Klinikum rechts der Isar
Technische Universität München

DIE DEUTSCHEN UNIVERSITÄTSKLINIKA

EVAR with sac embolization for the prevention of type II Endoleaks (EVAR-SE) - Rationale and design of a new RCT

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Disclosures

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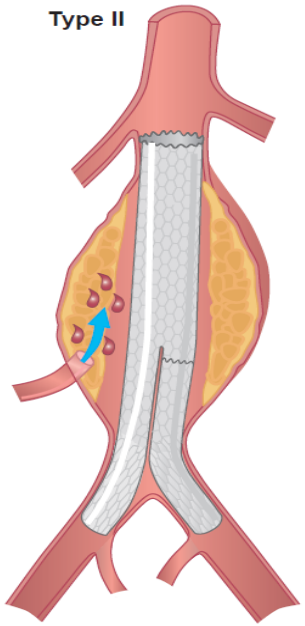
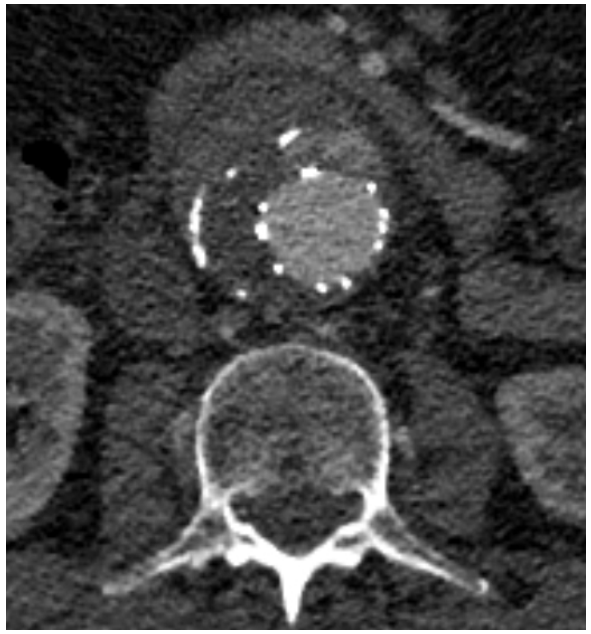
  - COOK
  - MEDTRONIC
- Local PI of TCAR trials (Roadster 2 and DWI Trial, SILKROAD)
- SC of the SPACE Trials and ACST-2 Trial
- Member of the Carotid Stenosis Trialist Collaboration (CSTC)

- All of them are unrelated to this talk

Type II Endoleak

- Flow inversion in IMA or lumbar arteries after EVAR
- 20–30% of all EVAR cases
- Expansion of aneurysm in 25%
- Risk for secondary T1EL or rupture
- Association with elevated mortality





Recommendation 88	Class	Level
Re-intervention for Type II endoleak after endovascular abdominal aortic aneurysm repair should be considered in the presence of significant aneurysm growth (see Recommendation 87), primarily by endovascular means.	IIa	C

ESVS AAA Guideline 2019

Stather et al. British journal of surgery. 2013;100(7):863-72.
Abularrage et al. Journal of vascular surgery. 2010;52(1):19-24.
Guo et al. PloS one. 2017;12(2):e0170600.
Lo et al. Journal of vascular surgery. 2016;63(4):895-901.

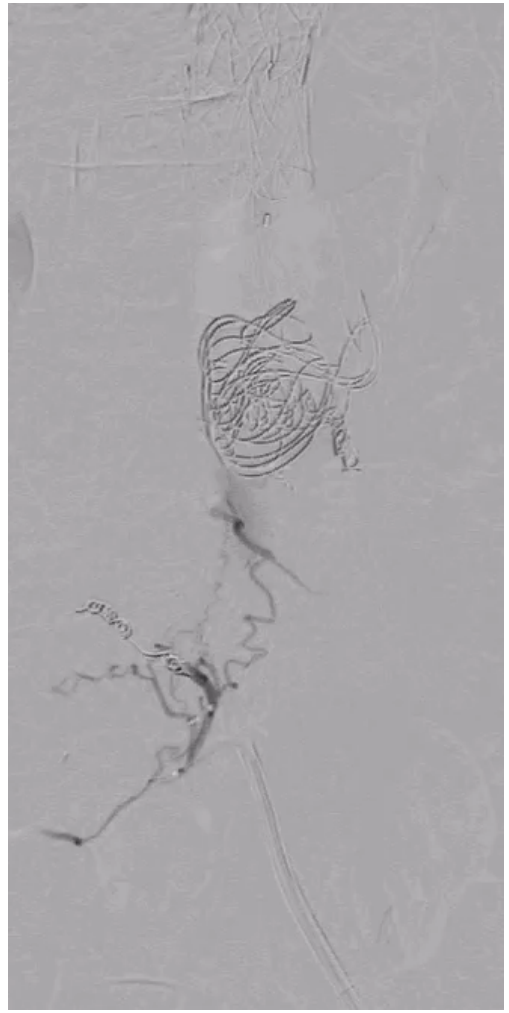
Type II Endoleak – endovascular therapy

Coiling:

- Freedom from EL: 40–70%
- Freedom from expansion: 30–60%

Polymer:

- Freedom from EL: 50%
- Freedom from Expansion: 60%

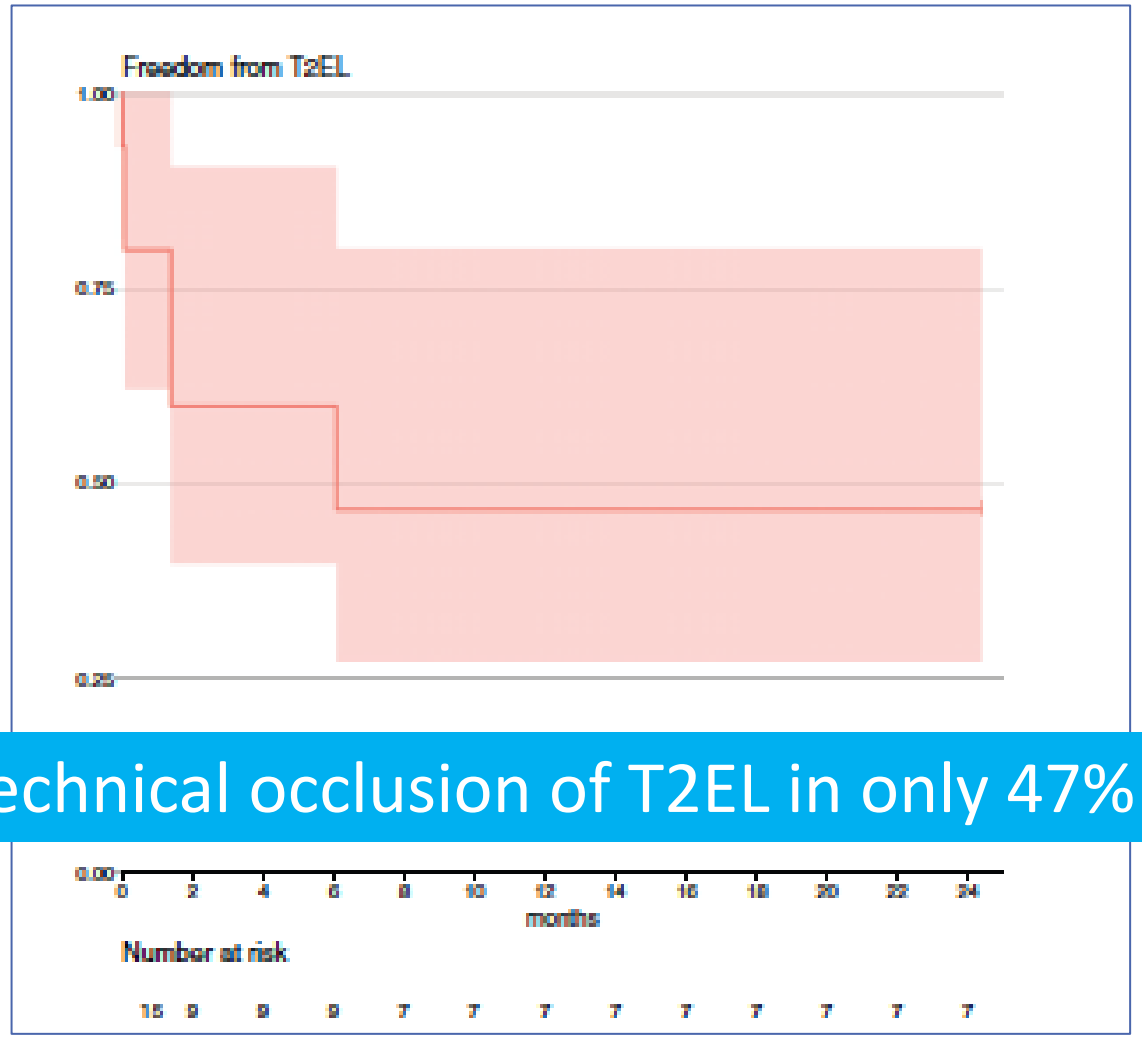


There is little evidence supporting the efficacy of secondary intervention for type II endoleaks after EVAR.

Ultee et al. EJVES. 2018; 56(6):794-807.

Sarac et al. Journal of vascular surgery. 2012; 55(1):33-40
Bryce et al. Cardiovasc Diagn Ther. 2018; 8: S131-137
Menges, Trenner et al. Vasa (2020): 49(6):483-491

Freedom from T2 EL after Onyx glue



Technical occlusion of T2EL in only 47% after two years

Original communication

Lack of durability after transarterial ethylene-vinyl alcohol copolymer-embolization of type II endoleak following endovascular abdominal aortic aneurysm repair

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Summary: *Background:* Type II endoleak (T2EL) after endovascular aortic repair is associated with AAA sac enlargements in up to 25%, reduction of attachment zones and rarely with aortic rupture. Indications for therapy and efficacy of interventions of T2EL are not clearly established. Transarterial embolization with application of ethylene-vinyl alcohol copolymer has been described with varying outcomes. Aim of this study is to evaluate durability of Onyx™ embolization (OE) in T2EL in a consecutive series at a single tertiary vascular center. *Patients and methods:* Demographic data, technical success, pre- and postoperative aneurysm growth, morbidity, mortality and reintervention rates during hospital stay as well as in follow up were recorded in patients treated with OE for T2EL between 01/2015 and 12/2017. The primary endpoint was defined as persistence or reoccurrence of T2EL (durability of OE). *Results:* In total 15 patients (78 ± 6 years, 13 men) were treated with OE because of sac enlargement (average growth of 12 ± 8%, n = 12), persistent bleeding after AAA rupture (n = 2) or persistent T2EL with stable but large aneurysm diameter (n = 1). Mean length of stay was 8 ± 11 days. Technical success was 93.3% (n = 14). Inhospital-morbidity was 26.7%, in-hospital- and 1-year-mortality rate were 6.6% (n = 1) and 20.0% (n = 3). T2EL persisted in 20.0% (n = 3) despite of OE. Re-EL-II occurred after 40 (30–114) days in 33.3% (n = 5). Reintervention rate was 13.3% (n = 2, at day 48 and 319). Altogether clinical success with stable aneurysm diameter was achieved in 80.0% (n = 12), but durable elimination of EL was only achieved in 46.7% of patients (n = 7). *Conclusions:* OE is technically possible in more than 90% of patients but might be associated with severe complications. Durability of this treatment is low, since T2EL persist or reoccur in more than 50% of all patients. OE of T2EL should be reserved for few selected cases.

Keywords: Onyx, Endoleak Type II, EVAR, AAA

Introduction

Endovascular aneurysm repair (EVAR) has become the standard of care for the majority of patients with infrarenal aortic aneurysms (AAA) in many countries [1–3]. ...ison to open aortic repair, retrograde perfusion of ...ac occurs in 20–40% of all EVARs, either imme- ...during follow-up [4, 5]. Type II endoleaks (T2EL) ...d by a retrograde perfusion of the aneurysm sac via the inferior mesenteric artery (IMA) or through lumbar arteries. Generally more than 60% of T2EL disappear spontaneously. 50% of persistent or late-onset T2EL endoleaks show AAA expansion, which might result in loss of sealing, secondary progression to type I or III endoleaks and can in some cases cause rupture [5–7].

The specific factors leading up to sac expansion and rupture are currently not well understood. There is evidence that pressure in the aneurysm sac could be a cause [8, 9]. In addition, atrophy of the aneurysm wall after EVAR has been demonstrated in size-expanding aortic aneurysms with T2EL [10]. Due to these aspects, current guidelines recommend to intervene primarily endovascularly in case of sac enlargement of >10 mm [5, 11]. However, evidence is weak and the level of recommendation is low.

The overall aim of any therapy is to reduce the pressure on the aneurysm wall and especially to prevent the ...econdary development of an EL type I [5]. Several options ...re available. Open or laparoscopic ligation of the IMA or

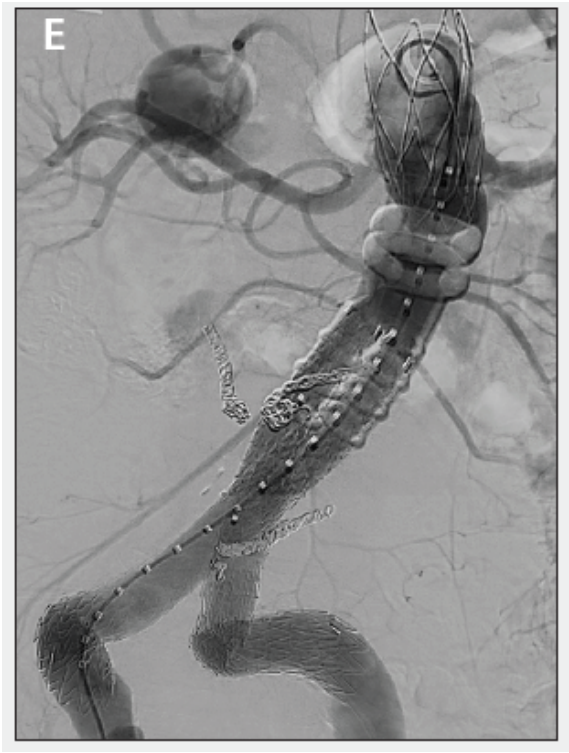
[a]These authors contributed ...

VASA 2020

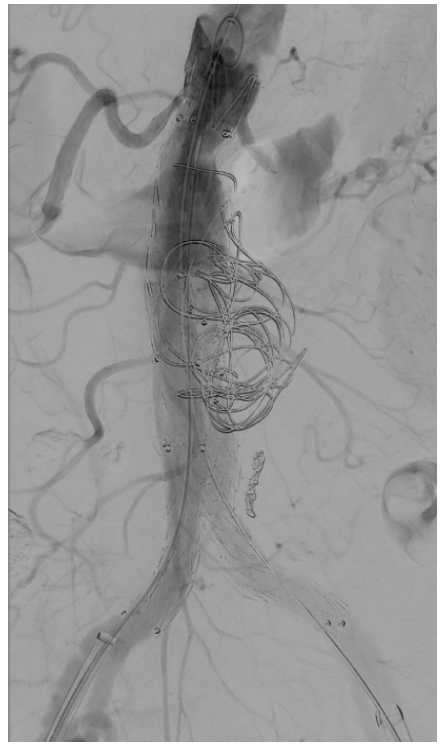
Vasa (2020), 49 (6), 483–491
https://doi.org/10.1024/0301-1526/a000905

Typ II Endoleak – Prevention

Endovascular Aneurysm Sealing (EVAS)
Stenson et al.
JVS 2020. 71:457-469



Side Branch Embolization
Branzan et al. , JVS 2021. 73(6): 1973-1979



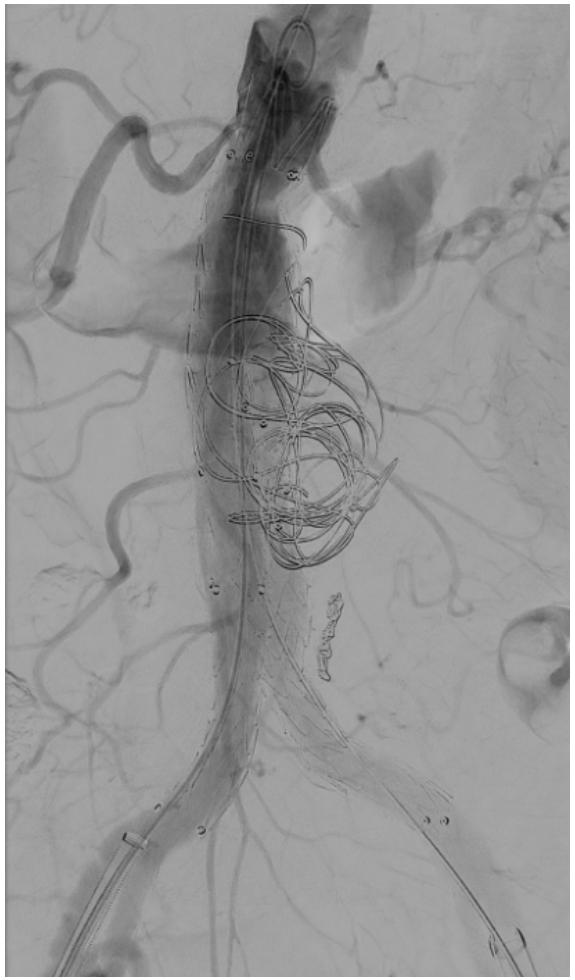
Sac Embolization

Bildquelle:
EVAS: https://trends.medicalexpo.de/project-418700.html
SBE: https://evtoday.com/articles/2020-apr/
SE: MAC/MRI

Type II Endoleak – Prevention

Sac embolisation (SE)

- During primary EVAR procedure
- 7–18 min additional procedure time
- 2–7 min additional fluoroscopy time
- Requires larger sheath (+4F) or additional 4F sheath on contralateral side
- Implantation of ≥2 metres of coils in aneurysm sac



ESVS 2019 AAA Guideline:

"Pre-operative sac embolization (…) has been suggested as a technique to reduce risk of Type II endoleak (…), but the benefit of a reduced number of late re-interventions or decreased incidence of rupture remains to be prove

Li et al. Journal of Endovascular Therapy (2020);27(1):109-16

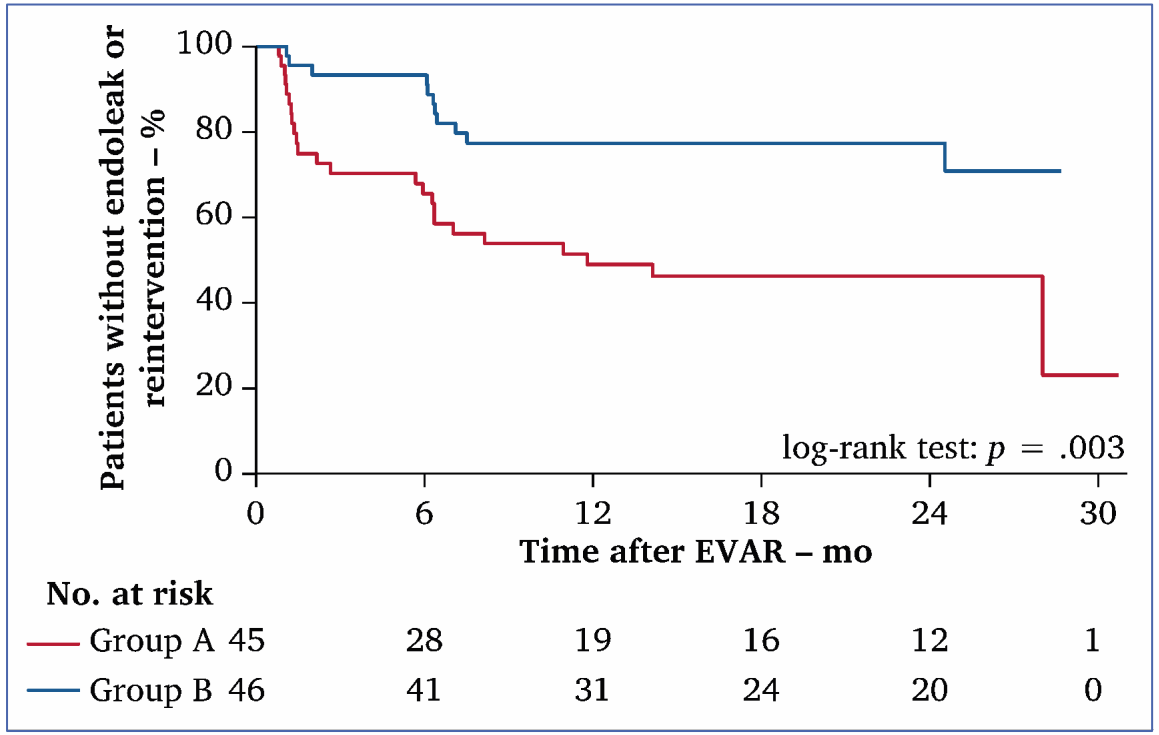
Type II Endoleak – Prevention

Fabre et al. European journal of vascular and endovascular surgery (2021); 61(2): 201-209

Level 1 evidence (SCOPE-1):

SE in patients at high risk for T2EL:

- 94 patients randomized
- T2EL after 12 months: 14% vs. 40% (p<0.01)
- T2EL after 24 months: 6.5% vs. 25% (n.s.)



Limitations:

- Definition of EPs
- Missing data
- Coils of single manufacturer
- FU with CT+DUS (no CEUS)
- No pat. relevant outcomes

EVAR-SE Trial - Multicentric explorative RCT (Funding through BMBF)

GEFÖRDERT VOM
Bundesministerium für Bildung und Forschung

Inclusion criteria

- AAA >50 mm, anatomically suitable for EVAR
- High risk for T2EL: ≥5 patent lumbar arteries and/or <40% thrombus in AAA

Primary endpoint: T2EL after 12 months (CEUS and CTA)

Hypothesis: Reduction of T2EL from 45% to 15% (OR 0.22)

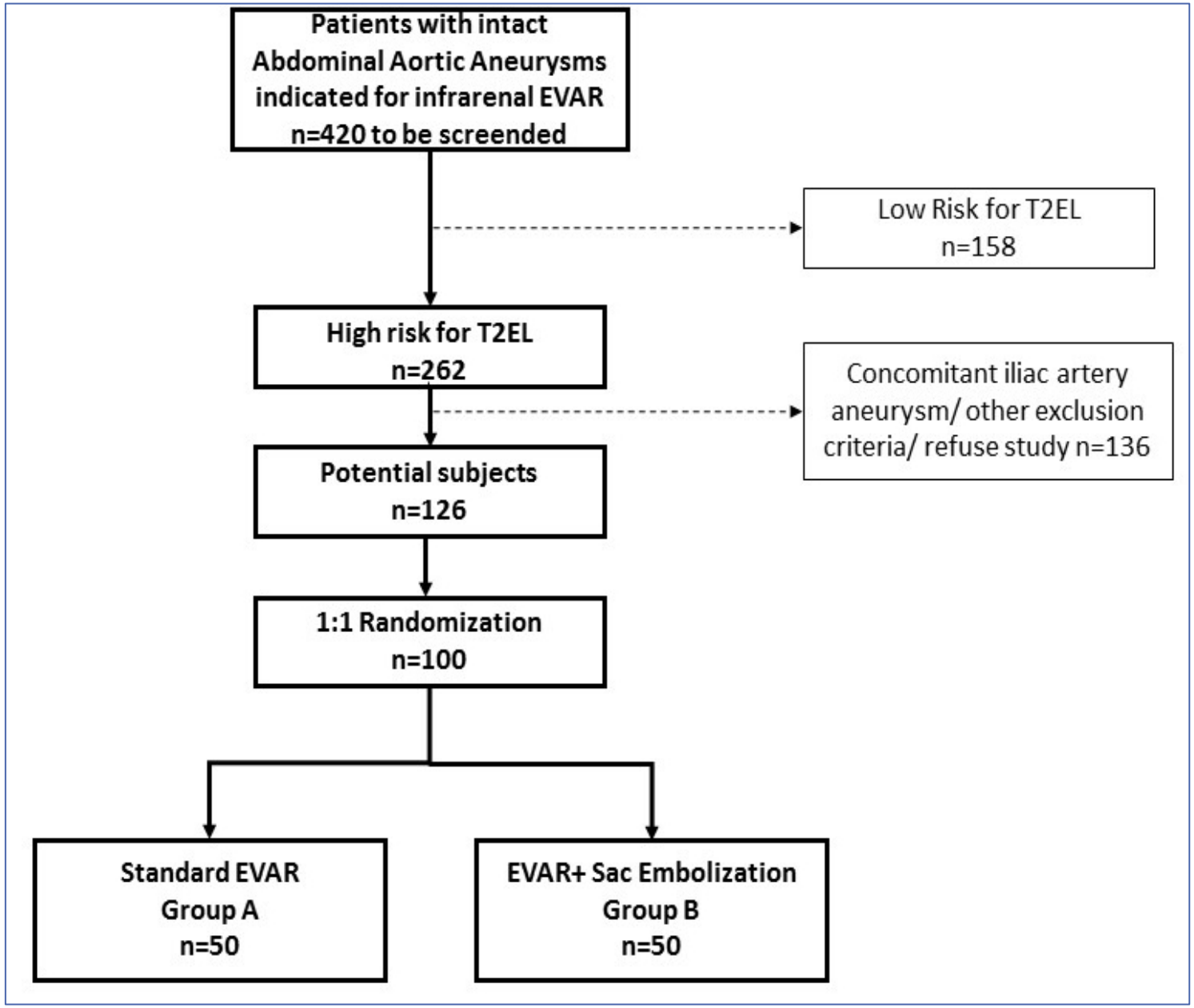
Secondary endpoints

- Patient safety (Reintervention, rupture, complications),
- QoL (SF-38)

Intended follow-up project

- 5 yrs survival and rupture rates

EVAR-SE Trial



Conclusions

- ✓ Type II endoleaks are a persisting problem after EVAR
- ✓ Prevention might be a key to improve long-term EVAR outcomes
- ✓ EVAR-SE trial will evaluate efficacy of sac embolization

Thank you very much

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