

Scientific release from the EFP
June 2017

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Study:



Non-surgical periodontal treatment in conjunction with three- or seven-day systemic administration of amoxicillin and metronidazole in severe chronic periodontitis patients. A placebo-controlled randomised clinical study

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Relevant background:

In severe chronic periodontitis patients, the potential additional effects of a three-day systemic administration of amoxicillin (AMX) and metronidazole (MET) are still uncertain as an adjunctive measure to non-surgical periodontal treatment (scaling and root planing, SRP).

Positive effects of the combination of antibiotics and SRP have been reported in the past, but resistance is a major side-effect of this therapy. A shorter regimen could possibly have the same potential positive effect but with less risk for causing antibiotic resistance.

Aims:

To evaluate the clinical results of the non-surgical periodontal therapy (SRP), with or without the adjunctive use of a three- or a seven-day systemic administration of AMX and MET.

Methods:

In this prospective, randomised, placebo-controlled, double-masked clinical trial, 102 patients with severe chronic periodontitis (≥ 1 site with $PD \geq 6$ mm per quadrant and radiographic signs of generalised severe chronic periodontitis) were treated.

After receiving oral-hygiene instructions and professional prophylaxis in order to improve self-performed daily oral-hygiene measures ($FMPS \leq 25\%$), the subjects were randomly divided into three equally sized groups.

Group A: treated with SRP within 24 h + placebo for seven days.

Group B: treated with SRP within 24 h + AMX + MET (both 500 mg x 3 times daily) for three days and placebo for four days.

Group C: treated with SRP within 24 h + AMX + MET (both 500 mg x 3 times daily) for seven days.

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Methods:
(cont.)

In all groups, following SRP, all the treated pockets were irrigated with 0.2% chlorhexidine digluconate solution and the patients were asked to brush their teeth with a 0.2% chlorhexidine digluconate toothpaste and to rinse twice daily with a 0.2% chlorhexidine digluconate mouth rinse for 14 days. Identical bottles containing assigned pills (antibiotics or placebo), according to the randomisation protocol, were given to all the subjects after completing the SRP. Recall visits were scheduled two weeks, three months, and six months after completion of SRP. At every appointment, any adverse event or any protocol deviation was recorded.

Furthermore, at the three- and six-month appointments, gingival bleeding index (GBI), FMPS, probing depth (PD), vertical CAL, and bleeding on probing (BOP) were evaluated. In addition, supra-gingival calculus was removed, when indicated.
Primary outcome variable: difference in number of sites per patient with PD \geq 6mm between baseline and six-month evaluation.
Secondary outcome variables: average changes in the periodontal clinical parameters, number of sites with PD \geq 6mm and number of sites with PD \geq 5 mm, total number of sites with PD = 4 mm and BOP+ or with PD \geq 5 mm.

Results:

Ninety-one patients completed the study and were included in the per-protocol analyses. No statistical differences could be found among the analysed groups in terms of gender, smoking status, baseline clinical parameters, or the amount and severity of adverse events.
At both three and six months, all three treatment protocols resulted in statistically significant improvements compared to baseline for all evaluated clinical parameters ($p < 0.001$).

At six months, a statistically significant greater reduction in the mean number of sites with PD \geq 6mm was observed in group B (28.62 ± 15.32 sites) and group C (30.45 ± 15.04 sites), compared to the placebo group (17.10 ± 14.68 sites). Furthermore, both the three- and the seven-day antibiotic regimens resulted in statistically significantly higher clinical improvements compared to the placebo group ($p < 0.05$).

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**Limitations,
conclusions
and impact:**

Limitations:

The short observational period constitutes the principal limitation of the present study. The initially reported benefits of the adjunctive use of systemic antibiotics could be reduced or disappear in long-term evaluations.

In all three groups, clinically relevant results (in terms of PD reductions and number of sites showing PD \geq 6 mm) were achieved, even if the subjects failed to maintain initial FMPS \leq 25% during the study period and despite the fact that chlorhexidine digluconate measures were used as additional adjunctive therapy in all groups.

As described by the authors, the number of subjects included in the study sample was not sufficient to make a comparison between the effects of the three- and seven-day antibiotic regimens.

Conclusions:

Within the limitations of this study, both the three- and the seven-day antibiotic regimens resulted in statistically significant improvements for all evaluated clinical parameters (greater mean PD reductions and CAL gains, reduced number of sites with PD \geq 6 mm), when compared to SRP alone, during the entire length of the study.

Impact:

In patients with severe chronic periodontitis, the non-surgical periodontal therapy in conjunction with a three- or seven-day antibiotic (AMX + MET) regimen may yield greater clinical improvements than non-surgical therapy alone.

However, from this study it is not possible to justify the choice of one antibiotic regimen compared to another. Long-term results are also needed to evaluate if these benefits would be maintained or lost over time.