Comparative effectiveness of an acellular synthetic matrix as an adjunct to standard care in the treatment of venous and mixed leg ulcers: Modeling of clinical data and routine data

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Objectives

The purpose of our study was to assess the effectiveness of a new acellular synthetic matrix (ASM) as an adjunct to standard care, using healing time as endpoint, in venous and mixed leg ulcers (VMLU) in German everyday clinical practice.

The ASM is a sterile acellular matrix for the treatment of hard-to-heal wounds, primarily venous leg ulcers. The acellular matrix works by replacing degraded wound matrix. The ASM binds to a prepared wound bed and provides a physical structure for cell attachment, which is a primary requirement for subsequent cell functions critical for healing, such as, cell proliferation, cell survival, migration and synthesis of new extracellular matrix. Newly attached cells in the wound bed subsequently produce new extracellular matrix de novo, which in turn, serves to guide normal tissue renewal, maturation and thereby restore healing.

Methods

Prospective data on chronic venous and mixed leg ulcers from a safety and effectiveness study on an ASM was compared retrospectively to matched data from a German Registry of Chronic Wounds (DRCW) database containing patients with equivalent leg ulcer disease, patient age and gender, baseline wound area, wound duration, same outcome measures, and comparable follow-up periods. The outcome of interest was healing time over 12-weeks of treatment.

The two study groups included were the intent-to-treat (ITT) population from the ASM study (ASM study group) and all patients from the DRCW database (DRCW study group) who met the equivalency criteria i.e. the main ASM study inclusion criteria.

In figure 2, a total of 64 patients, 38 from the wound center in the North and 26 from the wound center in the East of Germany, met the equivalency criteria for a comparative evaluation with the ITT ASM dataset (53 patients). Between the groups, wound factors as well as patient age and gender were all statistically equivalent:

1. baseline wound area: p = 0.935,
2. ulcer duration: p = 0.068,
3. gender: p = 0.481,
4. age: p = 0.128

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Conclusion

The ASM provides an effective, easy to use, new adjunct therapy for restoring healing in chronic, vascular ulcers. The results of our assessment suggest that replacing degraded wound with the ASM in addition to standard care may significantly reduce healing time compared to using standard care therapy alone in German everyday clinical practice. We predict that the ASM will show similar results in future pragmatic observational studies in Germany and in the UK.