $p<0.05$ were considered as significant and <0.001 were considered highly significant. Pain and anxiety scores were also calculated for each patient and average scores for both test and control groups were calculated and compared.
(¶ IBM SPSSModeler 18.3,2015 by Norman H.Nie)

Results:-

At the end of the study a total of 103 patients completed the follow up and their data was finally included for statistical analysis. There was a significant improvement in clinical parameters in both the groups, however, inter group comparison revealed no clinical difference among the test and control groups patients (Table 1).

The mean fear and anxiety score increased significantly after the treatment among both the groups with no statistically significant difference among test and control groups when compared in terms of PROMs (Table 2). All the participants in both the groups reported mild discomfort and pain with no significant difference between the groups (Table 3).

Clinical Parameters	**Control group (SRP) N=54**			**Test group (FMD) N=49**			**p value[±] FMD vs SRP**
	Baseline	3 months	Mean difference	baseline	3 months	Mean difference	
PI	2.12 ± 0.22	1.49±0.52	0.63±0.46 (p=0.002)	2.16±0.33	1.72±0.47	0.43±0.48 (p=0.002)	0.54
GI	2.11 ± 0.30	1.60 ± 0.50	0.50 ± 0.45 (p=0.002)	2.20 ± 0.30	1.86 ± 0.37	0.34 ± 0.37 (p=0.002)	0.40
PPD	2.7 ± 0.44	2.07 ± 0.47	0.59 ± 0.45 (p=0.0047)	2.8 ± 0.54	0.5 ± 0.53	0.36 ± 0.34 (p=0.0014)	0.36
CAL	3.1 ± 0.57	2.54 ± 0.59	0.56 ± 0.47(**p=<0.00001**)	3.28 ± 0.73	2.85 ± 0.68	0.41 ± 0.54(**p=<0.00001**)	0.30

Table 1: Clinical parameters at baseline and at 3 months in test and control group

Clinical Parameters	**Control group (SRP)**			**Test group (FMD)**			**p value[±] FMD vs SRP**
	Baseline	3 months	Mean difference	Baseline	3 months	Mean difference	
Fear and Anxiety	2.0 ± 0.58	3.6 ± 0.52	**1.6 ± 0.43 (p=0.001)**	2.3 ± 0.77	3.8 ± 0.39	1.4 ± 0.5 **(p=0.001)**	0.5

Table 2: Fear and anxiety at baseline and after 3 months in test and control group

Clinical Parameters	Control group (SRP)	Test group (FMD)	p value ± FMD vs SRP
VAS	2.17±1.80	2.43±1.64	0.51

Table 3: VAS in test and control group ±p value = 0.05(significant); 0.001(highly significant)

Discussion:-

Despite of recent advancements in periodontal disease management, NSPT remains the foundation of periodontal therapy. A successful NSPT not only prevents the progression of periodontal disease but also benefits the patients by avoiding the need for surgery or any additional interventions. Traditionally, the success of NSPT is measured by using surrogate markers like PI, GI, PPD and CAL,[27] however, PROMs are reported to be more relevant to patient's daily lives than objective changes in clinical parameters.[1-3,28] Hence, the primary goal of this study was to assess PROMs mainly in terms of fear, anxiety and pain levels as recorded using MDAS, DFS and VAS questionnaires. MDAS and DFS though take into account the factors associated with fear and anxiety, these tools are not specifically designed to assess PROMs and patient satisfaction in patients treated with NSPT. Therefore, an attempt was also made to know about various patient centred criteria which might affect satisfaction of patients who undergo NSPT.

Majority of the participants completed the study and there were only 17 participants who missed the follow-up visits. The patient who dropped out from the study cited various reasons like personal problems (5), difficulty in travelling from their native places and multiple visits required to get the treatment. When the data for PROMs among the patients in the control and test group was analyzed, it was interesting to note that fear and anxiety levels increased among all the participants irrespective of the treatment rendered to them. A probable reason for this observation in the control group could be multiple appointments and scheduling required for the treatment and lack of actual treatment experience about the treatment procedure among the patients (as majority of our patients belonged to the category of first visitors).

By the end of the study many patients in the control group also reported that they would be less anxious and fearsome in case the number of appointments required for the treatment were somehow less or reduced, which corelates with previous studies[28,29]. Many of the treated patients in the control group also reported that they were anxious due to the large number of the instruments used for manual scaling and root planing. Visualizing instruments which are sharp like scaler, curettes, syringes and even cotton might have increased anxiousness and fear levels among the patients treated with scaling and root planing. Previous studies in the literature have also linked increased levels of anxiety and fear with visualization of instruments and equipment's used during the procedure by the operators.[30,31]

In the test group, patients were treated within two consecutive days using ultrasonic scaler. Visual impact of ultrasonic scaler, sound and vibrations that was produced during the procedure while using ultrasonic scaler in patients treated with FMD technique could have made a negative impact on patients fear and anxiety levels. The current evidence available in the scientific literature also supports the same.In the study done by Sebastetian and Mariana in 2019 to assess dental anxiety factors among dental patients, visual inputs (tip of the scaler and handpiece) and sound from high frequency vibrations (produced by ultrasonic scaler in our study) resulted in irritation and triggered sensory motors in such a fashion that increased the levels of anxiety and fear levels.[32] One of the side effects associated in the test group was the presence of post operative hypersensitivity after ultrasonic scaling.Studies have amply proven that scaling which was performed in single step using ultrasonic scaler lead to increase of dentinal hypersensitivity among the patients.[33-35] It is also a fact that unpleasant dental experiences result in increased anxiousness among the patients while anticipating future dental treatment.[36]

Some of the common factors which could have lead to poor patient satisfaction among the patients treated in both test and control groups were: atmosphere of the waiting room and presence of relatively young and female participants in majority in the current study.

Since the study was done in an educational institute which is also a public hospital with a large inflow of patients from across the state, the waiting area and treating areas are mostly occupied. Patients in the waiting area invariably

interact with each other and share their experiences. In addition, being an educational institution, various posters depicting several periodontal diseases and their treatment are displayed within the premises and waiting area. Furthermore, the treatment rendered was itself done in a common working area of the department and not in an isolated operatory. Direct visualization of photos and pictures of patients, actual patient's reactions and listening to the past experiences and traumatic stories from them about their past dental treatments can be directly transmitted and can become a source of learned fear.[37] Therefore, it is suggested to design the dental operatory and waiting area in such a fashion that it results in a calm and relaxing environment rather than acting as a trigger factor for anxiety.

Since majority of the patients in both the groups were young adults (mean age: 38.32±8.9) and previous studies suggest that older individuals are generally less fearful and anxious of getting dental treatment then their younger counter parts[38], this could be one of the reasons for increased anxiety levels among the participants in the current study. Similarly, majority of the participants in current study were females who are generally more prone to anxiety and dental phobia.[39,40] Their opinions on fear and anxiety scale could have dominated over their male counter parts and hence are reflected in the current study results.

There was a significant improvement in the scores of clinical parameters irrespective of the treatment rendered to the patients, pointing to an improvement in overall periodontal health after NSPT. This positive impact on the clinical parameters was also corelated well with the alleviation of symptoms such as 'swollen gums', 'sore gums', 'receding gums', 'bad breath'. The positive effect of SRP and FMD is well documented in several clinical trials and systematic reviews.[41-44]

In the current study pain response was assessed using a VAS which is considered to be the most reliable tool for assessing pain during treatment.[45]However, it is important to mention here that many patients were not able to distinguish between actual dental pain and discomfort due to dentinal hypersensitivity. Despite the fact that majority of the participants were females, who have generally low pain threshold, insignificant pain scores in the current study clearly indicated that both of the treatments were not associated with any significant pain. Moreover, our results are further justified as both SRP and FMD are non-invasive, non-surgical periodontal procedures which generally do not require any local anaesthesia and hence, painless.[46]

An additional important finding of this study was that the questionnaires used in this study although popular, are not specifically designed for periodontal patients and thus, failed to record factors which might have reduced patient's comfort and satisfaction during NSPT. Moreover, both these tools (i.e. MDAS and DFS) were proposed more than 2 decades ago and purely focus on fear and anxiety levels associated with the treatment ignoring various other important factors affecting patient satisfaction like the role of environment, clinical skills and behaviour of operator, time spent, number of visits required and post operative experience.[47,48] Although, there are tools available in the literature to assess fear, anxiety and satisfaction levels among patients undergoing surgical/dental surgical therapy there is lack of any specific tool to assess patient satisfaction among patients treated non-surgically.[49] Therefore, the study highlights that there is an urgent need to develop assessment tool which specifically addresses patient related factors associated with NSPT. The authors thus propose a PROMs assessment tool specifically designed for patients undergoing NSPT although this tool can also be utilized for other non-surgical periodontal /dental procedures. The tool takes into account various parameters related to various aspects of NSPT. Based on patients experience at various stages of NSPT the patient gives an objective score and rating namely: fully satisfied (score:3), satisfied (score:2) and unsatisfied (score :1). At the end of the treatment individual scores can be added to assess the success of NSPT based on PROMs (Table 4). The author suggests future research utilizing the suggested tool to assess its utility, reliability and validity.

Limitations:-

Since, the study was done in an institutional setup the variety of patients who participated in the study generally belong to the same socio-economic status which prevented gathering of more diverse data.

Conclusion:-

Hospital environment, design of the clinic, waiting area and number of visits have a clear-cut impact on patient's comfort and satisfaction. Despite being the mildest, non-invasive and painless form of periodontal therapy, NSPT may result in poor patient satisfaction if not planned by taking in to account patient centred criteria. Shohal's and

Mahajan's tool can fill in the existing gap in the literature by equipping the researcher with a PROM's assessment tool specifically focussed on patients treated non surgically.

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Conflicts Of Interest:
There are no conflicts of interest.

Aviability Of Data:
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Patient Centered Criteria	**Unsatisfied**[‡]	**Satisfied**[‡‡]	**Fully Satisfied**[‡‡‡]
Pre procedural stage:			
• Time spent and environment of waiting area			
• Clinical setup/ working area environment			
• Explanation of the procedure by the operator			
• Documentation			
Procedural stage:			
• Comfort with arrangement and display of instruments used in NSPT			
• Comfort with handling of tissues (retraction/intra oral/extra oral rests)			
• Use of hand instruments			
• Use of ultrasonic scaler			
• Use of antimicrobial mouth rinses			
• Noise and vibrations produced during NSPT			
• Duration			
Post procedural stage:			
• Understanding of post operative oral hygiene and toothbrushing instructions			
• Extent of post operative pain/discomfort/dentinal hypersensitivity			
• Use of medications (anti microbials /analgesics)			
• Number of follow up visits			
Overall satisfaction			
• Attending and listening to your periodontal problem			
• Confidence and clinical acumen of the operator			
• Empathetic, honest and respectful behavior by the operator			
• Delivering patient centered care			

Table no. 4: Shohal's and Mahajan's tool for PROM's

[‡‡‡]Fully Satisfied: Patient was well informed about the non-surgical periodontal therapy and treatment plan was designed keeping his/ her preferences. The treatment was delivered in a comfortable environment to minimize anxiety and improve patient compliance. Post operative phase was uneventful and patient was willing to follow the oral hygiene instructions given by the clinician. A score of 2 will be given.

[‡‡]Satisfied: Patient felt there were some gaps in terms of explaining, planning and delivering the treatment making the overall experience less satisfactory for the patient compared to a fully satisfied patient. Patient compliance for revisits is limited as there were some associated postoperative complications/side effects. A score of 1 will be given.

[‡]Unsatisfied: Patient's experience with the periodontal treatment was poor due to major gaps in explaining, planning and delivering the treatment resulting in increased postoperative complications, usage of medications and poor patient compliance, patient unwilling to continue the treatment in future. A score of 0 will be given.