Comparison of Endovascular and Open Repair of Juxta- and Pararenal Abdominal Aortic Aneurysm on Short- and Long-term Clinical Outcomes

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A Note from the Investigator

Dear Collaborator,

On behalf of all project collaborators, welcome! We are very excited to be working with you to investigate whether there is a difference in terms of short-/long-term outcomes of open versus endovascular treatment for juxta-/pararenal abdominal aortic aneurysm (AAA). Thank you for committing to participate in this project.
This document has been prepared to assist you and your team in preparing your Institutional Review Board (IRB) submission. In the sample proposal, you will find information that IRBs commonly request in their review of prospective observational studies that qualify for expedited review. We understand that every IRB has a unique application and varied review process; please use your discretion to modify the sample and accommodate the needs of your IRB.
We are available to provide any additional information that your IRB may request. Please do not hesitate to contact Petar Zlatanovic via email at petar91goldy@gmail.com if you need additional assistance or have any questions.

We look forward to working with you.
Sincerely,

Petar Zlatanovic MD and Lazar Davidovic MD Ph.D., principal investigators.

Project Title

Comparison of Endovascular and Open Repair of Juxta and Pararenal Abdominal Aortic Aneurysm on Short and Long-term Clinical Outcomes

Keywords

Abdominal aortic aneurysm (AAA)
Juxtarenal AAA - AAA where the neck is shorter than 1cm
Pararenal AAA - AAA where the aneurysm involves at least one renal artery orifice
Endovascular repair
Open repair
Short-term outcomes
Long-term outcomes

Background and Significance

Endovascular abdominal aortic aneurysm repair (EVAR) has gained a widespread acceptance in the treatment of patients with abdominal aortic aneurysm (AAA). Prospective randomized trials (RCTs) have demonstrated several short-term advantages over open repair such as less blood loss, operative time, hospital stay, morbidity and mortality [1-3]. The applicability of EVAR is limited by the presence of inadequte neck or involment of the visceral arteries. Thus consequently open AAA repair is now being performed primarily for complex aortic anatomy, such as juxtarenal and pararenal aneurysms.

Open repair remains the gold standard for fit patients with complex AAA [4-6]. In the past decade, an evolution of devices, design, components and delivery systems expanded the applcation of EVAR in these challenging anatomies. Fenestrated stent-grafts are now commercially available for the repair of complex AAA in the United States and Europe. Initial reports have demonstrated high techniqual success rate, low renal dysfunction rate and low morbidity and mortality with promissing short- and long-term results [7-10]. Other reports have shown excessive morbidity and mortality with fenestated EVAR (FEVAR) [11].

Studies comparing endovascular and open repair are sparse, especially when it concerns long-term outcomes. There are till nowdays only two propensity score matched studies, one showing worse short-term and another long-term clinical outcomes for fenestrated-branched EVAR (F/BEVAR) over open surgical repair (OSR) [11,12].

Vascular surgeons are therefore left with a paucity of data to guide decision-making.

Study objectives:

1. Primary aims

a. Compare Kaplan-Meier freedom from aortic related reintervention rate between endovascular and open repair group

Primary endpoint: Kaplan-Meier aortic related reintervention rate at last follow-up

b. Compare Kaplan-Meier mortality rates between two study groups

Primary endpoint: Kaplan-Meier survival rate at last follow-up

3. Secondary aim: compare short term outcomes in terms of 30-day complications rate, especially acute kidney injury according to the RIFLE criteria [13]

Secondary endpoint: 30-day complications rate, especially acute kidney injury according to the RIFLE criteria [13]

Study design

Subject selection

Inclusion criteria:

- All patients (over 18 years of age) with a history of juxta- and pararenal AAA repair from January 2011 to January 2021
- All management strategies will be included (endovascular and open)

Exclusion criteria:

- Patients who are pregnant
- Patients who are under 18 years of age
- Patients who have ruptured AAA
- Patients with thoracoabdominal aortic aneurysm (ThAAA)
- Patients who have a mycotic AAA
- Patients with connective tissue disorder

Sample size: To ensure sufficient statistical power to answer hypothetical questions, approximately 700 subjects will be entered into the database.

Aortic-related reintervention rate is the primary end point being used to calculate sample size. Assuming a difference of 7% in the late reintervention rate between endovascular and open repair, 221 patients would be required in each arm to achieve a statistical power of 85% at

p=0.05. With two arms (endovascular versus open), assuming a 20% rate of missing data, a total N of 550 patients is required.

Research Design

This is a prospective study with patients treated for juxta- and pararenal AAA from 2011 through 2021 treated at six different vascular surgery centers:

1. Clinic for Vascular and Endovascular Surgery Belgrade

2. Department of Vascular Surgery, Policlinico S. Orsola-Malpighi, Bologna, Italy

3. Department of Vascular Surgery, San Raffaele Hospital, Milan, Italy

4. Department of Vascular Surgery, Dijklander Ziekenhuis, Hoorn, Netherlands

5. Department of Vascular Surgery, Amsterdam Univeristy Hospital, Amsterdam, Netherlands

6. Department of Vascular Surgery, Helsinki University Hospital, Helsinki, Finland

Procedures Involved

The study does not involve any patient contact and will not impact the care that patients receive. Data regarding the patients will be compiled and analyzed to accomplish the proposed study objectives. Data collection will include demographic information, patient-related factors and comorbidities, diagnostic imaging information, laboratory data, surgical procedure information, complications of surgery and outcomes.

Multi-Institutional research

After the data has been collected at a participating institution, the data will be transmitted to a central analytic center located at the Clinic for Vascular and Endovascular Surgery/Clinical Center of Serbia/Medical Faculty, University of Belgrade.

Risks and Benefits

Risks to Subjects

As this is a prospective observational cohort study, there is no potential for physical risks to subjects. There is a minimal risk of breach of confidentiality that could occur when patient information is collected and analyzed for the proposed study. However, appropriate measures will be taken to minimize the risk as much as possible. All information recorded will be de-identified. This study will abide by all regulations related to protecting human subjects and protected health information.

Potential Benefits to Subjects

There is no direct benefit to the subjects. However, future patients with juxta- and pararenal AAA may benefit from improved care as a result of this study.

Statistics and Data Analysis

Continuous variables will be described using the median and interquartile range or mean and standard deviation. Categorical variables will be described using frequencies and percentages. Group comparisons will be performed by using the Student t-test or Mann-Whitney U test, as appropriate. Categorical data will be expressed as percentages and were compared using the chi-square test or Fisher exact test. Propensity score analysis will be performed by matching endovascular to open surgery group in 1:1 ratio controlling for demographics, baseline comorbidities and AAA parameters. Differences will be considered statistically significant at $p < 0.05$. The cumulative incidences of all cause mortality and aortic-related complications will be estimated using the Kaplan-Meier method. Differences between curves will be tested using the log-rank test. Analyses will be done with SPSS software, version 20.0 (SPSS, Chicago, IL, USA).

Conflict of Interest

The investigators have no conflict of interest to report.

Funding Source

There are no plans to apply for grants or additional funding. No funding is required for the completion of this study.

Publication Plan

All research personnel listed on this protocol will be eligible for authorship in any resulting abstracts and publications in accordance with the qualifications outlined by the International Committee of Medical Journal Editors. The order of authors will be determined prior to manuscript development and depend on each individual's contribution to the study.

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