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TITLE PAGE – Original Article

Radiographically Quantified Sarcopenia and Traditional Cardiovascular Risk Assessment in

Predicting Long-term Mortality after EVAR

Paavo Paajanen, MD<sup>1,5\*</sup>, Iisa Lindström, MD, PhD<sup>2,5</sup>, Niku Oksala, MD, PhD<sup>2,3,4</sup>, Suvi Väärämäki,

MD, PhD<sup>3</sup> Petri Saari, MD, PhD<sup>6</sup>, Kimmo Mäkinen, MD, PhD<sup>1</sup>, Jussi M. Kärkkäinen, MD, PhD<sup>1</sup>

<sup>1</sup> Heart Center, Kuopio University Hospital, Kuopio, Finland

<sup>2</sup> Faculty of Medicine and Health Technology, Tampere University, Tampere, Finland

<sup>3</sup> Vascular Centre, Tampere University Hospital, Tampere, Finland

<sup>4</sup> Finnish Cardiovascular Research Center Tampere, Finland

<sup>5</sup> Department of Surgery, Jyväskylä Central Hospital, Jyväskylä, Finland

<sup>6</sup> Department of Clinical Radiology, Kuopio University Hospital, Finland.

\* Corresponding author & post-publication corresponding author: Paavo Paajanen, Jyväskylä

Central Hospital, Hoitajantie 3, 40620 Jyväskylä, +358440214232, paajanenpaavo@hotmail.com

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# **ARTICLE HIGHLIGHTS**

Type of Research: Dual center, retrospective cohort study

**Key Findings:** Risk stratification tool using the combination of traditional cardiovascular risk assessment (ASA-score) together with radiographically quantified sarcopenia identified a high-risk group with 1-year survival estimate of 80% and 5-year survival estimate of only 40% in a cohort of 480 elective infrarenal EVAR patients.

**Take home Message:** Careful consideration of risks and benefits are needed in AAA patients with cardiovascular comorbidities and sarcopenia.

# **Table of Contents Summary**

In this retrospective dual center study of 480 patients undergoing EVAR for infrarenal AAA, a risk stratification tool combining ASA-score and radiographically quantified sarcopenia found a high-risk group with 5-year survival estimate of only 40%. This risk stratification tool may help to identify patients with excessively high mortality.

### **Abstract**

## Objective:

This study evaluated radiographically quantified sarcopenia and patient's comorbidity burden based on traditional cardiovascular risk assessment as potential predictors of long-term mortality after endovascular aortic repair (EVAR).

#### Methods:

The study included 480 patients treated with standard EVAR for intact infrarenal abdominal aortic aneurysms. Patient characteristics, comorbidities, aneurysm dimensions and other preoperative risk factors were collected retrospectively. Preoperative computed tomography was used to measure psoas muscle area (PMA) at L3 level. Patients were divided into three groups based on ASA-score and PMA. In high-risk group, patients had sarcopenia (PMA <8.0 cm² for males and <5.5 cm² for females) and ASA score 4. In medium-risk group, patients had either sarcopenia or ASA 4. Patients in the low-risk group had no sarcopenia and ASA score was less than 4. Risk factors for long-term mortality were determined using multivariable analysis. Kaplan-Meier survival estimates were calculated for all-cause mortality.

# Results:

Patients in the high- and medium risk-groups were older than in the low-risk group (77 $\pm$ 7, 76 $\pm$ 6 and 74 $\pm$ 8 years, respectively, p<0.01). Patients in the high-risk group had higher prevalence of coronary artery disease, pulmonary disease and chronic kidney disease. There were no differences in 30-day or 90-day mortality between the groups. The independent predictors of long-term mortality were age, ASA-score, PMA, chronic kidney disease and maximum aneurysm sac diameter. The estimated one-year mortality rates were 5 $\pm$ 2% for the low-risk, 5 $\pm$ 2% for the medium-risk and

 $18\pm5\%$  for the high-risk group (p<0.01). Five-year mortality estimates were  $23\pm4\%$ ,  $36\pm3\%$  and  $60\pm6\%$ , respectively (p<0.01). The mean follow-up time was  $5.0\pm2.8$  years.

# Conclusions:

Both ASA and PMA were strong predictors of increased mortality after elective EVAR. The combination of these two can be used as a simple risk stratification tool to identify patients in whom aneurysm repair or the intensive long-term surveillance after EVAR may be unwarranted.

# Keywords:

psoas muscle, sarcopenia, mortality, endovascular aortic repair, abdominal aortic aneurysm, risk factors

### Introduction

Endovascular aortic repair (EVAR) has offered surgeons the ability to treat elderly and frail patients with abdominal aortic aneurysms (AAA), who may be considered unfit for open surgery. However, a large proportion of elderly patients with AAA succumb to other diseases (1). Careful patient selection has a key role in prophylactic aneurysm repair. The surgeon needs to balance the preoperative risk factors against the life expectancy of the patient. Risk stratification models are needed to aid in the decision making.

There are several previously well-known preoperative risk factors for higher mortality after EVAR. These include advanced age, large maximum aneurysm diameter, aneurysm neck morphology, ischemic heart disease, cardiac failure, chronic kidney disease, chronic obstructive pulmonary disease, cerebrovascular disease, diabetes mellitus, very low or very high body mass index (BMI), frailty, and sarcopenia (2-5). In the past few years, there has been an increasing number of studies on radiologically determined sarcopenia used as a prognostic factor for oncologic surgery, major elective abdominal surgery, and also, for AAA surgery (4, 6-8). Sarcopenia is thought to reflect the patient's physical degradation during a long period of time. Psoas muscle area (PMA) has been widely used as a surrogate for sarcopenia (4). A recent meta-analysis with 1440 patients suggested that patients with sarcopenia had an increased risk of long-term mortality after elective EVAR (4). In contrast, a recent study by Waduud et al. concluded that radiographically quantified PMA is not a suitable risk stratification tool for elective AAA surgery (9). Another study by Indrakusuma et al suggests that low PMA is not associated with poor long-term survival after elective AAA surgery (10). Therefore, it seems that the role of radiographically quantified sarcopenia alone as a preoperative risk factor for mortality after EVAR remains under debate.

American Society of Anesthesiologists (ASA) scale is clinically widely used as a surrogate for patient's comorbidity burden, and it has been accepted worldwide as a pre-surgery risk stratification tool. It is a subjective assessment of the patient's current status. A recent meta-analysis

on preoperative risk factors influencing survival after elective AAA repair concluded that high value on the ASA scale was a significant predictor of increased mortality. (5)

Since the role of sarcopenia as an independent prognostic factor has remained unclear, the aim of this study was to look for a risk stratification tool based on both a) the traditional cardiovascular risk assessment (ASA) projecting patient's current comorbidity status and b) radiographically quantified sarcopenia which reflects the patient's chronic state of physical degradation.

#### **Materials and Methods**

This study was a retrospective dual-center cohort study. The study population consisted of two separate cohorts from two academic tertiary referral centers including all consecutive patients with preoperative computed tomography angiogram (CTA) available who had undergone elective EVAR for infrarenal AAA, excluding isolated iliac artery aneurysms, between years 2006 and 2016. The study was approved in both hospitals by local Institutional Review Boards. Formal informed consent was not needed. Patient characteristics, comorbidities, ASA score, aneurysm dimensions, aneurysm related death (defined as death due to rupture or treatment related complications), preoperative risk factors and follow-up data were collected retrospectively. Preoperative CTA analysis was done retrospectively in a standardized fashion by two researchers. The study patients' survival status was extracted from the national Digital and Population Data Services Agency. The causes of death were retrieved from a national population registry. Patients were followed until December 2020.

Preoperative imaging protocol included CTA of the chest, abdomen and pelvis with contrast bolus tracking. Arterial phase of the CTA was used to measure the variables. PMA was measured from the axial pack of the preoperative CTA at third mid lumbar vertebrae (L3) level by a freehand drawing tool provided in the picture archiving and communication system (Carestream

Vue PACS viewer version 11.4.0.1253, Rochester, NY). Mid L3 was chosen based on a previous publication with validation of PMA measurement and interobserver agreement analysis (11)The technical aspects of the measurements are described in detail in two previous publications (11,12). PMA was defined as the mean value of left and right psoas muscle measurements (PMA= PMA<sub>left</sub> + PMA<sub>right</sub> / 2).

## Statistical analysis

Statistical analysis was performed with SPSS version 27 for Windows (IBM, Armonk, NY, USA). The primary endpoint was all-cause long-term mortality; secondary endpoints were 30-day, 90-day mortality, aneurysm-related mortality and re-interventions. Independent risk factors for the time-dependent primary endpoint were determined in univariable and multivariable analyses using Cox regression models. Variables with p<0.05 in the univariable analysis were considered as risk factors for mortality and included in the multivariable Cox regression analyses. Variables with confounding interactions were divided into separate multivariable models. The results were expressed as hazard ratios (HRs) with 95% confidence intervals (CIs).

PMA was tested in Cox regression hazard model with splines for the association with the time-dependent mortality to determine the optimal cut points for males and females, separately, for the grouping of patients. The cut point was determined at the approximated PMA value where the HR crossed 1.0 representing the median survival of the study population. Regarding the traditional cardiovascular risk assessment, ASA score 1-3 was defined as normal risk whereas ASA score 4 was considered high risk. Differences between the risk groups were analyzed using Fisher's exact test for categorical variables and Kruskal-Wallis test for continuous variables. The Kaplan-Meier method and log-rank test were used to compare survival between the groups. Categorical variables were expressed as numbers and percentages, continuous variables as mean  $\pm$  standard deviation (SD). P values <0.05 were considered statistically significant.

### Results

During the study period, 220 patients were treated with elective standard EVAR in Kuopio University Hospital, Finland and 260 in Tampere University Hospital, Finland. The combined study cohort consisted of 480 patients. The mean follow-up time was  $5.0 \pm 2.8$  years. Hypertension and coronary heart disease were the two most prevalent preoperative conditions in 70% and 53% of the patients, respectively. The mean age of the patients was  $76 \pm 7$  years. The majority, 87% of the patients, were male (**Table I**). Between male and female sex, there were no difference in mean BMI (26.7 versus 27.3 kg/m², respectively, P=0.41), however, the mean PMA was significantly higher in men compared to women (7.8 versus 5.1 cm², respectively, P<0.01) (**Supplementary Figure 1**). The data on BMI was missing for 169 (34%) patients and therefore BMI was excluded from further analyses.

Based on Cox regression hazard model with splines, PMA values below 8.0 was considered as sarcopenia for males and PMA below 5.5 for females (**Figures 1 & 2**). Patients were divided into three groups based on ASA-score and PMA. In high-risk group, patients had radiographically identified sarcopenia and ASA-score 4. In the medium-risk group, patients had either sarcopenia or ASA-score 4. Patients in the low-risk group had no sarcopenia and ASA-score was less than 4 (**Table II**).

In the univariable analysis, statistically significant risk factors for long-term mortality were age, ASA score, chronic kidney disease, glomerular filtration rate (GFR), maximum aortic diameter and PMA (**Supplementary table I**). Independent predictors for long-term mortality in the multivariable analysis were age, chronic kidney disease, aortic diameter, low PMA and ASA scale 4, as well as belonging to the high-risk group (**Table III**).

CKD and age were strong independent risk factors in the multivariable analysis

(Table III) and based on this we performed a subgroup analysis for patients in the high-risk group
who suffered from CKD. Additionally the risk-groups were stratified by age. There were 28

patients (5%) who belonged in the high risk group and suffered from CKD. The hazard ratio from the univariable cox regression model was 3.39, and 95% confidence interval was 2.22-5.20 (p<0.001). The 5-year survival estimate for this subgroup was  $23 \pm 8$ . When the patient groups were stratified by age, the 5-year survival estimates for the octogenarian patients in the low-risk group was  $54 \pm 8$ %, for the medium-risk group it was  $53 \pm 5$ % and for the high-risk group it was  $26 \pm 9$ %. The corresponding 5-year survival estimates for nonoctogenarian patients was  $83 \pm 4$ %,  $84 \pm 4$ %  $48 \pm 8$ % (p<0.001).

The low-risk group included 159 (33%) patients, medium-risk group 249 (52%) patients and high-risk group 72 (15%) patients. The mean age in the high- and medium-risk groups were higher (77  $\pm$  7 and 76  $\pm$  6 years, respectively) than in the low-risk group (74  $\pm$  8 years, p<0.01). Accumulation of comorbidities was the highest in the high-risk group (**Table I**). Preoperative GFR was significantly lower in the high-risk group compared to the low- and medium-risk groups (P=<0.01). There were no differences in the preoperative maximum aortic diameter between the study groups. (**Table I**)

The 30-day mortality of all patients was 2% and 90-day mortality was 3%. The 30-day mortality for the low-risk group was 2%, 1% for the medium-risk group, and 3% for the high-risk group (p=0.63). Similarly, 90-day mortality for low-risk group was 3%, 2% for medium-risk group and 7% for high-risk group (p=0.17). Altogether 236 patients (49%) died during the follow-up of whom 53 died from cardiovascular diseases, 15 from aneurysm-related cause, 6 from cerebrovascular disease, 17 respiratory disease related cause, 47 from cancer-related cause, 35 from other known causes and the cause of death remained unknown in 63 patients. The crude rates of cardiovascular death were 7% in the low-risk group, 12% in the medium-risk group and 16% in the high-risk group. The corresponding rates of aneurysm-related death was 2% in the low-risk group, 4% in the medium-risk group and 1% in the high-risk group. Based on the Kaplan-Meier method, the estimated 5-year freedom from aneurysm-related death was  $98 \pm 2\%$ ,  $96 \pm 2\%$  and  $98 \pm 2\%$  and  $98 \pm 2\%$ ,  $96 \pm 2\%$  and  $98 \pm 2\%$  and  $98 \pm 2\%$ ,  $96 \pm 2\%$  and  $98 \pm 2\%$  and  $98 \pm 2\%$ ,  $96 \pm 2\%$  and  $98 \pm 2\%$ ,  $96 \pm 2\%$  and  $98 \pm 2\%$ .

2%, respectively (p=0.22). During the follow-up, 100 patients (21%) required re-intervention related to the index procedure. The crude re-intervention rates were 26% in the low-risk group, 19% in the medium-risk group and 15% in the high-risk group. The estimated 5-year freedom from re-intervention was  $79 \pm 4\%$ ,  $79 \pm 3\%$  and  $79 \pm 6$ , respectively (p=0.56). (Supplementary Table II)

Kaplan-Meier estimates for long-term mortality at 1 year were  $5 \pm 2\%$  for the low-risk group,  $5 \pm 2\%$  for the medium-risk group and  $18 \pm 5\%$  for the high-risk group (p<0.01). Five-year mortality estimates were  $23 \pm 4\%$ ,  $36 \pm 3\%$  and  $60 \pm 6\%$ , respectively (**Figure 3, Table II**).

### **Discussion**

This study showed that the combination of preoperative ASA-score and radiographically quantified sarcopenia (PMA) can be used as a novel risk stratification tool that predicts long-term mortality after elective infrarenal EVAR. The study indicates that if a person has an ASA score 4 together with sarcopenia, based on the suggested thresholds, the 5-year survival estimate is as low as 40%. In contrast, if the patient has no signs of sarcopenia in preoperative CTA and the ASA class is 3 or below, the 5-year survival is estimated at approximately 80%. In the clinical setting this may be helpful in making the decision on who should be treated and who should be followed in patients with aneurysms that are close to the generally accepted treatment threshold.

A recent study by Lancaster and colleagues included 1033 patients with AAAs who were followed without repair even though the aneurysm size was above the currently accepted treatment threshold. The 3-year cumulative risk for aneurysm rupture was 2.2% for aneurysms sized 5.5-6.0 cm, 6.0% for aneurysms sized 6.1-7.0 cm and 18.4% for aneurysms sized >7cm. (13) When our results were adjusted to this time span. The 3-year mortality estimate for the high-risk group was 43% (Figure 3). When taking into consideration the relatively small rupture risk of aneurysms sized 5.5-6.0 cm, patients with such small aneurysms falling into the high-risk group should be

followed rather than treated, given that almost half of the patients are dead after 3 years even when treated.

The data suggests that PMA and ASA-score are both independent risk factors for allcause mortality, but combined, they seem predict long-term mortality better than alone. This may be because sarcopenia is a chronic state and reflects degradation of physical health over a long period of time. In contrast, ASA class represents the current preoperative comorbidity status of the patient and may sometimes even be improved with medical or operative interventions such as, for example, coronary artery stenting or medical treatment of a pulmonary disease. As a surrogate for sarcopenia, PMA is an objective measure whereas ASA-score is based on subjective assessment. While a recent meta-analysis by Khasram and colleagues showed that ASA class is an independent risk factor for mortality after AAA surgery (HR 1.30, 95% CI 1.16-1.47, p <0.01) (5), ASA is subject to interobserver variability making it less reliable alone (14-16). Furthermore, there may be institutional differences in how ASA is determined as the classification system has evolved over time (17). While ASA class has limitations, it has been validated in multiple studies as a prognostic factor for mortality after AAA repair (18-19). Combining an objective measure of patient's muscle mass with traditional cardiovascular risk assessment may, therefore, improve patient risk assessment. Both ASA and PMA are easy and quick to acquire with no additional investigations needed, and this stratification may help the surgeon to weigh whether EVAR is likely to increase the patient's life expectancy or not. Interestingly, it seems that high muscle mass is protective of mortality even in the high-risk ASA class group. This study adds to the previous evidence suggesting that patients with high muscle mass may have reserve to withstand endovascular surgery despite advanced age and the burden of multiple comorbidities (11, 20).

CKD and age were strong independent risk factors in the multivariable analysis and based on this we performed a subgroup analysis for patients in the high-risk group who suffered from CKD and stratified the risk groups by age. We found out that the hazard ratio and 5-year

mortality estimate was even higher in this subgroup than in the high-risk group alone. There were only 28 patients in this subgroup, and thus we think that the size of our cohort is not large enough to make any suggestions based on this result. When the patient groups were stratified by age, the results suggested that the model was more accurate predicting mortality in the younger population, but it still seems to work very well in distinguishing those patients who are in excessively high risk for EVAR.

Ten previous studies have focused on radiographically quantified sarcopenia as a prognostic factor on AAA surgery. In seven of these, the study population consisted exclusively of elective EVAR patients (11, 21-26) while the other cohorts were a mixture of patients who had undergone open or endovascular AAA repair. In our review of the literature it became clear that the previous studies on the subject were heterogenous in terms of study population and methodology. Five of the previous studies used radiographically quantified PMA as the measure of sarcopenia (21-24, 26). All five studies concluded either that radiographically quantified PMA as a surrogate for sarcopenia had a strong correlation on poor survival or that it was an independent prognostic factor for poor survival after elective EVAR. These studies are in line with ours regarding the methodology and findings. Population size in these previous retrospective studies varied from 135-407 with mean follow-up times ranging from two to three years (22-23, 26). Our study had significantly longer follow-up than these previous studies, and thus, provide reliable 5-year survival estimates. With a large amount of 480 patients, our study adds to the existing evidence that sarcopenia is a major factor in patient survival after EVAR.

A meta-analysis done by Antoniou and colleagues including seven studies and 1440 pooled patients and who underwent open or endovascular AAA repair concluded that high muscle mass was associated with survival benefit during the follow up, but no link to perioperative mortality or morbidity was shown in two of the included studies that reported early outcomes (4). A subgroup analysis of patients who specifically underwent EVAR in this meta-analysis showed

lower mortality for patients without low skeletal muscle mass (HR 1.86, 95% CI 1.00–3.43; P=0.05). However, statistically, the difference was marginal. In our study, the association of PMA and mortality in EVAR patients was statistically much stronger (P<0.001 in univariable and P=0.01 in multivariable analysis) compared to the previous meta-analysis. The reason may be that the meta-analysis consisted of studies that used variable methods for radiographically quantified sarcopenia. The meta-analysis did not include studies reporting aneurysm-related death or re-interventions during follow-up. There were no differences between the study groups concerning aneurysm-related death or re-intervention rates during the follow-up.

The meta-analysis by Antoniou and colleagues included two studies (9-10), in which the study population consisted of both EVAR and open surgical patients. Contradictory to the other studies in the meta-analysis, these two studies concluded that radiographically quantified sarcopenia had no statically significant correlation with long-term mortality after elective AAA surgery. We suspect that since the physiological insult caused by open AAA repair is far greater compared to EVAR, the patient populations are inevitably different to begin with. It is likely that elderly and frail patients are treated more often with EVAR, and sarcopenia may not be such a prominent issue in well-selected patients undergoing open repair. There is some overlap between this study and a previously published paper in the Annals of Vascular Surgery (11). The previous study included both open and EVAR patients, and both, elective and emergency cases. In the present study, we included only elective EVAR patients and more than doubled the number of patients. Moreover, learning from our previous experience, we established different cut offs for sarcopenia for males and females. Also, we took into the account the patients' comorbidity burden to establish a stronger risk stratification exclusively for patients considered for EVAR. The earlier publication showed that there was no interobserver variability in the measurements between three observers and the reproducibility of PMA is very good given that the correct level in the axial CTA images is chosen.

One limitation of this study was that due to the retrospective design we had missing BMI data in one-third of the patients. For this and several other reasons we elected not to include BMI in the multivariable analyses. It has been previously shown that the relationship with BMI and long-term mortality after complex EVAR and coronary artery bypass grafting is U-shaped (12, 27). The minimum risk is located around 30 kg/m2, thus, overweight or mild obesity. The mortality risk is significantly increased in the underweight and severely obese patients. Therefore, at least three categories of BMI should be established for the risk analysis making the multivariable analysis more complicated. Furthermore, it seems that there is no clear relationship between PMA and BMI (Supplementary figure 1). There are patients that are both obese and sarcopenic. In the future research, it may be worth trying to adjust PMA to the patients' anthropometry, other than BMI alone, to produce even stronger predictor of outcome.

A second limitation of this study was that since we had two centers performing the operations, we had no standardized reporting of adverse events or complications. Therefore, the relationship of PMA with major complications was not assessed. A third limitation was that ASA scoring was based on the subjective assessment of the anesthesiologist preoperatively, and thus it was not validated for the study. Another limitation of this study was the size of the cohort. In the future a larger cohort would be needed to assess the role of CKD, aneurysm diameter and age in addition to PMA and ASA class. The strength of this study was a relatively large homogenous study population of patients undergoing standard elective EVAR for infrarenal AAAs, and the long follow-up time with no patients lost to follow up.

In conclusion, radiographically quantified sarcopenia and ASA-score, combined, are strong prognostic factors of long-term mortality after elective EVAR of infrarenal AAAs. The results of this study suggest that patients belonging in the high-risk group with small aneurysms should undergo surveillance, and the treatment threshold for these patients should be kept high.

## **Conflicts of interest**

Paavo Paajanen – none

Iisa Lindström – none

Niku Oksala – none

Petri Saari – none

Mäkinen Kimmo – none

Kärkkäinen Jussi – none

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