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EFP European Federation of Periodontology

Scientific release from the European Federation of Periodontology

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Study:

Is progression of periodontitis relevantly influenced by systemic antibiotics? A clinical randomised trial

Harks, I., Koch, R., Eickholz, P., Hoffmann, T., Kim, T.S., Kocher, T., Meyle, J., Kaner, D., Schlagenhauf, U., Doering, S., Holtfreter, B., Gravemeier, M., Harmsen, D., Ehmke, B.

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Relevant background to study:

Periodontitis is an inflammatory disease caused by a microbial biofilm. In industrialised countries, approximately 50% of the adult population suffers from moderate or severe periodontitis. Basic periodontal therapy usually comprises mechanical debridement of the teeth, i.e. the disruption of biofilm, followed by lifelong maintenance therapy.

Mechanical debridement in patients with moderate to severe periodontitis can be supplemented with systemic antibiotics, such as amoxicillin and metronidazole. The rationale for the adjunctive use of antibiotics is to exert an antimicrobial effect at sites inaccessible to mechanical therapy and possibly to suppress periodontal pathogens.

Study aims:

This large multi-centre trial aimed at determining the efficacy of systemic antibiotics on periodontal disease progression. The hypothesis was that empirical systemic adjunctive antibiotics reduce the proportion of sites exhibiting further disease progression.

Methods:

This prospective, randomised, double-blind, placebo-controlled multi-centre trial (eight university hospital centres) comprising patients suffering from moderate to severe chronic and aggressive periodontitis, evaluated the impact of rational adjunctive use of systemic amoxicillin 500mg plus metronidazole 400mg (3x/day, 7 days) on attachment loss. The primary outcome was the percentage of sites showing further attachment loss (PSAL) ≥1.3mm after the 27.5 months observation period. Within 1.5 months after baseline examination, patients received supra and subgingival debridement in up to two sessions on two consecutive days.
After completion of mechanical therapy, patients in the antibiotics group received two empirical antibiotics [amoxicillin 3H2O 574mg with metronidazole 400mg] and placebo-group patients were given two placebo drugs, each to be taken three times a day for seven days. Re-evaluation was performed 3.5 months after baseline. Thereafter all patients received maintenance therapy, at three-month intervals.

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Results:

From 506 participating patients, 406 were included in the intention-to-treat analysis (placebo: n = 200, antibiotics n = 206). Median PSAL observed in the placebo group was 7.8% compared to 5.3% in the antibiotics group (Q25 4.7%/Q75 14.1%; Q25 3.1%/Q75 9.9%; p < 0.001 respectively).
At baseline (ITT-collective), the median proportion of sites displaying PPD of ≥ 5mm was 15.7% (Q25 10.4%/Q75 27.8%) for the placebo and 17.5% (Q25 10.3%/ Q75 27.8%) for the antibiotics group (p = 0.66).

At 27.5 month, % PPD of ≥5mm had decreased to 5.5% (Q25 1.7%; Q75 12.6%) in the placebo and to 2.1% (Q25 0.6%; Q75 5.8%) in the antibiotics group (p < 0.001).

The median proportion (ITT-collective) of sites with attachment gain ≥1.3mm over the 27.5 months period was 12.2% (Q25 7.1%; Q75 23.0%) for the placebo and 19.4% (Q25 10.4%; Q75 32.7%) for the antibiotics group (p < 0.001).

Limitations, conclusions and impact:

Limitations:

Tooth loss should be considered as a true outcome measure; however, durations of prospective studies are too short for such an outcome.
In most of the antibiotic studies, surrogates such as changes of probing pocket depths or proportion of remaining deep pockets were used to determine treatment success.
In this study, the primary outcome was PSAL since it reflects periodontal disease progression and may be assessed within reasonable periods of observation.
It is questionable if the small differences found between the placebo and the antibiotic group in the present study can be extrapolated in a linear way for longer periods of time.
The study mixed cases of aggressive periodontitis and chronic periodontitis and there are environmental concerns over prescribing systemic antibiotics for chronic periodontitis, which is a multi-factorial disease.
The small magnitude in outcome difference calls into question the risk-benefit of employing systemic antibiotics for managing chronic periodontitis, given the global epidemic of antibiotic resistance.

Conclusions:

From a clinical point of view, both therapeutic approaches were very effective and the absolute clinical differences between groups were small.
Empiric adjunctive systemic antibiotics showed a small absolute, although statistically significant, additional reduction in further attachment loss.
Therapists should consider the patient's overall risk for periodontal disease when deciding for or against the prescription of adjunctive antibiotics.

Impact:

What can we learn as practitioners?

After weighing up the pros and cons of adjunctive antibiotic administration, it was found that a simple clinical cut-off is hard to define.
Empirical use of antibiotic drugs may be considered for patients suffering from aggressive periodontitis, generalised severe chronic periodontitis, or disease progression despite proper mechanical therapy, but must be weighed against the global burden of antibiotic resistance.
A risk-related therapeutic approach considered by the periodontist may be even more important.