Ul Haq et al. “Bleomycin Foam Treatment of Venous Malformations: A Promising Agent for Effective Treatment with Minimal Swelling.” JVIR 2015; 26:1484-1493

Ul Haq et al:

- 20 patients underwent 21 Bleomycin procedures
- 6 procedures involved additional sclerosants
- 40% complication rate (per patient basis)
- 30% minor, 10% major
- 29% complication rate (per procedure basis)
- 22% major, 7% major
- All patients had decrease in symptoms

Ul Haq et al:

- “...use of Bleomycin should be reserved for locations where post-procedure swelling would be dangerous.”
- 1 patient required endotracheal intubation for 4 days due to severe and prolonged tongue swelling to maintain airway for 4 days.
- Another patient required prolonged intubation and hospitalization for 15 days after Bleomycin and ethanol in the tongue.

Ul Haq et al:

- “Swelling was seen only in the area treated with alcohol, not in the area treated with Bleomycin foam.”
- 10% had prolonged intubation secondary to severe swelling obstructing the airway.
- This severe swelling is a potential with any sclerosant injections.

Hassan et al:
- 71% effectiveness rate; 29% failure rate
- 14% complication rate
- 5 major ulcerations in 75 patients treated


Sainsbury et al:
- 82.7% effectiveness rate; 17.3% failure rate
- Complications included:
  - Severe Blistering
  - Ulcers
  - Severe Swelling
  - Infections
  - Recurrences


Bai et al:
- 43% effectiveness rate; 57% failure rate with IR endovascular treatment alone
- 74% effectiveness rate; 26% failure rate with IR Rx followed by surgery

Young et al:
- 81% effectiveness rate; 19% failure rate – Macrocystic LM
- 63% effectiveness rate; 37% failure rate – Microcystic LM
- Complications included:
  - Ulcerations
  - Hematoma
  - Bleeding
  - Fevers
  - Soft Tissue Atrophy


Zhang et al:
- 138 children consecutively treated
- 71 of 75 patients (95%) had “cured”, “markedly effective” or “effective treatment” with absolute ethanol
- 41 of 63 patients (65%) had “effective” treatment in the Bleomycin group
- The difference in ETOH group and Bleo group were statistically significant: $\chi^2=19.6; P<0.05$
- ETOH group of 75 patients had 14 cases of skin necrosis
- Bleo group of 63 patients had 5 cases of skin necrosis
- ETOH group statistically superior to Bleo group

Zhang et al:
- “Cured” = disappearance post-Rx without recurrence
- “Markedly Effective” = >80% was ablated
- “Effective” = improved, <80% reduction
- “Ineffective” = No VM reduction or continued increase
Zhang et al Ethanol Group:
- 30 cases 1 treatment, 30 cases 2x, 15 cases 3x
- Superficial VMs: 38 of 40 (95%) effective rate
- Deep VMs: 33 of 35 (94%) effective rate
- 15 of 75 cured; 33 markedly effective; 13 effective; 4 ineffective
- Failure rate: 5.3%
- Skin Necrosis: 14 superficial cases; 35%

Zhang et al Bleomycin Group:
- 6 cases 1 treatment, 23 cases 2x, 31 cases 3X, 3 cases 4x
- Superficial VMs: 32 of 47 (68%) effective rate
- Deep VMs: 9 of 16 (56%) effective rate
- Failure rate: 33.1%
- Skin Necrosis: 5 superficial cases; 10.6%

Lee et al.
- 87 patients; 399 procedures
- 95% significant or complete ablation
- 12.4% complication rate


Johnson et al:
• Tongue VMs; 100% success rate
• 1 patient with massive tongue VM and concurrent breathing difficulties prior to treatment remained intubated 5 days and then uneventfully discharged


Su et al:
• Head and Neck VMs; 56 of 60 patients cured (90%)
• 4 minimal residual
• No skin necrosis; no nerve injuries


Orlando et al:
• Used local anesthesia only; 39 patients with extremity VMs with main symptoms of pain
• Complete cure or significant symptom improvement 94%
• 1 skin ulcer; 3 transient paresthesias

Lee et al:
- 87 patients; craniofacial VMs
- Mean follow-up 35 months; 305 procedures
- 71 of 87 excellent outcomes (75% reductions)
- 1 Pt transient tongue decreased sensation; 1 pt transient facial nerve palsy
- No skin necrosis


Vogelzang et al:
- VMs in 31 patients; AVMs in 15 patients
- Major complication rate:
  - AVMs: 13.3% (per patient); 3.9% (per procedure)
  - VMs: 9.7% (per patient); 5.4% (per procedure)
- Minor complication rate:
  - AVMs: 6.7% (per patient); 2% (per procedure)
  - VMs: 16.1% (per patient); 9.8% (per procedure)
- Major: 1 ulcer injury, digit amputation; 1 leg compartment syndrome requiring fasciotomy; 1 skin ulcer; 1 transient sciatic neuropathy
- 24 patients cured; 12 patients significantly improved; 10 patients no change

January 2002 – December 2017

Embolization Statistics
- Procedures: 17,440
- Patients: 8,139
- Ethanol: 281,347 ml

Malformation Location
- VM/LM : AVM 10:3 Ratio
- Head & Neck 1,722
- Upper Extremity 1,146
- Lower Extremity 2,167
- Chest/Abdomen 1,362
- Pelvic/Buttock 962
### Minor Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue Injury</td>
<td>368</td>
</tr>
<tr>
<td>Temporary Nerve Injury</td>
<td>129</td>
</tr>
<tr>
<td>Superficial Blood Clot</td>
<td>24</td>
</tr>
<tr>
<td>Infection</td>
<td>165</td>
</tr>
<tr>
<td>Bleeding</td>
<td>31</td>
</tr>
</tbody>
</table>

### Major Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT</td>
<td>27</td>
</tr>
<tr>
<td>PE</td>
<td>10</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>6</td>
</tr>
<tr>
<td>Permanent Nerve Injury</td>
<td>4</td>
</tr>
<tr>
<td>Cardiac-Pulmonary Arrest</td>
<td>5</td>
</tr>
<tr>
<td>Amputation</td>
<td>2</td>
</tr>
<tr>
<td>Hypoxia/Airway Compromise</td>
<td>13</td>
</tr>
<tr>
<td>Complications from Focal Swelling</td>
<td>14</td>
</tr>
<tr>
<td>Cerebrovascular Accident</td>
<td>6</td>
</tr>
<tr>
<td>Peripheral Ischemia</td>
<td>11</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>1</td>
</tr>
<tr>
<td>Bowel Perforation</td>
<td>2</td>
</tr>
</tbody>
</table>

### Summary

- Ethanol publications state its efficacy routinely at 90-100% of cases.
- All other second tier sclerosants state their efficacy 60-80%.