

生物活性玻璃凝胶治疗菌斑性牙龈炎的4周临床研究

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【摘要】目的 评价生物活性玻璃凝胶治疗菌斑性牙龈炎4周后的临床有效性和不良事件的发生情况。**方法** 采用多中心、随机、双盲的临床研究方法, 将124名受试者随机分成试验组(生物活性玻璃凝胶)和安慰剂组(同公司生产的不含主要有效成分的凝胶)。受试者早晚刷牙后分别用4g试验凝胶处理全口牙龈并保持3min。在受试者入组当天、第(14±2)天及第(28±2)天时进行随访检查, 评价其龈沟出血指数(SBI)、菌斑指数(PLI)及随访期间不良事件的发生率。**结果** 在治疗第(28±2)天后, 实验组SBI、PLI较基线值均出现明显降低($P < 0.001$); 随访期间实验组不良事件的发生率为9.68%, 安慰剂组1.61%, 差异无统计学意义($P > 0.05$); 且两组均无严重不良事件的报告。**结论** 生物活性玻璃凝胶可以缓解牙龈出血和抑制牙菌斑, 可推荐用于治疗菌斑性牙龈炎症。

【关键词】 生物活性玻璃 菌斑 牙龈炎 抗菌

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A four-week clinical trial of the effects of bioactive glass gel on treatment of plaque-induced gingivitis

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【Abstract】Objective To evaluate the clinical efficacy and adverse effects of bioactive glass gel on the treatment of plaque induced gingivitis. **Methods** This study was a multicentric, randomized double-blinded and placebo controlled clinical trial. 124 subjects were included in this study and randomly divided into two groups: the test group (bioactive glass gel) and the control group (gel without effective components). All the subjects were treated by the gel on gingival for 3 minutes after toothbrushing. Sulcus bleeding index (SBI) and plaque index (PLI) were examined at the baseline (0 day), (14±2) days and (28±2) days. **Results** After (28±2) days, both the SBI and PLI of test group were decreased significantly ($P < 0.001$). The occurrence rates of adverse events in the test group and in the control group were respectively 9.68% and 1.61%, showed no significant difference between two groups ($P = 0.114$). No severely adverse event was reported in both groups. **Conclusion** Bioactive glass gel could relieve the symptoms of bleeding gingival and reduce dental plaque, suggesting it is effective and safe for treating plaque induced gingivitis.

【Key words】 Bioactive glass Plaque Gingivitis Anti-bacterial

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