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A randomized study of Biatain foam vs. gauze dressing in diabetic foot ulcers

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Aims: “Modern” wound dressings supposed to be more effective and easier in use than “traditional” (“simple”) ones but they are usually more expensive and some concerns exist about possibly higher risk of wound infection in moist conditions. We conducted a randomized study to compare: (1) efficacy, (2) safety and (3) treatment costs of “modern” and “simple” dressings. **Methods:** 40 patients (56 ulcers) with diabetic foot or leg ulcers of Wagner grade I or II in granulation stage were included into the study. They were randomly assigned to 2 months treatment with foam dressing (Biatain, (Coloplast)) - group 1 (Gr.1) or with standard treatment (atraumatic non-medicated gauze) - group 2 (Gr.2). Other components of treatment were: off-loading (TCC or half-shoe), antibiotics (25%), diabetes control. Biatain dressing was changed every 2-4 (up to 5) days; in standard treatment group dressing was usually changed daily. 20 patients (28 ulcers) in Gr.1 and 15 (21 ulcers) in Gr.2 completed the study. Of them, 41 ulcer (84%) were neuropathic, 5 ulcers - neuroischemic (with non-critical limb ischemia), 3 - were leg ulcers of several origins. Most of ulcers (14 of 20 in Gr.1, 13 of 15 in Gr.2, $p>0.05$) were non-ischemic non-infected. **Results:** M:F ratio, age, DM1:DM2 ratio, glucose level, diabetes treatment, ulcers duration and size, prevalence of ischemia and wound infection, duration of antibiotics before/after enrollment, off-loading modalities didn't differ significantly between groups ($p>0.05$). Efficacy: During study period, 70% of patients in Gr.1 and 53% in Gr.2 healed ($p=0.48$) with median healing time 45 (13-61) days in Gr.1 and 18 (7-65) days in Gr.2 ($p=0.18$). No significant difference between groups was found in Kaplan-Meyer analysis, in healing rates and healing times. Safety of treatment: didn't differ significantly ($p>0.05$). In 2 patients (1 in every group) study was stopped due to progression to osteomyelitis, in 2 more (1 in every group) - due to low treatment efficacy demanding change of dressing type. Treatment costs: despite of 8 times higher cost of Biatain dressing, its usage needed less frequent dressing changes and cheaper secondary dressing. As a result, costs of all dressing materials for 1 patient treatment course were only 2.4 times higher in Gr.1. Taking into account cost of personnel labor time Biatain treatment was 1.75 times cheaper than atraumatic gauze, $p=0,003$. **Conclusions:** (1) “Modern” materials are not more effective and (2) not less safe than “simple” ones. (3) Real ratio of costs of “modern” and “simple” dressings treatment is less than ratio of 1 sheet of dressing costs; reducing of dressing change frequency allows to save costs of treatment.