



Title	A Prospective Randomized Controlled Trial and Economic Modeling of Antimicrobial Silver Dressings Versus Non-Adherent Control Dressings for Venous Leg Ulcers: The VULCAN Trial
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Aim

To examine whether antimicrobial silver-donating dressings were more effective than simple nonadherent dressings beneath compression bandaging in treating venous ulcers.

Conclusions and results

No significant differences ($p > 0.05$) were found between the group that had silver-donating antimicrobial dressings and the group with the control dressing for the primary outcome measure of proportion of ulcers healed at 12 weeks (59.6% for silver and 56.7% for control dressings). The overall median time to healing was not significantly different between the two groups ($p = 0.408$). Mean utility valuations for both the EQ-5D and SF-6D showed no statistically significant differences between the groups at 1, 3, 6, or 12 months. Compared to the control group, the antimicrobial group had an incremental cost of 97.85 pounds sterling (GBP) and an incremental QALY gain of 0.0002 giving an incremental cost-effectiveness ratio (ICER) for the antimicrobial dressings of 489.250 GBP. Cost-effectiveness modeling of the results of the RCT showed, for the base case model, that only included variables that were predictive of healing antimicrobial dressings were not cost effective. Sensitivity analysis where dressing type was forced into the model, and where a small benefit in utility was assumed to occur at the point of healing, resulted in a small average incremental benefit for the antimicrobial dressings. However, this was not sufficient to justify the additional cost, and there remained a high probability that the treatment was not cost effective.

Recommendations

This study found no significant difference in either primary or secondary endpoints between the use of antimicrobial silver dressings and the control group of low adherent dressings. The cost analysis showed a significantly higher cost for those treated with antimicrobial dressings. Cost-effectiveness modeling showed antimicrobial dressings to be dominated by inert dressings: no

difference was found in clinical outcomes, and antimicrobial dressings were associated with higher cost.

Methods

See Executive Summary link at www.hta.ac.uk/project/1380.asp.

Further research/reviews required

- 1) Development of a disease-specific, quality-of-life measure for venous ulcer patients that can be used in economic evaluations.
- 2) Research to ensure clear descriptions of epidemiology, treatment methods, and experiences of staff engaged in compression bandaging.
- 3) Research into new treatments for leg ulcers, including mathematical modeling to establish the potential value of further clinical trials and to assist in appropriate trial design prior to undertaking large and potentially expensive clinical trials.
- 4) Research on problems of ulcers that fail to heal after 12 weeks of compression, and whether antimicrobial dressings might have advantages in patients who are unable to tolerate compression.
- 5) Clarification of whether the diagnosis of "infection" in leg ulcers might be relevant to the use of antimicrobials.
- 6) Studies on how clinicians make decisions regarding dressing type, particularly the influence of sales representatives as sources of evidence and guidance.