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Evaluation of a decontamination protocol prior to a full-mouth disinfection procedure: A randomised clinical study

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The objective of this study was to test the hypothesis that the application of a chlorhexidine-based decontamination protocol during two weeks prior to scaling root planing (SRP) would reduce bleeding on probing (BoP) at the time of SRP. Secondary outcomes were other clinical parameters. Another secondary aim was to assess whether the improvement of periodontal conditions, if any, would have a benefit up to 3 months later. In this mono-centre, parallel, single blind, randomised, controlled clinical study, thirty subjects affected by chronic periodontitis were randomly allocated 1:1 to either a control group (n=15, individuals subjected to a standard one-stage full-mouth disinfection procedure fifteen days after inclusion), or a test group (n=15, individuals had to apply a decontamination protocol consisting of tongue brushing and mouth rinsing with chlorhexidine-based products during the fifteen days intervening between inclusion and SRP. BoP, probing depth (PD), plaque index (Pl.I) and clinical attachment loss (CAL) were measured at the inclusion and at t_{SRP}=baseline, when individuals were subjected to SRP, and after 30 and 90 days. Immediately before SRP, BoP was significantly reduced in test (68.31±14.70) with respect to control group (29.54±11.97, p<0.0001). The other clinical parameters (except for CAL) were significantly reduced, with comparable improvements between the two groups after 30 and 90 days. Although investigations on a larger sample are desirable, the early application of a disinfection procedure improves the condition of patients undergoing full-mouth therapy. This leads to marked advantages both for patients, who exhibit reduced bleeding, swelling and pain, and the operator, who is less operatively limited during the hygiene session.

Key words: Full-mouth disinfection, scaling and root planing, periodontitis, periodontal therapy.

INTRODUCTION

Non-surgical periodontal therapy has been demonstrated to be an effective treatment for patients with chronic periodontitis. Periodontal therapy traditionally consists of subgingival debridement by scaling and root planing (SRP)

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procedures. Such mechanical therapy is carried out by hand using ultrasonic instrumentation in combination with scalers and curettes, and its efficacy in improving periodontal conditions is well documented in the scientific literature (Badersten et al., 1984). The aim of SRP is to remove calculus, dental biofilm, bacteria and bacterial toxins from the surface of dental roots (Aleo et al., 1974; O'Leary, 1986). Having done this, a periodontal maintenance is necessary to prevent periodontal pockets from re-colonisation. In the '80s, the role played by patients' self-performed plaque control was extensively studied; oral disinfection procedures proved to be helpful in improving probing depth (PD), bleeding on probing (BoP) and clinical attachment level, whose effects were observed over a long time period after the initial oral hygiene session (Lindhe et al., 1984; Knowles et al., 1979; Badersten et al., 1987). Subsequently, a number of periodontal maintenance procedures were developed in the following years (Position Paper, 2003).

However, conventional non-surgical periodontal therapy has certain disadvantages, being time-consuming, requiring high skill and dedication from the operator, and can additionally lead to some unavoidable discomfort for the patient. Moreover, conventional non-surgical periodontal therapy is performed on a quadrant basis with time intervals of 1 to 2 weeks (quadrant scaling and root planing, QRP). Over this time, re-colonisation by periodontopathogenic microorganisms may occur since they can freely migrate from the yet untreated pockets to the already instrumented ones, resulting in delayed tissue healing (Quirynen, 2001). As part of a new approach, Quirynen et al. (1995) introduced the 'one-stage full-mouth disinfection' procedure. The authors compared the clinical and microbiological effects of full-mouth scaling and root planing (FMRP) with the widespread QRP practice. The rationale behind their treatment strategy was to prevent treated sites from re-infection by bacteria still colonising the remaining untreated pockets and intra-oral niches. This strategy consists of full-mouth scaling and root planing to be carried out within a time period of 24 h, combined with gingival irrigation with a 1% chlorhexidine (CHX) solution, tongue brushing with a 1% CHX gel and a final rinse with a 0.2% CHX solution. Subsequently, patients were required to follow a home-based oral hygiene protocol for two months, consisting of tongue brushing with a 1% CHX gel and followed by a mouth rinse with a 0.2% CHX solution, twice a day. In further studies by Quirynen et al. (1999, 2000, 2006), the FMRP approach was seen to be effective in reducing microbial load and improving clinical parameters. The beneficial effects of the one-stage full-mouth disinfection procedure, in improving clinical and microbiological parameters in patients affected by different forms of periodontitis, have been successively assessed in several clinical trials and are well documented in the literature (Aimetti et al., 2011; Swierkot et al., 2009; Teughels et al., 2009).

The aim of this study was not focused on testing the efficacy of the one-stage full-mouth disinfection procedure, which is already well documented (Eberhard et al., 2008; Farman and Joshi, 2008). The idea underlying the study was that bacterial load reduction was achieved with the application of the disinfection protocol proposed, consisting of tongue brushing and mouth rinsing with chlorhexidine-based products, at home, would accordingly lead to a decrease in swelling, pain sensitivity and especially bleeding, making the subsequent SRP procedure more comfortable for the patients. The operator would receive benefits as well, being less operatively limited during the oral hygiene session. In the current study the hypotheses that the application of a disinfection protocol consisting of tongue brushing and mouth rinsing with chlorhexidine-based products during two weeks prior to SRP would 1) reduce BoP at the time of SRP, 2) improve clinical parameters related to periodontitis, and 3) provide for improvement of periodontal tissue conditions up to three months was tested. Thus, the primary aim of this study was to assess if changes in BoP between inclusion and the time SRP occur in patients who applied the oral disinfection protocol for two weeks prior to SRP, compared to patients who did not perform the early disinfection procedure. Secondary outcomes of the study where other clinical parameters such as probing depth, the percentage of sites with plaque and clinical attachment loss, were evaluated at the time of SRP and compared with the inclusion. Another secondary aim of this study was to assess whether the improvement of periodontal conditions, if any, observed at the time of SRP, would have a long-lasting benefit up to 3 months later.

MATERIALS AND METHODS

Study population

This study was carried out from March 2010 to March 2011 at the Tuscan Stomatologic Institute, Department of Dentistry, Versilia General Hospital, Lido di Camaiore (LU), Italy. The study protocol was approved by the ethical committee of the same hospital. Thirty (30) subjects affected by chronic periodontitis and who met the following inclusion criteria were included: (i) presence of at least 30% of periodontal pockets with pocket depth ≥ 4 mm; (ii) BoP of at least 30% of sites; (iii) exhibiting good general health and not on regular drug use; (iv) absence of systemic disorders which might affect periodontium (such as diabetes); (v) non smoking patients. Subjects who met at least one of the following criteria were excluded from the present study: (i) pregnancy; (ii) lactation; (iii) previous periodontitis treatment during the last 6 months before the beginning of the present study; (iv) the use of antibiotic drugs during the last 30 days before the beginning of the present study. Oral and written

information was given to each enrolled subject. All the subjects signed a consent form before their enrolment.

Sample size calculation

Sample size calculations were performed with PS Power and Sample Size Calculations version 3.0. In a previous study (Quirynen et al., 2006), the response in BoP within each group had standard deviation of 20. If the true difference in the experimental and control means is 25, 11 experimental subjects and 11 control subjects are necessary to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with the test of this null hypothesis is 0.05. To compensate for possible losses during the follow-up, 15 subjects per group (30 patients in all) were recruited.

Study design and treatment procedure

The present study is an independent, mono-centre, parallel, single blind, randomised, controlled clinical study. In order to reduce the impact of various risk factors in the test and control group, a stratified randomisation method was applied. The main periodontal risk factors including high plaque index (Pl.I) score were considered in the stratification process. A total number of two strata were calculated. A computer restricted randomisation within the strata was obtained. Finally, a computer generated randomisation schedule (Random Allocation Software version 1.0, downloadable from http://mahmoodsaghaei.tripod.com/Softwares/randalloc.html) was created and the randomisation codes were enclosed in sealed, opaque and sequentially numbered envelopes by a single operator (OM). The envelopes were kept in a safe and inaccessible place at the same institute, and sequentially opened after enrolling the patient and having his/her consent form signed.

Accordingly, each one of the thirty subjects was randomly allocated in a 1:1 ratio to test and control groups, as follows:

(1) Control group (or standard full-mouth group, n=15), in which individuals were subjected to a standard full-mouth disinfection procedure, enrolling CHX usage after SRP, fifteen days after inclusion.
(2) Test group (or modified full-mouth group, n=15), in which individuals had to perform early full-mouth oral hygiene during the fifteen days intervening between inclusion and SRP. Such modified full-mouth protocol consisted ina home-based pre-treatment by means of tongue brushing with a 1% chlorhexidine gel (Dentosan, Pfizer Consumer Healthcare, Rome, Italy) and followed by a mouth rinse with a 0.2% chlorhexidine solution (Dentosan, Pfizer Consumer Healthcare, Rome, Italy), twice a day for 2 weeks.

At the inclusion, proper and personalized oral hygiene instruction was given to each one of the participants, belonging to both control and test groups. The difference between the two groups consisted of additionally assigning the disinfection protocol with CHX to test subjects only. This pre-treatment was begun just after the inclusion, at which time patients allocated to the test group received proper instructions about how to correctly carry out the home-based disinfection protocol. The said home-treatment program also comprised mechanical plaque control consisting of using toothbrush, toothpaste and interdental cleaning devices.

For all the subjects who met the inclusion criteria, clinical parameters typical of periodontitis were measured. The evaluation of the same parameters was repeated at t_{SRP} = baseline, then individuals from both groups were subjected to scaling and root planing (SRP), according to standard procedures. For each subject, the oral hygiene performance was evaluated at baseline, before the SRP session. The same operator (A.M.G.) performed SRP for all the subjects of the study and measured the clinical parameters. Scaling and root planning was performed under local anaesthesia (2% Mepivacaine) by using manual and ultrasonic devise. Neither the operator nor the evaluator (M.R.) was aware of the group each patient had been allocated to. Furthermore, all the subjects had to follow the standard full-mouth protocol as a home treatment program. The measurement of clinical parameters was then repeated at t_{30} and t_{90}, that is thirty (30) and ninety (90) days after SRP, respectively. In case of need for an improvement, oral hygiene was repeated. In particular, oral hygiene was repeated, at the discretion of the hygienist, when the patient had severe inflammation despite the initial oral hygiene session.

Since the primary aim was focussed on a reduction of bleeding at the time of SRP, BoP at t_{SRP} was selected as the primary outcome of the study (Checchi et al., 2009). Secondary outcomes were PD, Pl.I and clinical attachment loss (CAL) at tSRP, as well as BoP, PD, Pl.I and CAL at t_{30} and t_{90}. Moreover, another goal of the present study was gaining information about discomfort/pain sensation perceived by the patients during the SRP session. For this reason, voluntary feedbacks from the patients were collected right after SRP, when the operator asked them to report about pain, discomfort and anxiety feelings they experienced.

Clinical parameter determination

The following clinical parameters were evaluated: BoP, PD, Pl.I and CAL. They were determined at six measure sites (mesio- buccal, buccal, disto-buccal, mesio-palatal, palatal and disto-palatal) using a periodontal probe (University of North Carolina periodontal probe) of each

tooth and expressed as a percentage ratio to the total number of sites. Upon a whole mouth evaluation, involving an examination of all the present teeth, the teeth with at least one site with PD ≥ 4 mm were selected to undergo treatment. All parameters were recorded by the same operator (A.M.G.) throughout the study.

Statistical analysis

Data are expressed as a mean ± standard deviation (SD). Comparisons between control and test groups were carried out using the nonparametric Mann-Whitney U test for independent samples, while the Student's *t*-test for dependent samples was used to assess changes within the groups at different observation times. A value of $p \leq 0.05$ was taken as statistically significant. A statistical analysis was performed using the Open Stat version 26.03.2012 (www.statprograms4u.com), considering the subject as the unit of analysis.

RESULTS

Socio-demographic and clinical data for all the 30 enrolled patients were summarised in Table 1. All of the subjects attended their follow-up visits and all the participants completed treatment as originally allocated, as illustrated in Figure 1. The results of the present study are summarised in Tables 2 to 5. In particular, Table 2 reports the mean ± SD values of the number of sites presenting BoP. The two groups were not significantly different at the inclusion.

No statistically significant differences were observed, within the control group between the inclusion and the time of SRP, t_{SRP}, while a marked difference was observed at t_{90} ($p<0.0001$ versus the inclusion and versus t_{SRP}) in terms of reduction of the total number of BoP sites. A comparison between groups at different times showed that subjects following an early full-mouth disinfection procedure were still characterised by significantly lower percentages of BoP sites ninety days after SRP ($p<0.0001$ at both t_{30} and t_{90}).

A similar trend might be observed for the percentage of sites with PD≥4 mm; test group showed a significant reduction in terms of number of sites with PD≥4 mm if compared with control group (Table 3). The two groups were not significantly different at the inclusion. Moreover, no statistically significant differences were observed within the control group between the inclusion and the time of SRP, t_{SRP}, while a marked difference was observed at t_{30}, that is, thirty days after the SRP procedure ($p<0.0001$ versus both inclusion and t_{SRP}). A further significant decrease in the percentage of sites presenting pockets with PD≥4 mm was observed at t_{90}, that is, ninety days after SRP ($p<0.0001$ versus inclusion and t_{SRP}, $p<0.05$ versus t_{30}). Data concerning the percentage of sites with plaque were summarized in Table 4. The two groups, which were not statistically different at the inclusion were different ($p<0.0001$) at t_{SRP}, and such a difference is still observed at t_{30} ($p<0.0001$) and t_{90} ($p<0.05$). The reduction of the percentage of plaque sites in time within each group is similar to the time progression observed for the other clinical parameters. Indeed, a significant reduction is observed at t_{30} versus t_{SRP} ($p<0.0001$ for both groups), whose reduction persisted even at t_{90}.

Finally, Table 5 summarizes CAL values; Table 5 suggested that CAL did not show significant differences between test and control group. On the contrary both groups showed a similar behaviour in terms of CAL improving during the follow-up period.

DISCUSSION

All the assessed clinical parameters (especially the primary BoP outcome) showed significant improvements, as expected from the application of a disinfection procedure whose efficacy is widely recognised, in a comparable manner between the two groups. However, the most interesting data were certainly obtained at t_{SRP}, two weeks after the beginning of the oral decontamination and immediately before scaling and root planing. The assessed clinical parameters at $t_{SRP,}$ with exception made for CAL, resulted in being significantly reduced versus the inclusion. Nevertheless, the main goal of the present study was not merely focused on the already well-documented efficacy of the one-stage full-mouth disinfection procedure (Morgandini et al., 1999; Quirynen et al., 1999, 2000, 2006; Aimetti et al., 2011; Swierkot et al., 2009; Teughels et al., 2009), when applied under the commonly used conditions. The hypothesis of the present study was that the application of a disinfection protocol consisting of tongue brushing and mouth rinsing with chlorhexidine-based products during two weeks prior to SRP would (1) reduce BoP at the time of SRP, (2) improve clinical parameters related to periodontitis, and (3) provide for improvement of periodontal tissue conditions up to three months and finally, (4) facilitate the clinicians in their job.

This study is a mono-centre, parallel, single blind, randomised, controlled clinical study, for which thirty periodontal subjects were enrolled. Patients were randomly allocated 1:1 to both groups. Patients placed in control group (n=15) were treated with a standard one-stage full-mouth disinfection procedure fifteen days after inclusion without any decontamination protocol. Patients placed in the test group (n=15) were instructed in order to apply the decontamination protocol discussed during the fifteen days intervening between inclusion and SRP. Patients' clinical data were collected from March 2010 to March 2011 at the Tuscan Stomatologic Institute, Versilia General Hospital, Italy.

Many papers and documents describing the efficacy of

Table 1. Socio-demographic and clinical data.

Parameter	Control group (n=15)	Test group (n=15)
Age		
Range	42-68	40-65
Mean±SD	52±16.3	56±11.0
Gender		
Male	42%	47%
Female	58%	53%
Number of teeth	21±4	20±4
PD (Mean±SD)	5.17±0.08	5.37±0.22
Percentage of sites with PD≥4 mm (Mean±SD)	84.47±14.26	87.33±22.21

Table 2. Comparison of the mean ± SD values of the percentage of sites with BoP between groups and between observation times.

Parameter	Control group (n=15)	Test group (n=15)	Control group *vs.* Test group (*p*-values)
Inclusion	65.16±17.67	58.53±31.11	p>0.05
t_{SRP}	68.31±14.70	29.54±11.97	p<0.0001
t_{30}	23.52±10.44	12.02±8.69	p<0.0001
t_{90}	19.74±8.50	6.20±4.28	p<0.0001
Comparison between different observation times (*p*-values)			
t_{SRP} *vs.* Inclusion	p>0.05	p<0.05	-
t_{30} *vs.* Inclusion	p<0.0001	p<0.0001	-
t_{90} *vs.* Inclusion	p<0.0001	p<0.0001	-
t_{30} *vs.*t_{SRP}	p<0.0001	p<0.0001	-
t_{90} *vs.*t_{SRP}	p<0.0001	p<0.0001	-
t_{90} *vs.* t_{30}	p>0.05	p<0.05	-

Table 3. Comparison of the mean ± SD values of the number of sites with PD≥4 mm between groups and between observation times.

Parameter	Control group (n=15)	Test group (n=15)	Control group *vs.* Test group (*p*-values)
Inclusion	57.30±9.66	59.19±12.33	p>0.05
t_{SRP}	59.15±9.82	40.25±15.95	p<0.05
t_{30}	29.92±11.22	23.53±8.25	p<0.05
t_{90}	21.07±6.90	21.37±11.17	p>0.05
Comparison between different observation times (*p*-values)			
t_{SRP} *vs.* Inclusion	p>0.05	p<0.05	-
t_{30} *vs.* Inclusion	p<0.0001	p<0.0001	-
t_{90} *vs.* Inclusion	p<0.0001	p<0.0001	-
t_{30} *vs.* t_{SRP}	p<0.0001	p<0.05	-
t_{90} *vs.* t_{SRP}	p<0.0001	p<0.05	-
t_{90} *vs.* t_{30}	p<0.05	p>0.05	-

the “standard” full-mouth disinfection procedure are available in the literature Eberhard et al. (2008) and Farman and Joshi (2008). Nevertheless, no documents are present, at the best of the authors’ knowledge, dealing with the assessment of possible effects of an early application of a decontamination protocol on

Table 4. Comparison of the mean ± SD values of the percentage of sites with plaque between groups and between observation times.

Parameter	Control group (n=15)	Test group (n=15)	Control group *vs.* Test group (*p*-values)
Inclusion	68.59±20.61	74.58±12.75	p>0.05
t_{SRP}	71.84±16.33	33.02±15.88	p<0.0001
t_{30}	27.35±9.57	6.96±7.52	p<0.0001
t_{90}	26.83±10.62	12.88±19.24	p<0.05
Comparison between different observation times (*p*-values)			
t_{SRP} *vs.* Inclusion	p>0.000.1	p<0.0001	-
t_{30} *vs.* Inclusion	p<0.0001	p<0.0001	-
t_{90} *vs.* Inclusion	p<0.0001	p<0.0001	-
t_{30} *vs.* t_{SRP}	p<0.0001	p<0.0001	-
t_{90} *vs.* t_{SRP}	p<0.0001	p<0.05	-
t_{90} *vs.* t_{30}	p>0.0001	p>0.0001	-

Table 5. Comparison of the mean ± SD values of CAL (mm) between groups and between observation times.

Parameter	Control group (n=15)	Test group (n=15)	Control group *vs.* Test group (*p*-values)
Inclusion	3.0±0.2	3.1±0.3	p>0.05
t_{SRP}	3.0±0.2	2.8±0.3	p>0.05
t_{30}	2.5±0.3	2.6±0.2	p>0.05
t_{90}	1.9±0.2	1.8±0.2	p>0.05
Comparison between different observation times (*p*-values)			
t_{SRP} *vs.* Inclusion	p>0.05	p>0.05	
t_{30} *vs.* Inclusion	p<0.05	p<0.0001	
t_{90} *vs.* Inclusion	p<0.0001	p<0.0001	
t_{30} *vs.* t_{SRP}	p<0.05	p>0.05	
t_{90} *vs.* t_{SRP}	p<0.0001	p<0.0001	
t_{90} *vs.* t_{30}	p<0.0001	p<0.0001	

n.s.: Not statistically significant.

periodontal conditions at the time of SRP. The present study does possess some limitations, mainly related to the small sample size. Nonetheless, it provided interesting findings, worthy of further investigation. In particular, regarding the primary outcome, test group showed a significant difference reduction of BoP sites at 90 days if compared to the control group. The second parameters analyzed in the present study was the PD; the study could not be statistically significant for two main reasons: (1) the power of the study was not calculated on the basis of the secondary outcomes; (2) in some cases, the statistical significance is unclear, for example in the case of clinical data collected at t_{90}. Thus, the present study may be regarded as significant in terms of the BoP, whereas it only has an explorative nature regarding the PD. As a consequence, a deeper investigation is suggested to better assess the PD. Furthermore, the present study used a merely subjective evaluation of the pain sensation perceived during the SRP session, which was based on the voluntary feedback from the patients. As a result of the said patients' feedbacks, a general trend was observed that patients belonging to test group experienced less discomfort during SRP. Patient's anxiety related to bleeding appeared to be reduced as well. A future study could introduce the use of the Visual Analogue Scale (VAS) as a measurement instrument of pain. Strong evidence for the efficacy of full-mouth disinfection procedure was already available. However, the results obtained in the present study might have a strong impact in the treatment of periodontitis. Indeed, this simple disinfection procedure can greatly improve the condition of periodontal patients undergoing scaling and root planing. The SRP practice would, therefore, result in being less uncomfortable for the patients, who have decreased swelling and bleeding and, accordingly, a lower pain sensation. Consequently, this could increase

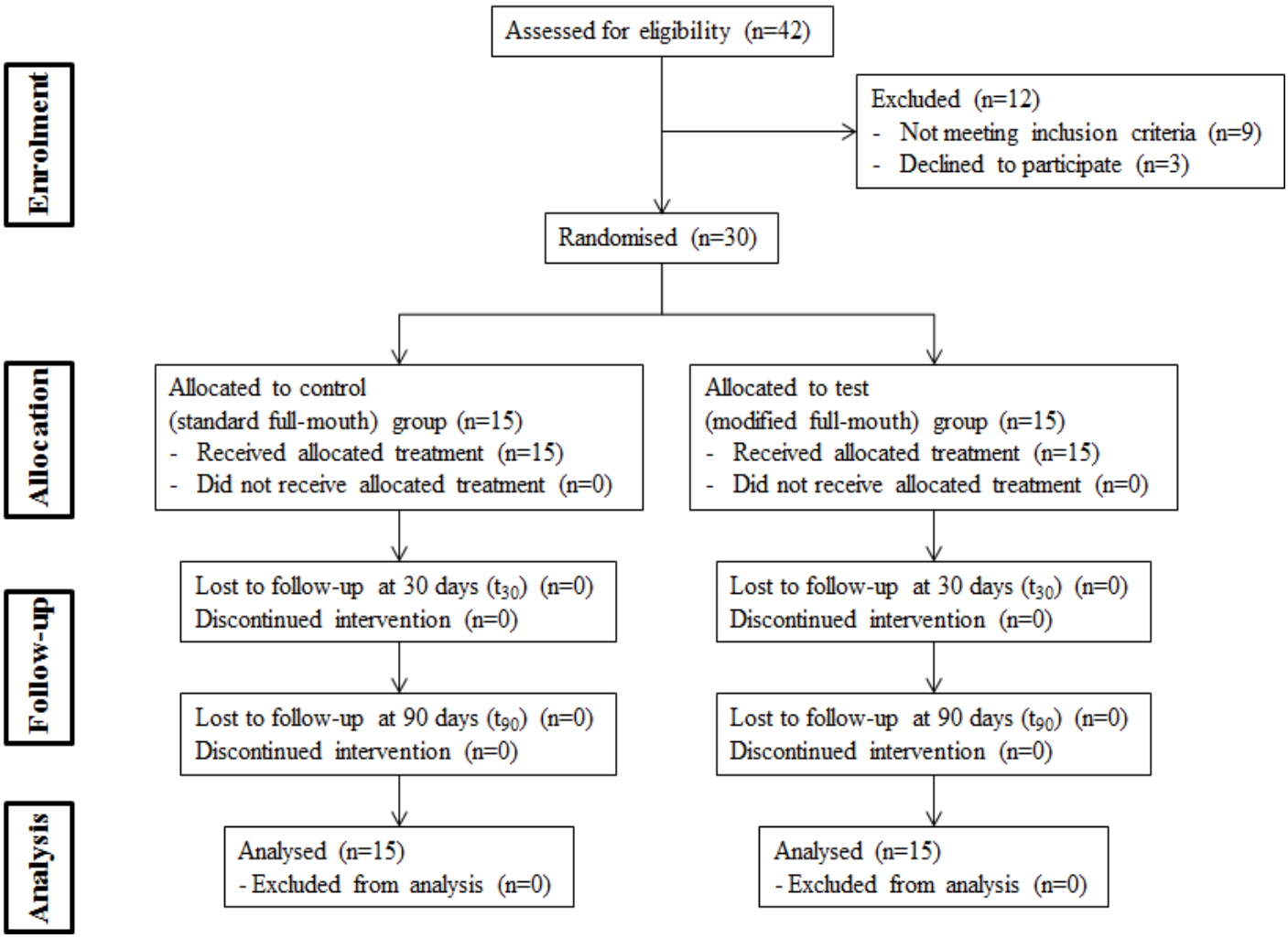

Figure 1. Flow chart for the present study.

the patients' compliance towards the required periodontal therapies. There are also benefits for the operator, who has to tackle less operative limitations due, for example, to an excessive bleeding which may be responsible for poor visibility and difficult accessibility to periodontal pockets. In summary, the overall result for patients is an improvement in the efficacy of the SRP procedure in the treatment of periodontitis.

As for the underlying mechanism, chlorhexidine is presumably responsible for a decrease in bacterial load of the affected periodontal tissues, which accordingly leads to reduce bleeding, swelling, and pain feeling as well. As mentioned earlier, this is the first time the effects of early application of a decontamination protocol are investigated. Thus, further studies are required to confirm and validate the results obtained and reported in this paper. If future investigation will confirm the present findings, they could bring to new perspectives for the said decontamination protocol to be routinely applied prior to SRP in order to improve the performance of SRP itself.

Conclusion

The hypothesis of the present study was that the application of a disinfection protocol consisting of tongue brushing and mouth rinsing with chlorhexidine-based products during two weeks prior to SRP would (1) reduce BoP at the time of SRP, (2) improve clinical parameters related to periodontitis, and (3) provide for improvement of periodontal tissue conditions up to three months. Although the present study does have limitations, mainly due to the small sample size, it did however effectively demonstrate that an early application of a decontamination protocol prior to full-mouth disinfection procedure, at home, for two weeks before scaling and root planing can reduce the inflammation symptoms of periodontal tissues at t_{SRP}. The improvement of clinical parameters at t_{SRP}, that is,

immediately before SRP, enhances the efficacy of SRP itself in the treatment of periodontitis. Moreover, although data collected are preliminary, insights were gained about the fact that patients feel less discomfort during the SRP session, discomfort which is mainly due to bleeding, swelling and pain sensitivity, while the operator benefits from a better visibility and wider accessibility of the areas to be instrumented.

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Conflict of Interest

The authors declare no conflict of interest.

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