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Patients' perceptions of antimicrobial photodynamic therapy in the management of chronic periodontitis

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ABSTRACT

The aim of this study is to evaluate patients' perception of antimicrobial photodynamic therapy (aPDT) in the management of chronic periodontitis. 90 patients (51 females and 39 males) with untreated localized chronic periodontitis were randomly assigned to receive SRP with aPDT (test group) or SRP alone (control group) in a single-centered double-blinded randomized and controlled clinical trial. Patients' perception in terms of changes in bleeding gums, pain in gums while chewing, bad breath and sensitive gums along with pain during the procedure and patient acceptance were recorded for 6 months after treatment by a periodontist who was blinded to the procedure. Inter-group and intra-group statistical analyses were performed. Significant difference between the frequencies of two groups with respect to each variable was assessed using non-parametric test. Patients' report of bleeding gums and pain in the gums while chewing showed statistically significant reduction in the test group at 2 weeks and 1 month ($p < 0.05$). Also, a significant difference was detected at 1 month between SRP and SRP + aPDT in terms of halitosis ($p < 0.05$). No statistically significant change was observed between two groups in terms of sensitive gums, pain during procedure and patient acceptance. Patients perceived short-term benefits of single session of aPDT therapy due to the reduction in bleeding gums, halitosis and pain while chewing following treatment. Further studies are required to assess the effectiveness of aPDT for a longer-term and following multiple sessions.

1. Introduction

Interest in the outcome of oral health problems has been the subject of significant research activity over the past few decades following a paradigm shift within health care to 'patient-centered' care [18]. Traditionally, clinical findings combined with various indices have been used to describe the magnitude of improvement after treatment of periodontal diseases. It was shown that these measures of health outcomes do not capture the full impact of treatment on health status [14,15]. So, over the past few years, patient-based outcomes (PBOs) or "true endpoints" have been recognized as subjective measures which capture patients' perspectives of disease or therapy and complement conventional clinical (surrogate) measures [11,26]. Patient's perception of their treatment experience is now becoming the yardstick that will also help determine the services we provide. At the 2003 World Workshop on Emerging Science in Periodontology, patient-based outcomes were identified as a research priority [25]. This concept is gaining a widespread agreement as there is a need to include patient-reported assessments of oral health status and the effect of treatment in dental research and practice [1]. In a systematic review of aPDT in periodontitis [3], has recommended that patient perspectives including patient acceptance, discomfort, and pain (or lack thereof), halitosis etc should be analyzed in future studies.

The umbrella term patient reported outcomes (PRO) proposed by Food and Drug Administration (FDA) is 'a measurement of any aspect of a patient's health status that comes directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)' [27]. Studies report that enhanced treatment adherence and outcomes can be obtained by giving attention to patient feedback on healthcare outcomes and patient behavior change. Patient based outcome is important also because patient's perspective of their oral health and related quality of life

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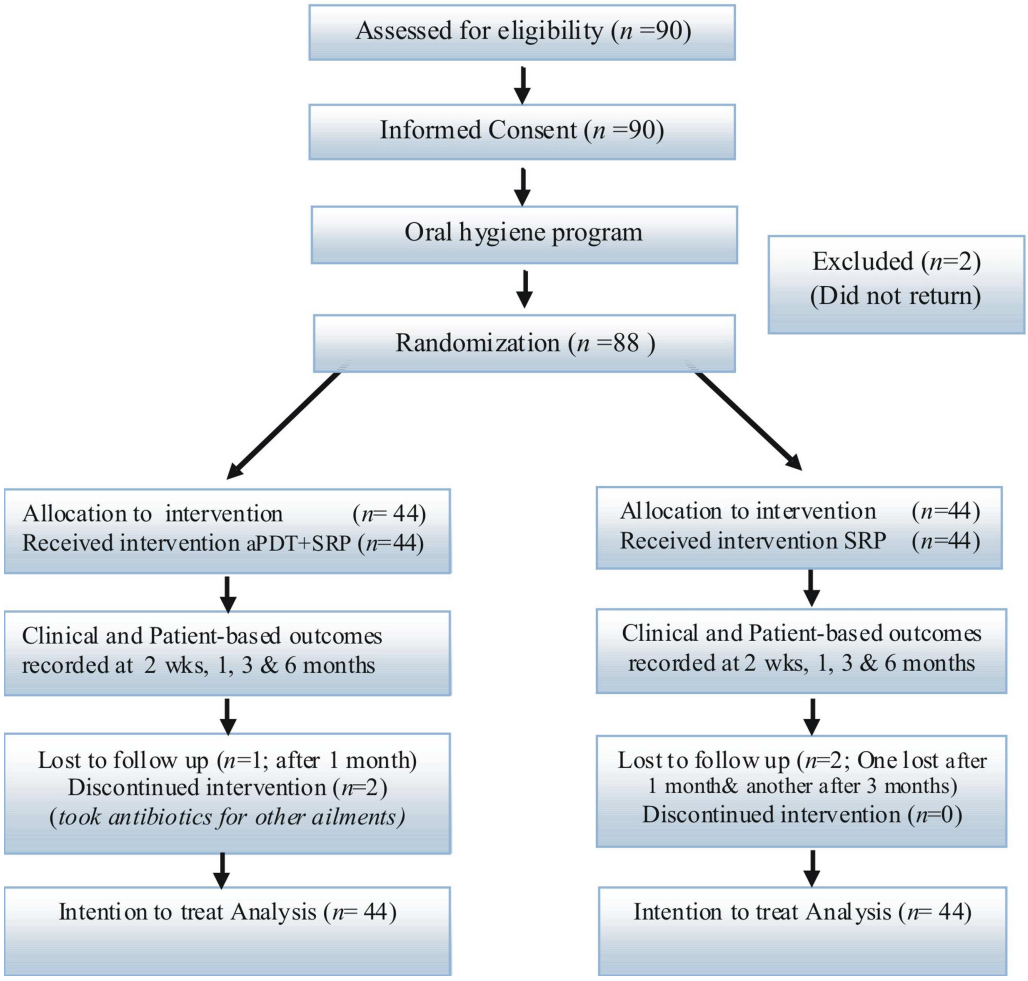

Fig. 1. CONSORT statement.

markedly differs from that of health care professionals who rely on traditional clinical endpoints [21]. On the other hand, clinicians can use this information from patient-based measures of health and disease for overall assessment of the patient and that its feedback to clinicians can increase the possibility detection of related psychological and functional problems [9].

The use of PROs in clinical practice is being investigated in a variety of disease areas, with oncology being one of the most common in recent years. In the case of dental diseases also, associated symptoms (impairments) and activity limitations (disabilities) have been reported. Periodontal disease is known to negatively affect oral health-related quality of life (OHRQoL) [22,21]) while its management had a small positive impact on pain [2]. Patients' perception of disease and its improvement is increasingly being recognized to play a vital role in the long term success of the treatment. It is still inconclusive whether it can have an impact on the assessment of management, patient outcome, or improve health related quality of life and patient satisfaction [9] although generally, clinicians have found PRO data useful and not disruptive to their practices.

Therefore, it appears logical that patients' perception should also be taken into account while evaluating treatment results especially chronic illnesses like periodontitis. Moreover, PROs are reported to be more relevant to patient's daily lives than objective changes in PPD or CAL [15,20,21]. However, most widely studied patient outcome in Periodontology appears to be pain perception and anxiety among patients [10]. There is only little evidence how patients perceive other aspects of periodontal treatment procedures like aPDT [7,6,12], though there is a large body of evidence regarding the clinical and antimicrobial effects of aPDT in non-surgical treatment of chronic periodontitis [24] Campos et al., 2013; [16,23,4]. Therefore, the aim of this paper is to evaluate the patient based outcome measures during aPDT and its safety in the management of chronic periodontitis and up to a period of 6 months after the treatment.

2. Materials and method

2.1. Subjects

Ninety patients (51 females and 39 males) diagnosed with chronic periodontitis were enrolled in this study conducted over a period of 1 year (June 2011–June 2012) at the outpatient unit of Department of Periodontics, Government Dental College (GDC), Thiruvananthapuram, Kerala, India. The mean age of study population was 39.6 ± 8.7 years. The study was in accordance with the Declaration of Helsinki (as amended in Edinburgh, 2000) and was approved by the Institutional Ethics Committee (IEC) of GDC, vide IEC no. IEC/C/42-A/2011/DCT/dated 18-01-2011. The clinical trial was registered at the Clinical Trial Registry of India (CTRI) vide registration no. REFCTRI2010006105. All subjects were explained about the study protocol and their informed consent was obtained prior to the initiation of the study. The study was conducted at Department of Periodontics of GDC with the PDT unit developed at the Biophotonics Laboratory of the Center for Earth Science Studies.

2.2. Treatment protocol (interventions)

All the 88 subjects were randomized into control group (SRP) and test group (SRP + aPDT) treated by an experienced periodontist and clinical outcomes were measured by another periodontist who was blinded to patient selection and aPDT procedures as per the consort flowchart (Fig. 1). The control group (Group 1) was administered SRP by hand scalers and universal curettes (Hu-Friedy) and ultrasonic scaler (Woodpecker). No other treatment was given to this group. Full-mouth supragingival and subgingival scaling was performed at all sites within 24 h including the evaluated sites until the operator felt that tooth and root surfaces were adequately debrided and planed. This group included 44 subjects (29 women and 15 men; mean age: 38.4 ± 9.6 years). The test group (Group 2) included 44 subjects (22 women and 22 men; mean age: 40.8 ± 8.3 years) and was managed by aPDT in addition to SRP. Methylene blue (MB) was the photosensitizer used which was freshly prepared by suspending MB crystals [methylene blue (MB) M9140; Sigma–Aldrich, St. Louis, MO, USA] in double distilled water at a concentration of 10 mg/ml. PDT was carried out using a diode laser (655 nm, 1 W, CW, CNI Opto-electronics Tech. Co., Ltd, China) for 60s at an intensity of 60 mW/cm^2, at each sites. The intensity of the laser output was measured with power meter (Ophir, Israel, Model: PD-300—30 W). The selected teeth had 4–6 mm pockets at mesiobuccal, distobuccal, mesiolingual or distolingual sites. 2 ml of MB was applied topically to these sites with 4–6 mm pocket depth for 60 s using a syringe. The laser beam was guided through a flexible fiber-optic cable (200 μm dia.) terminated with a custom-designed stainless steel (SS) hand piece. The outer diameter of the SS probe tip was 0.5 mm, which facilitated easy access inside periodontal pockets. After 3 min., the site was irrigated with distilled water to flush out excess MB as it can act as an optical shield during laser irradiation. Single session of aPDT along with SRP was performed in each patient, within 24 h. During aPDT, both clinicians and patients were provided with the appropriate safety eyewear. Clinical outcome was measured at 2 weeks, 1 month, 3 months and 6 months after treatment. To ensure a sufficient level of plaque control, all subjects were initially enrolled in an oral hygiene program and were given oral hygiene instructions that included twice daily brushing before they returned for treatment after 1 week.

2.3. Sample size calculation

The sample size of 90 was determined based on probing depth (PD) as the primary outcome measure assuming normality. Assuming that the common standard deviation is 0.6 mm, a sample size of 37 per group would provide 80% power to detect a moderate difference between the before- and after-treatment groups with an effect size of 0.5. 20% was added to compensate for loss during follow up.

2.4. Patient based outcome measures

In this paper the patient based outcome measures are being reported (Clinical parameters & halitosis were reported earlier). Toward this, patients' chief complaints and associated changes following aPDT were recorded and followed up till 6 months along with the clinical and microbiological parameters. The responses were collected in an interview manner and marked in the questionnaire. Changes in patients' chief complaints after treatment at specific point of time were recorded. The chief complaints included bleeding gums, pain in gums while chewing, halitosis and sensitive/itchiness of gums. Pain during procedure and patient acceptance was also recorded. Table 1 lists the socio-demographic characteristics of the patients enrolled for the trial at baseline while Table 2 shows the characteristics of patient- based outcome measures of these patients at baseline.

Table 1
Socio-demographic characteristics of patients at baseline in test and control group.

Variable	Category	aPDT + SRP	SRP	*p*-Value
Gender	Male	22(50.0%)	15(34.1%)	0.101$^{ns, \$}$
	Female	22(50.0%)	29(65.9%)	
Occupation	Agriculture/laborers	30(68.2%)	31(70.5%)	0.113$^{ns, \$}$
	Private employees	9(20.4%)	10(22.7%)	
	Government employees	5(11.4%)	3(6.8%)	
Education	Middle school	17(38.6%)	18(40.9%)	0.176$^{ns, \$}$
	High school	13(29.6%)	16(36.4%)	
	College	14(31.8)	10(22.7%)	
Income	Rs. 2000–6000	16(36.4%)	19(43.2%)	0.881$^{ns, \$}$
	Rs. 6000–10000	20(45.4%)	17(38.6%)	
	Rs. 10000 and above	8(18.2%)	8(18.2%)	
SES	Average	28(63.6%)	30(68.2%)	0.464$^{ns, \$}$
	High	16(33.4%)	14(31.8%)	
Age	Mean	40.8	38.4	0.180$^{ns, \#}$
	SD	8.3	9.6	

ns: not significant.
$ Chi-square test.
# Mann–Whitney test.

Patients' perception of bleeding gums and sensitive gums present before treatment and upto 6 months after it was recorded using a Likert scale. The scores were initially recorded from 1–5 that categorized patient response as strongly disagree for 1, disagree for 2, neither agree nor disagree for 3, agree for 4 and strongly agree for 5. However, score 1 and 5 were not included in this study as our patients in the pilot study were unable to differentiate between 1 and 2 and also between 4 and 5. Nevertheless, the chosen 3 point scale is balanced on both sides of a neutral option as it presents symmetry of categories about a midpoint.

Patients' experience of pain felt in the gums while chewing before treatment and upto 6 months after treatment was recorded using the Verbal rating scale (VRS). Here, pain is depicted as a five-point scale: no, mild, moderate, severe and very severe pain. Perceptions of pain experienced during and after procedure were also similarly recorded at each given time. VRS was used in this study because during the pilot study many patients were not able to identify their intensity of pain on the horizontal line of VAS scale. Pain felt during treatment in both groups were recorded similarly.

Halitosis as a perceived by the patient based on self-assessment by the patient's hand on mouth technique was recorded at baseline, 2 weeks,1 month, 3 months and 6 months of treatment using Likert scale of 1–5 that categorizes patient response as strongly disagree for 1, disagree for 2, neither agree nor disagree for 3, agree for 4 and strongly agree for 5. Score 0 and 5 were not included in this study as our patients in the pilot study were unable to differentiate between 0 and 1 and also between 4 and 5.Patient acceptance at the end of the treatment were also recorded similarly.

The questions were written in English and then translated into the local language (Malayalam) using a backward-forward translation method by two bilingual translators [17] which was pilot tested on a group of 10 subjects. Reproducibility of the questionnaire was tested on five patients with chronic periodontitis (probing depths 4–6 mm), not related to the study. They answered the questionnaire on two separate occasions, 5 min apart. Reproducibility was accepted if their answers at both occasions were the same in more than 90% of the cases. Internal consistency and reliability were tested using Cronbach's alpha. The calculated alpha value was 0.85 indicating that the questionnaire is highly reliable in measuring the study variables.

Table 2
Characteristics of patient-based parameters at baseline in test and control group.

Variable	Category	SRP + aPDT	SRP	*p*-Value
Do you have 'bleeding gums'	Disagree	9(20.5%)	17(38.6%)	0.47[ns, #]
	Neither agree nor disagree	20(45.5%)	10(22.7%)	
	Agree	15(34.1%)	17(38.6%)	
Do you have 'bad breath'	Disagree	11(25.0%)	8(18.2%)	0.21[ns, #]
	Neither agree nor disagree	15(34.1%)	12(27.3%)	
	Agree	18(40.9%)	24(54.5%)	
Do you feel 'pain inside gums'	No pain	9(20.5%)	10(22.7%)	0.62[ns, #]
	Mild pain	22(50.0%)	18(40.9%)	
	Moderate pain	12(27.3%)	12(27.3%)	
	Severe pain	1(2.3%)	4(9.1%)	
	Very severe pain	0	0	
Do you have 'sensitivity'	Disagree	9(20.5%)	25(56.8%)	0.74[ns, #]
	Neither agree nor disagree	20(45.5%)	8(18.2%)	
	Agree	15(34.1%)	11(25.0%)	

ns: not significant.
[#] Mann–Whitney test.

2.5. Data management and statistical analyses

Prior to the statistical analyses, data were entered into a spreadsheet and proofed for data-entry errors. Analyses were performed by a statistician who was masked, without the knowledge of treatment group assignment.

Statistical analysis was done for each of the parameters using SPSS software (ver. 16). Patient responses being qualitative data, the frequency of response were calculated in both test and control group. Since the data distribution in the present study did not obey the Gaussian Law by Kolmogorov–Smirnov test ($p < 0.05$), non-parametric methods were used for analyzing the data. Significant difference between the test and control groups was assessed using Mann–Whitney-*U* test. Likewise, Wilcoxon's Signed Rank Test was used for finding significant changes from baseline to various intervals within the test and control group. *P*-value less than 0.05 were considered statistically significant. The data are expressed as frequency distribution and percentage because interpretation of qualitative data such as patient responses is more meaningful when expressed in terms of frequency.

3. Result

Patient based outcome measures of 88 patients following SRP with or without aPDT is reported here. Although, 90 patients were enrolled in the oral care program, 2 did not return for randomization. In the test group, one patient was lost to follow up, one did not respond to aPDT treatment and two patients reported to have taken antibiotics for other ailments while two patients were lost to follow up and 2 did not respond to treatment in the control group.

The test and control groups did not show any statistically significant differences with respect to socioeconomic status ($p > 0.05$) (Table 1). Similarly, no significant differences were found between the test and control group of patients with regard to the baseline values of patient based outcome measures ($p > 0.05$) as shown in Table 2. As compared to control group, patients report of bleeding gums showed statistically significant reduction in the test group at 2 weeks and 1 month ($p < 0.05$) and is given in Table 3 whereas no significant difference was seen between test and control group in term of sensitive/itchiness of gums at any given point of time (Table 4). Table 5 shows the statistically significant reduction in pain while chewing was noticed after 2 weeks and 1 month of treatment while Table 6 shows a significant difference was detected at 1 month between SRP and SRP + aPDT in terms of halitosis ($p < 0.05$). No statistically significant change was observed in terms of pain during procedure and patient acceptance as seen in Table 7.

Table 3
Comparison of patient's perception of bleeding gums in test and control groups at baseline, 2 weeks, 1 month, 3 months and 6 months after treatment.

Duration	Do you have bleeding gums?	SRP + aPDT	SRP	*p*-Value
Baseline	Disagree	9(20.5%)	17(38.6%)	0.47[ns, #]
	Neither agree nor disagree	20(45.5%)	10(22.7%)	
	Agree	15(34.1%)	17(38.6%)	
2 weeks	Disagree	32(72.7%)	29(65.9%)	0.04[*, #]
	Neither agree nor disagree	9(20.5%)	8(18.2%)	
	Agree	3(6.8%)	7(15.9%)	
	p-Value[‡]	<0.01[**]	<0.01[**]	
1 month	Disagree	35(79.5%)	31(70.5%)	0.05[*, #]
	Neither agree nor disagree	7(15.9%)	6(13.6%)	
	Agree	2(4.5%)	7(15.9%)	
	p-Value[‡]	<0.01[**]	<0.01[**]	
3 months	Disagree	35(79.5%)	36(81.8%)	0.94[ns, #]
	Neither agree nor disagree	7(15.9%)	4(9.1%)	
	Agree	2(4.5%)	4(9.1%)	
	p-Value[‡]	<0.01[**]	<0.01[**]	
6 months	Disagree	32(72.7%)	29(65.9%)	0.41[ns, #]
	Neither agree nor disagree	9(20.5%)	9(20.5%)	
	Agree	3(6.8%)	6(13.6%)	
	p-Value[‡]	<0.01[**]	<0.01[**]	

ns: not significant.
[*] $p < 0.05$.
[**] $p < 0.01$.
[#] Mann–Whitney-*U* test.
[‡] Wilcoxon's signed rank test.

4. Discussion

We believe this study is one of the first to report in detail the patient- based outcomes measures with respect to aPDT in chronic periodontitis. These approaches, along with clinical outcomes are critically important and necessary to determine the efficacy and safety of aPDT. Although a couple of studies [7,6,12] reported level of pain in aPDT patients, here a broader perspective of patient's perception of this treatment is discussed. aPDT is a relatively newer treatment modality in the management of periodontitis. The observed changes in terms of PPD of this study showed significant difference in the test group at 3 months while gingival inflammation and bleeding in probing showed improvement as early as 2 weeks [4]. Within the limitations of this study, few important conclusions related to the patients' perception can be drawn.

In this study, experience of pain was evaluated at three occasions. Usually, Visual analog scale (VAS) consisting of a vertical or

Table 4
Comparison of patient's perception of sensitive/itchiness of gums in test and control groups at baseline, 2 weeks, 1 month, 3 months and 6 months after treatment.

Duration	Do you have sensitivity/itchiness of gums?	SRP + aPDT	SRP	*p*-Value
Baseline	Disagree	9(20.5%)	25(56.8%)	0.74[ns, #]
	Neither agree nor disagree	20(45.5%)	8(18.2%)	
	Agree	15(34.1%)	11(25.0%)	
2 weeks	Disagree	26(59.1%)	26(59.1%)	0.86[ns, #]
	Neither agree nor disagree	10(22.7%)	12(27.3%)	
	Agree	8(18.2%)	6(13.6%)	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	
1 month	Disagree	33(75.0%)	31(70.5%)	0.24[ns, #]
	Neither agree nor disagree	9(20.5%)	10(22.7%)	
	Agree	2(4.5%)	3(6.8%)	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	
3 months	Disagree	32(72.7%)	32(72.7%)	0.89[ns, #]
	Neither agree nor disagree	9(20.5%)	11(25.0%)	
	Agree	3(6.8%)	1(2.3%)	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	
6 months	Disagree	35(79.5%)	37(84.1%)	
	Neither agree nor disagree	8(18.2%)	6(13.6%)	0.59[ns, #]
	Agree	1(2.3%)	1(2.3%)	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	

ns: not significant.
** $p < 0.01$.
# Mann–Whitney-*U* test.
‡ Wilcoxon's signed rank test.

Table 5
Comparison of patient's perception of pain in the gums while chewing in test and control groups at baseline, 2 weeks, 1 month, 3 months and 6 months after treatment.

Duration	Do your gums pain while chewing?	SRP + aPDT	SRP	*p*-Value
Baseline	No pain	9(20.5%)	14(31.8%)	0.62[ns, #]
	Mild pain	22(50.0%)	18(40.9%)	
	Moderate pain	12(27.3%)	12(27.3%)	
	Severe pain	1(2.3%)	0	
	Very severe pain	0	0	
2 weeks	No pain	24(54.5%)	17(38.6%)	0.03[*, #]
	Mild pain	20(45.5%)	20(45.5%)	
	Moderate pain	0	7(15.9%)	
	Severe pain	0	0	
	Very severe pain	0	0	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	
1 month	No pain	35(79.5%)	26(59.1%)	0.04[*, #]
	Mild pain	8(18.2%)	18(40.9%)	
	Moderate pain	1(2.3%)	0	
	Severe pain	0	0	
	Very severe pain	0	0	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	
3 months	No pain	36(81.8%)	35(79.5%)	0.79[ns, #]
	Mild pain	7(15.9%)	8(18.2%)	
	Moderate pain	1(2.3%)	1(2.3%)	
	Severe pain	0	0	
	Very severe pain	0	0	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	
6 months	No pain	35(79.5%)	33(75.0%)	0.59[ns, #]
	Mild pain	7(15.9%)	8(18.2%)	
	Moderate pain	2(4.5%)	3(6.8%)	
	Severe pain	0	0	
	Very severe pain	0	0	
	p-Value[‡]	$p < 0.01^{**}$	$p < 0.01^{**}$	

ns: not significant.
* $p < 0.05$.
** $p < 0.01$.
# Mann–Whitney-*U* test.
‡ Wilcoxon's signed rank test.

Table 6
Comparison of patient's perception of bad-breath in test and control groups at baseline, 2 weeks,1 month, 3 months and 6 months after treatment.

Duration	Do you have bad-breath?	SRP + aPDT	SRP	*p*-Value
Baseline	Disagree	11(25.0%)	8(18.2%)	0.21[ns, #]
	Neither agree nor disagree	15(34.1%)	12(27.3%)	
	Agree	18(40.9%)	24(54.5%)	
2 weeks	Disagree	13(29.5%)	9(20.5%)	0.32[ns, #]
	Neither agree nor disagree	15(34.0%)	14(31.8%)	
	Agree	16(36.4%)	21(47.7%)	
	p-Value[‡]	<0.01**	<0.01**	
1 month	Disagree	19(43.2%)	12(27.3%)	0.06[*, #]
	Neither agree nor disagree	18(40.9%)	19(43.2%)	
	Agree	7(15.9%)	13(29.5%)	
	p-Value[‡]	<0.01**	<0.01**	
3 months	Disagree	22(50.0%)	29(65.9%)	0.15[ns, #]
	Neither agree nor disagree	18(40.9%)	12(27.3%)	
	Agree	4(9.1%)	3(6.8%)	
	p-Value[‡]	<0.01**	<0.01**	
6 months	Disagree	20(45.5%)	23(52.3%)	0.59[ns, #]
	Neither agree nor disagree	19(43.2%)	15(34.1%)	
	Agree	5(11.4%)	6(13.6%)	
	p-Value[‡]	<0.01**	<0.01**	

ns: not significant.
* $p < 0.05$.
** $p < 0.01$.
# Mann–Whitney-*U* test.
‡ Wilcoxon's signed rank test.

horizontal line, 10 cm in length, with words that convey "no pain" at one end and "worst pain" at the opposite end is usually used to record the pain patients' experiences. However, VRS was used in this study because during the pilot study many patients were not able to identify their intensity of pain on the horizontal line of VAS scale. Similar problem was faced by a study done by Hamdan et al. where subjects failed to understand its purpose and variation in reproducibility were found along the length of the line.

Our previous paper reported changes in halitosis as perceived by the patient following aPDT in periodontitis. Although organoleptic measurement is the most commonly used method for assessing halitosis, we have used hand on mouth method. Following treatment, halitosis scores showed statistically significant change after one month in the test group ($p < 0.05$). This could be related to the significant reduction in the total bacterial load achieved by aPDT after 1 month of treatment in this group of patients (our unpublished data). However, this result did not continue further. Probably, repeated application of aPDT could have resulted in improved control of halitosis.

An interesting finding was that clinically, significant reduction in BOP was noticed after 2 weeks of treatment and it correlates with the patients' perception of reduction in bleeding gums after 2 weeks and 1 month. This is truly a clinical significance where the tangible effects aPDT correlates well with the clinical effects.

Patient acceptance of aPDT with SRP was found to be marginally higher than SRP alone. The relative lower pain score and significant reduction in bleeding and painful gums after aPDT could be probable reasons for slightly increased patient acceptance in test group. The observed benefits in these patients due to the use of an additional treatment can not be ruled out. A recent systematic review reports that patient based outcome measures could be associated with improved symptom control, increased supportive care measures, and patient satisfaction [13]. These parameters can also enable comparisons of providers' performances to stimulate improvements in services.

Few earlier studies on perception of pain related to aPDT in periodontitis was reported on VAS scale [7,6,12]. However, we found that verbal descriptions helped patients respond better. None of the

Table 7
Comparison of patient's perception of pain during treatment and patient acceptance at the end of treatment in test and control groups.

Parameters	Grading	SRP + aPDT	SRP	*p*-Value
Did you feel pain during the treatment?	No pain	11(25.0%)	7(15.9%)	0.39[ns, #]
	Mild pain	21(47.7%)	16(36.3%)	
	Moderate pain	10(22.7%)	17(38.6%)	
	Severe pain	2(4.5%)	4(9%)	
	Very severe pain	0	0	
Do you accept this treatment?	Disagree	0	2(5.0)	0.36[ns, #]
	Neither agree nor disagree	9(22.5)	10(25.0)	
	Agree	31(77.5)	28(70.0)	

ns: not significant.
[#] Mann–Whitney-*U* test.

patients reported pain or discomfort during the procedure of aPDT. In both groups the pain score given by patients were due to the mild discomfort of mechanical debridement which was told to us by the patients. In the study by [12], there were no differences in VAS score between protocols for any parameter described. SRP treated sites required significantly more anesthesia than those treated with the other therapies. None of our patients described any such toward incidence. The approach of understanding the pain and discomfort experienced by patients during and after any therapy is vital so that it may be eliminated in future treatment procedures if any. In this study, during the revaluation of pain and discomfort upto 6 months after aPDT, no one reported of pain which they associated to this procedure. Few patients who had some mild discomfort considered it to be associated the disease which decreased with time. Thus our study provides a broader perspective of effect of aPDT as perceived by patients.

Although various questionnaires have been reportedly used elsewhere to evaluate patient based outcome, we have used rating scales to assess patients' experience of aPDT due to lack of any validated questionnaire for our local population. Also, single question about the extent of any change in their health resulting from treatment (so called single transitional items) and also questions about any adverse consequences (complications) as followed in this study is also an accepted method instead of multi-item questionnaire [5].

Apart from the benefits of evaluating treatment results from patient's view-point, patient-centered reports of periodontitis have been used by the Centers for Disease Control and Prevention (CDC), in collaboration with the American Academy of Periodontology (AAP), for assessing the use of alternative non-clinical measures for the population-based surveillance of periodontal disease through a model-based approach [8].

4.1. *Strengths and limitations of the study*

This paper is the first of its kind to report a broad perspective of patients' perception about aPDT in chronic periodontitis patients for a period of 6 months. No matter how the clinician perceives the disease and its treatment, understanding the patients' perspective plays an important role in long term results and better patient compliance. A limitation of this study is that would have been more appropriate but due to lack of a validated questionnaire, we chose to report the most significant patient based outcome measures. The results of this paper should be carefully interpreted based on the specific characteristics of the targeted population such as the literacy, reading level (are Qs worded at an appropriate level of complexity, so that they can be understood by all patients) and validation in local language [19]. Period of recall may also have an impact in collecting accurate patient responses. Shorter recall periods more accurately capture patient's actual experiences. In this study, recall periods got longer toward the later part.

4.2. ***Interpretations*** *and implications of patient b****ased outcome measures in clinical trial***

Patient based measures of health need to be are implemented in routine practice as they may have an impact on the treatment effectiveness. It is recommended that implementation of strategies that are guided by theories of individual and organizational change might allow the barriers to using patient-based measures of health in routine practice to be identified and overcome more effectively [9]. This approach may be used to promote patient centered care by improving communication, enabling patients to become more involved in managing their health and potentially leading to better patient treatment adherence. Not only do patient centered outcome measures help clinician, it also serves as a benchmark for what the public expects to see from their health services.

5. Conclusion

Patients perceived short-term benefits of single session of aPDT therapy due to the reduction in bleeding gums, halitosis and pain while chewing following treatment. Further studies are required to assess the effectiveness of aPDT for a longer-term and following multiple sessions.

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References

[1] P.F. Allen, Assessment of oral health related quality of life, Health Qual. Life Outcomes 1 (1) (2003) 40.
[2] M. Åslund, J. Suvan, D.R. Moles, F. D'Aiuto, M.S. Tonetti, Effects of two different methods of non-surgical periodontal therapy on patient perception of pain and quality of life: a randomized controlled clinical trial, J. Periodontol. 79 (6) (2008) 1031–1040.
[3] A. Azarpazhooh, P.S. Shah, H.C. Tenenbaum, M.B. Goldberg, The effect of photodynamic therapy for periodontitis: a systematic review and meta-analysis, J. Periodontol. 81 (1) (2010) 4–14.
[4] J. Betsy, C.S. Prasanth, K.V. Baiju, J. Prasanthila, N. Subhash, Efficacy of antimicrobial photodynamic therapy in the management of chronic periodontitis: a randomized controlled clinical trial, J. Clin. Periodontol. 41 (6) (2014) 573–581.
[5] N. Black, Patient reported outcome measures could help transform healthcare, Br. Med. J. (Clin. Res. Ed.) 346 (2013) f167.
[6] V.S.M. Campanile, C. Giannopoulou, G. Campanile, J.A. Cancela, A. Mombelli, Single or repeated antimicrobial photodynamic therapy as adjunct to ultrasonic debridement in residual periodontal pockets: clinical, microbiological, and local biological effects, Lasers Med. Sci. (2013) 1–8.
[7] I. Cappuyns, N. Cionca, P. Wick, C. Giannopoulou, A. Mombelli, Treatment of residual pockets with photodynamic therapy, diode laser, or deep scaling. A

randomized, split-mouth controlled clinical trial, Lasers Med. Sci. 27 (5) (2012) 979–986.
[8] P.I. Eke, R.J. Genco, CDC periodontal disease surveillance project: background, objectives, and progress report, J. Periodontol. 78 (7S) (2007) 1366–1371.
[9] J. Greenhalgh, K. Meadows, The effectiveness of the use of patient-based measures of health in routine practice in improving the process and outcomes of patient care: a literature review, J. Eval. Clin. Pract. 5 (4) (1999) 401–416.
[10] E. Guzeldemir, H.U. Toygar, U. Cilasun, Pain perception and anxiety during scaling in periodontally healthy subjects, J. Periodontol. 79 (12) (2008) 2247–2255.
[11] P.P. Hujoel, Endpoints in periodontal trials: the need for an evidence-based research approach, Periodontology 2000 36 (1) (2004) 196–204.
[12] M.F. Kolbe, F.V. Ribeiro, V.H. Luchesi, R.C. Casarin, E.A. Sallum, F.H. Nociti Jr., M.Z. Casati, Photodynamic therapy during supportive periodontal care: clinical, microbiological, immunoinflammatory, and patient-centered performance in a split-mouth RCT, J. Periodontol. (2014) 1–15.
[13] G. Kotronoulas, N. Kearney, R. Maguire, A. Harrow, D. Di Domenico, S. Croy, S. MacGillivray, What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A Systematic review of controlled trials, J. Clin. Oncol. (April) (2014), http://dx.doi.org/10.1200/JCO.2013.53.5948.
[14] C. Laine, F. Davidoff, Patient-centered medicine: a professional evolution, J. Am. Med. Assoc. 275 (1996) 152–156.
[15] D. Locker, F. Allen, What do measures of 'oral health-related quality of life'measure? Community Dent. Oral Epidemiol. 35 (6) (2007) 401–411.
[16] V.H. Luchesi, S.P. Pimentel, M.F. Kolbe, F.V. Ribeiro, R.C. Casarin, F.H. Nociti, M.Z. Casati, Photodynamic therapy in the treatment of class II furcation: a randomized controlled clinical trial, J. Clin. Periodontol. 40 (8) (2013) 781–788.
[17] W. Maneesriwongul, J.K. Dixon, Instrument translation process: a methods review, J. Adv. Nurs. 48 (2) (2004) 175–186.
[18] S. Marshall, K. Haywood, R. Fitzpatrick, Impact of patient-reported outcome measures on routine practice: a structured review, J. Eval. Clin. Pract. 12 (5) (2006) 559–568.
[19] S.D. Mathias, D.O. Castell, E.P. Elkin, M.L. Matosian, Health-related quality of life of patients with acute erosive reflux esophagitis, Dig. Dis. Sci. 41 (11) (1996) 2123–2129.
[20] M. Naito, H. Yuasa, Y. Nomura, T. Nakayama, N. Hamajima, N. Hanada, Oral health status and health-related quality of life: a systematic review, J. Oral Sci. 48 (1) (2006) 1–7.
[21] S.K. Ng, W.K. Leung, A community study on the relationship of dental anxiety with oral health status and oral health-related quality of life, Community Dent. Oral Epidemiol. 36 (4) (2008) 347–356.
[22] R.R. Patel, P.S. Richards, M.R. Inglehart, Periodontal health, quality of life, and smiling patterns-an exploration, J. Periodontol. 79 (2) (2008) 224–231.
[23] F. Sgolastra, A. Petrucci, R. Gatto, G. Marzo, A. Monaco, Photodynamic therapy in the treatment of chronic periodontitis: a systematic review and meta-analysis, Lasers Med. Sci. 28 (2) (2013) 669–682.
[24] L.H. Theodoro, S.P. Silva, J.R. Pires, G.H.G. Soares, A.E.F. Pontes, E.P. Zuza, V.G. Garcia, Clinical and microbiological effects of photodynamic therapy associated with nonsurgical periodontal treatment. A 6-month follow-up, Lasers Med. Sci. 27 (4) (2012) 687–693.
[25] M.S. Tonetti, I. Fourmousis, J. Suvan, P. Cortellini, U. Brägger, N.P. Lang, Healing, post-operative morbidity and patient perception of outcomes following regenerative therapy of deep intrabony defects, J. Clin. Periodontol. 31 (12) (2004) 1092–1098.
[26] G. Tsakos, P.F. Allen, J.G. Steele, D. Locker, Interpreting oral health-related quality of life data, Community Dent. Oral Epidemiol. 40 (3) (2012) 193–200.
[27] J.M. Valderas, J. Alonso, Patient reported outcome measures: a model-based classification system for research and clinical practice, Qual. Life Res. 17 (9) (2008) 1125–1135.