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Daniela Alexandra Lopes Barros Ferreira Pinheiro Impact of Sarcopenia in Aorto-Iliac Occlusive Disease

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Dr. João Rocha Neves

E sob a Coorientação de:

Dr. Marina Felicidade Dias Neto

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Device Alexander loss Berry Fersia Pilipa



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| NOME | | |
|---|--|----------|
| Daniela Alexandra Lopes Barros Ferreira Pinheiro | | |
| | | |
| NÚMERO DE ESTUDANTE | E-MAIL | |
| 201400564 | danyoffice@gmail.com | |
| DESIGNAÇÃO DA ÁREA DO PROJECTO | | |
| Angiologia e Cirurgia Vascular | | |
| | | |
| TÍTULO DISSERTAÇÃO | | |
| Impact of Sarcopenia in Aorto-Iliac Occlusive Disea | se | |
| ORIENTADOR | | |
| | | |
| João Manuel Palmeira Rocha Neves | | |
| | | |
| COORIENTADOR (se aplicável) | | |
| Marina Felicidade Dias Neto | | |
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| ACCINALE ADENIAC LIMA DAC ODCÕEC. | | |
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| ILUSTRAÇÕES, GRÁFICOS, ETC.) NÃO É PERMITIDA A REPROD | | |
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Faculdade de Medicina da Universidade do Porto, 02/01/2020

Assinatura conforme cartão de identificação: Denice Alexandra Lopes Berro, Ferris Pinio

IMPACT OF SARCOPENIA IN AORTO-ILIAC OCCLUSIVE DISEASE

António Pereira-Neves^{1,2,3}, Daniela Barros³, João Rocha-Neves^{1,2,3}, Luís Gamas^{2,3}, Marina Dias-Neto^{2,3}, Alfredo Cerqueira³, José Vidoedo⁴, José Teixeira³

- 1 Department of Biomedicine Unit of Anatomy, Faculdade de Medicina da Universidade do Porto, Portugal
- 2 Department of Phisiology and Surgery, Faculdade de Medicina da Universidade do Porto, Portugal
- 3- Department of Angiology and Vascular Surgery, Centro Hospitalar Universitário de São João, EPE, Porto, Portugal
- 4 Department of Angiology and Vascular Surgery, Centro Hospitalar do Tâmega e Sousa, EPE, Penafiel, Portugal

Key Words: aorto-iliac arterial occlusive disease; sarcopenia; major adverse cardiovascular events; major adverse limb events

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ABSTRACT

Introduction:

Sarcopenia is a progressive and generalised skeletal muscle disorder involving the accelerated loss of muscle mass and function that is associated with increased adverse outcomes. Psoas muscle area and density represent an analytic morphometry and an easy way to define sarcopenia.

The aim of this study was to validate these morphometric predictors in survival, in major cardiovascular and cerebrovascular events (MACCE) and in major adverse limb events (MALE) on Transatlantic Inter-Society Consensus type D (TASC D) aorto-iliac peripheral artery disease (AI-PAD) patients.

Methods: A cohort of consecutive patients undergoing revascularization of AI-PAD with lesions classified as TASC D were retrospectively included from the period of January 2013 to July 2019 at two Portuguese centers, a referral center, and a peripheral hospital. For inclusion the patient had to present a recent (<6 months) computed tomography (CT) previously to the revascularization procedure. Both centers offered to their patients open and endovascular repair of AI-PAD.

Results: In total, 57 TASC D AI-PAD patients were included. The median follow-up was 20 months (95% confidence interval [CI], 0-42.6). Survival at 30-days was 93 \pm 3.4% and at 48 months was 62.7 \pm 8.6%.

For both predictors the best discriminative threshold was obtained (2175.8 mm² for TPA and 51.75 HU for PMD). With these thresholds, both morphometric variables were transformed in categoric variables and longitudinal analysis was applied. Statistical significance for TPA was demonstrated, but not for PMD, for both 1-year survival (P=0.003 and P=0.291, respectively) and MACCE (P=0.005 and P=0.206, respectively). None showed statistical significance for MALE (P=0.516 and P=0.313, respectively).

<u>Conclusion</u>: In this study, TPA and PMD were tested for the advantage of being less time-consuming and so, more pragmatic for clinical application. TPA demonstrated prognostic value for survival and MACCE concerning patients with TASC D AI-PAD lesions in a Mediterranean

population. It is possible that they become independently or part of a still-to-define frailty score, applicable predictors, adding not only prognostic but also possible therapeutic monitoring.

INTRODUCTION

The aorto-iliac (AI) sector represents one of the biggest decisional and therapeutic challenges of the peripheral arterial disease (PAD). Since several options are available for AI-PAD treatment, contemporary therapeutic decision considers several factors further than anatomic ones. Frailty and sarcopenia are risk predictors emerging in several areas including vascular surgery since are frequent conditions among vascular patients (1, 2).

Sarcopenia is a progressive and generalised skeletal muscle disorder involving the accelerated loss of muscle mass and function that is associated with increased adverse outcomes including falls, functional decline, frailty and mortality (3). Although commonly being regarded as an age-related process, it is very frequent in life-threatening pathology (3). Psoas muscle area and density represent an analytic morphometry and an effortless way to define sarcopenia. Low total psoas area (TPA) has been associated with major complications and mortality in vascular, trauma, cancer and transplant surgery (4-12). Low psoas muscle density (PMD) is also being described as a predictor of mortality in cardiac (13), cancer (14-17) and trauma surgery (18) as well as in other pathologies (19, 20). Identifying patients at risk is an important step in the decision-making process of whether a patient would benefit from an intervention or even understand if there is any reversibility and preoperative optimization that can be provided to the patient in order to improve outcomes. However, the ongoing research and subsequent clinical utility is being challenged by different definitions and the still undisclosed optimal frailty tool to use in vascular surgery and its subpopulations.

The aim of this study was to validate these morphometric predictors in survival and in cardiovascular and cerebrovascular endpoints on extensive AI-PAD patients.

METHODS

A cohort of consecutive patients undergoing revascularization of AI-PAD with lesions classified as Transatlantic Inter-Society Consensus type D lesions (TASC D) (22) (A.P.N. and J.R.N.) were retrospectively included from the period of January 2013 to July 2019 at two Portuguese centers, a referral center and a peripheral hospital. For inclusion criteria the patient had to present a recent (<6 months) computed tomography (CT) before the revascularization procedure. Both centers offered to their patients open and endovascular repair. Patients with aneurysmatic disease or other etiology rather than atherosclerosis were excluded. The study protocol was approved by the local Ethics Committee and is according to Helsinki declaration (23).

Data was obtained by an ongoing vascular registry and from detailed review of the patient's clinical records. All data regarding patients and procedure were defined according to the Society for Vascular Surgery reporting standards for lower extremity ischemic peripheral arterial disease (24).

Definitions

Major Adverse Cardiovascular and Cerebrovascular Event (MACCE) was defined as a composite outcome of stroke, myocardial infarction, coronary reintervention, acute heart

failure and all-cause death. Major Adverse Limb Event (MALE) was defined as loss of primary patency (interventions for assisted primary patency, secondary patency or loss of patency without reintervention), and major amputation.

TPA as well as PMD were assessed on CT using the program Sectra 7® (SectraMedical - Linkoping, Sweden). For measurement purposes, a single cross-sectional slice at the upper level of L4 was used. The borders of the left and right psoas muscle were hand marked using the region of interest tool in mm² and the TPA constituted the sum of both areas (9). Psoas muscle density was calculated by the average of bilateral Hounsfield Units (HU) of the psoas muscle cross-sectional area. Measurements were obtained by the mean of the measurements made by two independent trained researchers (A.P.N. and L.G.) using standard graphics tools available in Sectra workstation IDS7®. Protocol was strictly followed and both researchers were blinded to previous measurements and clinical data.

For statistics purposes, SPSS (IBM Corp., released 2017. IBM SPSS Statistics for Windows, version 25.0, Armonk, NY, USA) was used. Baseline characteristics were compared using Chi-Square, Student t-test and Mann-Whitney, as appropriate. Outcome variables were expressed as Kaplan-Meier curves. Differences in baseline features were tested upon outcomes variables using log rank test. The threshold for significance was set for a P value <0.05. Risk stratification criteria were based on optimal sensitivity and specificity generated from receiver operating characteristic (ROC) curve analysis and the Youden index. Using the above-mentioned thresholds, both morphometric variables were transformed in categoric variables and longitudinal statistics was applied

The necessary sample for a two-sided test a survival test was calculated resorting to WinPepi $^{\circ}$ V11.65, aiming for a statistical power (β) of 80% and an α <0.05 (25). The described survival rate at 1-year follow-up is above 90% (26) for an event rate difference of 30% between groups the estimated sample was 52 patients (27).

RESULTS

Baseline characteristics

Table 1 summarizes the results of the demographic and clinical data from patients undergoing revascularization for aorto-iliac TASC-D lesions.

In total, 57 TASC D AI-PAD patients that underwent revascularization had a CT meeting all the inclusion criteria. Mean age was 60 ± 8.2 years old and 96% of the patients were male. Smoking (current or former smoker) (96.0%), arterial hypertension (64.9%) and dyslipidemia (64.9%) were the most prevalent cardiovascular risk factors in this population. Thirty-five patients (61.4%) presented with limb threatening ischemia (Table 1).

Open surgery was the preferred method by the surgeon with 32 (56.1%) open surgeries vs 25 patients (43.9%) who underwent endovascular therapy. Technical success in the first procedure was achieved in 51 patients (89.5%). In 5 patients with a failed endo-first approach, a later open surgery (aortobifemoral) was performed yielding a total of 56 (98.2%) successfully revascularizations. The mean ABI value increased from 0.30 ± 0.11 to 0.77 ± 0.18 after successful treatment.

Sarcopenia assessment

Psoas Muscle Area ranged from 1285 to 3459 mm 2 with a mean \pm standard deviation of 2447 \pm 491.4 mm 2 and PMD ranged from 28.5 to 87.5 HU with a mean \pm standard deviation of

Survival

The median follow-up was 20 months (95% confidence interval [CI], 0-42.6). Survival at 30-days was 93 \pm 3.4%, at 1-year was 78% \pm 6.4% and at 48 months was 62.7 \pm 8.6%. By the end of follow-up 16 patients had died.

When performing ROC curves for 1-year mortality, TPA performed better comparing with PMD, obtaining an Area Under the Receiver Operating Curve (AUROC) of 0.721 (95% CI, 0.477-0.966; Figure 1) while PMD had an AUROC of 0.596 (95% CI, 0.405-0.788; Figure 1). The best discriminative threshold was obtained based on ROC curves and Youden index. For TPA the threshold was set at 2175.8 mm² with a 70% sensitivity and 89.3% specificity and for PMD was 51.75 HU with 80% sensitivity and 50% specificity.

Using the above-mentioned thresholds, both morphometric variables were transformed in categoric variables and longitudinal analysis was applied. Statistical significance for TPA (P=0.003; Figure 2) was demonstrated, but not for PMD (P=0.291; Figure 2).

TPA below threshold had a 1-year survival of $35.5 \pm 15.6\%$ and above $92.9 \pm 4.0\%$ (P=0.003) (Figure 2). PMD below threshold had a 1-year survival of $68.9 \pm 9.5\%$ while above threshold had a 1-year survival of $89.3 \pm 7.2\%$ (P=0.08) (Figure 2).

MACCE

Of the studied population, during follow-up, 19 patients presented a MACCE. When performing ROC curves for 1-year MACCE, TPA was superior to PMD as a morphometric predictor, obtaining an AUROC of 0.702 CI 95% [0.477 - 0.928] (P=0.045) while PMD had an AUROC of 0.592 CI 95% [0.406 - 0.77] (p=0.360) (Figure 1).

The TPA scoring point was once again 2175 mm² with 67% sensitivity and 89.3% specificity. For PMD the threshold was 51.7 HU, with 75% sensitivity and 53.6% specificity. Statistical significance for TPA (P=0.005) (Figure 2) was demonstrated, but not for PMD (P=0.206) (Figure 2).

TPA below threshold had an 18-month survival of $32.6 \pm 14.7\%$ and above $90.5 \pm 4.5\%$. PMD below threshold had an 18-month survival of $67.1 \pm 9.4\%$ while above threshold had an 18-month survival of $85.6 \pm 7.8\%$.

MALE

Of the studied population, there were 14 MALE events. ROC curves for 1-year MALE showed poor prediction ability for both TPA (AUROC of 0.583 [95% CI, 0.366-0.799]) (Figure 1) and PMD (AUROC of 0.55 [95% CI, 0.326-0.773]) (Figure 1). Concerning MALE thresholds, ROC analysis was also performed. For TPA, 2449 mm² demonstrated the best performance with 63.9% sensitivity and 54.5% specificity while for PMD, 45.5 HU was the best cut off point with 54.5% sensitivity and 63.6% specificity.

Using the Kaplan Meier method with the categoric variables obtained by ROC curve analysis, no statistical significance either for TPA (P=0.516) (Figure 2) or PMD (P=0.313) (Figure 2) was found.

Length of stay

Neither TPA (P=0.557 and P=0.734, respectively) or PMD (P=0.331 and P=0.447, respectively) were associated with the length of stay in nursery or intensive care unit.

DISCUSSION

In this study, TPA and PMD were tested for the advantage of being less time-consuming and more pragmatic for clinical application. Furthermore, despite being important prognostic markers, the literature presents a gap regarding the threshold of morphometric parameters to define sarcopenia consistently or the risk patients. In this study, TPA< 2175 mm² was validated has a diagnostic cut-off for this Mediterranean population, mainly composed of male patients.

While TPA reflects frailty and a propensity towards lower functional status, PMD reflects frailty with a close relationship to patient nutritional status (28), as also higher densities were related with lower inflammatory markers (29). Literature about PMD is scarce compared to TPA, inclusively in vascular surgery. A lack of universal thresholds for defining low PMA and PMD and substantial differences in the measurements across the included studies are the main challenges to PMA and PMD use as stated before.

Chowdhury et al.(30) tested different morphometric predictors including TPA and PMD in older vascular surgery patients, and concluded that TPA was significantly associated with readmission-free survival but no statistical significant result concerning PMD was detected. TPA is validated for abdominal aortic aneurysms (5, 31) and with growing literature concerning peripheral arterial disease (1, 9). Nowadays is considered a frailty tool with moderate quality and capable of predicting long-term survival after major vascular surgery (32). These studies corroborate the previous evidence available in other surgical fields, revealing higher risk of mortality for lower TPA (6, 11, 14, 16).

Neither TPA or PMD revealed statistical significance for MALE (P=0.516 and P=0.313, respectively). In previous studies, PMD also failed to achieve statistical significance with PAD severity or amputation free survival.

Several clinical applications are evident from the results of this study. First, TPA was validated as survival and MACCE predictor concerning patients with aorto-iliac TASC D lesions in a Mediterranean population. Sarcopenia does not imply non-operability but rather tailored planning for this group, with careful perioperative interventions. Therefore, frailty should be regarded as a therapeutic target with peri-operative management and close monitoring and follow-up. In order to slowdown frailty and sarcopenic progression, multiple interventions are advised such as nutritional intervention, physical rehabilitation and planned discharge with home assistance, although still with poor supporting evidence (34, 35). Second, these predictors, mainly TPA, present the advantage of being ready collectable alongside with the increase number of CTAs as part of medical investigation. It is possible that they become independently or part of a still-to-define frailty score, adding not only prognostic but also possible therapeutic monitoring (36, 37).

Limitations

Being a two-institution retrospective cohort, several limitations arise. Selection bias was present since the frailest patients might were deemed non-eligible for revascularization. Another major limitation arising from selection bias, is the fact that in this cohort, patients with iliac stent had smaller areas. External validity is limited due to the specificity of this subset of

patients. Although efforts were made to minimize missing data, 44% of patients were excluded because of missing CTs largely from peripheral hospitals that drained the patients to the referral center, which were not uploaded to the electronic system. Furthermore, it is possible that different cut-off values regarding gender may apply (38), although this was not addressed in this study, since the sample is manly composed of males.

These limitations aside, this study provides a useful evaluation of growing literature on sarcopenia as a predictor of outcomes in vascular surgery.

CONCLUSION

In this study, TPA demonstrated prognostic value for survival and MACCE concerning patients with aorto-iliac TASC D lesions while allowing fast straightforward assessment with reproducibility. However, neither TPA or PMD revealed statistical significance for MALE. This study adds to the growing literature on sarcopenia as a predictor of outcomes in vascular surgery and should be seen as a stimulus for further research to achieve the full potential of these markers in the guidance for clinical decision, patient counseling on operative risk and management of perioperative interventions by multidisciplinary teams in order to improve outcomes.

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ATTACHMENT

Table 1 – Demographic and clinical data from patients undergoing revascularization for aorto- iliac TASC D lesions.

| Variables | n=57 |
|----------------------------------|------------|
| Demographics | |
| Age (years), mean ± SD | 60 ± 8.2 |
| Sex (male), n (%) | 55 (96) |
| Cardiovascular risk factors | |
| HTN, n (%) | 37 (64.9) |
| Smoking, n (%) | 55 (96) |
| CKD, n (%) | 7 (12.3) |
| DM, n (%) | 19 (33.3) |
| Dyslipidemia, n (%) | 37 (64.9) |
| Comorbidities | |
| CAD, n (%) | 14 (24.6) |
| CHF, n (%) | 4 (7) |
| COPD, n (%) | 5 (8.8) |
| Functional Status, n (%) | |
| Dependent | 0 |
| Partially Dependent | 4 (7) |
| Independent | 53 (93) |
| ASA, mean ± SD | 2,6 ± 0.59 |
| Limb status | |
| Rutherford, n (%) | |
| 3 | 17 (29.8) |
| 4 | 27 (47.4) |
| 5 | 9 (15.8) |
| 6 | 3 (5.3) |
| Limb threatening ischemia, n (%) | 35 (61.4) |
| Intervention | |
| Open, n (%) | 32 (56.1) |
| Endo, n (%) | 25 (43.9) |

Legend: SD – standard deviation; HTN – Hypertension; CKD (creat>1.5mg/dl); DM – Diabetes Mellitus; CAD – Coronary Arterial Disease; CHF – Chronic Heart Failure; COPD - Chronic Obstructive Pulmonary Disease; ASA – American Society of Anesthesiologists Classification

FIGURES

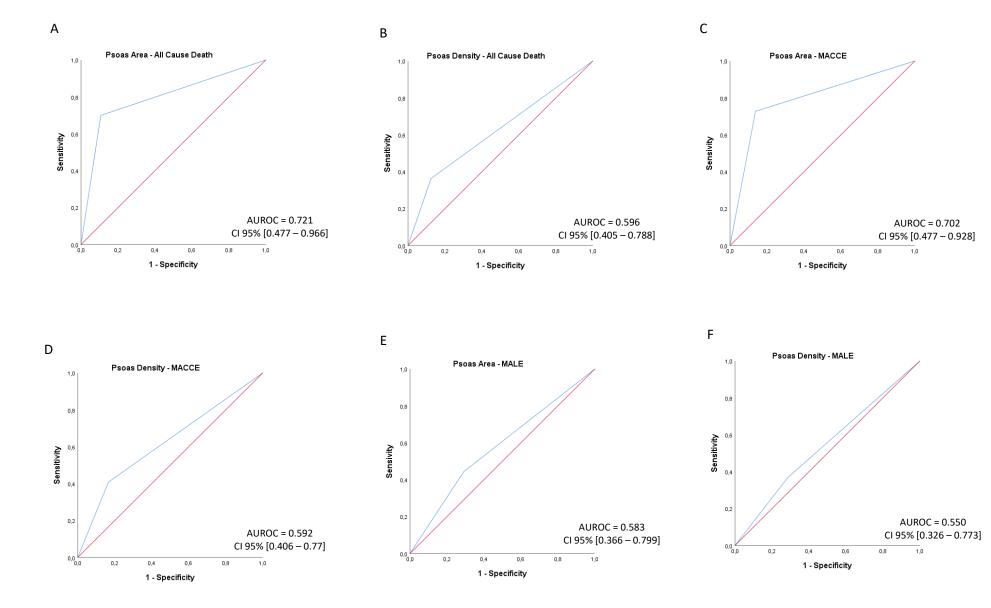
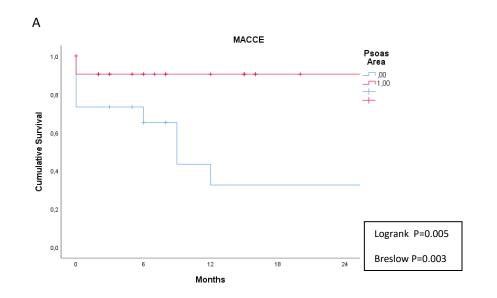
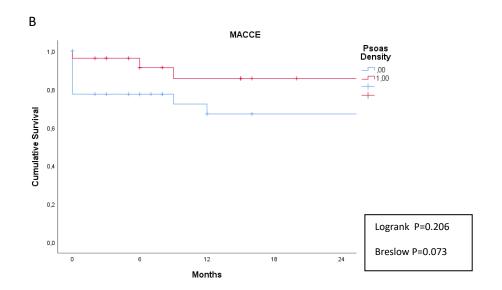


Figure 1 – A. ROC curves for 1-year mortality for TPA. B. ROC curves for 1-year mortality for PMD. C. ROC curves for MACCE for TPA. D. ROC curves for MACCE for PMD. E. ROC curves for MALE for TPA. F. ROC curves for MALE for PMD.

AUROC - Area Under the Receiver Operating Curve

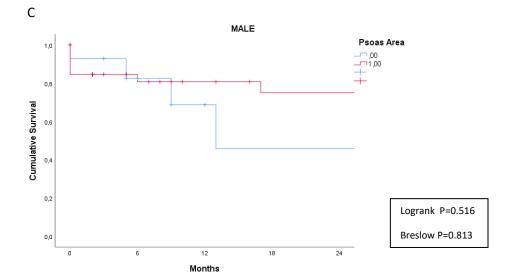
MACE - Major Adverse Cardiovascular Event, MALE - Major Adverse Limb Event, TPA - Total Psoas Area, PMD - Psoas Muscle Density.

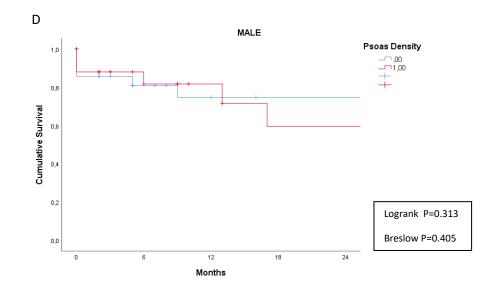




| Time (months) | | 1 | 6 | 12 | 18 |
|---------------|-----------------------|------|------|------|------|
| Total psoas | Survival (%) | 73.3 | 65.2 | 32.6 | 32.6 |
| area < 2175 | SE (%) | 11.4 | 12.7 | 14.7 | 14.7 |
| mm² | Under FU (n) | 11 | 7 | 3 | 3 |
| | Cumulative events (n) | 4 | 5 | 8 | 8 |
| Total psoas | Survival (%) | 90.5 | 90.5 | 90.5 | 90.5 |
| area > 2175 | SE (%) | 4.5 | 4.5 | 4.5 | 4.5 |
| mm² | Under FU (n) | 37 | 37 | 37 | 37 |
| | Cumulative events (n) | 4 | 4 | 4 | 4 |

| Time (months) | | 1 | 6 | 12 | 18 |
|---------------|-----------------------|------|------|------|------|
| Psoas | Survival (%) | 77.4 | 77.4 | 67.1 | 67.1 |
| Muscle | SE (%) | 7.5 | 7.5 | 9.4 | 9.4 |
| density < | Under FU (n) | 23 | 18 | 12 | 11 |
| 51.7 HU | Cumulative events (n) | 7 | 7 | 9 | 9 |
| Psoas | Survival (%) | 96.2 | 91.3 | 85.6 | 85.6 |
| Muscle | SE (%) | 3.8 | 5.9 | 7.8 | 7.8 |
| density > | Under FU (n) | 25 | 19 | 15 | 11 |
| 51.7 HU | Cumulative events (n) | 1 | 2 | 3 | 3 |





| Time (months) | | 1 | 6 | 12 | 18 |
|---------------|-----------------------|------|------|------|------|
| Total psoas | Survival (%) | 89.3 | 78.4 | 71.3 | 62.4 |
| area < 2175 | SE (%) | 5.8 | 8.8 | 10.5 | 12.4 |
| mm² | Under FU (n) | 23 | 13 | 8 | 7 |
| | Cumulative events (n) | 3 | 5 | 6 | 7 |
| Total psoas | Survival (%) | 84 | 84 | 84 | 74.7 |
| area > 2175 | SE (%) | 7.3 | 7.3 | 7.3 | 11 |
| mm² | Under FU (n) | 20 | 14 | 11 | 8 |
| | Cumulative events (n) | 4 | 4 | 4 | 5 |

| Time (months) | | 1 | 6 | 12 | 18 |
|---------------|-----------------------|------|------|------|------|
| Psoas | Survival (%) | 83.3 | 76.4 | 67.9 | 67.9 |
| Muscle | SE (%) | 8.8 | 10.4 | 12.3 | 12.3 |
| density < | Under FU (n) | 14 | 9 | 8 | 7 |
| 51.7 HU | Cumulative events (n) | 3 | 4 | 5 | 5 |
| Psoas | Survival (%) | 88.6 | 84.1 | 84.1 | 68 |
| Muscle | SE (%) | 5.4 | 6.7 | 6.7 | 11.6 |
| density > | Under FU (n) | 29 | 18 | 11 | 8 |
| 51.7 HU | Cumulative events (n) | 4 | 5 | 5 | 7 |

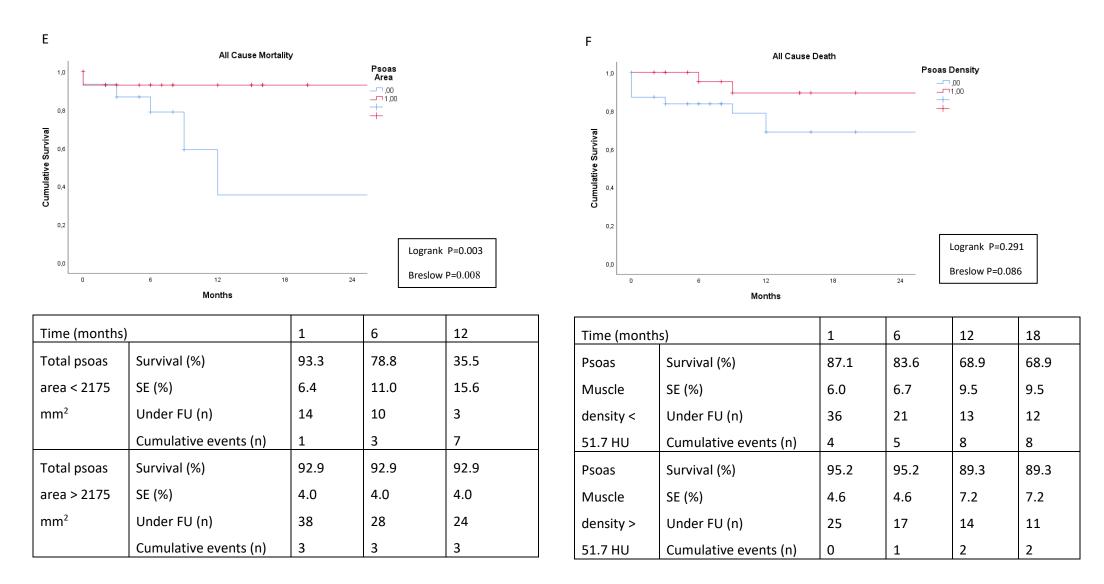


Figure 2 - Survival plots. 12 and 18 months follow-up Kaplan Meier survival plots for different clinical events post- Aorto-iliac revascularization, for Total Psoas Area and Psoas Muscle Density. A – MACCE for total Psoas Area; B MACCE for Psoas Muscle Density; C–MALE for total Psoas Area; D - MALE for Psoas Muscle Density; F –All-cause Death for Psoas Muscle Area; G – All-cause Death for Psoas Muscle Density.

MACCE – Major Adverse Cardiovascular and Cerebrovascular Event; MALE – Major Adverse Limb Event



JOURNAL OF SURGICAL RESEARCH

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R Official Publication of the Association for Academic Surgery

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