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Joana Araújo de Azevedo

Associação entre expectativas dos pacientes e resultados reais em cirurgia a patologia degenerativa da coluna.

Association between patient's expectations and real outcomes for degenerative spine surgery.

Março, 2020

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UC Dissertação/Projeto (6º Ano) - DECLARAÇÃO DE INTEGRIDADE

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Neurocirurgia

TÍTULO DISSERTAÇÃO/MONOGRAFIA (riscar o que não interessa)

Association between patient's expectations and real outcomes for degenerative spine surgery.

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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.	☒
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Faculdade de Medicina da Universidade do Porto, 10/3/2020

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Para aqueles que percorreram
este caminho comigo.

Title:

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Title: Association between patient's expectations and real outcomes for degenerative spine surgery.

Abstract

Purpose: The aim of this study is to compare patient's expectations before surgery for degenerative spine disease to postoperative perceived outcomes and identify main factors that correlate with higher expectations and their fulfillment. The study question is whether patient's pre-surgical expectations can predict actual outcomes.

Methods: Consecutive patients submitted to degenerative spine surgery between August 2018 and May 2019 in our spine center were enrolled. Patient's expressed expectations were recorded using the Lumbar/Cervical Spine Surgery Expectations Survey and compared to the same instrument, three months after surgery. Patient reported outcomes were evaluated using the COMI questionnaire before and after surgery.

Results: A total of 120 patients were analyzed. The mean score of expectations reported by patients was 82.87%±14.57% and post-surgical score was significantly lower, 60.5±20.6% (p<0.001). In a multivariate analysis, only a history of spine surgery and a longer duration of symptoms were associated with low pre-surgical expectations. Lumbar surgery was associated to a lower ratio between postoperative and preoperative Expectations Survey scores. An improvement on the COMI score after surgery was achieved in 85% of the patients, but only 14% reported that their expectations were matched or exceeded.

Conclusion: The pre-surgical expectations were significatively high, but the post-surgical results were less optimistic. Lower expectations and lower perceived success after surgery can be anticipated on some patients based on preoperative features. Although 85% of patients improved after surgery, their expectations weren't met in most cases.

Keywords

Spine Surgery; Patient Expectations; Patient Satisfaction; Surgery outcomes; COMI score; Patient outcomes;

Introduction

Surgery for degenerative pathology of the spine is becoming more frequent and the role of elective surgery is progressively overriding [1]. Patients may present with a long list of symptoms, that can seriously interfere with quality of life, functional capacity, social and professional life [2]. The elective feature of the surgery makes patient's expectations about a possible improvement a very important factor when considering and undertaking this type of interventions [3] [4].

Traditionally, evaluation of surgical outcomes and efficacy has been mostly based on objective parameters with the purpose of assessing the functional status and neurological function, as well as on imaging methods [5]. More recently, patient's perception of outcomes has been more and more integrated in post-surgical evaluation [6]. Patient satisfaction with how much the surgery influenced his/her physical and psychological well-being is also an important parameter in assessing surgery effects. These topics should be considered during the pre-surgical discussion, to help decision-making about the surgical strategy, since it is a critical issue to try that the patient feels fulfilled and enjoyed with the results, while understanding what is effectively achievable within his/her clinical condition [5].

To assess patient's expectations it is essential to create standardized tools based and centered on the patient [2]. Questionnaires should be based, not only in disease-specific symptoms and physical outcomes, but also on everyday aspects and how the spine condition interferes with patient's activities, professional and social life [7].

The purpose of this study is to explore the association between patient pre-surgical expectations and the outcomes three months after surgery, trying to understand if expectations can somehow predict patient's satisfaction and analyze whether there is any relation with demographic data, surgical factors, clinical parameters and functional outcomes.

Materials and Methods

A prospective observational study was conducted, involving all consecutive patients undergoing surgery for degenerative spine pathologies in the Neurosurgery department of Centro Hospitalar Universitário São João, between August 2018 and May 2019. Approval for data collection was obtain from hospital's ethics committee.

Eligible criteria included patients with eighteen years or older, undergoing lumbar or cervical spine surgery for a degenerative pathology. Patients with non-degenerative pathologies, without at least a valid pre-surgical questionnaire and who did not consent to participate in the study, were not included.

Patients answered a questionnaire the day before surgery to assess patient's expectations of improvement with the procedure, as well as COMI questionnaire for cervical or lumbar pathology (Core Outcome Measures Index). The same questionnaires were sent by mail to patient's address and six weeks later, if a reply has not been received, telephone contact was established.

The expectation questionnaire is an adaptation to Portuguese of the Lumbar/Cervical Spine Surgery Expectation Survey from the Hospital for Special Surgery, New York, NY [8], which evaluates pain, functional and work capacity, leisure, mental well-being, present condition and future improvement in a series of twenty one questions. Three months after surgery it was applied a questionnaire, with the

same questions, about patient satisfaction with surgery results. From these questionnaires we calculated two scores, the Expectation Survey Score (ESS), related with pre-surgical expectations, and the post-surgical satisfaction. Both scores were calculated through the equation [number of total points/(4 x number of questions answered)]. The denominator was the number of maximum possible points to score in the questions that were answered by the patient (excluding questions that patient chose the answer "I have no expectations about this point or doesn't apply to me"). The answers score from 0 to 4, where 4 corresponds to "Back to normal or total improvement", 3 to "Great improvement", 2 to "Moderate improvement", 1 to "Little improvement" and 0 to "I have no expectations about this point or doesn't apply to me".

The COMI cervical and lumbar were used as a Patient Related Outcome measure. The COMI assesses the effects of spine pathology in patient's life and has been validated for Portuguese language. It includes the dimensions of Pain, Symptom-specific well-being, Quality of life and Disability [9], [10].

The remaining data were obtained from patients' clinical records, and included age, gender, actual or past occupation, education level, history of psychiatric disease, body mass index, smoking status, incapacity for work previous to surgery, number of previous spine surgeries for degenerative pathology, symptom duration before surgery and data about surgery, such as the number of levels operated and type of surgery (anterior cervical, posterior cervical, non-instrumented lumbar, instrumented lumbar). Data related to patient occupation was categorized according to Portuguese Classification of Occupations 2010 [11].

For descriptive analysis mean and standard deviation were used for continuous variables and proportion for categorical. The T-test was used for related and independent samples to compare means when normal distribution was verified. For exploratory analysis, correlation between continuous variables was determined using Spearman correlation. For the comparison of answer-to-answer paired samples regarding scores before and after surgery, the analysis of closeness of agreement were used calculating the Intraclass Correlation Coefficient (ICC). To analyze how variables influenced pre-surgical expectation score, a univariate and multivariate Linear Regressions Model was used. To investigate variable's influence in the fulfillment of expectations, we have defined the variable "Expectation ratio" (Post-surgical Score / Pre-surgical Score). A result between 0 and 1 means that the outcome after surgery did not meet expectations, values equal or higher that 1 mean that expectations were matched or exceeded. A univariate and multivariate Logistic Regression Model was undertaken using this Expectation ratio and potentially related variables. Statistical analysis was performed considering 0.1 for univariate analysis and 0.05 for every other test as p-value for statistical significance. Statistical analysis was carried out using the IBM SPSS Statistics 25.0. STROBE recommendations for reporting observational studies were used for paper writing.

Results

In this study, 120 patients undergoing cervical or lumbar surgery for degenerative pathologies were analyzed. One-hundred and four patients answered both pre- and post-surgical questionnaires and 16 did not answered to post-surgical ones. The mean age at time of surgery was 55.9±5.20, varying between 23 to 88 years, and 55.0% were males. Psychiatric disorders (mainly depression) were reported by 30.0% and 48.3% of patients had completed only the first cycle of education. Table 1 shows the main demographic

features of our sample. Of the 120 patients 72.5% had symptoms for over 12 months and 27.5% had past spine surgeries for degenerative pathologies. Of our sample, 73.3% underwent lumbar surgery. Table 2 describes some clinical and surgical characteristics.

Table 3 shows pre-surgical expectation score and post-surgical score, calculated based on the Expectation survey as described above. Men (82.0%) and women (84.4%) had similar expectations. About functional status, the mean COMI score was 7.70±1.55 pre-surgical and 4.90±2.80 post-surgical, and *p* value was statistically significant ($p<0.001$).

Patient's expectations about surgery

The mean score of expectations reported by patients was quite high, 82.87%±14.57%, with a median of 85.60% (Figure 1). There was a moderate Spearman correlation between the ESS and age ($\rho=-0.306$, $p=0.001$) (Figure 2) [12].

In this group of patients there were no statistically significant differences of the ESS regarding "Gender" (p=0.695) or "Type of surgery" ($p=0.572$) (Figure 3). The median expectation score of the patients submitted to cervical surgery was 84.13% (95% confidence interval: 78.93-89.33) and in lumbar patients was 82.42% (95% confidence interval: 79.31-85.53), this difference was not statistically significant ($p=0.572$).

To understand the influence of patient characteristics in the ESS we used a Linear Regression Model. A univariate analysis was used first and variables that showed correlation with the ESS were: "Age", "Education level", "Previous surgery" and "Symptoms duration" (Table 4). In a Multivariate analysis (Table 4), "Previous surgery" and "Symptom duration" maintained their association with ESS when controlled to "Age" and "Education level". A bigger difference was observed between the group with symptoms for less than three months and the ones with more than twelve months of symptoms.

Post-surgical analysis

The mean expectation score before surgery was 82.87±14.57%, however the post-surgical score was significantly lower, 60.5±20.6% ($p<0.001$). We calculated the ICC, that showed absence of agreement (One-way random effects model ICC, -0.386, p=0.951), meaning that there is no consistent relation between questionnaire answers in preoperative and postoperative periods. In the univariate analysis, the only variables associated with the Expectations ratio were "Type of surgery" (Cervical vs. Lumbar) and post-surgical COMI score. However, in multivariate analysis, only "Type of Surgery" maintained a statistically significant relation (Table 5).

Comparing the Expectations ratio with the postoperative COMI score it was realized that, although a significant percentage of patients (85%) achieved an improvement in the COMI score after surgery, only 14% matched or exceed their expectations (Table 3). In Figure 6a it is possible to visualize the rate of expectations' achievement according to "Type of Surgery". Expectations were not achieved in a higher proportion of patients submitted to lumbar surgery. However, when analyzing the change in COMI score considering "Type of surgery" the highest proportion of improved patients was after lumbar surgery (Figure 6b).

Discussion

The main purpose of this study was to investigate the relation between patient's expectations regarding the outcome of the surgery and the perception of its effectiveness three months later.

Patients' expectations about surgery

Postoperatively, patients' expectations were very high, with a mean of more than 80% of expected improvement with surgery, whereas the postoperative perception of improvement was around 60%. In addition, no agreement was found between pre- and postoperative answers-to-answer, meaning that, pre-surgical expectations couldn't predict patient's perception of outcome. An association between patient's expectations and surgical outcomes has been reported [6]. Soroceanu et al. demonstrated that higher pre-surgical expectations relate with higher postoperative satisfaction rates, but unrealistic expectations tend to correlate with lower satisfaction [13]. Ronnberg et al. reported that lower expectations correlate with less good endpoints, like lower rates of returning to work after surgery [14]. Other authors argue that it is not the expectations themselves that influence satisfaction, but instead if expectations were achieved [6], [15]. Lastly, it has been demonstrated that patients' expectations could represent their motivation, which could be a predictor of better post-surgical outcomes [16].

In this sample, a moderate correlation was found between patient's age and the results of the ESS. In addition, a univariate analysis demonstrated a relation between older age and lower expectations, however in a multivariate analysis this relation was not sustained, indicating that this not an independent contributing factor to the ESS. Likewise, the relation between lower education level and lower expectations identified in the univariate analysis was not confirmed in the multivariate model.

In our population, history of previous spine surgery and longer duration of symptoms correlated with less optimistic expectations. The greatest difference was between patients with symptoms for less than three months and patients with more than twelve months of symptoms. Both, history of spine surgery and a longer course of symptoms negatively influenced how much patients expect to recover in clinical, professional and social aspects of daily living and their perception of the potential benefit of surgery. Mancuso et al. also found that patients with history of previous surgery tend to expect less improvement, however they also correlated incapacity for work to lower expectations [2], which was not verified in the current study.

Post-surgical analysis

COMI score was the validated instrument used to assess patients' outcomes in the current study and the same questionnaire was used applied before and after surgery to evaluate patients' expectations and perceived outcome.

In the univariate analysis, both "Type of surgery" and post-surgical COMI showed a statistically significant relation with the Expectations ratio. Some studies also found that functional status before surgery may be a predictor of better or worse expectations [17], however in our analysis, when considering other variables, just the type of surgery was able to predict fulfillment of expectations. Patients who

underwent lumbar surgery had a higher probability of non-fulfillment of their expectations. Nevertheless, the majority of patients submitted to lumbar spine surgery reported improvement in COMI score, meaning that the procedure contributed to an improvement on their clinical and functional status.

Overall, despite only 14% of patients reported fulfilled or exceeded expectations, 85% improved on the COMI score, three months after surgery. So, a clear mismatch seems apparent between patient satisfaction and clinical and functional outcomes. This fact may raise an interesting discussion about what the surgeon wants to achieve with surgery and about trying to fulfil both aims by modulating patient's expectations, making them more adjusted to the recovery potential, and this way improving the rate of expectations fulfillment and satisfaction with surgery.

Variables such as history of previous surgery and duration of symptoms seem to relate to worse expectations, which can translate into a reduction on patients' trust about the success of the procedure. This information should be considered when informing a patient about his/her recovery potential. The results of this study raise concerns about unrealistic expectations from the patients, that are significantly higher from what is actually achievable. This difference can possibly reflect a poor communication between doctors and patients, hence it is critical that this discrepancy is discussed with the patients, in order to adjust their expectations regarding surgery [5], [8]. Some authors advocate that a pre-surgical discussion between patient and surgeon may have an enormous influence in patient's expectations about surgery [18]. Therefore, knowledge of patient's expectations may allow physicians to become more capable of counselling and outlining more realistic common goals [19], enabling a more personalized therapeutic strategy, adapted to the patient's own clinical condition and, furthermore, avoiding utopic ideas about recovery.

Limitations

This study has a number of limitations. The Expectations questionnaires were adapted from a pilot sample and have not been submitted to population validation. In addition, the discrepancy between the number of patients submitted to lumbar surgery and cervical surgery, limits the analysis in terms of subgroup evaluation. Lastly, the follow-up time was short, despite some studies showing a good correlation between outcomes reported three months after the surgery and the ones reported at twelve months [20].

Conclusion

Addressing patient's expectations about the outcome after a spine surgery, and comparing them with the surgeon's aims and estimates, is a cornerstone to an informed decision-making and to the perceived success of the treatment. This insight may contribute to a paradigm shift, where surgery is not only focused in improving physical symptoms, but also considers the psychological, professional and social aspects that are important for patient's satisfaction.

Tables

Table 1. Demographic and clinical variables.

Variable	Value
n	120
Age (years)	55.9±5.20
Males	55%
BMI (kg/m2)	27.8±5.20
Educational level	
First cycle*	48.3%
Second cycle*	15.8%
Third cycle*	17.5%
Secondary education	10.8%
Technical degree	0.8%
Bachelor's degree	4.2%
Master's degree	0.8%
Doctoral degree	-
Smoker	15%
IW	25%
Psychiatric disorders	30%
Previous spine surgey	27.5%

IW – Incapacity for work previous to surgery

BMI – Body mass index

*Basic education – First cycle (4th year), Second cycle (6th year), Third cycle (9th year)

Table 2. Clinical and surgical variables.

Variable	Value
Symptoms	
<3 months	9.2%
3 to 12 months	18.3%
>12 months	72.5%
Type of surgery	
Cervical	26.7%
Anterior	23.3%
Posterior	3.4%
Lumbar	73.3%
Non-instrumented	53.5%
Instrumented	20.8%

Surgery extension	
1 level	74.2%
2 levels	19.2%
3 levels	5%
4 or more	1.6%

Table 3. Expectations and function status.

	Pre-surgical	**Post-surgical**	***P***
Expectations			
Patients	82.9%	60.5%	**<0.001**
Men	82.0%	62.0%	
Women	84.4%	59.3%	
Functional status			
COMI	7.70±1.55	4.90±2.80	**<0.001**

Table 4. Linear Regression Model – Pre-surgical expectation survey score.

	Univariate		**Multivariate**	
	(B)	p	(B)	P
Age	-0.271	0.008**	-0.116	0.121
Gender	-3.777	0.159		
BMI	-0.312	0.225		
Smoker status	2.235	0.554		
Education level	2.283	0.011**	1.037	0.348
Occupation	0.011	0.986		
Previous surgery	-5.317	0.085**	-7.213	0.017*
Symptom duration	-4.293	0.037**	-5.581	0.008*
Pre-surgical COMI	0.911	0.269		
Psychiatric disorders	1.062	0.716		
Incapacity for work	1.736	0.586		
Surgery type	-1.864	0.144		

** Variables included in the Multivariate Model, significance level of 0.1.

* Variables with statistical significance in the Multivariate Model, level of significance of 0.05.

Table 5. Expectations Ratio (Achieved vs. Not-achieved) – Logistic regression model.

	Univariate		**Multivariate**	
	Exp(B)	P	Exp(B)	p
Age	1.015	0.505		
Gender	0.939	0.911		
BMI	1.017	0.739		
Smoker status	<0.001	0.999		
Education level	0.740	0.260		
Occupation	1.243	0.180		
Previous surgery	0.410	0.264		
Symptom duration	2.397	0.200		
Psychiatric disorders	1.368	0.604		
Incapacity for work	1.792	0.335		
Post-surgical COMI	0.800*	0.047*	0.807	0.064
Type of surgery	0.268	0.026*	0.282	0.037*
Entension of surgery	1.615	0.140		

* Variables with statistical significance in the multivariate model, significance level of 0.05.

Images

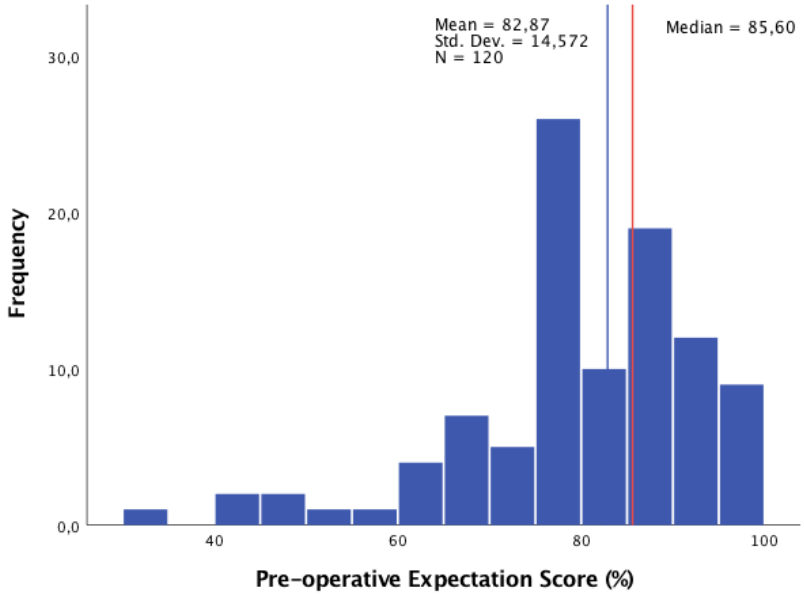

Figure 1. Expectation survey score distribution.

Figure 2. Relationship between age and pre-surgical expectation survey score.

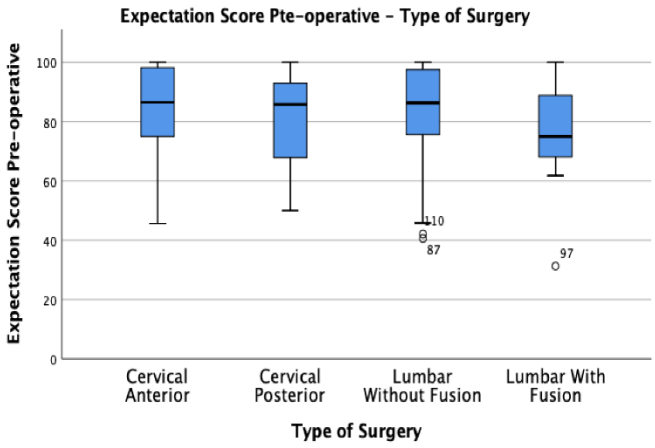

Figure 3. Expectation survey score distribution according to type of surgery.

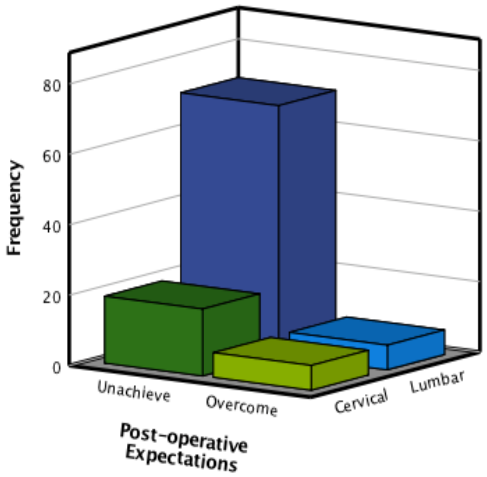

Figure 4a. Association between Type of surgery and postoperative achievement of expectations.

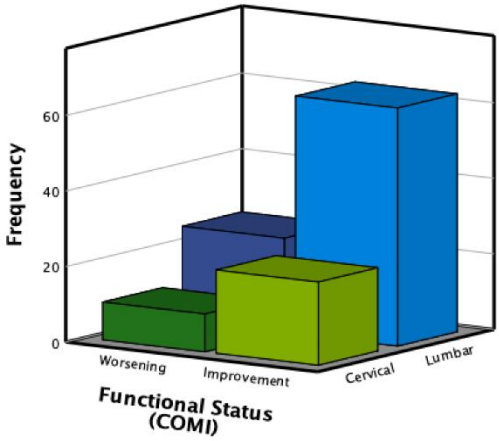

Figure 4b. Association between Type of surgery and COMI score variation.

Figura 4.

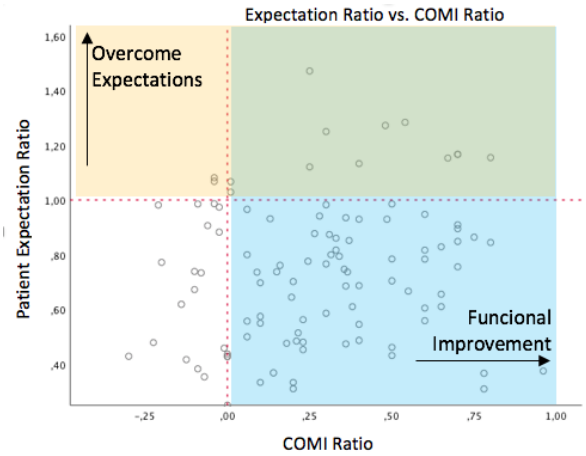

Figure 5. Expectations ratio distribution according to COMI variation.

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Anexos

1. Questionários utilizados na colheita de dados
2. Parecer da comissão de ética
3. Normas de publicação da revista European Spine Journal

QUESTIONÁRIO DE EXPECTATIVAS SOBRE A CIRURGIA À COLUNA CERVICAL

Por favor faça um **círculo** em volta do número que **melhor descreve** a sua resposta a cada questão.

Quanta melhoria espera alcançar nas seguintes áreas como resultado da sua cirurgia à coluna?

	De volta ao **normal** ou melhoria **completa**	Não completamente normal, mas…			Não tenho expectativas quanto a este ponto ou **não** se aplica a mim
		Grande melhoria	**Moderada** melhoria	**Pouca** melhoria	
Alívio da dor no pescoço	1	2	3	4	5
Alívio da dor no ombro, braço e mão	1	2	3	4	5
Alívio de sintomas que interferem com o sono	1	2	3	4	5
Melhorar a força nos braços e mãos	1	2	3	4	5
Alívio da dormência nos braços e mãos	1	2	3	4	5
Melhorar a capacidade para empurrar ou puxar	1	2	3	4	5
Melhorar a capacidade para usar as mãos em movimentos finos (como: abotoar uma camisa e escrever)	1	2	3	4	5
Melhorar a capacidade de posicionar a cabeça para ler	1	2	3	4	5
Melhorar a capacidade de gerir cuidados pessoais (tais como: pentear o cabelo, escovar os dentes, barbear)	1	2	3	4	5
Melhorar a capacidade para conduzir	1	2	3	4	5
Reduzir a necessidade de medicação para a dor	1	2	3	4	5
Melhorar a capacidade de interagir com outros (tais como: atividades sociais e familiares)	1	2	3	4	5
Melhorar a actividade sexual	1	2	3	4	5
Melhorar a capacidade para realizar atividades diárias (tais como: tarefas domésticas, compras, recados)	1	2	3	4	5
Melhorar a capacidade de praticar exercício físico	1	2	3	4	5
Melhorar a capacidade para praticar desportos	1	2	3	4	5
Se correntemente empregado: Cumprir as responsabilidades do trabalho (como: horas requeridas pelo trabalho, cumprir tarefas)	1	2	3	4	5
Se correntemente com baixa médica ou desempregado devido ao problema da coluna: Voltar a trabalhar	1	2	3	4	5
Reduzir o stress emocional ou sentimentos tristes	1	2	3	4	5
Impedir que o meu problema de coluna piore	1	2	3	4	5
Remover as dificuldades que o problema de coluna tem sobre a minha vida	1	2	3	4	5

QUESTIONÁRIO DE EXPECTATIVAS SOBRE A CIRURGIA À COLUNA LOMBAR

Por favor faça um **círculo** em volta do número que **melhor descreve** a sua resposta a cada questão.

Quanta melhoria espera alcançar nas seguintes áreas como resultado da sua cirurgia à coluna?

	De volta ao **normal** ou melhoria **completa**	Não completamente normal, mas…			Não tenho expectativas quanto a este ponto ou **não** se aplica a mim
		Grande melhoria	**Moderada** melhoria	**Pouca** melhoria	
Alívio da dor	1	2	3	4	5
Alívio de sintomas que interferem com o sono	1	2	3	4	5
Melhorar a capacidade de andar mais do que apenas alguns metros	1	2	3	4	5
Melhorar a capacidade de estar sentado por mais de meia hora	1	2	3	4	5
Melhorar a capacidade de permanecer de pé por mais de meia hora	1	2	3	4	5
Recuperar a força nas pernas	1	2	3	4	5
Melhoria do equilíbrio	1	2	3	4	5
Melhorar a capacidade de subir e descer escadas	1	2	3	4	5
Melhorar a capacidade de gerir cuidados pessoais (tais como: vestir, tomar banho)	1	2	3	4	5
Melhorar a capacidade para conduzir	1	2	3	4	5
Reduzir a necessidade de medicação para a dor	1	2	3	4	5
Melhorar a capacidade de interagir com outros (tais como: atividades sociais e familiares)	1	2	3	4	5
Melhorar a atividade sexual	1	2	3	4	5
Melhorar a capacidade para realizar atividades diárias (tais como: tarefas domésticas, compras, recados)	1	2	3	4	5
Melhorar a capacidade de praticar exercício físico	1	2	3	4	5
Remover restrições nas atividades (como: tornar-se mais móvel, não ter que descansar após poucos minutos)	1	2	3	4	5
Se correntemente empregado: Cumprir as responsabilidades do trabalho (como: horas requeridas pelo trabalho, cumprir tarefas)	1	2	3	4	5
Se correntemente com baixa médica ou desempregado devido ao problema da coluna: Voltar a trabalhar	1	2	3	4	5
Reduzir o stress emocional ou sentimentos tristes	1	2	3	4	5
Impedir que o meu problema de coluna piore	1	2	3	4	5
Remover as dificuldades que o problema de coluna tem sobre a minha vida	1	2	3	4	5

QUESTIONÁRIO DE SATISFAÇÃO SOBRE A CIRURGIA À COLUNA CERVICAL

Por favor faça um **círculo** em volta do número que **melhor descreve** a sua resposta a cada questão.

Como classifica o resultado da sua cirurgia à coluna em relação aos seguintes pontos?

	De volta ao **normal** ou melhoria **completa**	Não completamente normal, mas…			Este ponto **não** se aplica a mim
		Grande melhoria	**Moderada** melhoria	**Pouca** melhoria	
Alívio da dor no pescoço	1	2	3	4	5
Alívio da dor no ombro, braço e mão	1	2	3	4	5
Alívio de sintomas que interferem com o sono	1	2	3	4	5
Melhorar a força nos braços e mãos	1	2	3	4	5
Alívio da dormência nos braços e mãos	1	2	3	4	5
Melhorar a capacidade para empurrar ou puxar	1	2	3	4	5
Melhorar a capacidade para usar as mãos em movimentos finos (como: abotoar uma camisa e escrever)	1	2	3	4	5
Melhorar a capacidade de posicionar a cabeça para ler	1	2	3	4	5
Melhorar a capacidade de gerir cuidados pessoais (tais como: pentear o cabelo, escovar os dentes, barbear)	1	2	3	4	5
Melhorar a capacidade para conduzir	1	2	3	4	5
Reduzir a necessidade de medicação para a dor	1	2	3	4	5
Melhorar a capacidade de interagir com outros (tais como: atividades sociais e familiares)	1	2	3	4	5
Melhorar a actividade sexual	1	2	3	4	5
Melhorar a capacidade para realizar atividades diárias (tais como: tarefas domésticas, compras, recados)	1	2	3	4	5
Melhorar a capacidade de praticar exercício físico	1	2	3	4	5
Melhorar a capacidade para praticar desportos	1	2	3	4	5
Se correntemente empregado: Cumprir as responsabilidades do trabalho (como: horas requeridas pelo trabalho, cumprir tarefas)	1	2	3	4	5
Se correntemente com baixa médica ou desempregado devido ao problema da coluna: Voltar a trabalhar	1	2	3	4	5
Reduzir o stress emocional ou sentimentos tristes	1	2	3	4	5
Impedir que o meu problema de coluna piore	1	2	3	4	5
Remover as dificuldades que o problema de coluna tem sobre a minha vida	1	2	3	4	5

QUESTIONÁRIO DE SATISFAÇÃO SOBRE A CIRURGIA À COLUNA LOMBAR

Por favor faça um **círculo** em volta do número que **melhor descreve** a sua resposta a cada questão.

Como classifica o resultado da sua cirurgia à coluna em relação aos seguintes pontos?

	De volta ao **normal** ou melhoria **completa**	Não completamente normal, mas…			Este ponto **não** se aplica a mim
		Grande melhoria	**Moderada** melhoria	**Pouca** melhoria	
Alívio da dor	1	2	3	4	5
Alívio de sintomas que interferem com o sono	1	2	3	4	5
Melhorar a capacidade de andar mais do que apenas alguns metros	1	2	3	4	5
Melhorar a capacidade de estar sentado por mais de meia hora	1	2	3	4	5
Melhorar a capacidade de permanecer de pé por mais de meia hora	1	2	3	4	5
Recuperar a força nas pernas	1	2	3	4	5
Melhoria do equilíbrio	1	2	3	4	5
Melhorar a capacidade de subir e descer escadas	1	2	3	4	5
Melhorar a capacidade de gerir cuidados pessoais (tais como: vestir, tomar banho)	1	2	3	4	5
Melhorar a capacidade para conduzir	1	2	3	4	5
Reduzir a necessidade de medicação para a dor	1	2	3	4	5
Melhorar a capacidade de interagir com outros (tais como: atividades sociais e familiares)	1	2	3	4	5
Melhorar a atividade sexual	1	2	3	4	5
Melhorar a capacidade para realizar atividades diárias (tais como: tarefas domésticas, compras, recados)	1	2	3	4	5
Melhorar a capacidade de praticar exercício físico	1	2	3	4	5
Remover restrições nas atividades (como: tornar-se mais móvel, não ter que descansar após poucos minutos)	1	2	3	4	5
Se correntemente empregado: Cumprir as responsabilidades do trabalho (como: horas requeridas pelo trabalho, cumprir tarefas)	1	2	3	4	5
Se correntemente com baixa médica ou desempregado devido ao problema da coluna: Voltar a trabalhar	1	2	3	4	5
Reduzir o stress emocional ou sentimentos tristes	1	2	3	4	5
Impedir que o meu problema de coluna piore	1	2	3	4	5
Remover as dificuldades que o problema de coluna tem sobre a minha vida	1	2	3	4	5

Unidade de Investigação

Tomei conhecimento. Nada a opor.

17 de Dezembro de 2018

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

DIRECÇÃO CLÍNICA

Aprovado. Ao CA. 19/12/2018

(Prof.ª Doutora Ana Azevedo)

n.º 289/18

SÃO JOÃO

PEDIDO DE AUTORIZAÇÃO

Realização de Investigação

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

AUTORIZADO

CONSELHO DE ADMINISTRAÇÃO REUNIÃO DE 21 DEZ 2018

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)

Nome do Investigador Principal:

Joana Araújo de Azevedo

Título da Investigação:

Expectations in surgery for degenerative pathology of the spine: differences between patient and surgeon

Pretendendo 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, 18 *de* Setembro *de* 2018 . joana Araújo de Azevedo
assinatura

Centro de Investigação HSJ
RECEBI
20/11/2018

CES-IM005-0

SÃO JOÃO
HOSPITAL

Parecer da Comissão de Ética para a Saúde do
Centro Hospitalar de São João / Faculdade de Medicina da Universidade do Porto

Título do Projecto: Expectations in surgery for degenerative pathology of the spine: differences between patient and surgeon.

Nome da Investigadora Principal: Joana Araújo de Azevedo, aluna do Mestrado Integrado em Medicina da FMUP.

Onde decorre o Estudo: No Serviço de Neurocirurgia do CHUSJ. Dispõe de autorização do Prof. Rui Vaz. O profissional de ligação será o Dr. Pedro Santos Silva, neurocirurgião do CHUSJ.

Objectivos do Estudo: Estudo observacional com intervenção cujo objectivo principal é determinar as expectativas pré-cirúrgicas dos doentes submetidos a cirurgia por patologia degenerativa da coluna vertebral (cervical e lombar) e compará-las com os resultados da intervenção, 3 meses após a cirurgia. Uma análise idêntica será realizada em relação às expectativas dos profissionais.
O estudo será realizado no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação do Dr. Pedro Santos Silva.

Concepção e Pertinência do estudo: Para o efeito, está prevista a realização de questionários anonimizados aos doentes, dos quais de anexam as respetivas cópias.

Benefício/risco: Não existem riscos ou benefícios previstos para os participantes, com exceção do tempo despendido na resposta aos questionários.

Confidencialidade dos dados: Os dados dos doentes e as respostas aos questionários serão tratados com respeito pela confidencialidade.

Respeito pela liberdade e autonomia do sujeito de ensaio: Está prevista a obtenção consentimento informado, o qual é acompanhado de uma informação escrita para os participantes.

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

Data previsível da conclusão do estudo: janeiro de 2020.

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

Porto, 19 de outubro de 2018

O Relator da CES, Prof. Manuel Pestana

Comissão de Ética Centro Hospitalar São João / / Faculdade de Medicina da Universidade do Porto n.º 289 / 18

SÃO JOÃO

U.PORTO FMUP FACULDADE DE MEDICINA UNIVERSIDADE DO PORTO

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 infracitada, 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: Expectations in surgery for degenerative pathology of the spine: differences between patient and surgeon

Nome do investigador: Joana Araújo de Azevedo

Endereço eletrónico: joana.araujo.azevedo@gmail.com **Contacto telefónico:** 917425871

Caracterização da investigação:

☐ Estudo retrospetivo ☒ 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)*: Pedro dos Santos Silva

Endereço eletrónico: pedrodossantossilva@gmail.com

Local/locais onde se realiza a investigação: Departamento de neurocirurgia do Centro Hospitalar Universitário S. João

Data prevista para início: 1 / 11 / 2018 Data prevista para o término: 31 / 1 / 2020

PROTOCOLO DO ESTUDO

Síntese dos objetivos:

Este estudo pretende determinar as expectativas pré-cirúrgicas dos doentes submetidos a cirurgia por patologia degenerativa da coluna vertebral e compará-las com os resultados da cirurgia. Esperamos ainda encontrar alguma relação entre as expectativas dos médicos e dos doentes e tentar entender quais das opiniões se assemelham mais ao resultado pós-cirúrgico observado. Por fim, iremos ainda procurar estabelecer uma relação entre melhores ou piores expectativas e os anos de experiência de cada médico.

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

Este estudo é meramente observacional e os participantes não serão sujeitos a nenhum risco e não lhes será causado qualquer dano físico ou moral. Este estudo é desenvolvido com o sentido de permitir uma melhor prática clínica por parte dos médicos responsáveis, permitindo aos médicos e doentes uma tomada de decisão mais informada e consciente. Acreditamos que o conhecimento das expectativas dos doentes possa melhorar a informação pré-operatória prestada pelos cirurgiões aos doentes e a melhorar o grau de satisfação com o resultado da cirurgia.

CONFIDENCIALIDADE

De que forma é garantida a anonimização dos dados recolhidos de toda a informação?

Os inquéritos preenchidos pelos doentes e os dados fornecidos serão apenas visualizados pelos investigadores responsáveis pelo estudo.

O investigador necessita ter acesso a dados do processo clínico? ☒ Sim ☐ Não

Está previsto o registo de imagem ou som dos participantes? ☐ Sim ☒ Não

Se sim, está prevista a destruição deste registo após o sua utilização? ☐ Sim ☐ Não

CONSENTIMENTO

O estudo implica recrutamento de:

Doentes: ☒ Sim ☐ Não Voluntários saudáveis: ☐ Sim ☒ Não

Menores de 18 anos: ☐ Sim ☒ Não

Outras pessoas sem capacidade do exercício de autonomia: ☐ Sim ☒ Não

A investigação prevê a obtenção de Consentimento Informado: ☒ Sim ☐ Não

Se não, referir qual o fundamento para a isenção:

Existe informação escrita aos participantes: ☒ Sim ☐ Não

PROPRIEDADE DOS DADOS

A investigação e os seus resultados são propriedade intelectual de:

☒ Investigador ☐ Promotor ☐ Ambos ☐ Serviço onde é realizado

☐ Não aplicável Outro: _____

BENEFÍCIOS, RISCOS E CONTRAPARTIDAS PARA OS PARTICIPANTES

Benefícios previsíveis:

Este estudo poderá ter benefícios a nível da prática clínica dos médicos responsáveis pelos doentes, podendo eventualmente garantir um atendimento médico e terapêutico mais personalizado.

Riscos/incómodos previsíveis:

Nenhuns.

São dadas contrapartidas aos participantes:

- *pela participação* ☐ Sim ☐ Não ☒ Não aplicável
- *pelas deslocações* ☐ Sim ☐ Não ☒ Não aplicável
- *pelas faltas ao emprego* ☐ Sim ☐ Não ☒ Não aplicável
- *por outras perdas e danos* ☐ Sim ☐ Não ☒ Não aplicável

CUSTOS / PLANO FINANCEIRO

Os custos da investigação são suportados por:

☐ Investigador ☐ Promotor ☐ Serviço onde é realizado

☒ Não aplicável Outro: _____

Existe protocolo financeiro? ☐ Sim ☒ Não

LISTA DE DOCUMENTOS ANEXOS

- [x] 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)*
- [x] Protocolo do estudo
- [x] 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)
- [x] Profissional de ligação
- [x] Informação dos orientadores
- [x] Informação ao participante
- [x] Modelo de consentimento
- [x] Instrumentos a utilizar *(inquéritos, questionários,escalas, p.ex.)*: Lumbar/Cervical Spine Surgery Expectation Survey e Lumbar/Cervi
- [x] 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, 18 *de* Setembro *de* 2018

Nome legível: Joana Araújo de Azevedo

Joana Araújo de Azevedo
assinatura

Parecer da Comissão de Ética do Centro Hospitalar de São João/ FMUP Emitido na reunião plenária da CE de 19 / 10 / 18

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

289-18

RESPONSÁVEL PELO ACESSO À INFORMAÇÃO

SÃO JOÃO

Pedido de Reutilização de Registos Clínicos para Investigação e Desenvolvimento (I&D)

Número do Pedido
118011MM113
(A preencher pelo Gabinete de Apoio ao RAI)

Exmo. Senhor
Responsável pelo Acesso à Informação
(Artigo 9.º da Lei n.º 26/2016, de 22 de agosto)
Dr. Rui de Vasconcellos Guimarães

SÃO JOÃO

AUTORIZADO
RAI - Responsável pelo Acesso à Informação no Centro Hospitalar de São João (Art. 9º, Lei 26/2016, de 22/8)
18/M/2018

VASCONCELLOS GUIMARÃES
Administrador Hospitalar

1. Identificação do(s) Investigador(es) *Preenchimento Obrigatório*

1.1. Investigador Principal

Nome: Joana Araújo de Azevedo
Contacto telefónico: +351917425871
Endereço eletrónico: joana.araujo.azevedo @ gmail.com

1.2. Investigador(es) Associado(s)

Número Total: 2

Nome: Pedro dos Santos Silva
Contacto telefónico: +351925878701
Endereço eletrónico: pedrodossantossilva @ gmail.com

Nome:
Contacto telefónico:
Endereço eletrónico: @

Nome:
Contacto telefónico:
Endereço eletrónico: @

1.3. Afiliação Institucional do Investigador Principal

1.3.1. Grupo Profissional

☐ Médico(a) ☐ Enfermeiro(a) ☐ Docente ☒ Estudante
☐ Outro. Qual?

1.3.2. Documento de identificação pessoal ou profissional

☒ Cartão de Cidadão ☐ Bilhete de Identidade ☐ Célula Profissional
☐ Cartão de Docente ☐ Cartão de Estudante ☐ Outro. Qual?

Número de Documento: 14357670

2. Enquadramento e Identificação do Trabalho de Investigação e Desenvolvimento *Preenchimento Obrigatório*

2.1. Enquadramento da investigação

☒ Trabalho académico de investigação e desenvolvimento:
- ☐ Não conferidor de grau
- ☒ Conferidor de grau: ☐ Licenciatura ☒ Mestrado ☐ Doutoramento

☐ Projeto de investigação e desenvolvimento

RAI-IM002-0

2.2. Entidade(s) que tutela(m) a investigação

☒ Centro Hospitalar de São João

Serviço: Neurocirurgia

☒ Universidade do Porto

Faculdade / Instituto: Faculdade de Medicina

☐ Outra Instituição. *Qual?*

Há alguma parceria entre instituições?

☐ Não ☒ Sim. Qual(is)? Académica

2.3. Orientador Se Aplicável

Contacto telefónico 925878701

Endereço eletrónico pedrodossantossilva @ gmail.com

2.4. Título provisório

Expectations in surgery for degenerative pathology of the spine: differences between patient and surgeon

Deverá posteriormente indicar o título definitivo para emissão do Certificado de Reutilização pelo RAI – DAta REuse Certificate for Research – DARE através dos contactos disponíveis no fim deste formulário.

2.5. Acesso requerido

☒ Ficheiro

Descrição do património informacional a que pretende ter acesso, identificando a informação a obter, i.e. nome, morada, diagnóstico, idade, códigos dos distritos, entre outros.

Pretendemos aceder à história clínica e dados biopsicosociais do doente.

☒ Consulta de processos clínicos em ambiente papel:

☒ Bloco ☐ Consulta Externa ☐ Hospital de Dia ☒ Internamento ☐ MCDT ☐ Urgência

Deverá anexar ficheiro(s) contendo a identificação do pretendido, i.e. números de processos, episódios, números de utente, entre outros.

Anexar ficheiro no ato de envio

☐ Consulta de registos clínicos eletrónicos

Especificar os Sistemas de Informação:

Data previsível de fim de utilização das credenciais de acesso ____ - ____ - ____

☐ Outro Acesso. Qual?

2.3. Pareceres e Autorizações

☐ Autorização da Hierarquia

☒ Protocolo Científico Aprovado [1]

☒ Parecer da Comissão de Ética para a Saúde (CES) [1]

☐ Parecer do Centro de Epidemiologia Hospitalar [1]

Deverá anexar ficheiro(s) contendo cópia dos documentos referentes às opções selecionadas.

Anexar ficheiro no ato de envio

[1] Obrigatório quando aplicável.

3. Observações Preenchimento Facultativo

4. Aceitação dos Termos e Condições da Reutilização

Cumulativamente com as obrigações decorrentes da lei já citada *(n.º 2 e 3 do artigo 21 e o n.º 1 e 2 do artigo 12, ambos da Lei n.º 26/2016, de 22 de agosto)* ao submeter o presente pedido concordo e fico ainda vinculado aos seguintes termos e condições:

- Comprometo-me a manter confidencial toda a informação à qual vou ter acesso;
- Não vou elaborar registos, susceptíveis de identificar ou tornar identificável a identidade das pessoas a quem os mesmos dizem respeito;
- Não vou elaborar, nem ficar na posse, de cópias de bases de dados utilizadas na recolha de informação;
- Comprometo-me a obter junto da Comissão Nacional de Proteção de Dados (CNPD) as necessárias autorizações, para eventuais bases de dados que venha a conceber e utilizar no âmbito da presente investigação;
- Comprometo-me a devolver ao Centro Hospitalar de São João, na pessoa do seu Diretor Clínico, as bases de dados e o resultado da investigação;
- Comprometo-me a ocultar os elementos de identificação da(s) pessoa(s) a quem os registos digam respeito, em futuras e eventuais publicações de resultados;
- Comprometo-me a consultar os processos clínicos nas instalações que me forem indicadas para o efeito;
- Comprometo-me a obter os necessários pareceres, quer da Comissão de Ética do Hospital, quer do Centro de Epidemiologia Hospitalar, sempre que necessário;
- Comprometo-me a citar as fontes sempre que publicitar o trabalho de investigação independentemente de requerer a Certidão de Reutilização (DAta REuse Certificate for Research – DARE);
- Tomei conhecimento, que a violação de qualquer dos compromissos aqui assumidos, resultará no apuramento de responsabilidades disciplinares, civis e penais e ainda, à impossibilidade futura de aceder a informação de saúde para fins de investigação.

5. Decisão do investigador sobre requerer a DAta REuse Certificate for Research – DARE Preenchimento Obrigatório

☐ Pretendo desde já requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consultei em *http://portal-chsj.min-saude.pt/pages/710.*

☒ Não pretendo requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consultei em *http://portal-chsj.min-saude.pt/pages/710.*

6. Assinatura

Nota 1: Se o presente pedido for submetido eletronicamente ou faz assinatura digital qualificada; ou posteriormente vem ao Centro Hospitalar de São João exibir o seu documento de identificação pessoal; ou no âmbito do seu espaço de liberdade e como manifestação expressa do seu consentimento envia cópia do referido documento, neste caso, concluído o processo ser-lhe-á devolvida ou eliminada a cópia do documento de identificação pessoal, conforme as indicações que dê.
Nota 2: Se o presente pedido for entregue presencialmente, assina e exibe o documento de identificação a quem recebe o pedido.

Data 2018 - 09 - 18

Joana Araújo de Azevedo
Investigador Principal

Em caso de dúvida no preenchimento contacte através dos endereços eletrónicos
rai.reutilizacao.id@chsj.min-saude.pt **ou** ruiguimaraes@chsj.min-saude.pt
ou pelos números de telemóvel 962 204 194 **ou** 918 880 299

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European Spine Journal

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