Can Real World Experience Contradict RCTs (e.g. ESCHAR Trial)?

Alfred M Obermayer, MD
Vienna, Austria
Institute of Functional Phlebologic Surgery
Karl Landsteiner Society
www.phlebosurgery.org

Disclosure by Alfred M Obermayer:
I do not have any potential conflict of interest.

We suggest use of a standard definition of venous ulcer as an open skin lesion of the leg or foot that occurs in an area affected by venous hypertension and shows little or no tendency to spontaneous healing. [BEST PRACTICE]

Local venous hypertension

"It's the pressure!!"
To decrease the recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A).

Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum

**2011**

To decrease the recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A)

**2014**

How to decrease recurrence in case of non-healing ulcers???


ESCHAR – study

Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial.


Excluded: 918 = 65%

How to treat excluded patients?

ESCHAR – study

“Ulcer healing is not enhanced by superficial venous surgery”

Figure 2: Kaplan-Meier analysis of ulcer healing for all legs

ESCHAR – study

“Superficial venous surgery significantly reduced ulcer recurrence rate!”

Figure 3: Kaplan-Meier analysis of ulcer recurrence for all legs
Comparison of ESCHAR study with own results

<table>
<thead>
<tr>
<th></th>
<th>ESCHAR</th>
<th>Obermayer</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>74 (60-80)</td>
<td>68 (25-88)</td>
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<tr>
<td>Ulcer size ($cm^2$) - median</td>
<td>3 (1-20)</td>
<td>12 (1-500)</td>
</tr>
<tr>
<td>Ulcer chronicity (month)</td>
<td>5 (3-12)</td>
<td>12 (6-360)</td>
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<tr>
<td>ABPI &lt; 0.85 Excluded (19.5%)</td>
<td>20.5% (included)</td>
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<tr>
<td>Previously failed compression therapy</td>
<td>unknown</td>
<td>&gt;90%</td>
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<tr>
<td>Depth of ulcer</td>
<td>unknown</td>
<td>38% restricted to the dermis and subcuta 49% the fascia 11% tendons, bones, and joints were involved</td>
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Painful forefoot ulcers

m, 45ys, PTS, St. p. PE, Cumarine-therapy
Retractable ulcers despite 2 weeks inpatient care: Antibiotics Antimycotics, Compression

Duplex guided foam sclerotherapy


“Sourcing of the forefoot & toes”
Conclusion

Sometimes Real World Experience Contradicts RCTs

The Lower Evidence -
The Greater Experience you need