KEY POINTS

• A multicentre RCT in venous leg ulcers and pressure ulcers, to compare SILVERCEL® with control (ALGOSTERIL®, a calcium alginate dressing) to minimize risk of local infection, in 99 patients, over 4 weeks

• Of the patients that completed the 4-week study duration, 4/38 (10.5%) patients in the control group, and 0/40 (0%) in the test group were treated with systemic antibiotics at final visit (p=0.053)

• Fewer wounds developed a clinical infection in the 4-week follow up period in the test group (33% versus 46%, p=0.223)

• The wound severity score for the test group was significantly reduced after 4 weeks treatment (-32+-17% versus -23+-25%, p=0.034)

• The 4-week closure rate was significantly greater in the test group (0.32+-0.57cm²/day versus 0.16+-0.40cm²/day; p=0.024)

STUDY OBJECTIVE

To evaluate the clinical impact of SILVERCEL® (a silver-releasing hydroalginate) to minimize the risk of local infection in colonized chronic wounds compared to an alginate control (ALGOSTERIL®).

METHODS

Randomised (stratification according to wound type) open-label, multicentre comparative study

• 99 patients recruited at 13 centers followed for 4 weeks
• SILVERCEL® test dressing (n=51) 13 pressure ulcers, 38 venous leg ulcers (VLUs)
• Control alginate, ALGOSTERIL® (n=48) 15 pressure ulcers; 33 venous leg ulcers
• All VLUs also received compression bandaging
RESULTS

The total mASEPSIS score* over 14 days was not significantly different between groups (p=0.791). While the score was lower in the test group for pressure sores, the reverse was found in leg ulcers. This was thought to be due to low sensitivity of the scoring system and the heterogeneity of chronic wounds.

During the study period no significant difference in use of systemic antibiotics was observed between groups, however significantly fewer patients that completed the 4-week study duration were treated with systemic antibiotics at final visit (p=0.053); Control = 4/38 (10.5%) & Test group = 0/40 (0%). Also fewer wounds developed a clinical infection in the 4-week follow-up period in the test group (33% vs. 46%; p=0.223).

Compared to baseline, the absolute decrease in wound severity score at week 4 was higher in the test group (-5.6+/–3.2 versus –4.1+/–4.3; p=0.063); this was also true for percentage reduction (32 +/- 17% vs. 23 +/- 25%; p=0.034).

The global wound areas did not differ significantly for each of the 2 wound types; however, the surface area of VLUs was on average larger in the test group (44.8+/–46.3cm² versus 24.5+/–21.3cm²). To account for this difference, closure rate was calculated. Overall the 4-week closure rate was significantly greater in the test group (0.32+/–0.57cm²/day versus 0.16+/–0.40cm²/day; p=0.024).

The SILVERCEL® dressing was well tolerated; poor dressing tolerability was recorded as 10.4% in the control group and 9.8% in the test group.

CONCLUSIONS

This study suggests that the use of SILVERCEL® [a silver hydroalginate dressing] in wounds at high risk of infection may have a clinically favourable influence on wound prognosis.