

## The comparative efficacy of 0.12% chlorhexidine and amoxicillin to reduce the incidence and magnitude of bacteremia during third molar extractions: a prospective, blind, randomized clinical trial

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**Objective.** The purpose of this study was to directly compare the incidence and magnitude of bacteremia of a 0.12% chlorhexidine pre-procedure rinse to the AHA and the ADA/AAOS recommended 2 g amoxicillin antibiotic prophylaxis during third molar extractions.

**Study Design.** This study was a randomized, blind, placebo-controlled prospective clinical trial involving subjects assigned to a placebo, rinse, or antibiotic group. The incidence and magnitude of bacteremia were analyzed via  $\chi^2$  and Kruskal-Wallis/Friedman tests, respectively.

**Results.** There was no statistically significant difference in the incidence and magnitude of bacteremia between the three groups. However, the placebo group apparently resulted in the largest range and highest mean magnitude of bacteremia, followed by the rinse then the antibiotic group.

**Conclusions.** The results of this novel study may reasonably conclude an oral rinse or systemic antibiotic antimicrobial intervention does not statistically reduce the incidence and magnitude of bacteremia compared to no antimicrobial intervention. (Oral Surg Oral Med Oral Pathol Oral Radiol 2013;115:752-763)

The occurrence of a transient bacteremia originating from the oral cavity during gingival sulcus manipulation is well established.<sup>1-74</sup> Such types of gingival sulcus manipulation range from the daily routine/oral hygiene activities of chewing, toothbrushing, and flossing to dental treatment procedures. The gingival sulcus, the dentition, and the other mucosal surfaces of the oral cavity are populated by a diverse, complex endogenous microflora of more than 700 species of which approximately 400 species are located in the gingival sulcus/periodontal pocket.<sup>75,76</sup> Of

Funding for the study was provided by the 59th Clinical Research Training Division, Lackland AFB, TX. The views expressed in this material are those of the authors, and do not reflect the official policy or position of the U.S. Government, the Department of Defense, or the Department of the Air Force. The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and AFI 40 402, Protection of Human Subjects in Biomedical and Behavioral Research. The work reported herein was performed under United States Air Force Surgeon General approved Clinical Investigation No. FWH20110027H.

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Received for publication Nov 5, 2012; accepted for publication Nov 20, 2012.

Published by Elsevier Inc.

2212-4403/\$ - see front matter

<http://dx.doi.org/10.1016/j.oooo.2012.11.019>

the gingival sulcus/periodontal pocket microflora, 30% are streptococci primarily of the viridans group.<sup>76</sup> However, viridans group streptococci are also endogenous microflora of the skin, respiratory tract, and gastrointestinal tract. The dentition is unique as the only nonshedding surface of the human body where the plaque bacterial concentration can exceed  $10^{11}$  microorganisms/mg.<sup>77</sup> This microbial load of the oral cavity poses an even greater, potential source of bacteremia when one considers a human with periodontal disease of 4-5 mm probing depths equates to a venous access surface area of approximately 10-20 cm<sup>2</sup> and up to 30-40 cm<sup>2</sup> in humans with 50% horizontal bone loss.<sup>78</sup> It therefore becomes quite apparent that the oral cavity is a potential source of bacteremia, which has been implicated as a cause of distant site infections (DSI).

Infective endocarditis (IE) is one type of DSI implicating oral bacteria. Lockhart et al.<sup>42</sup> state that 275 bacterial species have been implicated as the etiology of IE while 170 bacterial species have been isolated from the vasculature following dental treatment procedures.

### Statement of Clinical Relevance

To the authors' knowledge, this was the first study to directly compare the incidence and magnitude of bacteremia of a 0.12% chlorhexidine pre-procedure rinse to the AHA and the ADA/AAOS recommended 2 g amoxicillin antibiotic prophylaxis during a dental treatment procedure.

Although not borne out by clinical studies, it is generally assumed that dental treatment procedures cause a transient bacteremia, which may predispose patients with cardiac anomalies to IE if not treated with antibiotic prophylaxis. However, toothbrushing also causes such a transient bacteremia where poor oral hygiene with generalized gingival bleeding may be a significant risk factor for developing a bacteremia originating from the oral cavity.<sup>79</sup> Accordingly, it has been estimated that 4%-19% of IE cases are due to dental treatment procedures<sup>80</sup> while Strom et al.<sup>81</sup> found no evidence that dental treatment procedures were a risk factor for IE. Furthermore, Wilson et al.<sup>76</sup> in a review concluded that minimal evidence-based data existed to support antibiotic prophylaxis for the prevention of IE during dental procedures. It has been estimated that daily routine/oral hygiene activities may cause a bacteremia for 90 hours/month whereas a dental treatment procedure may cause a bacteremia for an average of 6 min.<sup>82</sup> While the overall incidence of IE has not decreased since the use of systemic antibiotic prophylaxis,<sup>82,83</sup> it is interesting to note the proportion of IE cases due to viridans group streptococci has decreased during the same time period.<sup>40</sup> Lockhart et al.<sup>82</sup> noted there have been numerous documented failures of antibiotic prophylaxis with an estimate that only 6% of IE cases could be prevented by antibiotic prophylaxis in the Netherlands, which correlates to 240-480 IE cases per year in U.S.<sup>80</sup>

The American Heart Association (AHA) amended the antibiotic prophylaxis recommendations for IE in April 2007.<sup>76</sup> These recommendations noted IE is more likely to result from frequent exposure to transient bacteremias associated with daily routine/oral hygiene activities than from bacteremias induced by dental treatment procedures. These recommendations further noted that even if 100% effective, antibiotic prophylaxis may prevent IE in an extremely low number of susceptible patients who undergo a dental treatment procedure. Since the AHA published the first recommendation for the prevention of IE in 1955, there have been nine revisions, which have recommended either more conservative antibiotic regimens or fewer medical/dental indications requiring antibiotic prophylaxis. For example, the 2007 AHA guidelines decreased the number of patients receiving IE antibiotic prophylaxis by 90%.<sup>76</sup>

Another type of DSI implicating oral bacteria is late prosthetic joint infection (LPJI). The majority of prosthetic joint infections occur within three months of placement where the causative bacteria is usually a staphylococcus species, specifically *Staphylococcus epidermidis* and *Staphylococcus aureus*, which comprise approximately 0.005% of the normal oral flora.<sup>84,85</sup> In 2003, the joint consensus document involving the American Dental Association (ADA)/American Academy of Orthopedic Surgeons (AAOS) recommended antibiotic prophylaxis

within two years of a prosthetic joint placement.<sup>86</sup> However, in 2009 the AAOS unilaterally released a statement, which contradicts the 2003 joint recommendation.<sup>87</sup> The 2009 AAOS independent statement recommends antibiotic prophylaxis for any patient with a prosthetic joint, regardless of when it was placed. Similar to the circumstantial evidence noted by the AHA in regards to dental treatment procedures and IE, there is minimal evidence-based data to conclude a transient bacteremia of oral origin predisposes a patient with a prosthetic joint to an LPJI if not treated with antibiotic prophylaxis.<sup>84,85</sup> Moreover, the 2009 AAOS independent statement was based on no clinical trials, a number of insufficiently documented case reports, as well as one retrospective study which reported a 0.04%-0.2% incidence of LPJI involving circumstantial dental treatment procedures in medically compromised patients.<sup>84,85</sup>

The pre-procedure use of an antimicrobial rinse has demonstrated conflicting results in reducing the incidence of bacteremias during daily routine/oral hygiene activities and dental treatment procedures.<sup>1,3,15,22,23,40,42,47,53,68,74</sup> Antimicrobial rinse types and/or concentrations as well as the myriad of methods of gingival sulcus rinsing and/or irrigation make direct evidence-based comparisons difficult. For example, Lockhart<sup>40</sup> reported a 0.2% chlorhexidine pre-procedure rinse did not significantly reduce the incidence (control = 94%, chlorhexidine = 84%,  $P = .27$ ) of bacteremia at 1 min and 3 min following the start of a single dental extraction. In contrast, Tomas et al.<sup>68</sup> reported a 0.2% chlorhexidine pre-procedure rinse significantly reduced the incidence of bacteremia (control = 96%, chlorhexidine = 79%,  $P = .008$ ) at 30 s following the last extraction of multiple dental extractions. Although both studies used a 0.2% chlorhexidine pre-procedure rinse, each study utilized a different method; Tomas et al.<sup>68</sup> filled the patient's oral cavity with the rinse for 30 s under general anesthesia while Lockhart<sup>40</sup> had the patients rinse themselves twice for 30 s prior to the procedure.

Antibiotic prophylaxis according to the AHA guidelines and various additional antibiotic prophylaxis regimens have demonstrated a reduced incidence, nature, magnitude, and/or duration of bacteremia during dental treatment procedures, but are not 100% effective in preventing a bacteremia of oral origin.<sup>2,4-6,9,12,21,26,28-30,32,34-37,41,42,48,58,66,70,71</sup> Similar to the studies evaluating a pre-procedure antimicrobial rinse, the study methods evaluating the bacteremic efficacy of an antibiotic prophylaxis regimen following gingival sulcus manipulation are quite variable and again make direct evidence-based comparisons difficult. For example, Lockhart et al.<sup>41</sup> reported a 15% ( $P < .001$ ) incidence of bacteremia at one and a half minutes following the start of a single dental extraction (additional extractions were later completed)

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