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Clinical paper review for Health care professionals

"Direct percutaneous embolization of aneurysm sac: a safe and effective procedure to treat post-EVAR type II endoleaks". Fanelli F, et al. 2020



Highlights:

- 1. Double-center, prospective study
- 2. 50 patients
- 3. Percutaneous direct sac puncture with Onyx™
- 4. Follow-up at 6 and 12 months
- 5. Sac size reduced (68%) or stabilized (32%) at 1-year follow-up

Background

- Type II endoleaks remain the most common complication of endovascular aneurysm repair (EVAR).
- In approximately 40-58% of the cases, type II endoleaks are not correlated with sac enlargement and solve spontaneously. In those cases where they are responsible for a progressive increase in the aneurysm sac, treatment is required.
- Different percutaneous techniques have been already described, but none of them can be considered definitive, especially in more complex situations or in case of persistent endoleak.
- The paper reports the outcomes of fifty cases of type II endoleaks with increasing aneurysm sac diameter, successfully treated with direct percutaneous sac approach using Onyx[™] liquid embolic agent (alone or in combination with detachable micro-coils).

Study objective

To report safety and effectiveness of type II endoleak embolization, with percutaneous direct aneurysm sac puncture.

Materials and methods

Study Design

- This is a prospective, physician-initiated, study conducted in two centers, with approval by local ethics committees.
- Fifty patients, 31 males, mean age 63 ± 8 years (range 50-71 years), with post-EVAR type II endoleaks underwent percutaneous direct sac puncture.
- Indication to treatment was based on the presence of type II endoleak on CT angiography, performed during the follow-up, with aneurysm sac enlargement >5 mm in the last 6 months.

Embolization technique

- Procedures were performed under deep sedation to reduce pain related to DSMO injection.
- Sac puncture was done using a 20G needle under rotational angiography guidance. A coaxial system (4 Fr catheter + 2.7 microcatheter) was used to navigate the sac.
- Onyx[™] liquid embolic device was injected to fill completely the aneurysm sac.

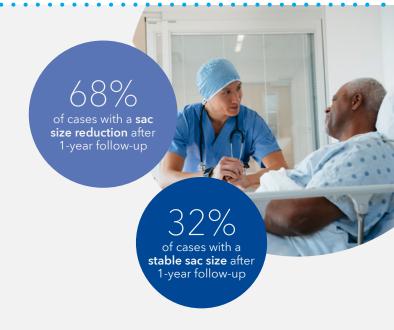
Patients' Feature	Value
Male, n (%)	31(62)
Age, range	50-71
Smoking habit, n (%)	10 (20)
Coronary artery disease, n (%)	20 (40)
COPD, n (%)	10 (20)
Hypertension, n (%)	35 (70)
Obesity (BMI > 30), n (%)	7 (14)
Diabetes, n (%)	21 (42)

Follow-up

• Follow-up was arranged with contrast-enhanced ultrasound at 6 and 12 months. In case of suspicious findings or endoleak recurrence, a CT angiography was performed.

Results

- Technical success, with complete embolization of the aneurysm sac with no more evidence of blood flow within the sac, was achieved in all cases.
- No complications, correlated with the direct percutaneous sac puncture or to Onyx[™] injection, occurred.
- All patients were discharged the day after the procedure.
- Freedom from re-intervention for recurrent endoleak was 97.9% at 12 months.
- A second embolization was required only in two cases (4%) for endoleaks type II recurrence - after 9 and 12 months, respectively



Median time between initial EVAR and endoleaks treatment	27 months (range 6-48 months)
Mean procedure time	51.36 min (range 36-68 min)
Mean fluoroscopy time	16.7 min (range 10-20 min)
Percutaneous sac puncture cases (%)	
with posterior left access	82%
with posterior right access	12%
with anterior access	6%
Cases with feeding vessels embolized with micro-coils (alone or with Onyx) (%)	38%
Total amount of Onyx (ml) (mean)	8 (range 3-15)

Conclusions

Procedure Outcomes

Percutaneous direct sac embolization using Onyx™ is a safe and valid technique to solve post-EVAR type II endoleaks.



Europe

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See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

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Reference

Fanelli F, et al. "Direct percutaneous embolization of aneurysm sac: a safe and effective procedure to treat post-EVAR type II endoleaks". Radiol med 2020 ; 126



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