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Complicações associadas às cirurgias de transferência da coracóide para
tratamento da luxação recidivante do ombro

Complications associated with coracoid transfer procedures for the treatment of
recurrent shoulder dislocation

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Eu, Ana Catarina Silva Pereira, abaixo assinado, nº mecanográfico 201106109, 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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Faculdade de Medicina da Universidade do Porto, 22/03/2017

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NÚMERO DE ESTUDANTE

201106109

DATA DE CONCLUSÃO

DESIGNAÇÃO DA ÁREA DO PROJECTO

Ortopedia e Traumatologia

TÍTULO DISSERTAÇÃO/MONOGRAFIA (riscar o que não interessa)

Complicações associadas às cirurgias de transferência da capsula para tratamento da luxação recidivante do ombro

ORIENTADOR

Doctor Manuel Guiterres

COORIENTADOR (se aplicável)

ASSINALE APENAS UMA DAS OPÇÕES:

É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTA TRABALHO APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	<input type="checkbox"/>
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Faculdade de Medicina da Universidade do Porto, 22/03/2017

Assinatura conforme cartão de identificação: Ana Catarina Silva Pereira

Abstract

Background: Different surgical procedures have been described for the treatment of the recurrent anterior dislocation of the shoulder. Despite the documented success of the open procedures, some studies suggest that the arthroscopic technique leads to more favourable results. However, there still seems to be some disagreement concerning the incidence of complications, when comparing open and arthroscopic techniques.

Objective and Methods: As an attempt to clarify these doubts about the incidence of complications associated with the different techniques, this study contains a free literature review along with a retrospective *case series* (level of evidence IV) of the patients who underwent these procedures in the CHSJ-Porto in the past 10 years.

Discussion and Conclusion: There are various techniques for the treatment of the recurrent dislocation of the shoulder, all of them with known success when it comes to prevention of recurrence. However, all of them are invariably associated to high complication rates.

Despite being associated with a slightly higher re-operation rate, in the literature, the arthroscopic technique was found to have an overall lower rate of complications when compared to the open procedures. CHSJ data presented a higher rate of *screw related complications* and *revision surgery* than the literature. However, concerning other complications and when assessing the procedures individually, no tendency was verified. One can therefore conclude that, despite being scarce, the CHSJ data roughly overlap the literature.

Keywords: Complications; Bristow; Latarjet; Open; Arthroscopic; shoulder; glenohumeral; instability; dislocation.

Abbreviations: CHSJ, Centro Hospitalar São João

Introduction

Different surgical procedures have been described for the treatment of the recurrent anterior dislocation of the shoulder ⁽¹⁾. Currently, efforts are being made to determine parameters that can be widely used to decide what procedure to perform. Balg e Boileau⁽²⁾ have created an instability score (ISIS) to determine pre-operative risk factors in patients with recurrent instability. This score intends to help the surgeon decide whether to perform a soft tissue procedure or a bone graft procedure. So, in patients with high recurrence risk, coracoid transfer procedures that place the coracoid process on the anteroinferior border of the glenoid cavity are an alternative to the soft tissue procedures (Bankart). The first coracoid transfer procedure was described by Latarjet⁽³⁾ in 1954 and by Helfet (who named the procedure after Bristow) in 1958, having suffered some modifications since then.

The difference between both (Latarjet and Bristow) lies in the coracoid graft position. The Bristow procedure places the longer axis of the graft perpendicularly⁽⁴⁾, whereas the Latarjet procedure places it parallel to glenoid cavity ⁽⁵⁾. In both, the final effect is a bone block that reinforces the anteroinferior border of the glenoid cavity and a stabilizing sling effect achieved by the transfer of the coracoid and conjoint tendon through the subscapular muscle⁽⁶⁾.

Despite the documented success of the open procedures, some studies suggested that the arthroscopic technique is associated with a cosmetically more favourable result, as well as with a lower post-operative morbidity and a faster recovery. And, as far as the procedure is concerned, studies claim that this minimally invasive technique allows a more accurate positioning of the graft, theoretically lowering the complications associated with its dislocation⁽⁷⁾. However, there still seems to be some disagreement concerning the incidence of complications, when comparing open and arthroscopic techniques ⁽⁸⁾.

This study focuses exclusively on coracoid transfer procedures, which, despite being effective on patients with a high risk of recurrence, are also associated with certain complications that must be taken into consideration before, during and after the surgery.

Thus, as an attempt to clarify these doubts about the incidence of complications associated with the different techniques, this study contains a free literature review alongside a retrospective *case series* (level of evidence IV) of the patients who underwent these procedures in the CHSJ-Porto in the past 10 years.

Methods:

A literature review was performed, using the PubMed database. The keywords were *Complications; Bristow; Latarjet; Open; Arthroscopic; shoulder; glenohumeral; instability; dislocation*.

Complication was defined as an adverse event or morbidity caused by the surgery.

The complications included in this study were recurrent instability (dislocation, subluxation and positive apprehension test), pseudarthrosis, graft dislocation, graft fracture, osteolysis/graft reabsorption, arthrosis, screw related complications (loose, migration, fracture), pain, hematoma, infection (deep or superficial), neuromuscular/vascular complications, revision surgery and functional restrictions.

The inclusion criteria were: English or Portuguese language studies published after 2005; Case series (level of evidence IV) with human participants; studies reporting the complications of the original or modifications of the Bristow/Latarjet procedures for the treatment of the recurrent dislocation of the shoulder.

The exclusion criteria were: studies on any language other than Portuguese or English; studies published before 2005; studies in animals; level of evidence V, opinion articles, anatomic studies, biomechanical studies, or studies referring only to the surgical or image techniques. Case reports, abstract only publications and revision articles with no original data were also excluded, as well as studies reporting only the outcomes of revision surgeries and isolated soft tissue stabilization procedures (Bankart).

The studies reporting the results of more than one technique were only included if a clear distinction of the outcomes of each procedure was possible.

The title, abstract or both of each article were reviewed. The full texts were reviewed when inclusion was anticipated, when there was no abstract available or when a decision regarding inclusion or exclusion could not be made from the title and/or abstract alone. The references of the included studies were also reviewed for potential inclusion, for any additional articles not identified through the database search.

A total of 19 articles were included ^(1, 5, 8-24).

The data were organized and descriptive statistics were calculated and analysed.

A retrospective review of the patients submitted to coracoid transfer procedures in the Orthopedics and Traumatology department of the *Centro Hospitalar São João* (CHSJ) – Porto was also performed. The data were extracted from computer records. The inclusion criteria were: surgeries performed between January 2006 and December 2015. The exclusion criteria were: soft tissue stabilization procedures and revision surgeries.

From the 69 patients submitted to stabilization procedures for the recurrent dislocation of the shoulder, only 34 were submitted to coracoid transfer procedures. The others underwent soft tissue procedures.

Thus, 34 patients were included. Such as in the literature review, the data were organized and descriptive statistics were calculated and analysed.

In the statistical analysis, the Chi-Square test was used to evaluate the differences in the incidence of complications among the different procedures. When the sample was too small, the Fisher's Exact test was used. A similar way was used to assess the qualitative differences of the functional scores results.

The t student test was used to analyse continuous variables. $P < .05$ was deemed statistically significant.

Results

- **Literature review**

In the literature review, a total of 962 shoulders out of 898 patients were included, of which 713 (79%) were male and 185 (21%) were female.

The mean age at the time of the procedure was 27,6 years old. The dominant side was involved in 365 (63%) cases whereas the non-dominant side was involved in 212 (37%). The average follow-up period was 8 years (ranging from 3 months to 35 years). (Table 1)

From all the operated shoulders, 429 underwent the Bristow procedure, 307 the Latarjet procedure and 226 the arthroscopic Latarjet procedure. (Table 1)

	Literature	CHSJ data
Analysed studies	19	-
Total of shoulders	962	34
Gender		
- Male	713	27
- Female	185	7
Mean age at the time of the surgery	27,6 years old	28 years old (15-57)
Operated shoulder		
- Dominant	365	-
- Non-dominant	212	-
- Left	-	15
- Right	-	19
Average follow up period	8 years (3 months – 35 years)	8 months (1 month - 5 years)
Technique		
- Bristow	429	19
- Latarjet	307	10
- Arthroscopic Latarjet	226	5

Table 1 – General data from the literature and CHSJ. Since many articles do not refer to some of the variables, the total number may not coincide in all of them.

The total number and percentage of complications (from all the techniques) is discriminated in Table 2.

	Literature	CHSJ data
Instability		
- Redislocation	25 (2,6%)	1 (2,9%)
- Subluxation	18 (1,9%)	-
- Positive apprehension test	39 (4%)	1 (2,9%)
Radiographic complications		
- Pseudarthrosis / Nonunion / Fibrous Union	45 (4,7%)	2 (3,2%)
- Graft dislocation	20 (2%)	-
- Graft fracture	5 (0,5%)	-
- Osteolysis/ Graft reabsorption	36 (3,7%)	2 (5,8%)
- Arthrosis	122 (12,7)	1 (2,9%)
- Screw related complications	29 (3%)	6 (16,1%)*
- Intraoperative complications	-	2 (5,8%)
Functional complications		
- Range of motion limitation	389 (40,4%)	15 (44,1%)
- Loss of strength	20 (2%)	
Pain	118 (12,3%)	4 (11,7%)
Hematoma	9 (0,9%)	1 (2,9%)
Infection		
- Superficial	11 (1,1%)	-
- Deep	1 (0,1%)	-
Neuromuscular/vascular complications	35 (3,6%)	5 (14,7%)
Revision Surgery	34 (3,5%)	4 (11,7%) *

Table 2 – Total of complications found in the literature and in CHSJ data. *=p<0,05

Range of motion limitation refers to movements in every direction, but the most significant one was the restriction in external rotation, found in 82% of the shoulders with *range of motion limitation*.

Screw related complications include screw fracture, migrations and the presence of loose or prominent screws.

Neuromuscular complications include intraoperative alerts (26), axillary nerve damage (5), musculocutaneous nerve damage (1) and deltoid muscle atrophy (3).

Besides intraoperative nerve alerts, no other intraoperative complications were reported in the literature.

Table 3 describes and allows the comparison between the complications associated with Bristow and Latarjet, as well as the comparison between open (Bristow and Latarjet) and all arthroscopic techniques. The statistically significant results are marked in the Table: * = p<0,05.

	Bristow (429) n(%)	Latarjet (307) n(%)	Open (Bristow+Latarjet) (736) n(%)	Arthroscopic (226) n(%)
Instability				
- Redislocation	19 (4,4%)*	5 (1,6%)	24 (3,2%)*	1 (0,4%)
- Subluxation	15 (3,5%)*	2 (0,6%)	17 (2,3%)	1 (0,4%)
- Positive apprehension test	15 (3,5%)	20 (6,5%)	35 (4,7%)	4 (1,8%)
Radiographic complications				
- Pseudarthrosis/ Nonunion / Fibrous Union	28 (6,5%)	11 (3,6%)	39 (5,3%)	6 (2,6%)
- Graft dislocation	12 (2,8%)	7 (2,3%)	19 (2,6%)	1 (0,4%)
- Graft fracture	4 (0,9%)	-	4 (0,5%)	1 (0,4%)
- Osteolysis/ Graft reabsorption	16 (3,7%)	17 (5,5%)	33 (4,5%)	3 (1,3%)
- Arthrosis	89 (20,7%)*	21 (6,8%)	110 (14,9%)*	12 (5,3%)
- Screw related complications	9 (2%)	9 (2,9%)	18 (2,4%)	11 (4,9%)
Functional complications				
- Range of motion loss	229 (53,4%)*	62 (20,2%)	291 (39,5%)	98 (43,4%)
- Loss of strength	20 (4,7%)*	-	20 (2,7%)*	-
Pain	59 (13,7%)	59 (19,2%)	118 (16%)*	-
Hematoma	1 (0,2%)	2 (0,6%)	3 (0,4%)*	6 (2,6%)
Infection				
- Superficial	6 (1,4%)	3 (0,9%)	9 (1,2%)	2 (0,8%)
- Deep	1 (0,2%)	-	1 (0,1%)	-
Neuromuscular/vascular complications		34 (11%)*	34 (4,6%)*	1 (0,4%)
Revision Surgery	13 (3%)	7 (2,3%)	20 (2,7%)	14 (6,2%)*

Table 3 - Complications associated with open (Bristow and Latarjet) and arthroscopic techniques found in the literature review. *=p<0,05

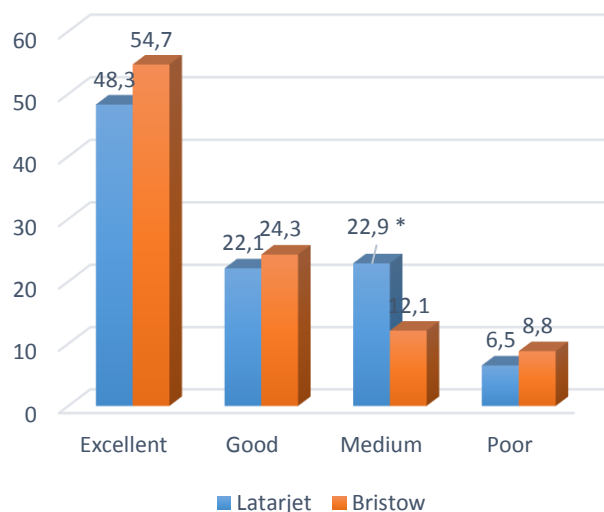
When comparing the Bristow and Latarjet techniques, there is a significantly higher number of *redislocation, subluxation, arthrosis* and *functional complications* when the Bristow technique is used.

Comparing open and arthroscopic techniques, there is a significantly higher number of *redislocation, osteolysis, arthrosis, loss of strength* and *pain* with the open techniques. On the other hand, the arthroscopic technique is associated with a significantly higher number of *hematoma* and *revision surgery*.

Relatively to the functional scores, graphics 1 and 2 compare the qualitative functional results (“Excellent”, “Good”, “Fair” and “Poor”) reported in the literature, associated with the Bristow and Latarjet techniques (Graphic 1) and with open and arthroscopic techniques (Graphic 2).

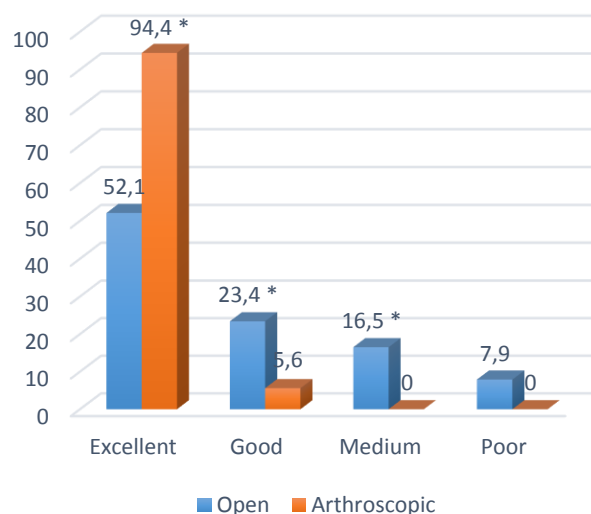
There was a significantly higher percentage of “Fair” results with the Latarjet procedure when compared to the Bristow procedure and there is a significantly higher percentage of “Excellent” results with the arthroscopic techniques when compared to the open procedures, while these were associated with higher “Good” and “Fair” results.

Graphic 1 - % of each functional result associated with Bristow and Latarjet procedures



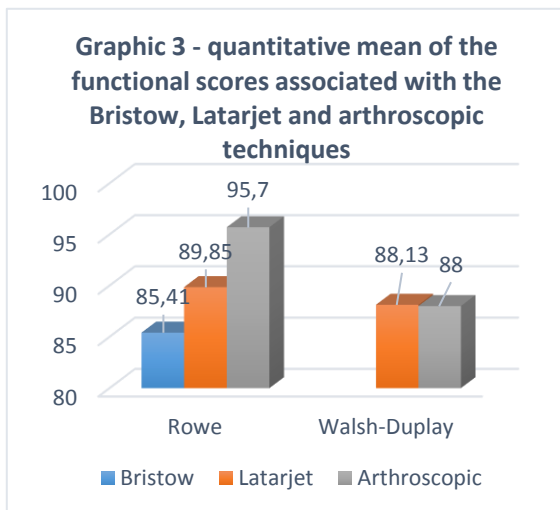
Graphic 1 – Percentage of each functional result associated with Bristow and Latarjet procedures. *=p<0,05

Graphic 2 - % of each functional result associated with open and arthroscopic procedures

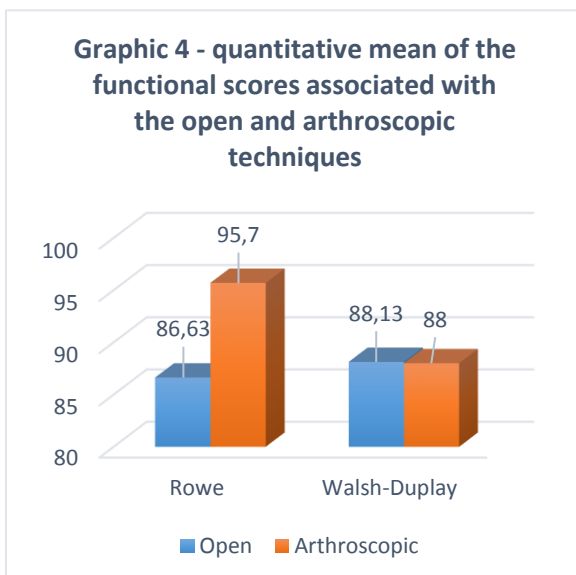


Graphic 2 – Percentage of each functional result associated with open and arthroscopic procedures *=p<0,05

Graphics 3 and 4 represent the comparison between the quantitative means of the Rowe and Walsh Duplay scores associated with Bristow, Latarjet and Arthroscopic (Graphic 3) and with the open and arthroscopic procedures (Graphic 4). The differences between the procedures were not statistically significant despite the overall better evaluation of the arthroscopic technique with the Rowe score. To be noted that only 2 studies relating to the arthroscopic procedure reported functional scores results: one of them used the Rowe Score and the other used the Walsh-Duplay score.



Graphic 3 - Quantitative mean of the functional scores associated with the Bristow, Latarjet and arthroscopic techniques



Graphic 4 - Quantitative mean of the functional scores associated with the open and arthroscopic techniques

- **CHSJ data**

Relatively to the CHSJ data, a total of 34 shoulders out of 34 patients were included, of which 27 (79%) were male and 7 (21%) were female. The mean age at the time of the procedure was 28 years old. Although the dominance of the operated shoulder was not registered, 15 of them were right shoulders and 19 were left. The average follow-up period was 8 months (ranging from 1 month to 5 years). (Table 1)

Out of all the operated shoulders, 19 underwent the Bristow procedure, 10 the Latarjet procedure and 5 the arthroscopic Latarjet procedure. (Table 1)
47% of all the surgeries were performed by the same surgeon.

The total number and percentage of complications (from all the techniques) is discriminated in Table 2.

The *intraoperative complications* include graft fracture and loss of fixation. Revision surgery was performed due to screw related complications (3) and graft reabsorption (1).

As found in the literature results, the most significant movement affected by the *range of motion limitation* was external rotation, found in 67% of the shoulders with *range of motion limitation*.

Neuromuscular complications included axillary nerve damage (1), atrophy of the deltoid muscle (2), atrophy of the triceps muscle (1) and chronic neurogenic atrophy (1).

Table 4 describes and allows the comparison between the complications found associated with Bristow and Latarjet, as well as the comparison between open (Bristow and Latarjet) and all arthroscopic techniques. The statistically significant results are marked in the Table: * = $p < 0,05$.

There was a significantly higher number of pseudarthrosis associated with the arthroscopic technique when compared with the open procedures. There were no other statistically significant differences relating to the other complications.

	Latarjet (10) n(%)	Bristow (19) n(%)	Open (Bristow+Latarjet) (29) n(%)	Artroscópica (5) n(%)
Instability				
- Redislocation	-	1 (5,3%)	1 (3,4%)	-
- Positive apprehension test	-	1 (5,3%)	1 (3,4%)	-
Radiographic complications				
- Pseudarthrosis	-	-	-	2 (40%)*
- Graft reabsorption	1 (10%)	-	1 (3,4%)	1 (20%)
- Arthrosis	-	-	-	1 (20%)
- Screw related complications	-	4 (21%)	4 (13,8%)	2 (40%)
- Intraoperative complications	1 (10%)	1 (5,3%)	2 (6,9%)	-
Functional complications				
- Range of motion limitation	3 (30%)	2 (10,5%)	14 (48,2%)	1 (40%)
Pain	1 (10%)	1 (5,3%)	3 (10,3%)	1 (40%)
Hematoma	1 (10%)		1 (3,4%)	-
Neuromuscular/vascular complications	-	5(26,3%)	5(17,2%)	-
Revision Surgery	1 (10%)	3 (15,8%)	4 (13,8%)	1 (40%)

Table 4- Complications associated with open (Bristow and Latarjet) and arthroscopic techniques found in the CHSJ data. *=p<0,05

No functional scores were registered.

- **Literature vs CHSJ data**

Relatively to the total of complications, the CHSJ data had a higher percentage of *screw related complications* and *revision surgery* when compared to the data reported in the literature (Table 2).

Considering only the Bristow procedure, there is a significantly higher proportion of *arthrosis* and *range of motion limitation* in the literature when compared to the CHSJ data.

Among all the open procedures, there is a significantly higher proportion of *arthrosis* in the literature when compared to the CHSJ data. On the other hand, there is a significantly higher proportion of *screw related complications* and *revision surgery* in the CHSJ data when compared to the literature.

Relatively to the arthroscopic procedure, there was a significantly higher proportion of *pseudarthrosis* and *screw related complications* in the CHSJ data.

Discussion

This study aimed to compare the incidence of complications associated to the different coracoid transfer procedures, open and arthroscopic, and simultaneously assess whether the data from the CHSJ differ significantly, or not, from the literature.

Despite being effective and widely used techniques for the treatment of recurrent dislocation of the shoulder, the Bristow-Latarjet procedures are generally associated with a substantial complication and reintervention rate, both in the literature and the CHSJ data.

In the literature, the arthroscopic technique had a lower proportion of complications, being, however, associated with a higher reintervention rate when compared to the open techniques. Note that due to the relatively low number of arthroscopic surgeries performed in the CHSJ so far and, possibly, due to the shorter follow-up period, the low number of complications registered in this hospital precludes a good comparative analysis between the different techniques.

The fact that the arthroscopic procedure is relatively recent and the surgeons are still in an early stage of the learning curve allows a greater room for progression so that better results can be achieved.

Another factor to consider is the duration of the surgery. Theoretically, this is longer for arthroscopic procedures, what could translate in a higher postoperative functional limitation rate. This tendency was verified in the literature but not in the CHSJ data.

Although *Infection* was a complication rarely found in the literature, it is still important to state that no case of infection was observed in the CHSJ data.

Functional complications such as *range of motion limitation* were found in a high percentage of patients both in the literature (40,4%) and the CHSJ data (44,1%) and there were no significant differences between techniques.

The restriction in external rotation (the most common functional complication), for instance, may have important implications for athletes and should be one of the topics taken into consideration when making the therapeutic decision.

Another complication widely mentioned in the literature was arthrosis (12,7%); however, it was only present in 2,9% of the CHSJ data. This discrepancy can be explained by the large difference between the follow up periods.

The percentages associated with each complication may not relate to their real incidence since not all the studies focus on the same outcomes. For example, only 2 studies referred to *neuromuscular/vascular complications*, one of them focusing solely on these.

Therefore, the short number of studies referring to *neuromuscular/vascular complications* limits the comparative analysis between techniques as far as this item is concerned. However, in theory, nerve and vascular damage during arthroscopic coracoid transfer would be of major concern because of the proximity of the brachial plexus and the axillary vessels.

There are several differences between the studies included in the literature review and the ones performed with the CHSJ data, namely, the sample size and the follow up period, which limit the comparison between literature and CHSJ data. The mean age and the gender distribution was similar.

Another limitation of this study lies in the scarcity of the hospital records and in the lack of standardized radiological assessment protocols in the CHSJ.

The complications found in the CHSJ were obtained exclusively from retrospective data, which could possibly underestimate their incidence, since the records may not include minor complications.

To sum up, there are various techniques for the treatment of the recurrent dislocation of the shoulder, all of them with known success when it comes to prevention of recurrence. However, all of them are invariably associated to high complication rates, which reinforces the need to discuss them with each patient pre-operatively.

Despite being associated with a slightly higher re-operation rate, in the literature, the arthroscopic technique was found to have an overall lower rate of complications when compared to the open procedures.

CHSJ data presented a higher rate of *screw related complications* and *revision surgery* than the literature. However, concerning other complications and when assessing the procedures individually, no particular tendency was verified. One can therefore conclude that, despite being scarce, the CHSJ data roughly overlap the literature.

An active search for complications as well as a functional evaluation through standardized scores, in a long term prospective study, would be a way to overcome this study's limitations and clarify which of the techniques would guarantee better long term outcomes, concerning stability, motion, functional scores and prevention of arthrosis.

Conflict of Interests:

The authors declare no conflicts of interest.

Captions of Figures/Tables

Table 1 – General data from the literature and CHSJ. Since many articles do not refer to some of the variables, the total number may not coincide in all of them.

Table 2 – Total of complications found in the literature and in CHSJ data. $*=p<0,05$

Table 3 - Complications associated with open (Bristow and Latarjet) and arthroscopic techniques found in the literature review. $*=p<0,05$

Graphic 1 – Percentage of each functional result associated with Bristow and Latarjet procedures. $*=p<0,05$

Graphic 2 – Percentage of each functional result associated with open and arthroscopic procedures. $*=p<0,05$

Graphic 3 - Quantitative mean of the functional scores associated with the Bristow, Latarjet and arthroscopic techniques

Graphic 4 – Quantitative mean of the functional scores associated with the open and arthroscopic techniques

Table 4- Complications associated with open (Bristow and Latarjet) and arthroscopic techniques found in the CHSJ data. $*=p<0,05$

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Agradecimentos

Em primeiro lugar, gostaria de destacar o papel desempenhado neste trajeto pelo meu orientador, o Prof. Manuel Gutierrez. Agradeço-lhe profundamente toda a disponibilidade e apoio. Espero deixa-lo orgulhoso no meu trabalho e no meu percurso profissional.

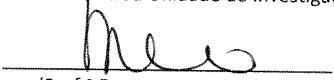
Dedico este trabalho aos meus pais e avós, pelo amor e apoio incondicional, sempre. Obrigada pelo exemplo que estabeleceram e pela educação que me deram.


E por último, um agradecimento especial aqueles com quem partilhei estes últimos 6 anos, por me ouvirem e por estarem por perto. Maior orgulho que, por daqui a meses, vos chamar “colegas”, é o de vos chamar Amigos.

A todos vós, um enorme e sentido obrigado

Anexos

1. Parecer da Comissão de Ética
2. Normas da Revista

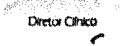
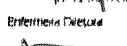
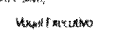
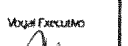
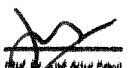



Unidade de Investigação
Tomei conhecimento. Nada a opor.
30 de Maio de 2016
A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

DIRECCÃO CLÍNICA
3 / 6 / 2016
Aprovado. Ao CA.

(Prof.ª Doutora Ana Azevedo)

108-16

AUTORIZADO

CONSELHO DE ADMINISTRAÇÃO DO UNICHO DE 03 JUN 2016
Presidente do Conselho de Administração

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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: Manuel Gutierrez

Título do projecto de investigação: Complicações associadas às cirurgias de transferência da coracóide para tratamento da luxação recidivante do ombro.

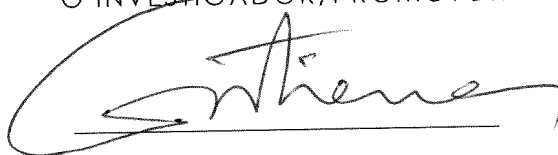
Pretendendo realizar no Serviço de Ortopedia do Centro Hospitalar de S. João – EPE o estudo/projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efectivação.

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, 07/Janeiro/2016

O INVESTIGADOR/PROMOTOR





Comissão de Ética para a Saúde do HSJ

Parecer

Projeto intitulado “Complicações associadas às cirurgias de transferência da coracoide para tratamento da luxação recidivante do ombro”.

Estudo que pretende vir a ser desenvolvido no Serviço de Ortopedia do CHSJ pelo Prof. Manuel Gutierrez, enquanto orientador da tese de mestrado integrado em Medicina pela FMUP da aluna Ana Catarina da Silva Pereira.

Do ponto de vista científico trata-se de um estudo clínico retrospectivo cujo objectivo principal consiste em avaliar a incidência das complicações associadas às cirurgias de transferência da coracoide nos doentes submetidos a estas intervenções no CHSJ entre 2004 e 2014. Para o efeito, serão consultados os processos clínicos dos doentes submetidos a estas cirurgias, e colhida a informação pertinente a analisar, estando ainda prevista a possibilidade de contacto telefónico com os doentes.

Não existem benefícios, riscos ou incómodos previstos para participantes e não serão realizados questionários.

Não está prevista a obtenção de consentimento informado, o qual, face à natureza do estudo, é dispensável.

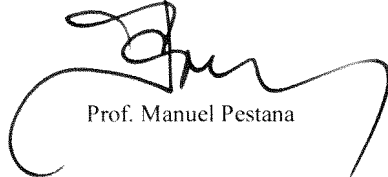
O investigador dispõe da competência científica para realização do estudo, que está autorizado pelo diretor do Serviço de Ortopedia.

O estudo não é financiado e não prevê a realização de quaisquer exames complementares.

Em face da análise do protocolo proponho a sua aprovação pela CES do CHSJ.

Porto, 19 de Abril de 2016

O relator



Prof. Manuel Pestana

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)

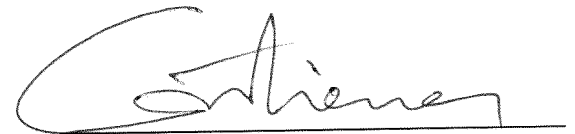
NÃO

NÃO APLICÁVEL

8. TERMO DE RESPONSABILIDADE

Eu, Manuel António Pereira Gutierrez, 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, 07 / Janeiro / 2016



O Investigador Principal

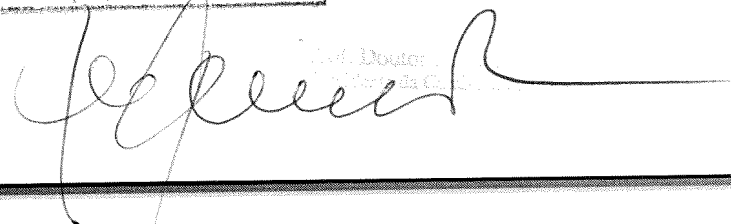
PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO	
emitido na reunião plenária da CES de 22, Abril, 2016	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> A Comissão de Ética para a Saúde APROVA por unanimidade o parecer do Relator, pelo que nada tem a opor à realização deste projecto de investigação. </div> 



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ISSN: 2444-8664

DESCRIPTION

Porto Biomedical Journal (PBJ) is an online free-to-submit and open-access journal devoted to the publication of top quality original research conducted in the biomedical fields, especially within the clinical and basic medical settings. The project aims to provide a valuable collection of generalist biomedical literature freely accessible to the international community, in order to become a reference in the current scientific landscape.

In addition, to ensure the quality and scientific relevance of PBJ, the journal counts with a diversified and international editorial board, and only accepts original research and review articles that undergo a strict revision process in a double-blind refereeing system, a procedure that safeguards the fairness of the article selection process.

As a generalist journal, PBJ accepts both original works and reviews in all biomedical areas, be they basic or clinical research. If you believe in a free and open scientific community and want to take your work one step further and closer to your peers, please consider submitting your work to *Porto Biomedical Journal*, the place "where Science meets Knowledge".

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GUIDE FOR AUTHORS

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Types of article

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These should describe fully, but as concisely as feasible, the results of original clinical, laboratory or biomedical research. *Special note regarding case studies:* Case studies will be considered for publication only in the Letters to the Editor section of the Journal. The average Original Article fills 7 pages in the printed journal, although manuscripts that exceed this may be occasionally accepted for publication at the Editors' discretion. In general, an Original Article should not exceed 3500 words, not including the abstract, figure legends, and references. Abstracts should be 250 words or less. If possible, each figure legend should be held to 60 words or less. Each Original Article may be accompanied by no more than 8 graphic presentations (tables and/or figures)-for example, 3 tables + 5 figures. (Additional text, tables, or figures can be designated as "supplemental" material, which will be included in the PBJ Online Repository. Please note: Original Article manuscripts that are determined to significantly exceed these limits, or that do not include all of the elements listed below, may be returned to the authors for revision prior to review.

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- 2) Have a short, relevant title. Please see the suggestions that appear above (under "A. Original Articles").
- 3) Have a complete title page (see section A1).
- 4) Be accompanied by a short summary that encapsulates the report's findings for a clinically oriented audience (see above).
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- 6) Close with the author's name(s), academic degree(s), institutions(s), and location(s).
- 7) Have no more than nine references.
- 8) List the references as complete bibliographic citations following the closure of the letter (see section above for formatting).
- 9) Present lists of Key words, as relevant (see sections above).
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Correspondence concerning recent publications in the Journal will be considered for publication and accepted based on their pertinence, their scientific quality, and available space in the Journal. If the correspondence is considered acceptable, a response will be requested from the authors of the referenced PBJ article. Upon review and approval by the Editor, the Correspondence and relevant Reply will both be published together. Both Correspondence and Reply manuscripts must:

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- 4) List the references as complete bibliographic citations at the end of the letter with the journal article being discussed as the first reference (see section above). The total number of references should be no more than seven. Replies should include the Correspondence to which they are replying as one of the references.
- 5) Have no more than one graphic presentation (table or figure). (See the section on Graphic Presentations below).
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Review articles. Definitive, in-depth, state-of-the-art reviews of clinical and research subjects. Unsolicited reviews are not generally published in PBJ. Before submitting any unsolicited reviews, please forward an outline to the Editor for consideration.

Systematic reviews and meta-analyses should follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (see <http://www.prisma-statement.org/>). A PRISMA flow diagram (<http://www.prisma-statement.org/documents/PRISMA%202009%20flow%20diagram.pdf>) should be used to describe the steps of the systematic review, and a complete PRISMA checklist (<http://www.prisma-statement.org/documents/PRISMA%202009%20checklist.pdf>) should be provided during submission.

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A brief description of a particular condition that provides insights into diagnosis or clinical management. A case report must make a distinct, novel contribution to the understanding of the etiologic agents, its clinical manifestations, and/or its diagnosis or treatment. Manuscripts must be written in good English (American or British usage is accepted, but not a mixture of these), be no longer than 1000 words and should consist of: Cover Page, Abstract, Introduction, Case, Discussion, Acknowledgements, Conflict of Interest Statement, and a maximum of 9 References.

Rostrum articles (type of article Short review in submission system). Opinion articles about subjects of particular interest and/or debate may be accepted for peer review after preliminary review by the Editor. Proposals for rostrum articles may be emailed to the Editorial Office; they will be evaluated based on level of interest, novelty, and the current needs of the Journal.

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All manuscripts must be submitted online through the PBJ's EVISE Web site at <http://www.evise.com>. <http://ees.elsevier.com/pbj>. Electronic files of the manuscript contents must be uploaded at that Web site, and the onscreen steps should be followed to submit the manuscript to the Editorial Office.

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