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José Pedro Moreira Tinoco da Costa

Predictors of poor outcome in patients submitted to minimally invasive transforaminal lumbar interbody fusion

Fatores preditivos de prognóstico em doentes submetidos a artrodese lombar transforaminal minimamente invasiva

março, 2018

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Mestrado Integrado em Medicina

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Doutor Paulo Pereira

E sob a Coorientação de:

Dr. Pedro dos Santos Silva

Trabalho organizado de acordo com as normas da revista:

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março, 2018

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Projeto de Opção do 6º ano - DECLARAÇÃO DE INTEGRIDADE

Eu, José Pedro Moreira Tinoco da Costa, abaixo assinado, nº mecanográfico 201204540, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro ter atuado com absoluta integridade na elaboração deste projeto de opção.

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Projecto de Opção do 6º ano – DECLARAÇÃO DE REPRODUÇÃO

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Neurocirurgia

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

Predictors of poor outcome in patients submitted to minimally invasive transforaminal lumbar interbody fusion

ORIENTADOR

Doutor Paulo Pereira

COORIENTADOR

Dr. Pedro dos Santos Silva

ASSINALE APENAS UMA DAS OPÇÕES:

É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTE TRABALHO APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☐
É AUTORIZADA A REPRODUÇÃO PARCIAL DESTE TRABALHO (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☒
DE ACORDO COM A LEGISLAÇÃO EM VIGOR, (INDICAR, CASO TAL SEJA NECESSÁRIO, Nº MÁXIMO DE PÁGINAS, ILUSTRAÇÕES, GRÁFICOS, ETC.) NÃO É PERMITIDA A REPRODUÇÃO DE QUALQUER PARTE DESTE TRABALHO.	☐

Faculdade de Medicina da Universidade do Porto, 22/03/2018

Assinatura conforme cartão de identificação: José Pedro Moreira Tinoco da Costa

ABSTRACT

Background: Minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) has become an increasingly popular method for lumbar arthrodesis. While having similar long-term outcomes when compared to open TLIF, it decreases the amount of intraoperative blood loss and iatrogenic muscle damage, the intensity of postoperative pain and the duration of hospital stay. However, uncertainty remains about which factors contribute to outcomes in these patients.

Objective: The purpose of this study was to retrospectively analyze a cohort of patients submitted to MI-TLIF and to identify factors that can be associated with a worse postoperative outcome.

Methods: All data was assessed through the patients' clinical records and, according to Odom's criteria, postoperative clinical outcome at 12 months was defined in excellent, good, fair and poor.

Results: The main variables associated with worse prognosis ("poor" class according to Odom's criteria) were: a period of sick leave longer than 3 months before the surgery, age under 50 years, lytic spondylolisthesis, L5-S1 fusion and occurrence of complications. These five conditions were included in a binomial logistic regression analysis, and three of them were independently associated to poor outcome: operative complications, age under 50 years and sick leave longer than 3 months before surgery.

Conclusions: Those who were younger, were on a period of sick leave longer than 3 months before surgery or suffered surgical complications tended to have less satisfactory results.

Key words: Clinical outcome, minimally invasive surgery, transforaminal lumbar interbody fusion, lumbar arthrodesis

INTRODUCTION

There are several widely used techniques for circumferential lumbar arthrodesis: anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF) and lateral lumbar interbody fusion (LLIF) [1]. However, TLIF has gained popularity for the treatment of a variety of lumbar disorders such as degenerative and lytic spondylolisthesis, one or two level degenerative disc disease and recurrent disc herniations. In TLIF a unilateral single-staged posterolateral approach to the spinal canal and disc is used, resulting in decreased retraction on the nerve roots and dural sac, and hence a lower risk of postoperative neurological deficit [2-4] in comparison to PLIF. This procedure also avoids the ALIF abdominal approach and the inherent risks of vascular and visceral injuries. Furthermore, TLIF was shown to result in excellent rates of arthrodesis and decreased operative time and blood loss, decreased morbidity, and decreased costs when compared to other approaches [5].

An advancement of the TLIF technique allowed for a minimally invasive approach. Introduced by Foley et al. in 2002 [6, 7], the minimally invasive TLIF (MI-TLIF) has since become an increasingly popular method of lumbar arthrodesis. The procedure is performed via a muscle-dilating approach, using a tubular retractor through a paraspinal incision and significantly diminishes the amount of iatrogenic soft-tissue dissection [8]. This approach was designed to fulfil the same advantages of TLIF, but to further reduce the amount of intraoperative blood loss and iatrogenic muscle damage, the intensity of postoperative pain, and the duration of hospital stay [6]. The main disadvantages of MI-TLIF include additional exposure time to intraoperative radiation, potentially increased cost, and the need for the surgeon to overcome the learning curve [9, 11].

MI-TLIF has been shown to have similar rates of fusion and similar long-term functional outcomes when compared to open TLIF [4, 10]. However, there is still insufficient evidence to show which patients may benefit more with this technique. The purpose of this study is to retrospectively analyze a cohort of patients submitted to MI-TLIF and try to identify factors that can be associated with a worse surgical outcome.

METHODS

Study and inclusion criteria

A single center database from the Neurosurgery Department of a tertiary hospital including patients older than 18 years old submitted to 1- or 2-level MI-TLIF from 2007 to 2016 was retrospectively examined. The surgical indications included degenerative spondylolisthesis, degenerative disc disease, lytic spondylolisthesis, recurrent lumbar herniation, foraminal stenosis, and revision surgery. The hospital's ethics committee approved the entire study protocol. Two hundred ninety (290) patients accomplished these criteria with seven (7) patients being excluded due to loss in follow-up. Two hundred eighty-three (283) patients were included in the final sample (figure 1).

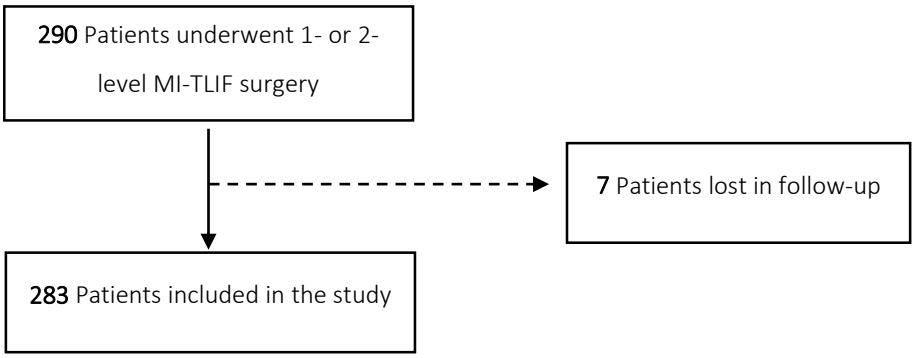

Figure 1. Flowchart of sample selection

Clinical data

The clinical records of the patients were reviewed and demographic variables (age, gender, body mass index, work status), clinical data (indication for surgery, smoking, medication, history of spine surgery, neurologic disease, psychiatric disorder or rheumatologic diseases), and surgery-related data (levels operated, duration of procedure, length of stay, complications, reoperation) were collected.

Outcome was drawn from clinical records at 12 months postoperative evaluation in the outpatient clinic and it was defined according to Odom's criteria in excellent, good, fair and poor. However, the full follow-up period was considered to assess reoperation rate.

Primary endpoint

This study primary endpoint was a statistically significant association between selected factors and bad clinical outcome ("poor" class according to Odom's criteria).

Statistical analysis

Continuous variables were transformed in categorical data and the dependent variable (Outcome, according to Odom's criteria) was dichotomized in "poor" or "other". Statistical analysis was performed using Chi-Square test for each association and binomial logistic regression for multivariate analysis. The software used for statistical analysis was IBM SPSS Statistics, version 24.0 and G*Power, version 3.1.9.3.

RESULTS

Sample description and surgical data

A total of 283 patients were included in the study, of which one hundred and ninety-four (68.6%) were women. The mean age at the time of surgery was 57.19 ± 11.86 years and fifty patients (17.7%) were smokers. The median (interquartile range [IQR]) body mass index (BMI) was 28 [6] kg/m^2.

Two hundred and thirty-nine patients (84.5%) underwent a single-level surgery. Median surgery time was 145 [87] minutes. Forty-one patients (14.5%) experienced complications with 39% of these being dural tears corrected during the surgery without cerebrospinal fluid leak in the postoperative period. The median hospital stay was 4 [3] days. The median follow-up was 55 months, ranging from 14 to 131 months. Thirty-five patients (12.4%) were reoperated, most of them due to screw misplacement or hardware failure. Further demographic and surgical data of the sample are summarized in table 1.

	Patients, no. (%)
Profession before/after surgery	
Employed	98 (34.6) / 61 (21.6)
Unemployed	27 (9.5) / 34 (12)
Retired	124 (43.8) / 148 (52.5)
Sick leave	33 (11.7) / 35 (12.4)
Previous Surgeries	
Lumbar surgery	68 (24)
Cervical surgery	15 (5.3)
Surgical indication	
Degenerative SPL	147 (60)
Lytic SPL	53 (18.7)
Recurrent LDH	21 (7.4)
Degenerative disc disease	17 (6)
Degenerative scoliosis	3 (1.1)
Foraminal stenosis	28 (9.9)
Revision surgery	14 (4.9)
Level of fusion	
L2-L3	2 (0.7)
L3-L4	19 (6.7)
L4-L5	135 (47.7)
L5-S1	82 (29)
L3-L4+L4-L5	22 (7.8)
L4-L5+L5-S1	23 (8.1)
Medical history	
Diabetes mellitus	41 (14.5)
Rheumatological disease	36 (12.7)
Neurological disease	13 (4.6)
Psychiatric disease	61 (21.6)
Medication	
Corticosteroids	9 (3.2)
NSAIDs	60 (21.2)

Table 1. Patients' demographics and surgical data (SPL – spondylolisthesis, LDH – lumbar disc herniation)

Clinical evaluation

According to Odom's criteria, thirty-six (12.7%) patients had a poor result. The distribution for each category of Odom's criteria is shown in table 2.

Odom's criteria	Patients, no. (%)
Excellent	57 (20.1)
Good	111 (39.2)
Fair	79 (27.9)
Poor	36 (12.7)

Table 2. Odom's criteria

Association between poor outcome and clinical variables

Age

Patients were divided into 2 groups: younger than 50 and older than 50 years old. Twenty-three out of the eighty-four patients (27.4%) younger than 50 years old had a poor outcome; in patients older than 50 years old group, only thirteen (6.5%) of the one hundred ninety-nine had bad outcomes (Chi-square, $p<0.001$). Age under 50 years old was related with a moderate degree of association (Phi=0.29) with worse surgical outcome.

Surgical indication

Fifty-three patients were submitted to MI-TLIF due to lytic SPL and twelve of these (22.6%) had poor outcome. On the other hand, from the two hundred and thirty patients with other surgical indications, twenty-four (10.4%) had bad results (Chi-square, $p=0.030$). Lytic SPL was the only surgical indication that seemed to affect the prognosis, with a low degree of association (Phi=0.14). No other relation was found between the other surgical indications and the outcome. However, revision surgeries were at the margin of statistical significance (Chi-square, $p=0.068$).

Working status

Patients were divided according to their working status (active worker, retired, unemployed and on sick leave) before and after surgery. Fifteen patients (26.8%) from those on sick leave for a period longer than 3 months before surgery had bad results versus 9.3% of patients with a working status other than sick leave longer than 3 months (Chi-

square, p=0.001; Phi=0.210). The association between the working status and poorer surgical outcome was then related to being on sick leave for more than 3 months.

Levels operated

While there is not a relation between the number of levels operated (1 versus 2 levels) and the surgical results (Chi-square, p=0.490), L5-S1 fusion in 1 or 2 levels MI-TLIF was associated with worse prognosis (Chi-square, p=0.023; Phi=0.15).

Complications

Forty-one patients (14.5%) had complications during or after the surgery and ten of these (24.4%) had poor clinical outcomes versus twenty-six out of the two hundred forty-two (10.7%) who had no complications (Chi-square, p=0.030; Phi=0.14).

The association between these previous five factors and bad prognosis is summarized in table 3.

Factors	**Poor Odom no. patients (%)**	**p-Value**	**Phi**
Age < 50 years old	23 (27.4)	<0.001*	0.29
Lytic SPL	12 (22.6)	0.030*	0.14
Sick leave > 3 months before surgery	15 (26.8)	0.001*	0.21
L5-S1	16 (19.5)	0.023*	0.15
Complications	10 (24.4)	0.030*	0.14

Table 3. Predictors of poor outcome.

Remaining variables

The patients' gender, BMI (power: 99%), previous spine surgical intervention, medical history, smoking habits (power: 49%), number of levels operated and the duration of surgery did not seem to be related with "poor" prognosis (table 4). Also the time at which patients were submitted to MI-TLIF is not a prognosis factor once patients with longer follow up periods are not associated with worse results.

Factors	p-Value
Sex	0.902
BMI	0.930
Previous Surgical Intervention	
Lumbar	0.884
Cervical	0.470
Medical history	
Diabetes mellitus	0.538
Reumathological disease	0.756
Psychiatric disease	0.160
Neurological disease	0.577
Medication	
NSAIDs	0.873
CCTs	0.244
Smokers	0.089
Number of levels operated	0.490
Duration of surgery	0.935

Table 4. Factors not associated with poor prognosis.

Psychiatric history and history of previous spinal surgical intervention

Although no other associations to bad prognosis ("poor" class according to Odom's criteria) were found, some other factors also seem to predict less favorable outcomes ("fair"/"poor" classes according to Odom's criteria). Patients with psychiatric disorder and previous lumbar surgery were associated with poor/fair clinical outcome (Table 5).

Factors	Poor/Fair Odom no. patients (%)	p-Value	Phi
History of lumbar surgery	36 (52)	0.026*	0.14
Psychiatric disorder	33 (54.1)	0.023*	0.14

Table 5. Predictors of poor/fair outcome.

Multivariate Analysis

The main variables associated with worse prognosis ("poor" class according to Odom's criteria) were: a period of sick leave longer than 3 months before the surgery, age under 50 years old, lytic spondylolisthesis, L5-S1 fusion and occurrence of complications. These five conditions were included in a binomial logistic regression analysis (table 6). The model was statistically significant (Chi-square: 33.381 df:5, $p<0.001$), with a Nagelkerke R2 of 21% and correctly classified 87.3% of cases.

				95% C.I. for OR	
Factors	**Coefficient**	**p-Value**	**OR**	**Lower**	**Upper**
Age < 50 years old	1.369	0.002	3.930	1.665	9.272
Lytic SPL	0.349	0.442	1.418	0.583	3.451
LS-S1 level	0.238	0.579	1.269	0.547	2.941
Sick leave>3months before surgery	1.011	0.014	2.747	1.230	6.134
Complications	1.183	0.010	3.263	1.321	8.062

Table 6. Binomial logistic regression analysis.

Three of them were independently associated with poor outcome: operative complications (OR: 3.26), age under 50 years old (OR: 3.93) and sick leave longer than 3 months before surgery (OR: 2.75).

DISCUSSION

While age under 50 years old was shown to be an independent prognosis factor by the binomial logistic regression model, this didn't happen neither with the diagnosis nor with the level operated. Therefore, it seems that there was an overlapping effect of L5-S1 fusion and lytic spondylolisthesis with age.

According to Lin et al. [12] the mean Oswestry Disability Index (ODI) score after MI-TLIF in older patients was higher than that in younger patients, being the higher rate of comorbidities commonly found in older patients a possible explanation for this finding. On the other hand, Wu et al. [13] didn't find significant differences between younger and older than 65 years old patients submitted to MI-TLIF, with both groups experiencing similar fusion rates and clinical improvement. A possible explanation for our findings of younger patient having a higher incidence of poor outcome may be that younger patients are more likely to keep working and have more active lifestyles when compared to the elderly.

Park et al. [14] divided in subgroups patients with lytic spondylolisthesis, degenerative spondylolisthesis and degenerative segmental instability to understand if minimally invasive TLIF optimally and equivalently alleviated the symptoms and disabilities related to these pathologies. They concluded that the improvement was comparable among the 3 subgroups and that these diagnostics were all optimal surgical indications for minimally invasive TLIF. In our study patients with lytic spondylolisthesis had a worse prognosis, but in multivariate analysis this finding was not an independent factor for poor outcome.

Ekman et al. [15], not only associated female gender with worse postoperative results, but even suggested that it would seem reasonable to inform not working female patients who do not exercise and that are candidates to lumbar fusion due to lytic spondylolisthesis, about the lower probability of an excellent outcome. In our study, there was no apparent relation between the gender and the outcome.

The fact that psychiatric disorder only had a moderate association with fair/poor outcome but not a statistically significant association with bad outcome was not expected. In fact, according to other studies, patients reporting poorer emotional status such as depression prior to surgery were significantly more likely to report poorer functional outcomes and pain improvement postoperatively [16, 17]. Parker et al. [17] suggested that preoperative depression was an independent predictor of poor functional outcome after revision lumbar fusion. In another study [18] it was even suggested that psychological

predisposition could be used to select more effectively patients with the greatest opportunity for a successful outcome and, at the same time, reduce the indirect costs of spine surgery due to increased duration of missed work days.

The non-association between patients' BMI and prognosis is consistent with findings from other studies. Lau et al. [19] and Park et al. [20] concluded that obese patients and normal BMI patients experienced similar complication rates, operative times, intraoperative blood loss, and length of hospital stay when undergoing MI-TLIF. Lau et al [9] also demonstrated that do not seem to exist significant differences in the complications rates between patients of different classes of obesity (Classes I, II or III) or between these and patients with normal BMI.

Although in this study revision surgery doesn't seem to predict the surgical outcome (Chi-square, p=0.068), a higher number of patients would increase the chance of detecting an association due to the effect of sample size on the likelihood of finding a statistically significant result. The same applies to smoking habits (Chi-square, p=0.089, power=49%). An emerging body of literature suggests that there is a correlation between smoking and a higher incidence of postoperative complications with diminished postoperative results and clinical outcomes [21-23]. Glassman et al. [23] found smokers to have significantly higher nonunion rates and lower return to work rates and mean patient satisfaction scores.

Lau et al. [11] explained that the level of surgical difficulty and the learning curve could have a role in morbidity and outcome, resulting in higher complication rates in patients submitted to MI-TLIF. In our study, patients with surgical complications were associated with worst clinical outcomes. However, the learning curve, if we can extrapolate it based on the follow-up period, didn't seem to affect the prognosis in a sense that patients submitted to MI-TLIF the longest (with longer follow-up periods) didn't have worse results.

CONCLUSION

Preoperative variables were identified as predictors of poor surgical outcome after MI-TLIF, suggesting that the result of lumbar fusion can be more limited in younger patients and those with sick leave for more than 3 months. Also, the occurrence of operative complications can decrease the likelihood of improvement.

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Ao Professor Doutor Paulo Pereira, o meu orientador, pelo profissionalismo e disponibilidade demonstrados ao longo de todas as diferentes fases deste trabalho.

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ANEXOS

1. Parecer da comissão de ética
2. Normas da revista *World Neurosurgery*

Unidade de Investigação

Tomei conhecimento. Nada a opor.

09 de Agosto de 2017

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

DIRECÇÃO CLÍNICA
11/8/2017

Aprovado. Ao CA.

(Prof.ª Doutora Ana Azevedo)

AUTORIZADO 191-17

CONSELHO DE ADMINISTRAÇÃO ◉ REUNIÃO DE 24 AGO 2017
Presidente do Conselho de Administração
(Dr. António Oliveira e Silva)
Diretor Clínico (Prof. Dr. José Artur Paiva) | Enfermeira Diretora (Enf.ª Filomena Cardoso) | Vogal Executivo (Dr. Luís Porto Gomes) | Vogal Executivo (Dr. Renato G. Matos)

Exmo. Senhor
Presidente do Conselho de Administração do
Centro Hospitalar de S. João – EPE

Assunto: Pedido de autorização para realização de estudo/projecto de investigação

Nome do Investigador Principal: José Pedro Moreira TInoco da Costa

Título do projecto de investigação: Fatores preditivos de prognóstico em doentes submetidos a artrodese lombar transforaminal minimamente invasiva

Pretendendo realizar no(s) Serviço(s) de Neurocirurgia do Centro Hospitalar de S. João – EPE o estudo/projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efectivação.

Para o efeito, anexa toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de S. João respeitante a estudos/projectos de investigação, à qual endereçou pedido de apreciação e parecer.

Com os melhores cumprimentos.

Porto, 12 / Junho / 2017

O INVESTIGADOR/PROMOTOR

José Pedro Moreira Tinoco da Costa

7. SEGURO

a. *Este estudo/projecto de investigação prevê intervenção clínica que implique a existência de um seguro para os participantes?*

SIM ☐ (Se sim, junte, por favor, cópia da Apólice de Seguro respectiva)
NÃO ☐
NÃO APLICÁVEL ☑

8. TERMO DE RESPONSABILIDADE

Eu, José Pedro Moreira Tinoco da Costa,
abaixo-assinado, na qualidade de Investigador Principal, 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 (com as emendas de Tóquio 1975, Veneza 1983, Hong-Kong 1989, Somerset West 1996 e Edimburgo 2000) e da Organização Mundial da Saúde, 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 no decurso do actual internamento ou da mesma consulta.

Porto, 12 / Junho / 2017

José Pedro Moreira Tinoco da Costa
O Investigador Principal

PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO

emitido na reunião plenária da CES de 14/07/17

A Comissão de Ética para a Saúde APROVA por unanimidade o parecer do Relator, pelo que nada tem a opor à realização deste projecto de investigação.

Prof. Doutor [illegible]
Presidente da Comissão de Ética

Parecer da Comissão de Ética para a Saúde do

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

Título do Projecto: Fatores preditivos de prognóstico em doentes submetidos a artrodese lombar transforaminal minimamente invasiva

Nome do Investigador Principal: José Pedro Moreira Tinoco da Costa

Serviço onde decorre o Estudo: No Serviço de Neurocirurgia do Centro Hospitalar de S. João. Apresentou declaração do Director de Serviço, Prof. Doutor Rui Vaz. Terá como profissional de ligação o Prof. Doutor Paulo Pereira, que é também o orientador.

Objectivos do Estudo:
Comparar dois grupos de doentes submetidos a artrodese lombar transforaminal minimamente invasiva, de acordo com o outcome da cirurgia (favorável vs desfavorável). Identificar possíveis factores que possam actuar no sentido de um pior prognóstico pós-cirúrgico
Insere-se no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação do Prof. Doutor Paulo Pereira.

Benefício/risco: N/A

Confidencialidade dos dados: Está garantido a anonimização dos dados obtidos.

Respeito pela liberdade e autonomia do sujeito de ensaio: N/A

***Curriculum* do investigador**: Adequado à investigação.

Data previsível da conclusão do estudo: Março de 2018

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

Porto, 14 de Julho de 2017

O Relator da CES, Dr. John Preto

WORLD NEUROSURGERY

AUTHOR INFORMATION PACK

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References: Spiotta AM, Barnett GH, Benzel EC: Great Hospitals of North America: Cleveland Clinic Neurological Surgery. World Neurosurgery 74(1):60-70, July 2010 Pereira EAC, Green AL, Stacey RJ, Aziz TZ: Great Hospitals of Europe: The Oxford Radcliffe. World Neurosurgery 74(4/5):407-413, October/November 2010 Saito N: Great Hospitals of Asia: The University of Tokyo Hospital. World Neurosurgery 75(3/4):364-368, March/April 2011 Poon WS: Great Hospitals of Asia: Neurosurgery at Prince of Wales Hospital. World Neurosurgery 75(3/4):383-386, March/April 2011 Kim DG, Park CK, Paek SH, Kim JE, Kim CH, Phi JH: Great Hospitals of Asia: The Department of Neurosurgery at Seoul National University College of Medicine. World Neurosurgery 75(3/4):397-406, March/April 2011

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