Onyx® Syndrome
Post embolization for Type II endoleak

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
• Endoleak remains the Achilles heel of endovascular aortic repair

• Type II is the most common type of endoleak

• Embolising the nidus of the vessel feeding these sac is an established strategy

• Onyx ® co-polymer is an expensive but effective agent that can be injected through micro-catheters
• Onyx ® is delivered in liquid form via intra-arterial catheter

• Solidifying after few seconds to induce thrombosis

• Onyx® has been approved for Pre-surgical embolisation of brain arteriovenous malformations (AVM)

• Recently it has been widely used for embolisation of (mainly) type II endoleak cases
Recognized adverse events

<table>
<thead>
<tr>
<th>EVENT NAME</th>
<th>Incidence of Complications</th>
<th>Onyx N=54</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TRUFILL N=63</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td>1 (1.9%)</td>
</tr>
<tr>
<td>Headache, nausea and vomiting</td>
<td></td>
<td>45 (83.3%)</td>
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<tr>
<td>Patient discomfort</td>
<td></td>
<td>39 (72.2%)</td>
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<tr>
<td>Laboratory-induced hyperkalemia</td>
<td></td>
<td>26 (48.2%)</td>
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<tr>
<td></td>
<td></td>
<td>12 (22.2%)</td>
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<tr>
<td></td>
<td></td>
<td>4 (7.4%)</td>
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<tr>
<td></td>
<td></td>
<td>3 (5.6%)</td>
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<tr>
<td></td>
<td></td>
<td>2 (3.7%)</td>
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<tr>
<td></td>
<td></td>
<td>1 (1.9%)</td>
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<tr>
<td></td>
<td></td>
<td>0 (0%)</td>
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<tr>
<td></td>
<td></td>
<td>0 (0%)</td>
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<tr>
<td>Respiratory failure</td>
<td></td>
<td></td>
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<tr>
<td>Seizures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTI (Urinary tract infection)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaso-vagal episode</td>
<td></td>
<td></td>
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<tr>
<td>Cardiac arrhythmia/hypertension</td>
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<td></td>
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<tr>
<td>Embolization of unintended vessels*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Premature polymerization time*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular access complication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolonged polymerization time*</td>
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</tr>
</tbody>
</table>

*Technical or Procedural Event only with no clinical sequelae.
According to Onyx® IFU, there are several adverse events reported from prospective, randomised, multi-centre trials comparing Onyx to TRUFIL in brain AVM embolisation.

Systemic complications are rare and limited to case reports post-embolisation of brain AVM.

Complications following Onyx® embolisation for type II endoleak have not been reported.
- Onyx® is comprised of ethylene vinyl alcohol co-polymer (EVAC) and is mixed in a dimethyl sulfoxide (DMSO) solvent, combined with micronized tantalum (a radio-opacifying agent)

- The catheter is flushed with DMSO to enable delivery of Onyx® in a liquid form to the target vessel
• As DMSO dissipates in the blood stream, the Onyx® copolymer forms an occlusive cast in the injected artery

• DMSO has been implicated in adverse pulmonary reactions that can include transient hypoxaemia during the embolisation process, with later pulmonary oedema and the development of SIRS
• DMSO can induce vasospasm, endothelial necrosis and an inflammatory response following intra-arterial injection

• DMSO dose-response data, toxic dose unknown

• A direct toxic effect of the Onyx® co-polymer is a possibility
Could the volume of Onyx® used for embolisation have an impact on intensity/frequency of adverse events?

Typical volume Onyx® used for AVM = 1-4 mls

Typical volume Onyx® used for Type II endoleak = 5-10 mls
Case Report

• We present a case describing pulmonary, renal and liver complications following the use of Onyx® for a type II endoleak

• 80 yrs old patient, EVAR when asymptomatic 6cm AAA, type II endoleak driving sac growth

• Patient underwent fluoroscopic guided embolisation with 18cc Onyx-34® via the left ilio-lumbar artery into the aneurysm sac with a satisfactory radiological result
- Over the week after the procedure, he developed shortness of breath, malodour, peripheral oedema, peri-oral paraesthesia and itching.

- Blood tests showed elevated creatinine levels as well as elevated alkaline phosphatase (ALP) and gamma-glutamyl transpeptidase (GGT) levels.

- Post-procedure CT imaging showed evidence of bilateral pleural effusions and signs of pulmonary oedema (hepatic reflux).
• The patient was managed conservatively and his symptoms subsided over a further 8 week period

• At the 8 week point liver and kidney functions had returned to normal, with complete resolution of symptoms.
Conclusion

• To our knowledge this is the first report describing systemic complications related to the use of Onyx® to treat type II endoleak

• Would greater volumes of Onyx® used for embolisation of endoleak play a role?

• Patients undergoing endovascular repair of AAA are likely to differ substantially from those suffering from brain AVMs
• Although rare, systemic complications should be considered after infusion of large volumes of Onyx® co-polymer

• Patients need to be informed of this rare but possible complication of Onyx® embolisation
Thank You