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Juliana Cardoso Costa Santos

Is the outcome after lumbar discectomy impacted  
by fatty infiltration of paraspinal muscles?

Relação entre os músculos paravertebrais e o  
outcome funcional em doentes com patologia  
lombar

Abril, 2021

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DESIGNAÇÃO DA ÁREA DO PROJECTO

MEDICINA CLÍNICA

TÍTULO DISSERTAÇÃO/MONOGRAFIA (riscar o que não interessa)

Is the outcome after lumbar discectomy impacted by fatty infiltration of paraspinal muscles?

ORIENTADOR

Paulo Miguel Silva Pereira

COORDENADOR (se aplicável)

João da Encarnação de Carvalho

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Faculdade de Medicina da Universidade do Porto, 04/04/2021

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Juliana Cardoso Costa Santos

Aos meus pais e irmão, por estarem sempre comigo e permitirem a  
realização deste sonho.

Ao meu namorado e aos meus amigos, por me acompanharem nesta  
caminhada.

À FMUP, por tudo o que aprendi.

Title:

**Is the outcome after lumbar discectomy impacted by fatty infiltration of paraspinal muscles?**

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## Abstract

*Study design:* Retrospective analysis of prospectively collected data study.

*Objective:* To study the prognostic value of lumbar paravertebral muscles atrophy on clinical outcome after surgery on patients with symptomatic lumbar disc herniation.

*Summary of Background Data:* Cross sectional area (CSA) and fat infiltration (FI) are the best parameters to assess paravertebral muscle atrophy. The role of muscle atrophy in the outcome of patients with symptomatic lumbar disc herniation undergoing surgery remains unclear.

*Methods:* Patients over 18 years of age with lumbar disc herniation and radicular pain who underwent single-level discectomy were included. Multifidus, erector spinae and psoas CSA and FI were measured by ImageJ software at the levels of L3-L4, L4-L5 and L5-S1 from T2-weighted Magnetic Resonance axial images. Clinical status was assessed preoperatively and one-year after surgery with patient reported outcome measurements (PROMS), that included Numeric Rating Score for back and leg pain, Core Outcome Measurement Index (COMI), Oswestry Disability Index and EuroQoL-5D. Univariate and multiple linear regressions were performed.

*Results:* There were negative correlations between psoas muscle CSA on the symptomatic side and preoperative PROMS. Erector spinae FI was the only muscle-related factor that correlated to post-surgery PROMS. Postoperative COMI was higher in patients with FI>30% (median: 4.4, IQR: 3.2) and lower when FI<15% (median: 1.2, IQR: 1.6) (Kruskal-Wallis,  $p<0.001$ ). Male gender was associated with better outcome as well as erector spinae FI<15%, while FI >30% was related to worse postoperative status.

*Conclusions:* In the current study, increased fat infiltration of erector spinae muscles correlated to less favourable clinical outcomes following lumbar discectomies.

**Key words:** Fat infiltration, paravertebral lumbar muscle, lumbar disc herniation, outcome, lumbar surgery, erector spinae muscle

## Resumo

Desenho do estudo: Análise retrospectiva de dados recolhidos prospetivamente.

Objetivo: Estudar a influência da atrofia dos músculos paravertebrais no *outcome* clínico de doentes com hérnia discal lombar sintomática submetidos a discectomia.

Contextualização teórica: A *cross sectional area* (CSA) e a infiltração adiposa (FI) são os melhores parâmetros para avaliar a atrofia dos músculos paravertebrais. A influência da atrofia muscular no prognóstico de doentes com hérnia discal lombar submetidos a discectomia permanece ainda incerta.

Métodos: Doentes com idade superior a 18 anos, com hérnia discal lombar e dor radicular, submetidos a discectomia lombar a um nível, foram incluídos no estudo. A CSA e a FI dos músculos múltípidos, eretor da espinha e psoas foram analisadas com o Software ImageJ, nos níveis L3-L4, L4-L5 e L5-S1, em cortes axiais de Ressonância Magnética ponderadas em T2. O estado clínico dos doentes foi avaliado no pré-operatório e um ano após a cirurgia, com questionários PROM (*patient reported outcome measurements*), que incluíram o *Numeric Rating Score* para dor lombar e membro inferior, *Core Outcome Measurement Index* (COMI), Índice de Incapacidade de Oswestry e o EuroQoL-5D. Foram realizadas regressão simples univariada e linear múltipla.

Resultados: Registaram-se correlações negativas entre a CSA do músculo psoas do lado sintomático e os questionários PROM pré-operatórios. A FI do eretor da espinha foi o único fator relacionado com os PROM pós-operatórios. O COMI pós-operatório foi maior no grupo com FI>30% (mediana: 4,4; intervalo interquartil: 3,2) e menor no grupo com FI<15% (mediana: 1,2; intervalo interquartil: 1,6) (Kruskal-Wallis;  $p<0,001$ ). O sexo masculino foi associado a melhores *outcomes* pós-operatórios, assim como FI<15% do eretor da espinha, enquanto que uma FI>30% se relacionou com um pior estado pós-operatório.

Conclusões: neste estudo, uma maior infiltração adiposa nos músculos eretores da espinha correlacionou-se com *outcomes* pós-operatórios menos favoráveis após discectomia lombar

**Palavras-chave:** Infiltração adiposa, músculos paravertebrais, hérnia discal lombar, *outcome*, cirurgia lombar, músculo eretor da espinha

## Introduction

Lumbar disc herniation is a highly prevalent degenerative spine condition. When a protruding disc compresses a nerve root it triggers low back pain (LBP), leg pain (sciatica) and movement restrictions [1]. Lumbar discectomy is the gold standard treatment for symptomatic lumbar disc herniation unresponsive to conservative care and requiring surgery. Although most patients treated with surgery have favourable outcomes, a significant part of them fall short of expectations [2, 3]. Multiple factors have been shown to negatively influence clinical outcomes, such as older age and female gender [4], mood disorders and smoking habits [5], physical inactivity [6, 7], patients' expectations and longer symptom duration [8]. However, the evidence for the role of anatomical characteristics in clinical outcome is scarce [9].

Paravertebral muscles act as structural and functional stabilizers of the spine [10, 11] and Magnetic Resonance Imaging (MRI) allows to determine the cross sectional area (CSA) as well as fat infiltration (FI) of these muscles, which are considered the best parameters to assess muscle atrophy [12, 13]. Fat infiltration reduces contractile and functional capacity of muscles [14-16]. Literature demonstrates higher atrophy levels of the paravertebral muscles in symptomatic patients with LBP, when compared to asymptomatic groups [1, 17]. Several studies suggest that fatty infiltration is higher on women, increases with aging, and seems to be more pronounced on the lower spine levels suggesting a caudal-cranial distribution [14, 18, 19]. However, the role of muscle atrophy in the outcome of patients with symptomatic lumbar disc herniation undergoing surgery remains controversial [20].

The aim of this study is to investigate the association between muscle atrophy on pre-operative MRI and clinical outcomes one year after lumbar discectomy, in order to understand if paravertebral muscles parameters can be used as a prognostic factor of clinical outcome.

## Materials and Methods

A retrospective analysis of prospectively collected data was conducted, selecting all patients over eighteen years old with lumbar disc herniation and radicular pain who underwent single-level discectomy at our department from January 2016 to December 2019. Study protocol and investigation were approved by the hospital's ethics committee.

Patients with deformities (scoliosis and kyphosis), spondylolisthesis, spinal stenosis, fractures, tumours and infections or previous lumbar surgeries were excluded.

All patients underwent lumbar spine MRI previously to surgery. Axial T2-weighted MRI slices at the levels of L3-L4, L4-L5 and L5-S1 intervertebral discs were selected; in each level, paravertebral muscles (multifidus, erector spinae and psoas) were investigated bilaterally. For each patient 36 measurements were undertaken. ImageJ software 1.8.0\_112 version (National

Institutes of Health, Bethesda, USA) was used to define regions of interest (ROI) which were the cross sectional areas (CSA), by manually delimiting muscular edges of multifidus, erector spinae and psoas according to the method proposed by Crawford et al [21]. The percentage of fat infiltration of paravertebral muscles (FI) was calculated by ImageJ software pseudo-colouring method, applying automatic thresholds (figure 1).

Clinical status was assessed according to preoperative and one-year postoperative patient reported outcome measurements (PROMS) questionnaires that included Pain Numeric Rating Scale (NRS) for back and leg pain, Core Outcome Measurement Index (COMI), Oswestry Disability Index (ODI) and EuroQoL-5D (EQ5D).

Patients' data were obtained from clinical records and included age, gender, weight (kg), height (cm), body mass index ( $\text{kg}/\text{m}^2$ ), smoking status, antidepressant medication and rehabilitation prior to surgery. Surgical data were also collected, such as surgery date, lumbar level of discectomy and side

### **Statistical Analysis**

R software (R Foundation for Statistical Computing, Vienna, Austria) version 4.0.3 was used for data analysis. Sample size calculation as performed considering postoperative COMI as the primary end point, leading to COMI mean comparison between two groups according to muscle characteristics (CSA or FI). The calculated sample size was 98, for one sided T-test, significance level of 0.05, power of 0.95 and effect size of 0.67. Effect size was calculated according to Cohen [22]: for means difference we used 1.7, the minimal clinically important difference (MCID) for portuguese language COMI [23], and we considered the standard deviation (SD) of 2.7 for postoperative COMI in patients with disc herniation (DH) from the study by Mannion et al [3].

Spearman's correlation ( $r_s$ ) was used for correlation between continuous variables; Kruskal-Wallis or Wilcoxon tests for mean comparison between independent or dependent samples, Fisher's test was used for associations between categorical variables.

Multiple linear regression was performed for adjustment for other variables. Decisions about the independent variables to include in the model were done by univariable selection with simple linear regression, based in a threshold of 0.1 for p-value, and then with backward selection. Continuous variables with non-linear relations to outcome were splitted in categories, based on visual plot analysis (locally estimated scatterplot smoothing) and in a step function (Supplemental file).

## Results

From 251 patients screened for eligibility, 112 patients (59 female and 53 male) were included in this study (Fig. 2). The mean age was  $46.1 \pm 12.7$  years, ranging between 20 and 78 years old. The average BMI was in the overweight category ( $27.1 \pm 3.89$  kg/m<sup>2</sup>). Lumbar discectomies were performed at levels L2-L3 (1.8%), L3-L4 (4.5%), L4-L5 (48.2%) and L5-S1 (45.5%). Demographic data are presented in Table 1.

Regarding the morphology of paravertebral muscles on MRI, erector spinae had the highest median cross section area (CSA) values (3025; IQR: 1845-3955), followed by multifidus (1703; IQR: 1176-2497) and psoas (195; IQR: 119-314). For erector spinae the median fat infiltration (FI) was also higher (27%; IQR: 21-33%) than for multifidus (19%; IQR: 13-25%) and psoas (2%; IQR: 1-3%) (Table 1). Fat infiltration percentage increased slightly from L3-L4 to L5-S1 on erector spinae and multifidus muscles. Psoas muscle CSA and FI remained stable across all spinal levels (Fig. 3). For each muscle, no significant differences were found between sides for CSA or FI (Wilcoxon tests, p values between 0.12 and 0.85). According to these results, median values of CSA and FI per muscle were obtained, grouping level and side, and those medians were used in the subsequent analyses.

### MRI analysis and pre-surgery clinical assessment

Psoas muscle CSA expressed weak to moderate correlations with pre-surgical PROMS, specifically with COMI ( $r_s = -0.29$ ), ODI ( $r_s = -0.32$ ) and EQ5D ( $r_s = 0.28$ ) scores. Both the CSA and FI of multifidus and erector spinae presented no correlation with patient clinical status before surgery. The association of psoas muscle CSA with preoperative scores was related to sciatica side. We found negative correlations between psoas muscle CSA on the symptomatic side and preoperative ODI, COMI and NRS-leg scores ( $r_s = -0.3$ ,  $-0.27$  and  $-0.26$ , respectively).

### MRI analysis and post-surgery clinical assessment

Erector spinae FI was the only muscle-related factor that correlated to post-surgery PROMS. In particular, erector spinae FI had a moderate correlation with postoperative COMI ( $r_s = 0.38$ ), leg NRS ( $r_s = 0.39$ ) and EQ5D ( $r_s = -0.3$ ); and weak correlations with postoperative ODI and NRS-back ( $r_s = 0.26$  and  $0.24$ ).

To understand if FI of erector spinae was an independent factor related to postoperative COMI, a multiple linear regression model was performed to control confounding variables. For factors selection, univariable simple linear regression was used and identified gender ( $p < 0.001$ ), age ( $p = 0.02$ ) and height ( $p = 0.01$ ) as being associated with postoperative COMI (supplemental

file). As the relation between erector spinae FI and postoperative COMI was not linear (Fig. 4), that variable was split in three groups: FI < 15% (10% of patients), FI 15-30% (59% of patients), FI > 30% (31% of patients). This split was based in visual plot analysis (Fig. 4) and in a step function (supplemental file). From clinical and statistical perspective, postoperative COMI was significantly different according to erector spinae FI groups (boxplots – fig. 4): postoperative COMI was higher in FI > 30% group (median: 4.4, IQR: 3.2) and lower in FI < 15% (median: 1.2, IQR: 1.6) (Kruskal-Wallis,  $p < 0.001$ ). Table 2 summarizes baseline characteristics of the patients included in each of the three groups.

Multiple linear regression model is displayed in table 3. After backward variable selection, only erector spinae FI and gender were independent factors related to postoperative status measured by COMI. Male gender was associated with better outcome as well as erector spinae FI < 15%, while FI > 30% was related to worse postoperative status.

## Discussion

Integrity of the paravertebral muscles (multifidus, erector spinae and psoas) ensures the normal function and alignment of the spine [15]; this musculature contains a high proportion of low tonic and fatigue-resistant fibers (type I), reflecting their role in maintaining posture and joint stability [1]. On the other hand, fat infiltration of these muscles is a sign of atrophy and has been associated with functional impairment, spine instability and low back pain [16]. Physical inactivity has also been correlated with atrophy and morphological abnormalities in the lumbar spine, which results in low back pain and disability [6].

Lumbar disc herniation may cause nerve roots impairment, which leads to structural changes in paravertebral muscles, such as increased fatty infiltration, atrophy of type I fibers and conversion to type II fibers [1], which can be related to low back pain and poorer spine function. In the current study, fat infiltration of the multifidus and erector spinae muscles revealed no correlation to preoperative PROMS. This result is in line with a retrospective study, conducted by Bhadressha et al. [24], including 165 patients with lumbar disc herniation, which concluded that muscle atrophy and fat content of lumbar paravertebral muscles were not associated with PROMS. Similar findings were reported by Hildebrandt et al., who found no significant correlation between fat infiltration of the multifidus muscles and self-assessed functional disability [25]. In the present study, we found weak to moderate correlations between psoas muscle CSA and preoperative PROMS. In addition, lower psoas CSA values on the sciatica side related to higher leg pain scores and disability levels, as assessed by the COMI and ODI scores. Barker et al. also found a positive correlation between the decrease in CSA of the psoas on the affected side and the pain scores [26]. Arabanas et al, found contradictory results, suggesting that patients with degenerative lumbar spine changes had bigger CSA of psoas muscles compared to

asymptomatic controls [27]. Despite this, the literature evidence about MRI features of psoas muscles and clinical outcomes is still unclear and controversial [26, 27].

In the present study, we performed a multilevel spine muscles evaluation that demonstrated a tendency of cranial to caudal increase of FI on erector spinae and multifidus. Several other studies found the exact same results, in which fat infiltration was far more evident on the lower lumbar spine levels [1, 10, 13, 24]. Hence, as stressed by Urrutia et al. no single-level muscle features are representative of the whole lumbar spine [13].

The literature raises the hypothesis that paravertebral muscle atrophy and higher levels of fat infiltration are related to less favourable clinical outcome after lumbar discectomy surgery, even though scientific evidence is still very limited. Storheim et al. found, in a randomized study with 173 patients submitted to a total disc replacement, that a lower multifidus fat infiltration ratio predicted a better clinical outcome [10]. Similar results were reported by Yang Liu et al. and Zotti and al., who concluded that less preoperative fat infiltration of the multifidus muscles is a predictor of better clinical outcome in patients with lumbar spinal stenosis [11, 28]. Our study found no correlation between multifidus CSA and postoperative outcomes. However, lower rates of fat infiltration of the erector spinae muscles were related to better postoperative clinical outcomes. All these results together support the hypothesis that muscle atrophy and especially higher levels of fat infiltration are related to poor prognosis and could be an effective prognostic measure of postoperative outcomes. However, unlike the present research, most of the referred studies did not follow either a standard quantitative or semi-quantitative calculation for ROI, did not specify the muscular groups and did not include pre and postoperative patient outcome measures.

Regarding age and gender factors, our results are in line with previous reported results. Our analysis indicated that older patients presented higher fat infiltration rates, which supports the physiopathological evidence that the aging process decreases skeletal muscle mass and promotes its replacement by noncontractile connective tissue [14, 18, 24, 29-31]. In accordance to former reports, we did not find any effect of BMI on paravertebral muscle atrophy [7, 32]. It is possible that higher BMI values, by themselves do not translate into an increase in adipose infiltration at the paravertebral muscles. Smoking habits, antidepressant medication and physical therapy prior to surgery, none of them seemed to correlate with paravertebral atrophy, nor influence postoperative outcome.

This study emphasizes that multiple factors are likely to influence postoperative outcomes after lumbar discectomy. Patients with worse paravertebral musculature, higher percentage of fatty infiltration of erector spinae muscles and female patients presented poorer clinical outcomes. This knowledge may guide our practice and help encouraging patients to reduce inactivity and implement supervised and specific training to improve their functionality, muscle-mass and hopefully reach better postoperative outcomes [15]. Few studies have suggested that specific

training can reduce symptoms and reverse the degenerative process in paravertebral muscles. Kim et al. [33] reported positive results after eight weeks of training in patients with degenerative disc disease. A case-control study, by Storheim et al. [10] revealed a tendency to increase muscle CSA and density in the group of patients who practiced a biweekly exercise protocol for 15 weeks.

Some limitations can be identified in this study. It is a single-centre study with a retrospective design, which limits the generalizability of the results. Surgeries were performed by different surgeons; therefore, it is not possible to appraise whether technical variations can impact the outcomes, in spite that most surgeries were performed by a small number of spine-specialized neurosurgeons using a similar surgical technique in the same operative room. There is also the possibility for other potential confounders, such as further medical comorbidities not taken into analysis. Although the sample size is modest (n=112), this study is adequately powered to demonstrate associations between paravertebral fat infiltration and clinical outcome. Validated and widely used patient-reported outcome scores were selected and a quantitative method was applied to assess the CSA and fat infiltration of the paravertebral muscles instead of a visual semi-quantitative method.

## **Conclusion**

To our knowledge, this is the first study to demonstrate an association between erector spinae muscles anatomy on pre-operative MRI and postoperative clinical outcome in patients with symptomatic lumbar disc herniations. Increased fat infiltration of erector spinae muscles correlated to less favourable clinical outcomes following lumbar discectomies.

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**Table 1** - Patient demographic and paraspinal muscle characteristics

	Overall (N=112)
<b>Gender</b>	
Female	59 (52.7%)
Male	53 (47.3%)
<b>Age, mean (SD)</b>	46.1 (12.7)
<b>BMI, mean (SD)</b>	27.1 (3.9)
<b>Rehabilitation prior to surgery</b>	
No	25 (22.3%)
Yes	87 (77.7%)
<b>Smoker</b>	
No	84 (75.0%)
Yes	28 (25.0%)
<b>Antidepressant drugs</b>	
No	64 (57.1%)
Yes	48 (42.9%)
<b>Level</b>	
L2-L3	2 (1.8%)
L3-L4	5 (4.5%)
L4-L5	5 (4.5%)
L5-S1	51 (45.5%)
<b>Pain Side</b>	
Left	60 (53.6%)
Right	45 (40.2%)
Bilateral	7 (6.2%)
<b>Preoperative PROMS, median (IQR)</b>	
COMI	7.8 (6.4, 9.0)
ODI	46.0 (34.8, 62.0)
NRS back	7.0 (5.0, 8.0)
NRS leg	8.0 (6.0, 9.3)
EQ-5D	0.516 (-0.009, 0.620)
<b>Postoperative PROMS, median (IQR)</b>	
COMI	3.2 (1.5, 4.9)
ODI	22.0 (12.0, 36.0)
NRS back	3.0 (1.0, 5.3)
NRS leg	3.0 (1.8, 5.0)
EQ-5D	0.795 (0.648, 0.879)
<b>CSA, median (IQR)</b>	

<b>Erector spinae</b>	3025.250 (1844.875, 3955.125)
<b>Multifidus</b>	1702.500 (1175.625, 2495.625)
<b>Psoas</b>	195.250 (119.125, 313.625)
<b>Fat Infiltration %, median (IQR)</b>	
<b>Erector spinae</b>	26.517 (20.816, 31.861)
<b>Multifidus</b>	19.191 (13.219, 24.536)
<b>Psoas</b>	1.977 (1.275, 2.945)

**Table 2** – Baseline characteristics of the patients included in each of the three groups for FI of erector spinae.

	FI ≤ 15% (N=11)	15-30% (N=66)	FI ≥ 30% (N=35)	p value
<b>Gender</b>				0.222 <sup>1</sup>
<b>Female</b>	3 (27.3%)	36 (54.5%)	20 (57.1%)	
<b>Male</b>	8 (72.7%)	30 (45.5%)	15 (42.9%)	
<b>Age, median (IQR)</b>	35.000 (30.500, 42.000)	45.500 (36.000, 50.750)	50.000 (43.000, 63.000)	<0.001 <sup>2</sup>
<b>BMI, median (IQR)</b>	24.690 (23.720, 27.750)	26.310 (24.260, 28.075)	28.410 (25.315, 32.165)	0.019 <sup>2</sup>
<b>Rehabilitation prior to surgery</b>				0.157 <sup>1</sup>
<b>No</b>	5 (45.5%)	14 (21.2%)	6 (17.1%)	
<b>Yes</b>	6 (54.5%)	52 (78.8%)	29 (82.9%)	
<b>Smoker</b>				0.256 <sup>1</sup>
<b>No</b>	6 (54.5%)	51 (77.3%)	27 (77.1%)	
<b>Yes</b>	5 (45.5%)	15 (22.7%)	8 (22.9%)	
<b>Antidepressant drugs</b>				0.538 <sup>1</sup>
<b>No</b>	8 (72.7%)	37 (56.1%)	19 (54.3%)	
<b>Yes</b>	3 (27.3%)	29 (43.9%)	16 (45.7%)	
<b>Preoperative PROMS, median (IQR)</b>				
<b>COMI</b>	7.800 (6.450, 9.025)	7.600 (6.525, 8.950)	7.900 (6.425, 9.05)	0.806 <sup>2</sup>
<b>ODI</b>	48.000 (25.000, 68.000)	46.000 (38.000, 60.000)	46.000 (35.000, 59.000)	0.997 <sup>2</sup>
<b>NRS back</b>	7.000 (4.500, 8.500)	7.000 (5.000, 8.000)	7.000 (5.000, 9.000)	0.991 <sup>2</sup>
<b>NRS leg</b>	6.000 (4.000, 8.500)	8.000 (6.000, 9.000)	8.000 (6.500, 10.000)	0.303 <sup>2</sup>
<b>EQ-5D</b>	0.516 (0.353, 0.603)	0.364 (-0.016, 0.620)	0.516 (0.055, 0.587)	0.616 <sup>2</sup>
<b>Preoperative PROMS, median (IQR)</b>				
<b>COMI</b>	1.300 (0.850, 3.050)	2.900 (1.400, 4.475)	4.400 (2.825, 6.050)	0.002 <sup>2</sup>
<b>ODI</b>	22.000 (10.000, 24.000)	19.000 (12.000, 32.000)	28.000 (17.000, 40.000)	0.064 <sup>2</sup>

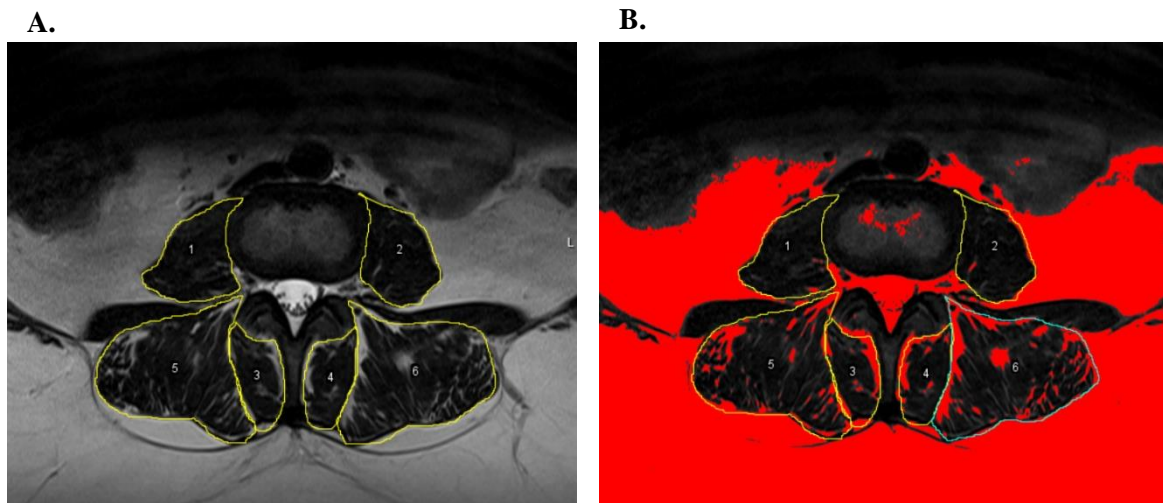
<b>NRS back</b>	2.000 (0.000, 3.500)	3.000 (2.000, 4.750)	5.000 (1.000, 6.000)	0.117 <sup>2</sup>
<b>NRS leg</b>	2.000 (0.000, 3.500)	2.000 (1.000, 4.750)	5.000 (3.000, 7.000)	0.001 <sup>2</sup>
<b>EQ-5D</b>	0.837 (0.837, 1.000)	0.782 (0.682, 0.879)	0.727 (0.592, 0.837)	0.032 <sup>2</sup>
<b>CSA, median (IQR)</b>				
<b>Erector spinae</b>	1251.500 (1151.500, 2368.750)	3039.000 (1816.750, 3940.375)	3219.500 (2635.750, 4635.750)	0.002 <sup>2</sup>
<b>Multífidus</b>	1010.500 (637.500, 1702.250)	1751.000 (1116.000, 2628.750)	1777.000 (1449.000, 2797.250)	0.020 <sup>2</sup>
<b>Psoas</b>	144.000 (96.000, 380.250)	187.000 (117.375, 274.000)	244.000 (136.000, 338.000)	0.237 <sup>2</sup>
<b>Fat infiltration, median (IQR)</b>				
<b>Erector spinae</b>	12.003 (11.124, 12.399)	24.285 (20.513, 27.240)	34.681 (32.029, 39.965)	< 0.001 <sup>2</sup>
<b>Multífidus</b>	10.308 (8.470, 12.479)	17.309 (13.154, 22.723)	17.309 (13.154, 22.723)	< 0.001 <sup>2</sup>
<b>Psoas</b>	1.117 (0.657, 1.667)	1.756 (1.116, 2.815)	2.551 (1.848, 4.373)	< 0.001 <sup>2</sup>

1. Fisher's Exact Test for Count Data
2. Kruskal-Wallis rank sum test

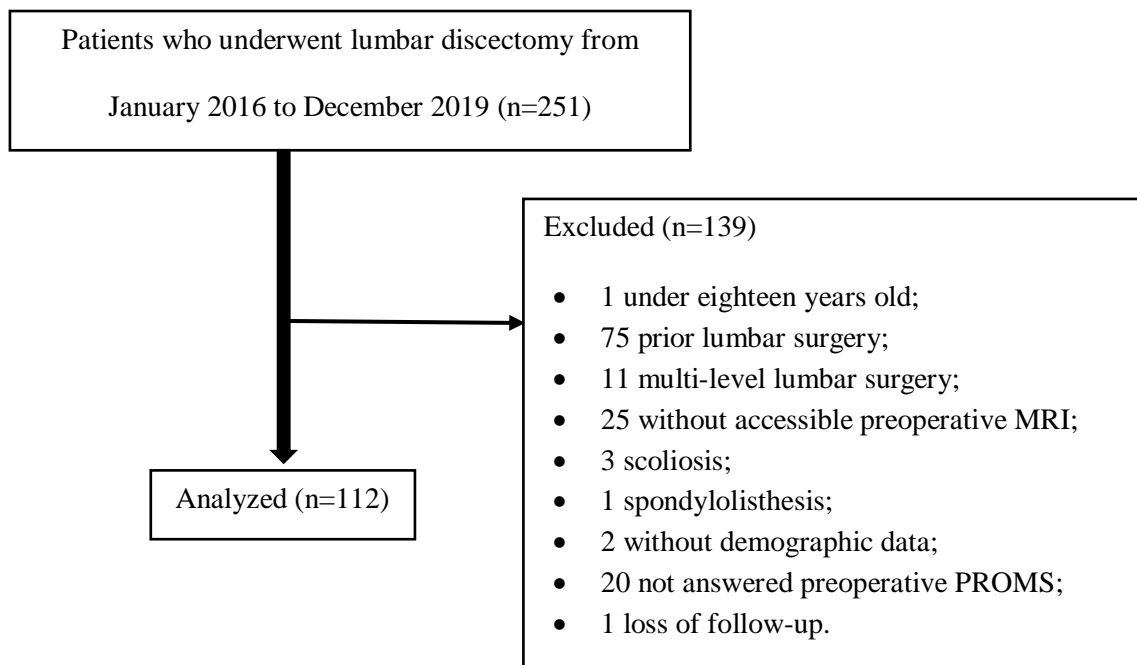
**Table 3** – Multivariable regression model for postoperative COMI.

Characteristic	Beta	95% CI	p-value
(Intercept)	2.5	1.2, 3.9	<0.001
Fat infiltration of erector spinae			
≤ 15%	—	—	
15-30%	1.1	-0.28, 2.4	0.12
≥30%	2.4	1.0, 3.8	0.001
Gender			
Female	—	—	
Male	-1.1	-1.8, -0.29	0.007

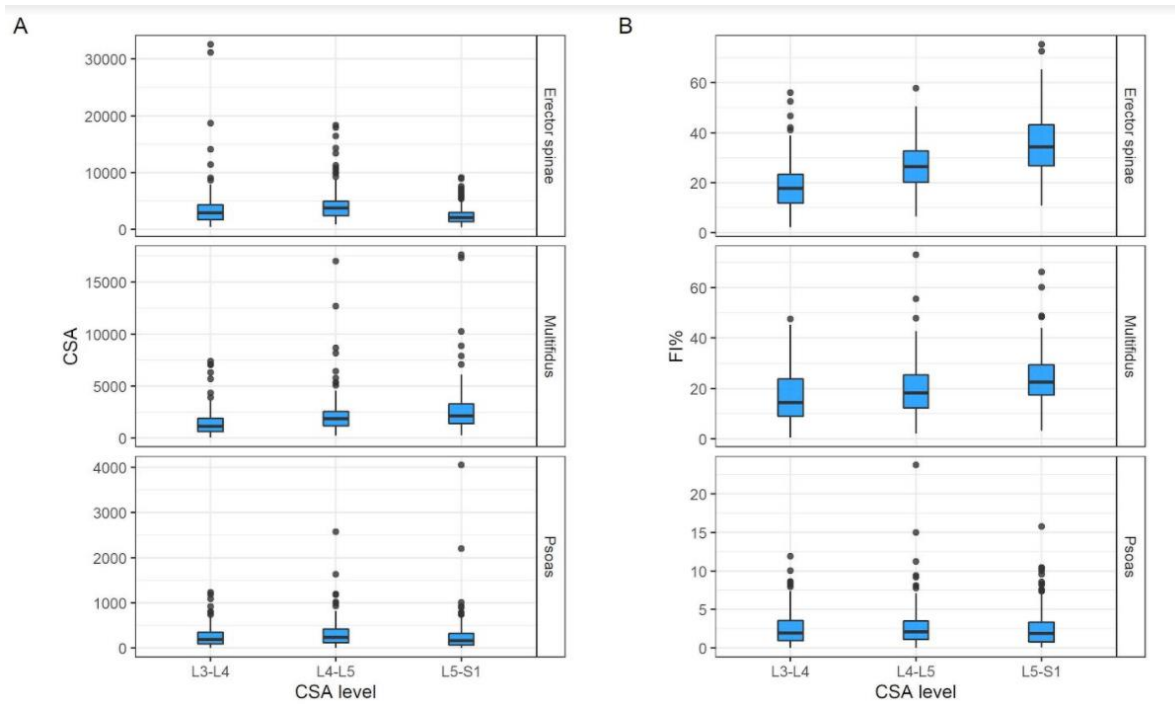
**Figure 1.** Regions of interest (ROI) (A) and fat infiltration (B) of paravertebral muscles measured by ImageJ software pseudo-colouring method, applying automatic thresholds.



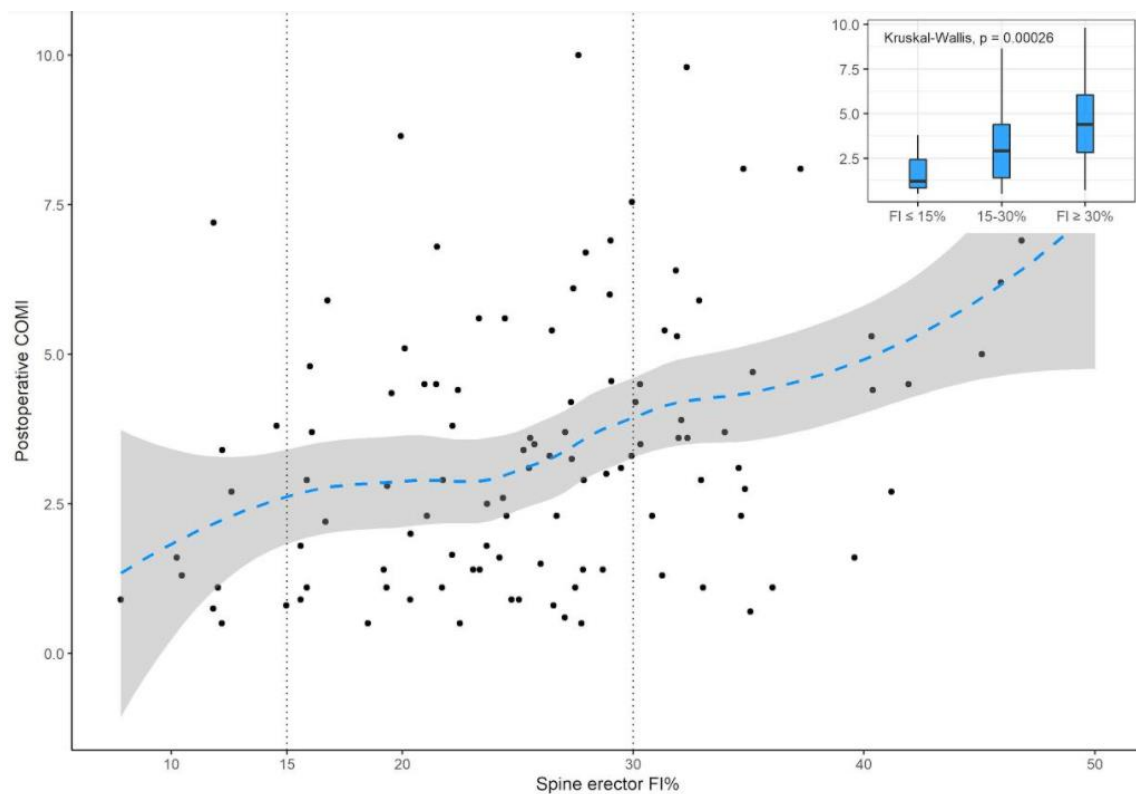
**Figure 2** - Flow diagram of participant screening, exclusion, and analysis.



**Figure 3** – Cross sectional area (CSA) (A) and fat infiltration (FI) percentage (B) at each disc level for erector spinae, multifidus and psoas muscles.



**Figure 4** – Relation between erector spinae FI and postoperative COMI. Boxplots: Postoperative COMI according to erector spinae FI groups.



# Supplemental file

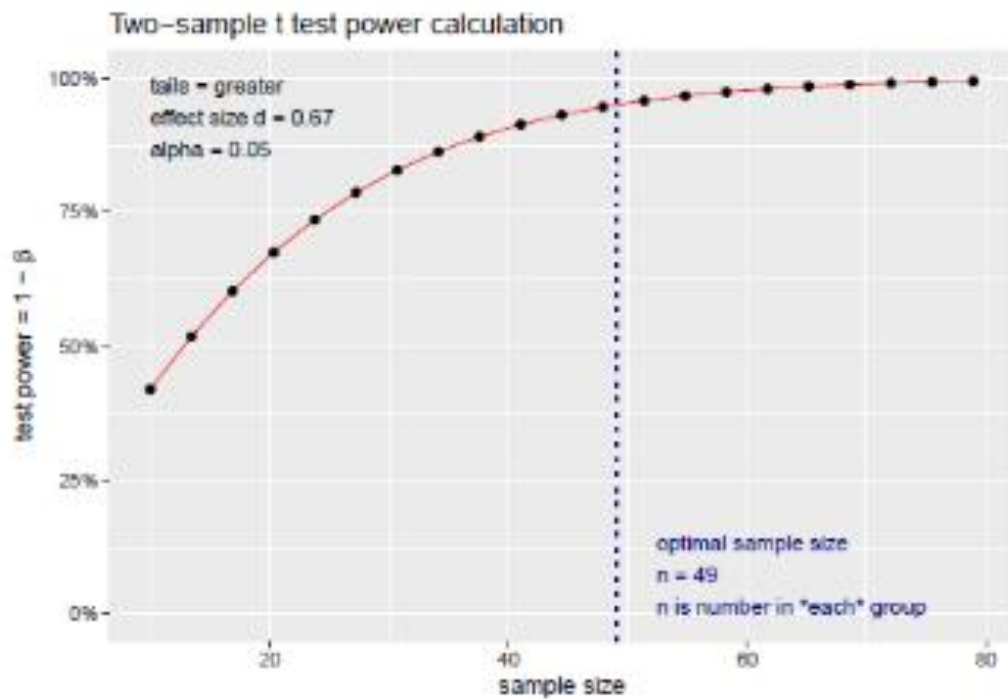
## Is the outcome after lumbar discectomy impacted by fatty infiltration of paraspinal muscles?

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### Sample size calculation

- Primary endpoint: postoperative COMI
- Objective: compare means of COMI between two groups according to muscle characteristics (FI or CSA).
- Sample size was calculated for one sided T-test sig. level of 0.05, power of 0.95
- Effect size calculated according to Cohen's  $d = (M2 - M1) / SD$ . The MCID for COMI (pt) is  $1.7 = (M2 - M1)$  (<https://doi.org/10.1007/s00586-011-2100-3>). We based the SD (2.7) for postoperative COMI in patients with DH in this work: <https://doi.org/10.1007/s00586-018-5469-4>.
- $d = 1.7/2.7 = 0.67$
- The calculated sample size was 98 patients ( $49*2$ ).



## Variables

- Demographics: Sex, Age, Kg (weight), cm (height), BMI
- Clinical: Smoker, Ans\_dep (anxiety/depression), PMR (physical therapy prior to surgery)
- Clinical Scores (preoperative, postoperative): COMI, NRS leg, NRS back, ODI, EQ-5D
- CSA: cross sectional area of muscle at one level (ROI area)
- CSA level
- FI%: percentage of fat infiltration of muscles
- Id: case identification
- muscle type
- muscle side
- Surgical: Surgery date, Previous surgery, Level, Side

## Patient demographic and paraspinal muscle characteristics

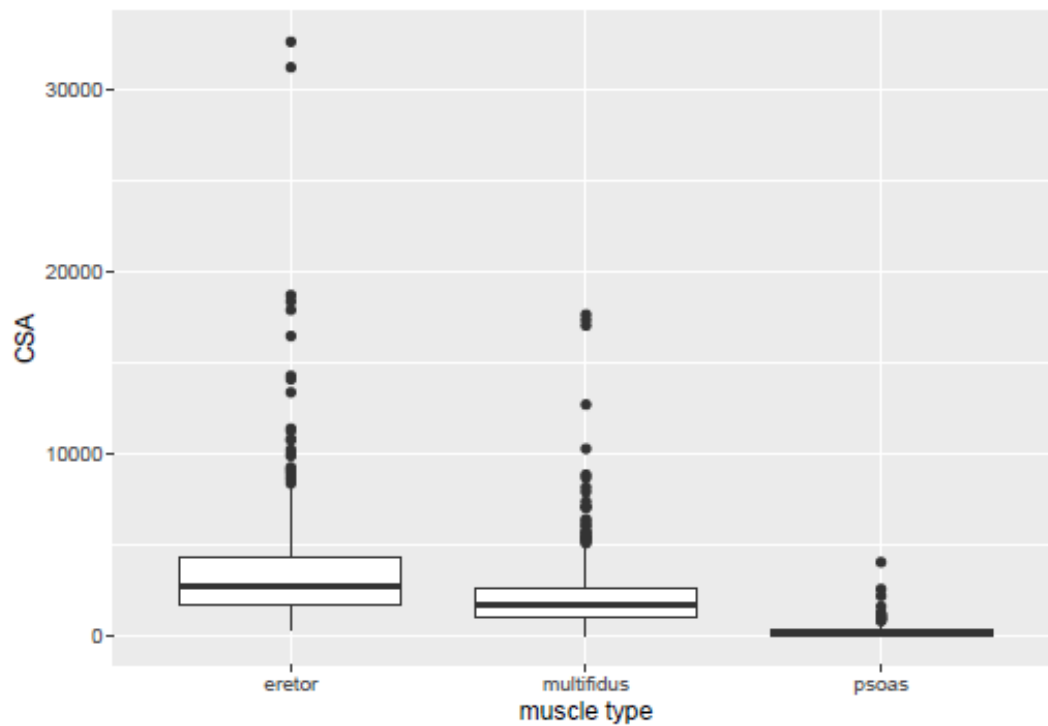
	Overall (N=112)
<b>Sex</b>	
F	59 (52.7%)
M	53 (47.3%)
<b>Age</b>	
Mean (SD)	46.134 (12.720)
Median (Q1, Q3)	46.000 (36.000, 54.250)
<b>Kg</b>	
Mean (SD)	76.149 (12.444)
Median (Q1, Q3)	76.000 (66.250, 85.750)
<b>cm</b>	
Mean (SD)	167.237 (9.643)
Median (Q1, Q3)	167.000 (160.000, 175.000)
<b>BMI</b>	
Mean (SD)	27.087 (3.890)
Median (Q1, Q3)	26.745 (24.305, 29.944)
<b>PMR</b>	
0	25 (22.3%)
1	87 (77.7%)
<b>Smoker</b>	
0	84 (75.0%)
1	28 (25.0%)
<b>Ans_dep</b>	
0	64 (57.1%)
1	48 (42.9%)
<b>Previous surgery</b>	
0	111 (99.1%)
1	1 (0.9%)
<b>Level</b>	
L2-L3	2 (1.8%)
L3-L4	5 (4.5%)
L4-L5	54 (48.2%)
L5-S1	51 (45.5%)
<b>Side</b>	
L	60 (53.6%)
M	7 (6.2%)
R	45 (40.2%)
<b>COMI preop</b>	
Mean (SD)	7.576 (1.714)
Median (Q1, Q3)	7.750 (6.438, 9.000)
<b>pNRS back</b>	
Mean (SD)	6.348 (2.563)
Median (Q1, Q3)	7.000 (5.000, 8.000)
<b>pNRS leg</b>	
Mean (SD)	7.330 (2.487)
Median (Q1, Q3)	8.000 (6.000, 9.250)
<b>ODI preop</b>	
Mean (SD)	48.226 (19.338)
Median (Q1, Q3)	46.000 (34.780, 62.000)

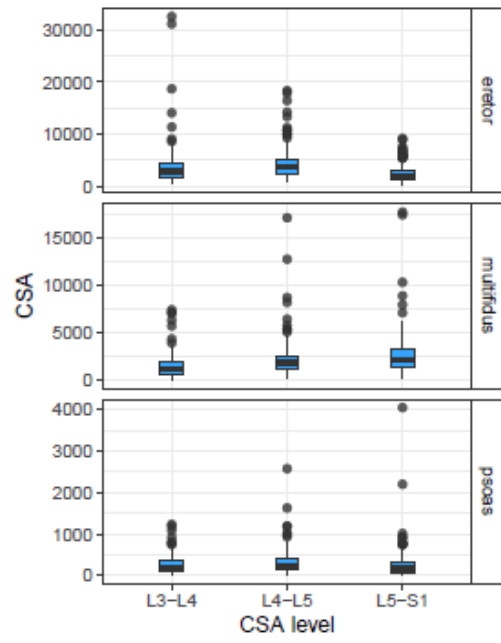
	Overall (N=112)
<b>EQ-5D preop</b>	
Mean (SD)	0.321 (0.367)
Median (Q1, Q3)	0.516 (-0.009, 0.620)
<b>COMI posop</b>	
Mean (SD)	3.512 (2.269)
Median (Q1, Q3)	3.175 (1.475, 4.850)
<b>NRS back</b>	
Mean (SD)	3.446 (2.647)
Median (Q1, Q3)	3.000 (1.000, 5.250)
<b>NRS leg</b>	
Mean (SD)	3.446 (2.599)
Median (Q1, Q3)	3.000 (1.750, 5.000)
<b>ODI posop</b>	
Mean (SD)	24.565 (15.921)
Median (Q1, Q3)	22.000 (12.000, 36.000)
<b>EQ-5D posop</b>	
Mean (SD)	0.750 (0.224)
Median (Q1, Q3)	0.795 (0.648, 0.879)
<b>var_COMI</b>	
Mean (SD)	4.065 (2.354)
Median (Q1, Q3)	4.150 (2.275, 5.725)
<b>var_NRS_back</b>	
Mean (SD)	2.902 (2.854)
Median (Q1, Q3)	3.000 (1.000, 4.000)
<b>var_NRS_leg</b>	
Mean (SD)	3.884 (3.176)
Median (Q1, Q3)	3.000 (2.000, 6.250)
<b>var_ODI</b>	
Mean (SD)	23.638 (18.657)
Median (Q1, Q3)	20.000 (10.000, 34.000)
<b>var_EQ5D</b>	
Mean (SD)	0.428 (0.382)
Median (Q1, Q3)	0.319 (0.146, 0.720)
<b>CSA_med_eretor</b>	
Mean (SD)	3414.049 (2447.963)
Median (Q1, Q3)	3025.250 (1844.875, 3955.125)
<b>CSA_med_multifidus</b>	
Mean (SD)	2048.402 (1697.845)
Median (Q1, Q3)	1702.500 (1175.625, 2495.625)
<b>CSA_med_psoas</b>	
Mean (SD)	236.371 (188.681)
Median (Q1, Q3)	195.250 (119.125, 313.625)
<b>FI_med_eretor</b>	
Mean (SD)	26.398 (8.697)
Median (Q1, Q3)	26.517 (20.816, 31.861)
<b>FI_med_multifidus</b>	
Mean (SD)	19.766 (8.834)
Median (Q1, Q3)	19.191 (13.219, 24.536)
<b>FI_med_psoas</b>	
Mean (SD)	2.401 (1.704)
Median (Q1, Q3)	1.977 (1.275, 2.945)

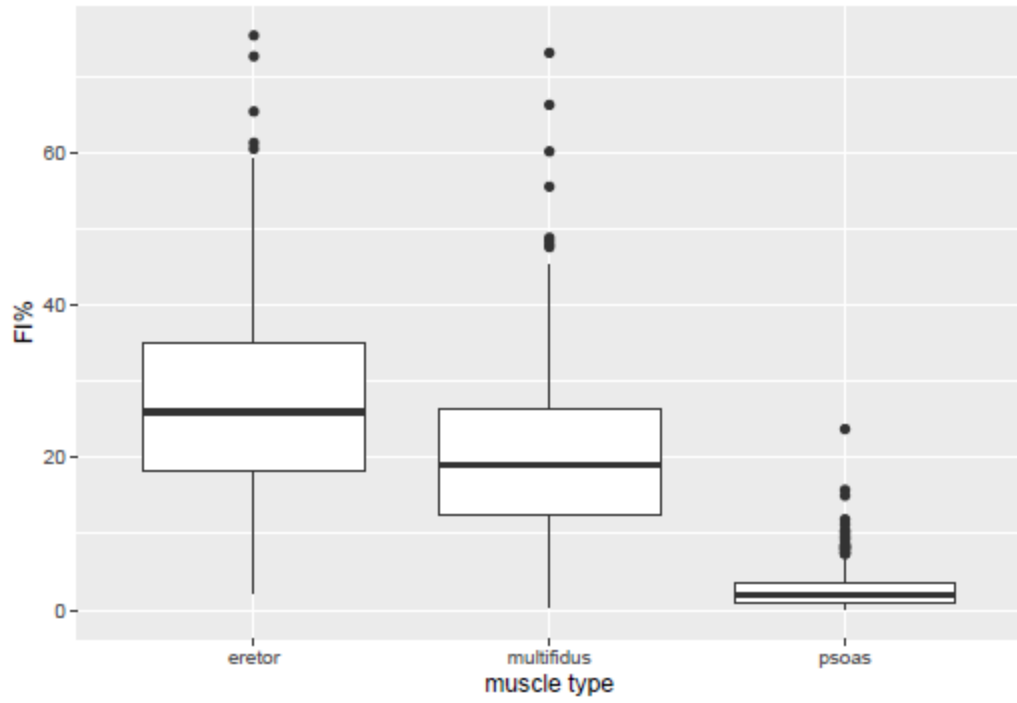
## CSA and FI patterns

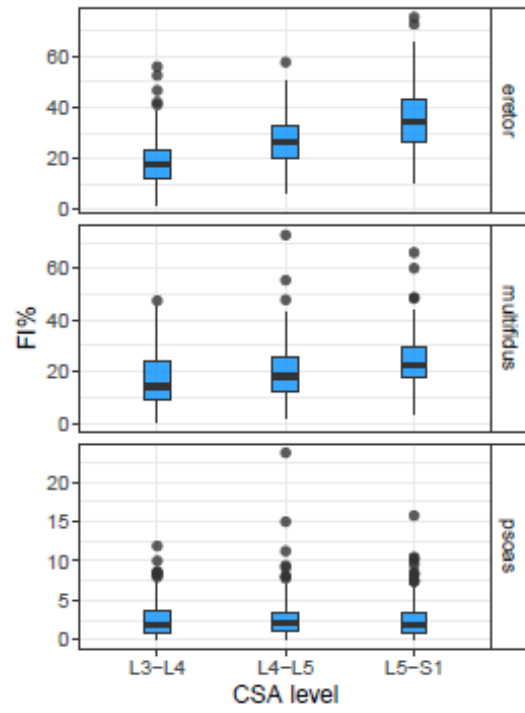
### Main findings:

- CSA and FI: erector > multifidus > psoas
- CSA is stable across the levels.
- FI slightly increases from L3 to S1 for erector and MF
- CSA and FI variables are not normally distributed
- It is correct to resume this values (for segment and side) with medians to have one CSA and FI value for muscle for patient
- Psoas is very stable but was weakly correlated with anthropometric variables, so it is not usefull as normalization criteria

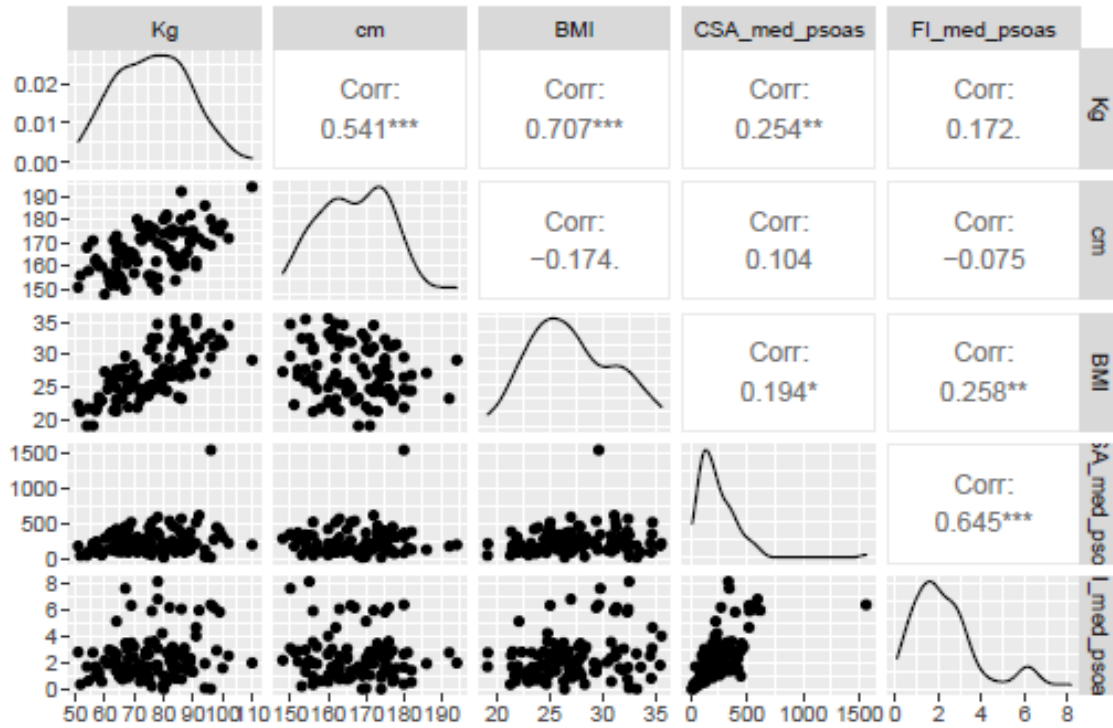








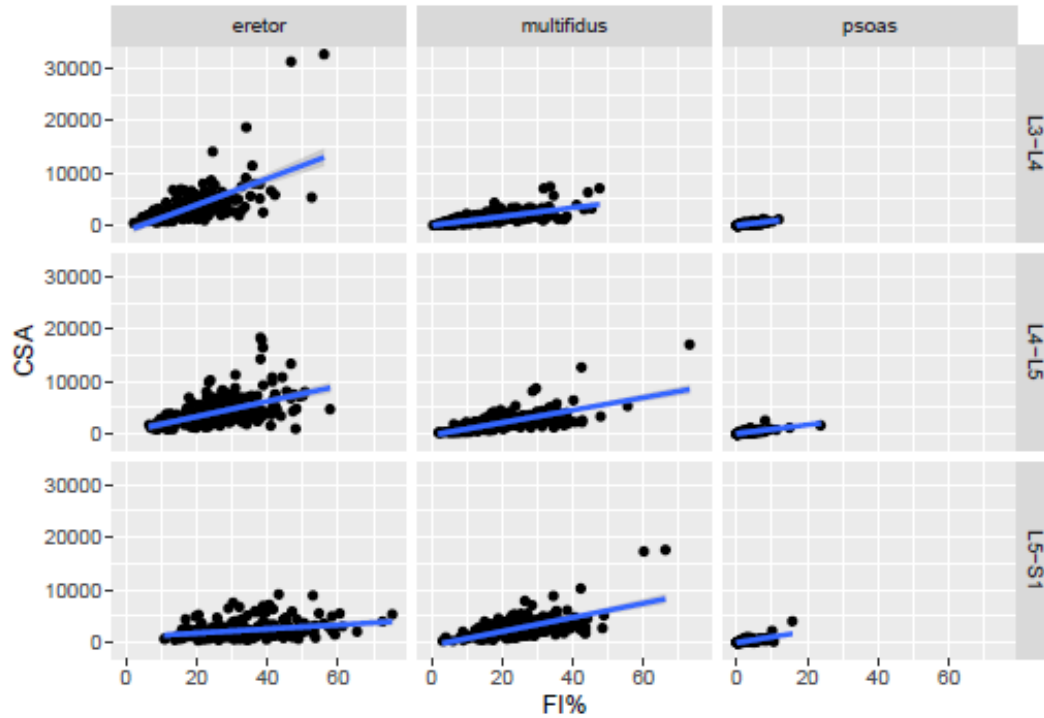
### Spearman correlations



### CSA - FI relation

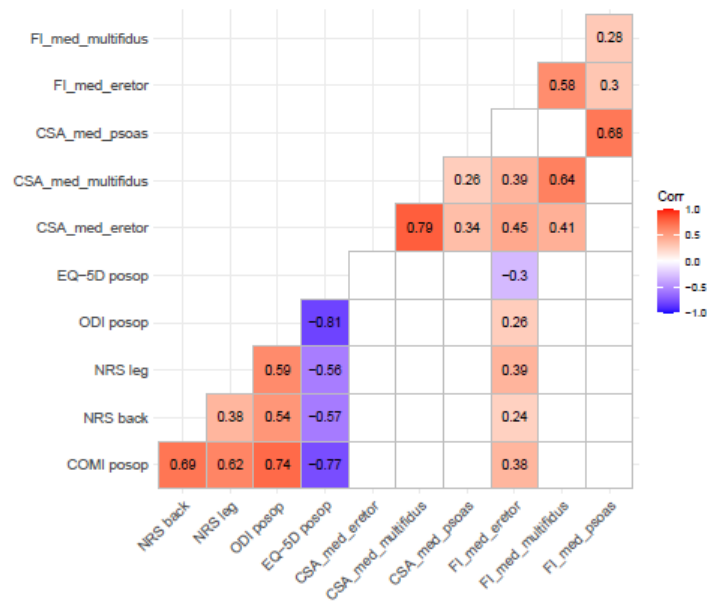
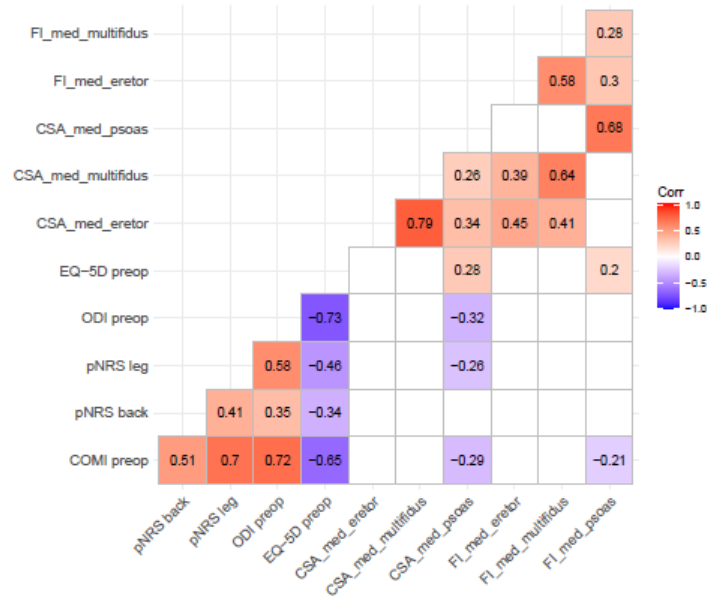
There is a CSA - FI linear relation, for erector and multifidus (except for erector in L5S1)

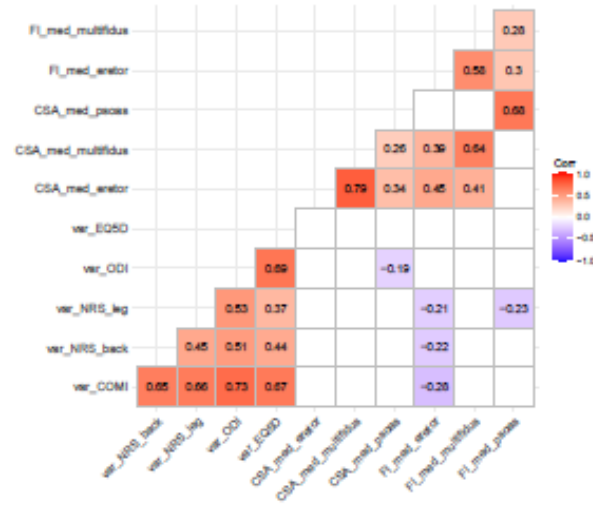
```
## `geom_smooth()` using formula 'y ~ x'
```



### Correlations

- Stronger correlations (Spearman) are between FI% of erector muscle (the only variable correlated to postoperative clinical scores) and postoperative COMI
- CSA of psoas muscle has a weak correlation with preoperative clinical scores





### Univariable Models for postop COMI

- Variables with no association with postoperative COMI: weight, BMI, previous PMR, smoker status, anxiety/depression, level of surgery
- Variables with association with postoperative COMI: age, height and sex

Characteristic	Beta	95% CI	p-value
Age	0.04	0.01, 0.07	0.015

Characteristic	Beta	95% CI	p-value
cm	-0.06	-0.11, -0.02	0.009

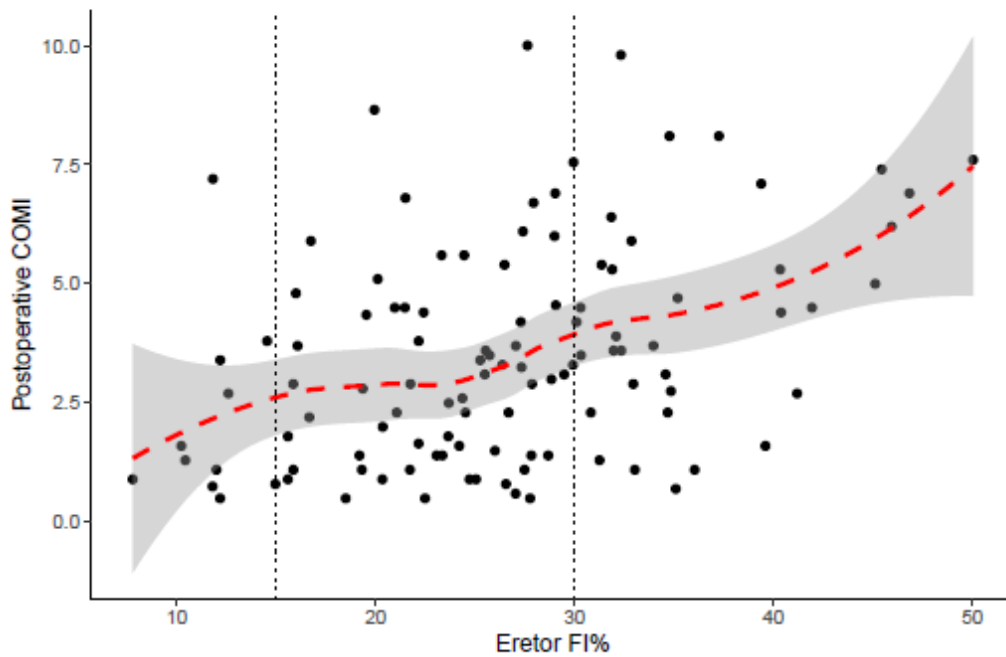
Characteristic	Beta	95% CI	p-value
Sex			
F			
M	-1.4	-2.2, -0.61	<0.001

### Split FI eretor - under 15, upper 30

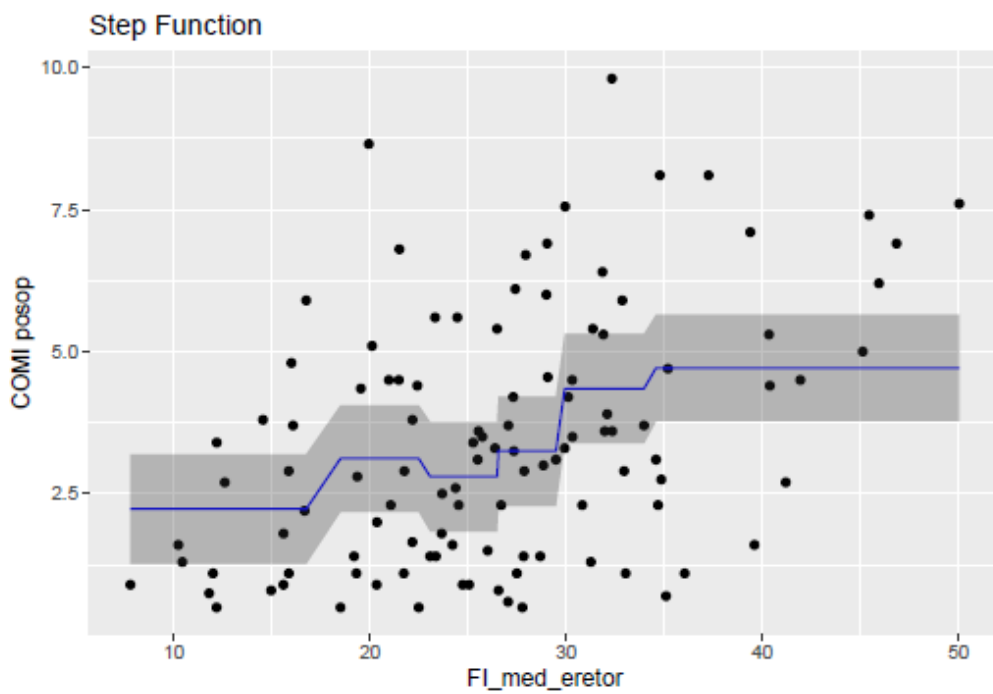
- There is no linear relation between FI% of eretor and COMI posop, so we proceed to split FI% of eretor muscle in a categorical variable
- By visual analysis it seems appropriate to split at 15% and 30%

- A step function after splitting FI eretor in 6 bins confirms this perception, also, the univariable model (COMI\_posop vs FI15\_30\_eretor) is significant
- The difference between the postoperative COMI medians for the 3 groups of FI eretor is statistically significant and clinically relevant, the difference between median postoperative COMI for eretor FI% <15% and eretor FI% >30% is 3.2.

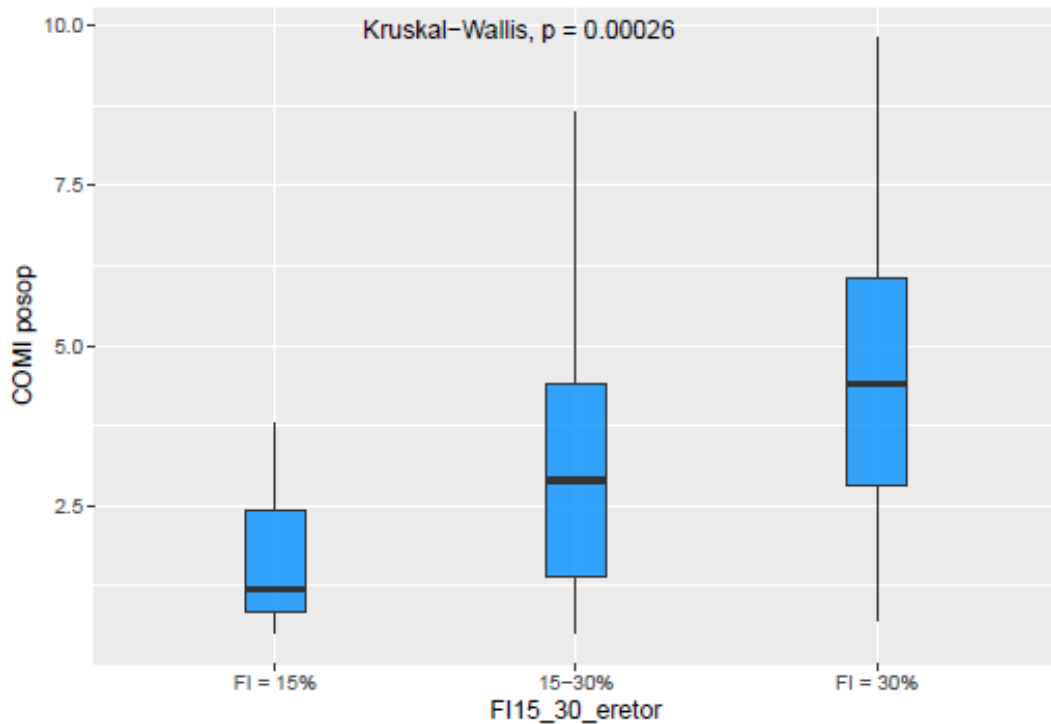
Locally estimated scatterplot smoothing: Eretor FI% vs Postoperative COM



<b>**Characteristic**</b>	<b>**Beta**</b>	<b>**95% CI**</b>	<b>**p-value**</b>
(Intercept)	2.2	1.3, 3.2	<0.001
FI_eretor			
[7.8,17.6]			
(17.6,22.5]	0.89	-0.44, 2.2	0.2
(22.5,26.5]	0.57	-0.78, 1.9	0.4
(26.5,29.5]	1.0	-0.33, 2.4	0.14
(29.5,34.3]	2.1	0.77, 3.5	0.002
(34.3,50]	2.5	1.2, 3.8	<0.001



<b>**Characteristic**</b>	<b>**Beta**</b>	<b>**95% CI**</b>	<b>**p-value**</b>
(Intercept)	1.7	0.42, 3.0	0.010
FI15_30_ereter			
FI = 15%			
15-30%	1.4	0.06, 2.8	0.040
FI15_30_ereterFI = 30%	2.8	1.4, 4.2	<0.001



FI15_30_erotor	median_COMI_pos	IQR
FI = 15%	1.2	1.600
15-30%	2.9	3.000
FI = 30%	4.4	3.225

### Multivariable model for postop COMI

- Exclude height and then Age from the model - not significant
- Independent factors: FI% of erector muscle and sex

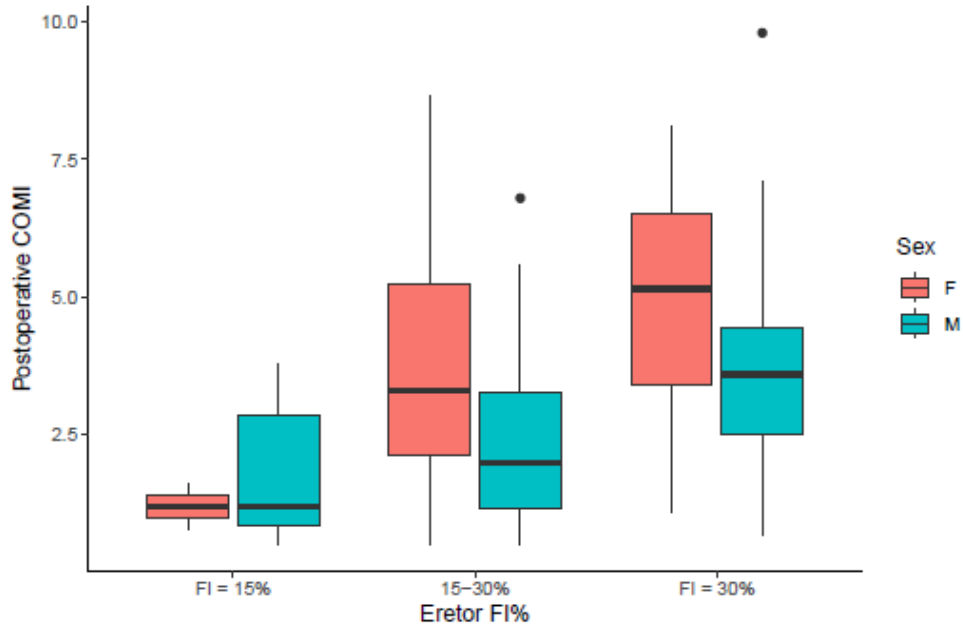
**Characteristic**	**Beta**	**95% CI**	**p-value**
(Intercept)	-4.8	-16, 6.6	0.4
FI15_30_erotor			
FI = 15%			
15-30%	0.58	-1.1, 2.3	0.5
FI15_30_erotorFI = 30%	1.8	-0.04, 3.7	0.055
Age	0.03	0.00, 0.07	0.064
cm	0.04	-0.02, 0.11	0.2
Sex			
F			
M	-1.8	-3.0, -0.60	0.004

<b>**Characteristic**</b>	<b>**Beta**</b>	<b>**95% CI**</b>	<b>**p-value**</b>
(Intercept)	1.8	0.00, 3.5	0.050
FI15_30_erector			
FI = 15%			
15-30%	0.87	-0.50, 2.2	0.2
FI15_30_erectorFI = 30%	2.1	0.54, 3.6	0.008
Sex			
F			
M	-1.1	-1.8, -0.31	0.006
Age	0.02	-0.01, 0.05	0.2

<b>**Characteristic**</b>	<b>**Beta**</b>	<b>**95% CI**</b>	<b>**p-value**</b>
(Intercept)	2.5	1.2, 3.9	<0.001
FI15_30_erector			
FI = 15%			
15-30%	1.1	-0.28, 2.4	0.12
FI15_30_erectorFI = 30%	2.4	1.0, 3.8	0.001
Sex			
F			
M	-1.1	-1.8, -0.29	0.007

Spine erector fat infiltration % vs Postoperative COMI



**Baseline characteristics of the patients included in each of the three groups for FI of erector spinae**

	FI = 15% (N=11)	15-30% (N=66)	FI = 30% (N=35)	p value
<b>Sex</b>				0.222 <sup>1</sup>
F	3 (27.3%)	36 (54.5%)	20 (57.1%)	
M	8 (72.7%)	30 (45.5%)	15 (42.9%)	
<b>Age</b>				< 0.001 <sup>2</sup>
Mean (SD)	36.091 (8.215)	44.682 (11.662)	52.029 (13.263)	
Median (Q1, Q3)	35.000 (30.500, 42.000)	45.500 (36.000, 50.750)	50.000 (43.000, 63.000)	
<b>Kg</b>				0.275 <sup>2</sup>
Mean (SD)	80.600 (14.431)	74.614 (12.622)	77.729 (11.339)	
Median (Q1, Q3)	77.000 (74.250, 83.750)	75.000 (64.000, 83.000)	78.000 (68.000, 87.000)	
<b>cm</b>				0.025 <sup>2</sup>
Mean (SD)	174.000 (13.540)	168.008 (8.750)	164.312 (9.617)	
Median (Q1, Q3)	177.000 (168.500, 178.500)	170.500 (161.750, 175.000)	163.000 (159.250, 170.000)	
<b>BMI</b>				0.019 <sup>2</sup>
Mean (SD)	26.044 (3.425)	26.380 (3.507)	28.747 (4.274)	
Median (Q1, Q3)	24.690 (23.720, 27.750)	26.310 (24.260, 28.075)	28.410 (25.315, 32.165)	
<b>PMR</b>				0.157 <sup>1</sup>
0	5 (45.5%)	14 (21.2%)	6 (17.1%)	
1	6 (54.5%)	52 (78.8%)	29 (82.9%)	
<b>Smoker</b>				0.278 <sup>1</sup>
0	6 (54.5%)	51 (77.3%)	27 (77.1%)	
1	5 (45.5%)	15 (22.7%)	8 (22.9%)	
<b>Ans_dep</b>				0.556 <sup>1</sup>
0	8 (72.7%)	37 (56.1%)	19 (54.3%)	
1	3 (27.3%)	29 (43.9%)	16 (45.7%)	
<b>Previous surgery</b>				1.000 <sup>1</sup>
0	11 (100.0%)	65 (98.5%)	35 (100.0%)	
1	0 (0.0%)	1 (1.5%)	0 (0.0%)	
<b>Level</b>				0.017 <sup>1</sup>
L2-L3	0 (0.0%)	0 (0.0%)	2 (5.7%)	
L3-L4	1 (9.1%)	3 (4.5%)	1 (2.9%)	
L4-L5	1 (9.1%)	33 (50.0%)	20 (57.1%)	
L5-S1	9 (81.8%)	30 (45.5%)	12 (34.3%)	
<b>Side</b>				0.635 <sup>1</sup>
L	7 (63.6%)	37 (56.1%)	16 (45.7%)	
M	1 (9.1%)	4 (6.1%)	2 (5.7%)	
R	3 (27.3%)	25 (37.9%)	17 (48.6%)	
<b>COMI preop</b>				0.806 <sup>2</sup>
Mean (SD)	7.295 (2.288)	7.523 (1.672)	7.766 (1.624)	
Median (Q1, Q3)	7.800 (6.450, 9.025)	7.600 (6.525, 8.950)	7.900 (6.425, 9.050)	
<b>pNRS back</b>				0.991 <sup>2</sup>
Mean (SD)	6.455 (2.382)	6.364 (2.358)	6.286 (3.025)	
Median (Q1, Q3)	7.000 (4.500, 8.500)	7.000 (5.000, 8.000)	7.000 (5.000, 9.000)	

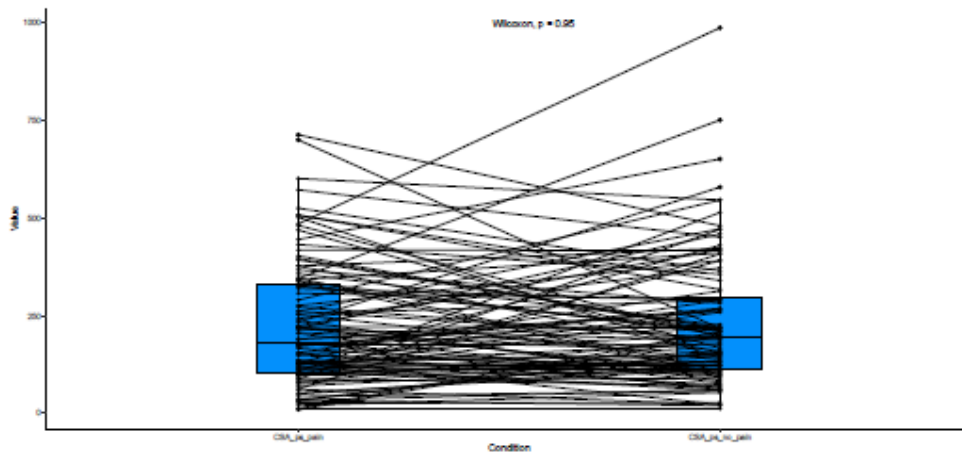
	FI = 15% (N=11)	15-30% (N=66)	FI = 30% (N=35)	p value
<b>pNRS leg</b>				0.303 <sup>2</sup>
Mean (SD)	6.273 (3.003)	7.333 (2.362)	7.657 (2.531)	
Median (Q1, Q3)	6.000 (4.000, 8.500)	8.000 (6.000, 9.000)	8.000 (6.500, 10.000)	
<b>ODI preop</b>				0.997 <sup>2</sup>
Mean (SD)	47.636 (26.181)	48.004 (18.666)	48.825 (18.757)	
Median (Q1, Q3)	48.000 (25.000, 68.000)	46.000 (38.000, 60.000)	46.000 (35.000, 59.000)	
<b>EQ-5D preop</b>				0.616 <sup>2</sup>
Mean (SD)	0.422 (0.338)	0.295 (0.370)	0.336 (0.372)	
Median (Q1, Q3)	0.516 (0.353, 0.603)	0.364 (-0.016, 0.620)	0.516 (0.055, 0.587)	
<b>COMI posop</b>				0.002 <sup>2</sup>
Mean (SD)	2.186 (2.007)	3.217 (2.139)	4.484 (2.274)	
Median (Q1, Q3)	1.300 (0.850, 3.050)	2.900 (1.400, 4.475)	4.400 (2.825, 6.050)	
<b>NRS back</b>				0.117 <sup>2</sup>
Mean (SD)	2.364 (2.292)	3.288 (2.522)	4.086 (2.884)	
Median (Q1, Q3)	2.000 (0.000, 3.500)	3.000 (2.000, 4.750)	5.000 (1.000, 6.000)	
<b>NRS leg</b>				< 0.001 <sup>2</sup>
Mean (SD)	2.091 (2.071)	2.848 (2.315)	5.000 (2.601)	
Median (Q1, Q3)	2.000 (0.000, 3.500)	2.000 (1.000, 4.750)	5.000 (3.000, 7.000)	
<b>ODI posop</b>				0.064 <sup>2</sup>
Mean (SD)	18.545 (11.596)	23.273 (16.543)	28.895 (15.182)	
Median (Q1, Q3)	22.000 (10.000, 24.000)	19.000 (12.000, 32.000)	28.000 (17.000, 40.000)	
<b>EQ-5D posop</b>				0.032 <sup>2</sup>
Mean (SD)	0.873 (0.127)	0.749 (0.238)	0.712 (0.212)	
Median (Q1, Q3)	0.837 (0.837, 1.000)	0.782 (0.682, 0.879)	0.727 (0.592, 0.837)	
<b>var_COMI</b>				0.031 <sup>2</sup>
Mean (SD)	5.109 (2.546)	4.306 (2.439)	3.281 (1.928)	
Median (Q1, Q3)	5.600 (3.375, 6.900)	4.375 (2.475, 5.975)	3.400 (1.900, 4.875)	
<b>var_NRS_back</b>				0.058 <sup>2</sup>
Mean (SD)	4.091 (2.914)	3.076 (2.937)	2.200 (2.564)	
Median (Q1, Q3)	4.000 (3.000, 6.000)	3.000 (2.000, 5.000)	2.000 (0.500, 4.000)	
<b>var_NRS_leg</b>				0.033 <sup>2</sup>
Mean (SD)	4.182 (3.488)	4.485 (3.110)	2.657 (2.930)	
Median (Q1, Q3)	3.000 (2.500, 7.000)	4.000 (2.000, 7.000)	3.000 (1.000, 4.500)	
<b>var_ODI</b>				0.378 <sup>2</sup>
Mean (SD)	29.091 (24.023)	24.711 (18.533)	19.930 (16.852)	
Median (Q1, Q3)	24.000 (8.000, 45.000)	22.000 (10.000, 38.000)	20.000 (11.000, 24.000)	
<b>var_EQ5D</b>				0.574 <sup>2</sup>
Mean (SD)	0.451 (0.395)	0.453 (0.386)	0.375 (0.375)	
Median (Q1, Q3)	0.321 (0.240, 0.519)	0.363 (0.154, 0.752)	0.279 (0.076, 0.616)	
<b>CSA_med_erector</b>				0.002 <sup>2</sup>
Mean (SD)	1904.227 (1192.759)	3203.182 (1693.702)	4286.200 (3471.947)	
Median (Q1, Q3)	1251.500 (1151.500, 2368.750)	3039.000 (1816.750, 3940.375)	3219.500 (2635.750, 4635.750)	
<b>CSA_med_multifidus</b>				0.020 <sup>2</sup>
Mean (SD)	1175.364 (676.005)	1904.394 (1055.432)	2594.343 (2559.968)	
Median (Q1, Q3)	1010.500 (637.500, 1702.250)	1751.000 (1116.000, 2628.750)	1777.000 (1449.000, 2797.250)	
<b>CSA_med_psoas</b>				0.237 <sup>2</sup>

	FI = 15% (N=11)	15-30% (N=66)	FI = 30% (N=35)	p value
Mean (SD)	220.045 (159.334)	224.371 (210.269)	264.129 (151.901)	
Median (Q1, Q3)	144.000 (96.000, 380.250)	187.000 (117.375, 274.000)	244.000 (136.000, 338.000)	
<b>FI_med_erector</b>				< 0.001 <sup>2</sup>
Mean (SD)	11.874 (1.971)	23.605 (4.160)	36.231 (5.456)	
Median (Q1, Q3)	12.003 (11.124, 12.399)	24.285 (20.513, 27.240)	34.681 (32.029, 39.965)	
<b>FI_med_multifidus</b>				< 0.001 <sup>2</sup>
Mean (SD)	10.672 (5.649)	18.306 (7.321)	25.376 (8.925)	
Median (Q1, Q3)	10.308 (8.470, 12.479)	17.309 (13.154, 22.723)	22.556 (19.922, 30.599)	
<b>FI_med_psoas</b>				< 0.001 <sup>2</sup>
Mean (SD)	1.272 (0.795)	2.124 (1.432)	3.280 (2.004)	
Median (Q1, Q3)	1.117 (0.657, 1.667)	1.756 (1.116, 2.815)	2.551 (1.848, 4.373)	

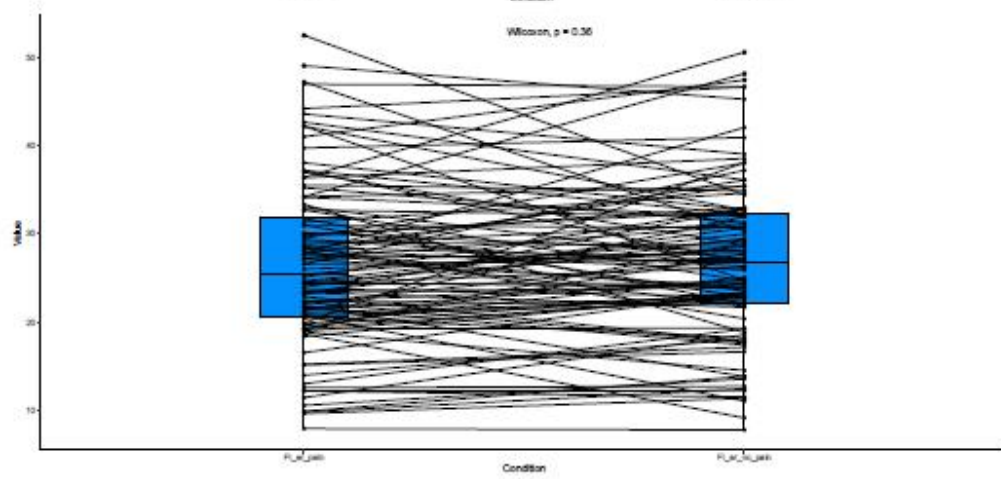
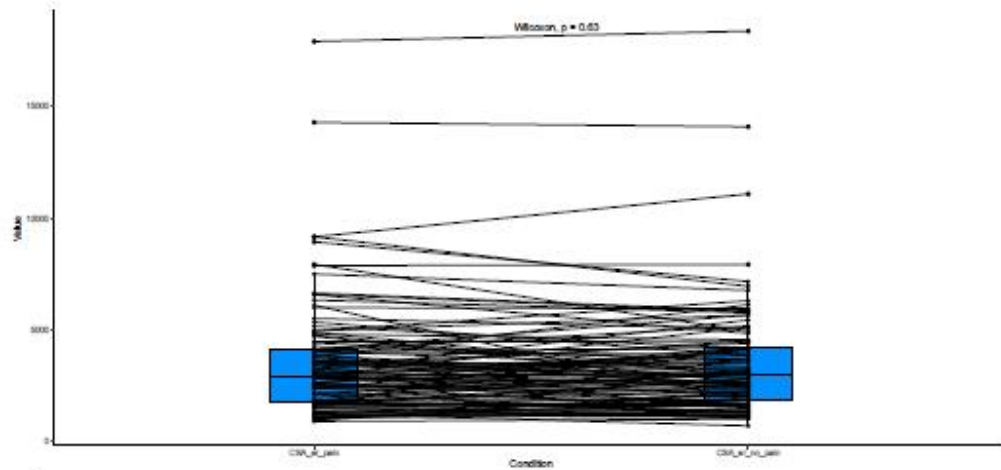
1. Fisher's Exact Test for Count Data
2. Kruskal-Wallis rank sum test

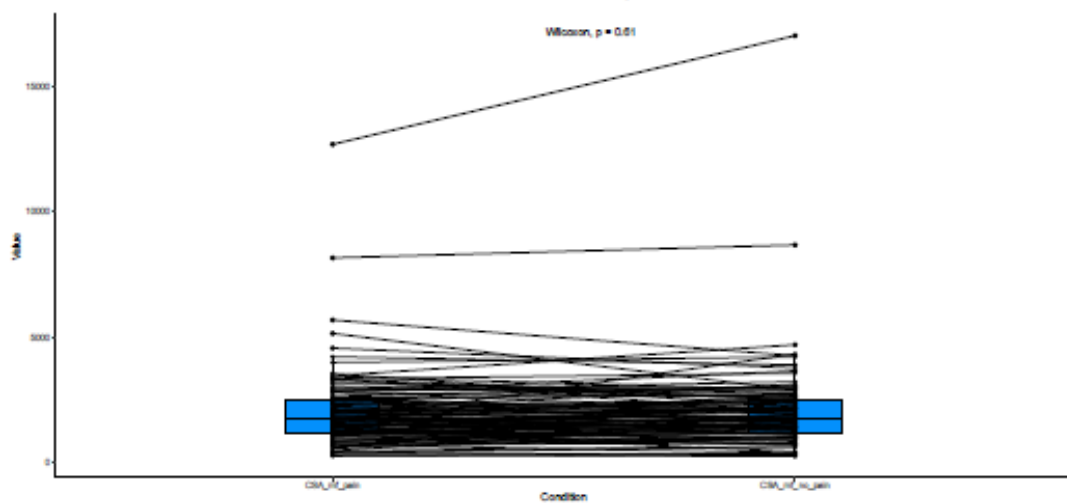
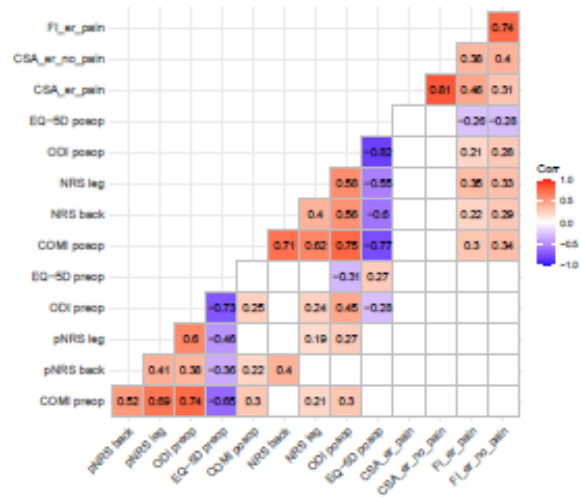
### Exploring asymmetries

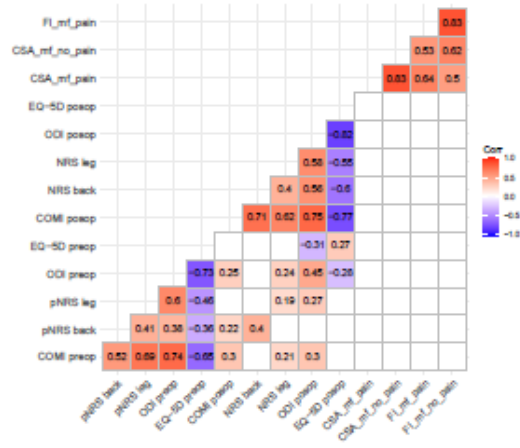
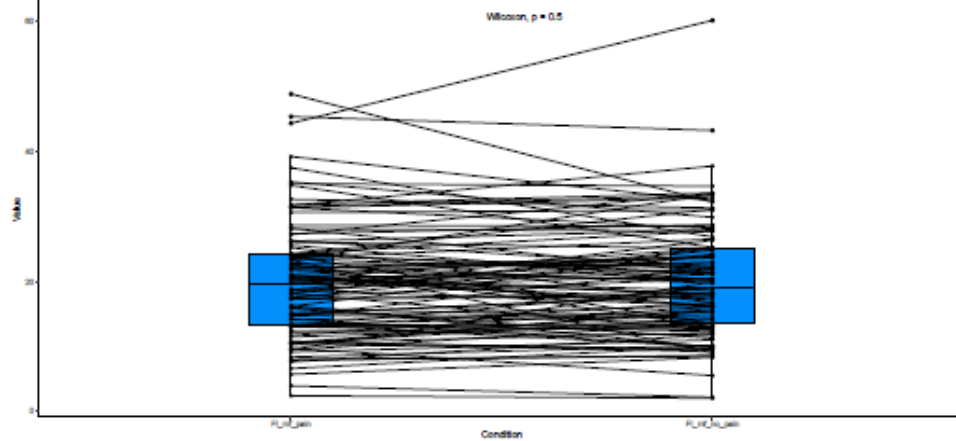
- Labeling muscle according to leg pain side prior to surgery
- The means between CSA of psoas (pain side vs no pain side) according to Wilcoxon test are not different
- However there are positive correlations between CSA/FI of psoas muscle from symptomatic side and worse preoperative status
- No other differences after exploring the other muscles for pain side, and L-R asymmetries in general (for CSA and FI)

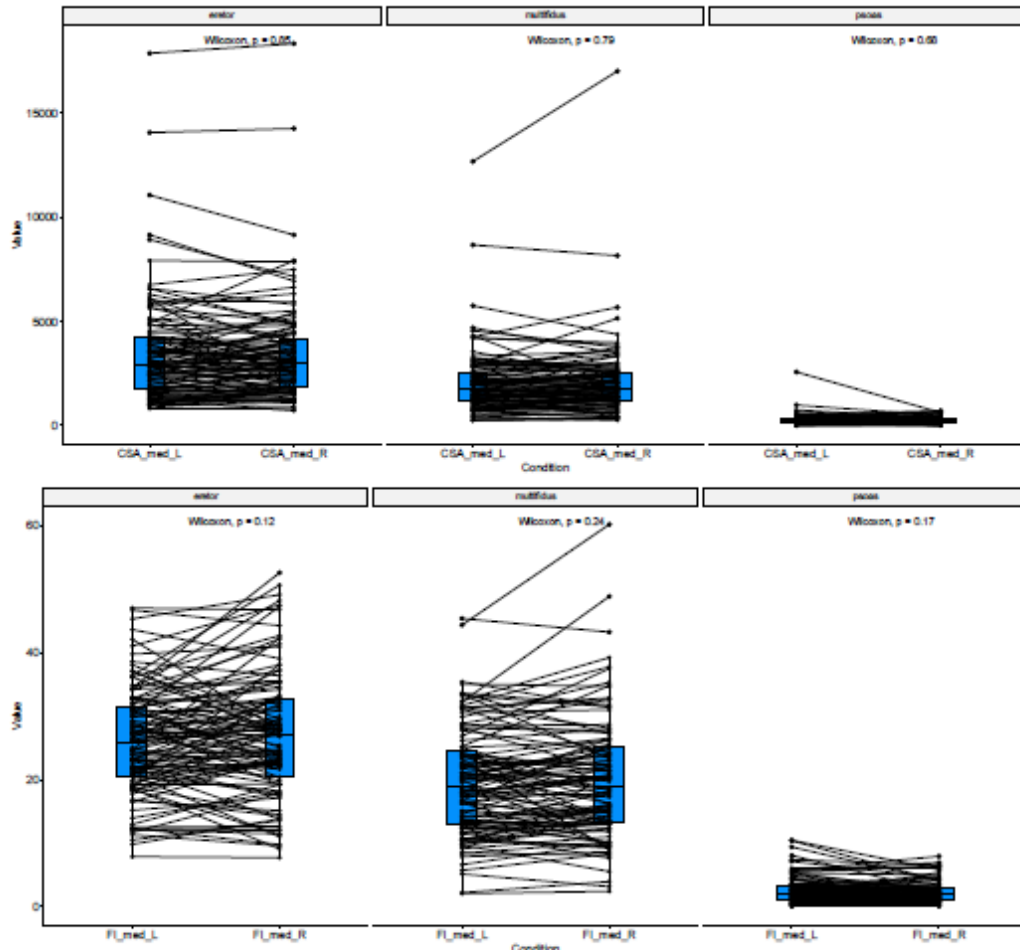













## **Anexos**

1. Parecer da comissão de ética
2. Normas de publicação da revista Spine
3. Reporting Guidelines

**Unidade de Investigação**  
 Tomou conhecimento. Fidei a expor. A DC.  
 18 de Novembro de 2020  
 A Coordenadora da Unidade de Investigação  
  
 (Prof.ª Cristina Ana Almeida)



n.º 426/2020

DIRECÇÃO CLÍNICA  
 2020.11.18

PEDIDO DE AUTORIZAÇÃO  
**Realização de Investigação**

Exmo. Senhor Presidente do Conselho de Administração  
 do Centro Hospitalar de São João

*de U.T.M*

**Nome do Investigador Principal:**

Juliana Cardoso Costa Santos

**Título da Investigação:**

Is the outcome after lumbar discectomy impacted by fatty infiltration of paraspinal muscles?

Pretendo realizar no(s) Serviço(s) de:

Neurocirurgia

a investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efetivação.

Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de São João/ Faculdade de Medicina da Universidade do Porto respeitante à investigação, à qual enderecei pedido de apreciação e parecer.

Com os melhores cumprimentos.

O Investigador/Promotor

Porto, 15 de Novembro de 2020.

Juliana Cardoso Costa Santos  
 Investigadora

• Centro Hospitalar São João -  
 Centro de Epidemiologia Hospitalar



## Questionário para submissão de Investigação

Exmo. Sr. Presidente da Comissão de Ética do Centro Hospitalar de São João/  
 Faculdade de Medicina da Universidade do Porto,

Pretendendo realizar a investigação infocitada, solicito a V. Exa., na qualidade de Investigador, a sua apreciação e a elaboração do respetivo parecer. Para o efeito, anexo toda a documentação requerida.

### IDENTIFICAÇÃO DO ESTUDO

Título da investigação: N-tta outcome after lumbar discectomy impacted by fatty infiltration of paraspinal muscles?

Nome do investigador: Juliana Cardoso Costa Santos

Endereço eletrónico: julianacos@ gmail.com

Contacto telefónico: 962520869

#### Caracterização da investigação:

- Estudo retrospectivo       Estudo observacional       Estudo prospetivo  
 Inquérito       Outro. Qual? \_\_\_\_\_

#### Tipo de investigação:

- Com intervenção       Sem intervenção

Formação do investigador em boas práticas clínicas (GCP):  Sim       Não

Promotor (se aplicável): \_\_\_\_\_

Nome do orientador de dissertação/tese (se aplicável): Professor Doutor Paulo Miguel da Silva Pereira

Endereço eletrónico: pereira.paulom@gmail.com

Local/locais onde se realiza a investigação: Serviço de Neurocirurgia do CHSJ

Data prevista para início: 30 / 10 / 2020

Data prevista para o término: 28 / 02 / 2021

### PROTOCOLO DO ESTUDO

#### Síntese dos objetivos:

- Determinar o grau de infiltração adiposa dos músculos paravertebrais (multífidos, eretor da espinha e psoas), em três níveis lombares (L3 a S1), em imagem de ressonância magnética, em doentes com hérnia discal lombar, que foram submetidos a discectomias lombares.
- Relacionar as alterações degenerativas e morfológicas desta musculatura com o outcome funcional pós-cirurgia.

#### Fundamentação ética (ganhos em conhecimento/ inovação; ponderação benefícios/riscos):

Têr-se verificado um crescente interesse no estudo da composição dos músculos paravertebrais como elemento potencial de diagnóstico e prognóstico na avaliação de doentes com patologia lombar. No entanto, poucos estudos se debruçaram sobre a influência da infiltração adiposa desta musculatura em doentes com hérnia discal lombar e de que forma esta poderá influenciar o outcome funcional destes doentes submetidos a cirurgia.

### LISTA DE DOCUMENTOS ANEXOS

- Pedido de autorização ao Presidente do Conselho de Administração do Centro Hospitalar de São João (se aplicável)
- Pedido de autorização à Diretora da Faculdade de Medicina da Universidade do Porto (se aplicável)
- Protocolo do estudo
- Declaração do Diretor de Serviço onde decorre o estudo  
(sendo um estudo na área de enfermagem deve anexar também a concordância da chefia de enfermagem)
- Profissional de ligação
- Informação dos orientadores
- Informação ao participante
- Modelo de consentimento
- Instrumentos a utilizar (inquéritos, questionários, escalas, p.ex.): \_\_\_\_\_
- Curriculum Vitae abreviado (máx. 3 páginas)
- Protocolo financeiro
- Outros:

### COMPROMISSO DE HONRA E DECLARAÇÃO DE INTERESSES

Declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (1960 e respetivas emendas), e da Organização Mundial da Saúde, Convenção de Oviedo e das "Boas Práticas Clínicas" (GCP/ICH) no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo, nos últimos três meses. Comprometo-me a entregar à CES o relatório final da investigação, assim que concluído.

Porto, 15 de Novembro de 2020

Nome legível: Juliana Cardoso Costa Santos

Juliana Cardoso Costa Santos  
assinatura

Parecer da Comissão de Ética do Centro Hospitalar de São João/ FMUP

Emitido na reunião plenária da CE de 18 / 12 / 2020

*Aguarda esclarecimentos.*

Prof. Doutor Filipe Mendonça  
Presidente da Comissão de Ética

*Filipe Mendonça*  
Centro Hospitalar São João

CONSIDERADOS QUE FORAM COMO SATISFATÓRIOS OS  
ESCLARECIMENTOS PRESTADOS PELO(A)  
INVESTIGADOR(A), A CES APROVA POR UNANIMIDADE O  
PARECER DO RELATOR, PELO QUE NADA TEM A OPOR À  
REALIZAÇÃO DESTE PROJETO DE INVESTIGAÇÃO.

Prof. Doutor Filipe Mendonça  
Presidente da Comissão de Ética

*Filipe Mendonça*

05 / 01 / 2021



### 3. Observações/Preenchimento/Respostas

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### 4. Aceitação dos Termos e Condições da Reutilização

Consolidadamente com as obrigações decorrentes da lei já citada (n.º 2 e 3 do art.º 21 e o n.º 1 e 2 do art.º 12 ambos da Lei n.º 25/2016, de 22 de Agosto) a o submeter o presente pedido concordo e fico ainda vinculado, juridicamente, aos seguintes termos e condições:

- Comprometo-me a manter confidencial toda a informação à qual vou ter acesso;
- Após exploração do RAI do CHUSJ, em linha a Lei 25/2016, de 22 de agosto, impõe-me como requisito a esta utilização sem possibilidades de reversão, tal decisão, é não só uma impossibilidade matemática já comprometida, como ainda resulta num prejuízo para a investigação, face à quantidade e qualidade da informação a retirar à fonte razão pela qual, concordando com o RAI, assumo-me como responsável e passível a sanções, o que implica uma avaliação e gestão do risco, mas que é ético-jurídico que ocorrerem e aos comprometo-me a colaborar;
- Não vou elaborar registos, suscetíveis de identificar ou tornar identificável a identidade das pessoas a quem os mesmos dizem respeito;
- Comprometo-me a consultar os processos clínicos nos termos e lo cais que me forem indicados para o efeito;
- Além do presente pedido para reutilizar registos clínicos, dirigi-o ao RAI, comprometo-me a obter os necessários pareceres quer do Encarregado da Proteção de Dados, quer da Comissão de Ética do Hospital, quer ainda do Centro de Epidemiologia Hospitalar;
- Comprometo-me a citar as fontes, sempre que publicitar o trabalho de investigação, independentemente de requerer a Certidão de Reutilização (DataREUse Certificate for Research - DARE);
- Tendo conhecimento que a violação de qualquer dos compromissos aqui assumidos, resultará no apuramento de responsabilidades disciplinares, civis e penais e ainda, à impossibilidade futuro de aceder a informação de saúde para fins de investigação.

### 5. Decisão do Investigador sobre requerer a Data REUse Certificate for Research - DARE (Desachamento/Requisição)

Pretendo desde já requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consultei em <http://portal-cha.jrntr-saude.pt/pagow/710>

Não pretendo requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consultei em <http://portal-cha.jrntr-saude.pt/pagow/710>

No circunstância de se apresentar não indicar qual a sua opção, presumir-se-á que pretende requerer o DARE.

### 6. Assinatura

Nota 1: Se o presente pedido for submetido eletronicamente ao sistema de assinatura digital qualificado, as posteriores alterações ao texto do Centro Hospitalar São João poderão ser documentadas eletronicamente, as alterações devem ser efetuadas através de uma ferramenta representativa a ser utilizada para este efeito de modo a garantir a integridade do documento e a sua validade jurídica. Consulte o presente site de distribuição de informações para obter mais informações: [portal-cha.jrntr-saude.pt](http://portal-cha.jrntr-saude.pt)

Nota 2: Se o presente pedido for entregue pessoalmente a este efeito a sua validade jurídica ficará garantida quando for assinada eletronicamente.

Data: 2020 - 12 - 03

  
Investigador Principal

Em caso de dúvida ou por qualquer outro contacto através dos endereços eletrónicos  
[rai.reutilizacao@cha.jrntr-saude.pt](mailto:rai.reutilizacao@cha.jrntr-saude.pt) e [alguitmanes@cha.jrntr-saude.pt](mailto:alguitmanes@cha.jrntr-saude.pt)  
ou pelo número de telefone: 902 304 194 ou 902 800 200

SUBMITER

Parecer da Comissão de Ética do

Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto

**Título do Projeto:** Is the outcome after lumbar discectomy impacted by fatty infiltration of paraspinal muscles?

**Nome da Investigadora Principal:** Juliana Cardoso Costa Santos

**Onde decorre o Estudo:** No Serviço de Neurocirurgia. Apresentou declaração do Prof. Doutor Rui Vaz.

**Objetivos do Estudo:**

Determinar o grau de infiltração adiposa dos músculos paravertebrais (multifidos, eretor da espinha e soas) em três níveis lombares (L3 a S1), em imagem de ressonância magnética, em doentes com hérnia discal lombar, que foram submetidos a discectomias lombares; relacionar as alterações degenerativas e morfológicas desta musculatura com o outcome funcional pós-cirurgia. Estudo realizado no âmbito do Mestrado Integrado em Medicina, sob orientação do Prof. Doutor Paulo Miguel da Silva Pereira e coorientação do Doutor Vasco Carvalho.

**Conceção e Pertinência do estudo:**

Tem-se verificado um crescente interesse no estudo da composição dos músculos paravertebrais como elemento potencial de diagnóstico e prognóstico na avaliação de doentes com patologia lombar. No entanto, poucos estudos se debruçaram sobre a influência da infiltração adiposa desta musculatura em doentes com hérnia discal lombar e de que forma poderá influenciar o outcome funcional destes doentes submetidos a cirurgia.

Estudo retrospectivo, de doentes com dor lombar crónica devido à presença de hérnias discais (L3-S1), que foram submetidos a discectomias/remoção de hérnias discais lombares, entre janeiro de 2016 a dezembro de 2019. Estão definidos os critérios de inclusão e exclusão, bem como os dados a recolher.

**Benefício/risco:** Não aplicável

**Confidencialidade dos dados:**

A base de dados conterá apenas um número identificador de cada doente, ou seja, os doentes são identificados com um número atribuído de forma individual. A publicação do estudo conterá apenas dados agregados, sem qualquer identificação dos doentes.

Apresentou um pedido de reutilização de registos clínicos para Investigação e Desenvolvimento ao RAI.

**Respeito pela liberdade e autonomia do sujeito de ensaio:** Não aplicável

**Curriculum da investigadora:** Adequado à investigação.

**Data previsível da conclusão do estudo:** fevereiro de 2021

**Conclusão:** Proponho um parecer favorável à realização deste projeto de investigação.

Porto, 5 de janeiro de 2021.

O Relator da CE, Doutor Pedro Brito



## Normas de publicação da revista Spine

### Spine

*Spine* is a peer-reviewed, multidisciplinary journal directed to an audience of spine physicians and scientists. The journal publishes original articles in the form of clinical and basic research. Spine will only publish studies that have institutional review board (IRB) or similar ethics committee approval for human and animal studies and have strictly observed a sufficient follow-up period. With the exception of reference presentation, Spine requires that all manuscripts be prepared in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. We follow the [COPE guidelines](#).

*Spine* periodically publishes the following special sections: Controversy, Historical Perspective, Journal Club, Legal Forum, and Spine Update.

### Manuscript Submission

Authors are to submit their manuscripts through the Web-based tracking system at <http://spine.edmgr.com/>. The site contains instructions and advice on how to submit manuscripts, guidance on the creation/scanning and saving of electronic art, and supporting documentation. In addition to allowing authors to submit manuscripts on the Web, the site allows authors to follow the progression of their manuscript through the peer review process. Authors who submit their manuscripts through the Web-based tracking system are asked not to send hard copies of the manuscript to the editorial office. Address all inquiries regarding manuscripts not yet accepted or published to the Journal's editorial office. The editorial office will acknowledge receipt of your manuscript and will give you a manuscript number for reference. Authors are instructed to select the Level of Evidence of their study using the Oxford Centre for Evidence Based Medicine Table (<http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf>). Basic Science, Biomechanics, and Case Report papers do not require levels of evidence.

### Revised Submission

Author's comments to the reviewers are required for revised submissions. Authors must address the reviewer's concerns/suggestions, whether the change is made or not. Authors must also highlight the changes made within the text. Do not track the additions or deletions to the manuscript.

**Patient anonymity and informed consent.** It is the author's responsibility to ensure that a patient's anonymity be carefully protected and to verify that any experimental investigation with human subjects reported in the manuscript was performed with informed consent and followed all the guidelines for experimental investigation with human subjects required by the institution(s) with which all the authors are affiliated. Authors should mask patients' eyes, private parts and remove patients' names from all figures. Photographs of patients should have bars placed over the eyes. In addition, permission from the patient is required and must be submitted with the manuscript.

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## Preparation of Manuscript

Manuscripts that do not adhere to the following instructions WILL BE RETURNED to the corresponding author for technical revision before undergoing peer review.

**General format.** All manuscripts should be submitted in English, and formatted for standard 8<sup>1</sup>/<sub>2</sub> x 11-inch (21 x 28-cm) paper with at least a 1-inch (2.5 cm) margin on all sides and double spaced. **Manuscripts should be no longer than 2700 words of text, excluding the abstract and references. Case Reports should be no more than 750 words of text.** All Case Reports must have a Structured Abstract and will be published online only. All papers published online only will be completely referenced and indexed.

**Style.** Pattern manuscript style after the *American Medical Association Manual of Style* (10th edition), *Stedman's Medical Dictionary* (27th edition) and *Merriam Webster's Collegiate Dictionary* (10th edition) should be used as standard references. Refer to drugs and therapeutic agents by their accepted generic or chemical names, and do not abbreviate them. Use code numbers only when a generic name is not yet available. In that case, supply the chemical name and a figure giving the chemical structure of the drug. Capitalize the trade names of drugs and place them in parentheses after the generic names. To comply with trademark law, include the name and location (city and state in USA; city and country outside USA) of the manufacturer of any drug, supply, or equipment mentioned in the manuscript. Use the metric system to express the units of measure and degrees Celsius to express temperatures, and SI units rather than conventional units.

**Submit manuscript electronically via Editorial Manager: <http://spine.edmgr.com/> in the following order:**

The research letter allows succinct publications of 750-1,000 words and can be selected for any type of investigation (basic science, clinical, prospective or retrospective study). Research letters are cited in PubMed.

1) Title page. Include on the title page (a) complete manuscript title; (b) authors' full names, highest academic degrees, and affiliations; (c) name and address for correspondence, including fax number, telephone number, and e-mail address; (d) address for reprints if different from that of corresponding author; (e) sources of support that require acknowledgment; (f) any other acknowledgment the authors wish to include. Please verify that the spelling, order, and affiliation of each author is correct. The Journal is not responsible for published misspelled names due to author error.

The title page must also include disclosure of funding received for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s).

**Please note: Research Letters are restricted to no more than four authors.**

**There is no abstract for research letters and no key points.**

2) Key Words. List ten to fifteen Key Words. Authors are instructed to select the Level of Evidence of their study using the Oxford Centre for Evidence Based Medicine Table (<http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf>)

3) Mini Abstract/Précis. Submit a short description of the manuscript to appear in the Table of Contents, consisting of approximately three sentences and of no more than 50 words. Place on a separate page.

4) Text. Organize the research letter into four main headings: Introduction, Materials and Methods, Results, and Discussion.

A Running Head should appear in the top right hand corner of every page. The running head should be no more than three to five words from the title, and should NOT include the authors' names.

Terms. Do not use the term *hardware*. Acceptable substitutions include implants and instrumentation. Constructs or montage may be used if the reference is to a particular pattern of fixation points for the instrumentation.

Abbreviations. For a list of standard abbreviations, consult the *Council of Biology Editors Style Guide* (available from the Council of Science Editors, 9650 Rockville Pike, Bethesda, MD 20814) or other standard sources. Write out the full term for each abbreviation at its first use unless it is a standard unit of measure.

5) References. The authors are responsible for the accuracy of the references. Key the references (double-spaced) at the end of the manuscript. Cite references in text in the order of appearance. Do not link the references to the text. Cite unpublished data, such as papers submitted but not yet accepted for publication or personal communications, in parentheses in the text. If there are more than three authors, name only the first three authors and then use et al. Refer to the *List of Journals Indexed in Index Medicus* for abbreviations of journal names, or access the list at <http://www.nlm.nih.gov/tsd/serials/lji.html>.

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Sample references are given below:

*Journal article*

1. Guiot BH, Khoo LT, Fessler RG. A minimally invasive technique for decompression of the lumbar spine. *Spine* 2002;27:432-8.

*Book chapter*

2. Sweitzer S, Arruda J, DeLeo J. The cytokine challenge: Methods for the detection of central cytokines in rodent models of persistent pain. In: Kruger L, ed. *Methods in Pain Research*. Boca Raton, FL: CRC Press; 2001:109-32.

#### *Entire book*

3. Atlas SW. *Magnetic Resonance Imaging of the Brain and Spine*. Philadelphia: Lippincott Williams & Wilkins; 2001.

#### *Software*

4. *Epi Info* [computer program]. Version 6. Atlanta: Centers for Disease Control and Prevention; 1994.

#### *Online journals*

5. Friedman SA. Preeclampsia: A review of the role of prostaglandins. *Obstet Gynecol* [serial online]. January 1988;71:22-37. Available from: BRS Information Technologies; McLean, VA. Accessed December 15, 1990.

6) Tables and Figures: Formatting requirements follow that of original research articles for Tables and Figures.

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#### **7) Tables and Figures:**

**Tables.** Create tables using the table creating and editing feature of your word processing software (e.g., Word, WordPerfect). Do not use Excel or comparable spreadsheet programs. **Tables should not exceed page width of 41 picas or 17.5 cm.** Supply tables together in a separate file. Cite tables consecutively in the text, and number them in that order. Key each on a separate sheet, include the table title, appropriate column heads, and explanatory legends (including definitions of any abbreviations used). **Do not embed tables within the body of the manuscript.** They should be self-explanatory and should supplement, rather than duplicate, the material in the text. **No more than five tables are acceptable.** Additional tables and tables that exceed 2 pages in length are subject to publication on Article Plus. (See below for more information.)

**Digital Figures.** All electronic art can be submitted through the Web-based tracking system <http://spine.edmgr.com/>

#### **A) Creating Digital Artwork**

1. Learn about the publication requirements for Digital Artwork: <http://links.lww.com/ES/A42>
2. Create, Scan and Save your artwork and compare your final figure to the Digital Artwork Guideline Checklist (below).
3. Upload each figure to Editorial Manager in conjunction with your manuscript text and tables.

## B) Digital Artwork Guideline Checklist

Here are the basics to have in place before submitting your digital artwork:

- Artwork should be saved as TIFF, EPS, or MS Office (DOC, PPT) files. High resolution PDF files are also acceptable.
- Crop out any white or black space surrounding the image.
- Diagrams, drawings, graphs, and other line art must be vector or saved at a resolution of at least 1200 dpi. If created in an MS Office program, send the native (DOC, PPT, XLS) file.
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- Each figure must be saved and submitted as a separate file. Figures should not be embedded in the manuscript text file.

### Remember:

- Cite figures consecutively in your manuscript.
- Number figures in the figure legend in the order in which they are discussed.
- Upload figures consecutively to the Editorial Manager web site and enter figure numbers consecutively in the Description field when uploading the files.

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Authors are now able to submit two to three summary slides with their articles. These slides must be created in PowerPoint and should summarize the article's key points regarding the study findings. One or two images, tables or key graphics can also be included. The PowerPoint slides should be uploaded as Supplemental Digital Content (SDC). The technical specifications and instructions for uploading SDC are described below.

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We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

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A listing of Supplemental Digital Content must be submitted at the end of the manuscript file. Include the SDC number and file type of the Supplemental Digital Content. This text will be removed by our production staff and not be published.

Example:

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**Figure legends.** Legends must be submitted for all figures. They should be brief and specific less than 150 characters or approximately 50 words. List figure legends on a separate page at the end of the manuscript text.

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### Manuscript Checklist

**(before submission for author reference only)**

[To top of page](#)

1. Title page

- Corresponding author designated, and full mailing address included on title page
- E-mail address of corresponding author included on title page
- Permission to reproduce copyrighted materials or signed patient consent forms
- Acknowledgments listed for grants, technical support, and corporate support on title page
- IRB approval/Research Ethics Committee, or local equivalent stated on title page

2. Structured Abstract (300 words) Please use the following headings

- Study Design
- Objective
- Summary of Background Data
- Methods
- Results
- Conclusion

3. Manuscript text with line and page numbers (2700 words for regular submissions; 750 words for Case Reports)

4. References double-spaced and cited in the order of appearance

5. Tables (word, word perfect)

6. Figure legends

7. Figures (eps, tiff, ppt)

8. Copyright Form fully completed and signed by each author

- Author attributions
- Device Status/Drug statement
- Financial/benefit disclosure statement(s)

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**Controversy.** Two authors write on opposing sides of an issue related to spine care. Each weighs the relative advantages and disadvantages of their approach. Each author should be limited to **1000** words. A brief introductory paragraph should be included, which explains what the controversial issue is and what the two arguable sides are.  
*Coordinating Editor: Robert F. McLain, MD*

**Historical Perspective.** Includes papers on specific milestones and pioneers who were instrumental in the development of spine research and the understanding of spinal disorders. All contributions should be thoughtful, well-reviewed, and documented by the proper citation of original works or secondary sources. It is recommended that authors get in contact with the university or institution where the subject of the paper worked or made noteworthy achievements. The departments of medical history at the various universities are very helpful in providing information, documentation, and original pictures. (limit to **750 words**)  
*Coordinating Editor: Jiri Dvorak, MD*

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*Coordinating Editor: William A. Abdu, MD*

**Spine Journal Club.** Includes critical examinations of the literature that forms the basis for medical practice. A related goal is to increase the sensitivity of the readership to research methodology. Invited are critiques on any topic related to spinal disorders. Critiques may be on one or more thematically related papers that have influenced thinking and/or practice in the care of patients with spinal disorders. The reviews should briefly summarize the articles in question and then critique their strengths and limitations. This should be followed by a discussion of whether current practice patterns reflect appropriate interpretation of the findings. Directions for future research or questions posed by the paper(s) may also be suggested. Great opportunity to work with junior colleagues, residents, and trainees! (limit to **750 words**)

*Coordinating Editor: Jeffrey N. Katz, MD*

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*Coordinating Editor: Robert D. Fraser, MD*

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## STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

\*Give information separately for exposed and unexposed groups.

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	1, 2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any <u>prespecified</u> hypotheses	4
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	4, 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	4
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	5
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study— <u>eg</u> numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants ( <u>eg</u> demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time ( <u>eg</u> , average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	6

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	6, 7
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

**Item 1:** Página 2 - “Retrospective analysis of prospective collected data study”, “study the prognostic value of paravertebral lumbar muscles atrophy on clinical outcome after lumbar surgery on patients with symptomatic lumbar disc herniation”, “Increased fat infiltration of erector spinae muscles correlates to less favourable clinical outcomes following lumbar discectomies”.

**Item 2 Background/rationale:** Página 4 – “the role of muscle atrophy in the outcome of patients with symptomatic lumbar disc herniation undergoing surgery remains controversial”

**Item 3 Objectives:** Página 4 – “The aim of this study is to investigate the association between muscle atrophy on pre-operative MRI and clinical outcomes one year after lumbar discectomies, in order to understand if paravertebral muscles parameters can be used as a prognostic value of clinical outcome”

**Item 4 Study design:** Página 4 – “We conducted a retrospective analysis of prospectively collected data”

**Item 5 Setting:** Página 4 – “patients who underwent single-level discectomy at our department from January 2016 to December 2019”

**Item 6 Participants:** Página 4 e 5 – “patients over eighteen years old with lumbar disc herniation and radicular pain”, “Patients with deformities (scoliosis and kyphosis), spondylolisthesis, spinal stenosis, fractures, tumours and infections or previous lumbar surgeries were excluded”, “Clinical status was assessed according to preoperative and one-year postoperative patient reported outcome measurements (PROMS) questionnaires”.

**Item 7 Variables:** Página 5 – “define regions of interest (ROI) which were the cross sectional area (CSA)”, “define regions of interest (ROI) which were the cross sectional area (CSA)”, “Pain Numeric Rating Scale

(NRS) for back and leg pain, Core Outcome Measurement Index (COMI), Oswestry Disability Index (ODI) and EuroQoL-5D”, “included age, gender, weight (kg), height (cm), body mass index (kg/m<sup>2</sup>), smoking status, antidepressant medication and rehabilitation prior to surgery”.

**Item 8 Data sources/ measurement:** Página 5 – “area (CSA), by manually delimiting muscular edges of multifidus, erector spinae and psoas according to the method proposed by Crawford et al. The percentage of fat infiltration of paravertebral muscles (FI) was calculated by ImageJ software pseudo-colouring method, applying automatic thresholds”.

**Item 9 bias:** Página 4 - “was calculated by ImageJ software pseudo-colouring method”

**Item 10 Study size:** Página 5 – “Sample size calculation as performed considering postoperative COMI as the primary end point, leading to COMI mean comparison between two groups according to muscle characteristics (CSA or FI). The calculated sample size was 98, for one sided T-test, significance level of 0.05, power of 0.95 and effect size of 0.67”

**Item 11 Quantitative variables:** Página 5 – “Continuous variables with non-linear relations to outcome were splitted in categories, based on visual plot analysis (locally estimated scatterplot smoothing) and in a step function.”

**Item 12 Statistical methods:** Página 5 – “Spearman’s correlation was used for correlation between continuous variables, Kruskal-Wallis or Wilcoxon tests for mean comparison between independent or dependent samples, Fisher’s test was used for categorical variables associations”, “Multiple linear regression was performed”

**Item 13 Participants:** Página 6– “From 251 patients screened for eligibility, 112 patients (59 female and 53 male) were included in this study (Fluxogram - Fig. 2).

**Item 14 Descriptive data:** Página 6 – “The mean age was 46.1±12.7 years, ranging between 20 and 78 years old. The average BMI was in the overweight category (27.1± 3.89 kg/m<sup>2</sup>). Lumbar discectomies were performed at levels L2-L3 (1.8%), L3-L4 (4.5%), L4-L5 (48.2%) and L5-S1 (45.5%). Demographic data are presented in Table 1.”

**Item 15 Outcome data:** Página 6 – “erector spinae had the highest median cross section area (CSA) values (3025; IQR: 1845-3955)”, “For erector spinae the median fat infiltration (FI) was also higher (27%; IQR: 21-33%)”.

**Item 16 Main results:** Página 6 e 7 – “Psoas muscle CSA expressed weak to moderate correlations with pre-surgical PROMS”, “negative correlations between psoas muscle CSA on the symptomatic side and preoperative ODI, COMI and NRS-leg scores (Spearman  $\rho = -0.3, -0.27$  and  $-0.26$ , respectively)”, “univariable simple linear regression was used and identified sex ( $p < 0.001$ ), age ( $p = 0.02$ ) and height ( $p = 0.009$ ) associated with postoperative COMI”, “postoperative COMI was significantly different according to erector spinae FI groups (boxplots – fig. 5): postoperative COMI was higher in FI > 30% group (median: 4.4, IQR: 3.2) and lower in FI < 15% (median: 1.2, IQR: 1.6) (Kruskal-Wallis,  $p < 0.001$ )”

**Item 18 Key results:** Página 8 – “lower rates of fat infiltration of the erector spinae muscles were related to better postoperative clinical outcomes.”

**Item 19 Limitations:** Página 9 – “Some limitations can be identified in this study. It is a single-centre study with a retrospective design, which limits the generalizability of the results. Surgeries were performed by different surgeons, therefore, it is not possible to appraise whether technical variations can impact the outcomes, in spite that most surgeries were performed by a small number of spine-specialized neurosurgeons using similar a surgical technique in the same operative room. There is also the possibility for other potential confounders, such as further medical comorbidities not taken into analysis”

**Item 20 Interpretation:** Página 8 – “The literature raises the hypothesis that paravertebral muscle atrophy and higher levels of fat infiltration are related to less favourable clinical outcome after lumbar discectomy surgery, even though scientific evidence is still very limited. Storheim et al. found, in a randomized study with 173 patients submitted to a total disc replacement, that a lower multifidus fat infiltration ratio predicted a better clinical outcome [10]. Similar results were reported by Yang Liu et al. and Zotti and al., who concluded that less preoperative fat infiltration of the multifidus muscles is a predictor of better clinical outcome in patients with lumbar spinal stenosis [11, 28].”

**Item 21 Generalisability:** Página 9 – “Although the sample size is modest (n=112), this study is adequately powered to demonstrate associations between paravertebral fat infiltration and clinical outcome”