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Treatment of anterior glenohumeral instability with Bankart repair versus Latarjet procedure: Isokinetic comparative study

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Treatment of anterior glenohumeral instability with Bankart repair versus Latarjet procedure: Isokinetic comparative study

Bankart and Latarjet isokinetic comparative study

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This study has the approval by the Ethical Committee from our Institution (Comissão de Ética para a Saúde do Centro Hospitalar de São João/ Faculdade de Medicina da Universidade do Porto).

Abstract

Background

Latarjet procedure and Bankart repair are common techniques used for surgical treatment of anterior shoulder dislocation. The purpose of this study is to investigate and compare the possible changes in internal rotation (IR) and external rotation (ER) of shoulder isokinetic strength after Bankart and Latarjet procedures.

Methods

We included 14 patients submitted to shoulder surgery (9 Bankart and 5 Latarjet). Data about gender, age, elapsed time from surgery, sports and professional activity was collected. Rowe score was obtained. The isokinetic parameters evaluated were peak torque to body weight (PTBW), average peak torque (APT), agonist to antagonist ratio (AGON/ANTG) and range of motion (ROM).

Results

The APT in ER of the shoulders submitted to Bankart and the PTBW of the shoulders submitted to Latarjet were significantly lower than the values in the uninvolved shoulder. The fatigue test at 240º/s in IR showed a significantly lower APT in the shoulders submitted to Latarjet comparing with the uninvolved shoulder. The AGON/ANTG was 85.2 at 240º/s in the Latarjet group.

Conclusion

This study showed a deficit in ER for both surgeries, particularly in APT in the Bankart group. Muscle fatigue in IR is an important factor to consider in patients submitted to the Latarjet procedure. Activities where an APT is important might benefit from the use of

the Latarjet procedure, whereas activities where the peak toque is more relevant might benefit from the Bankart repair.

Level of evidence

Level III; Retrospective comparative study; Treatment Study.

Keywords

Bankart repair; Latarjet procedure; isokinetic test; shoulder instability; subscapularis; rotator cuff.

Introduction

Shoulder dislocations are classified according to the position of the humeral head in relation to the glenoid cavity with anterior dislocation accounting for over 90% of all shoulder dislocations.[14,32] The treatment of anterior dislocations may be conservative or surgical but the high rate of recurrences of conservative treatment, particularly among men aged <30 years, people who participate in contact sports and in patients with hyperlaxity or bony defects makes the surgical treatment necessary.[1,8,13,29]

The 2 most used surgical approaches include the Bankart repair to reattach the avulsed labrum to the glenoid rim and Latarjet procedure which consists of the transfer of the coracoid process and conjoined tendon to the anterior edge of the glenoid.[7-9,13,17,25,34] There are some studies comparing the outcomes of these surgeries but there is a lack of studies in literature directly comparing the isokinetic strength of patients submitted to the Latarjet procedure with patients submitted to the Bankart repair.[1,4,5,7,23,43] Bessière *et al.*, reported less recurrence of instability and better Rowe scores in patients who had open Latarjet, over a mean 6 years follow up.[7] Abdul-Rassoul *et al*., demonstrated a higher return to preinjury level in patients who had arthroscopic Bankart surgery comparing to patients who had open Latarjet.[1]

The glenohumeral joint strength is maintained by the synergy of static and dynamic stabilizers, with the dynamic stabilization provided by the rotator cuff muscles playing an important role in the assessment of postoperative rehabilitation.[8,13] The strength of rotator cuff muscles is intimately related with shoulder function and can be used as an indicator of shoulder instability after surgical treatment.[2,17] Isokinetic evaluations are reliable for the evaluation of rotator cuff muscles and may be used to detect impairments in these muscles.[11,18,30]

54 The purpose of this study is to investigate and compare the possible changes in internal
55 and external rotation of shoulder isokinetic strength after Bankart and Latarjet procedures.

Methods

Subjects

Clinical records from patients with anterior glenohumeral instability submitted to shoulder surgery with either Bankart repair or Latarjet procedure by Hospital de São João's surgeons between 2014 and 2018 were retrospectively analysed.

The inclusion criteria were: Patients that underwent anterior instability correction surgery (Bankart or Latarjet) with a minimum follow up of 6 months and maximum 4 years.

The exclusion criteria were: Contralateral shoulder surgery; reinterventions.

A total of 51 patients were submitted to surgery during the inclusion period. Seventeen patients were unable to be contacted for evaluation and 16 were unwilling to participate. Four patients were excluded from the study after exclusion criteria were applied. Finally, 14 patients were included for analysis, 9 submitted to Bankart and 5 to Latarjet. The contralateral healthy shoulder was considered as control.

The study was approved by the Ethics Committee from our institution and all the patients gave their written informed consent.

Clinical evaluation

A shoulder functional evaluation was performed in all patients using the Rowe score which consists of 3 individual measures for motion (20 points), function (30 points) and stability (50 points). A questionnaire was used to record gender, age, elapsed time from surgery, sports and professional activity. Information on weight, height and dominant side was obtained before each test.

Isokinetic strength testing

Isokinetic evaluation was performed with the Biodex dynamometer Multi-Joint System-Pro 4. This assessment was performed by the same investigator and involved both shoulders, beginning with the non-operated shoulder. Subjects were seated upright, with 1 strap across the pelvis and 2 straps across the chest. The shoulders were in a neutral position at 45º of abduction, with elbows at 90º of flexion and forearms in neutral prono-supination position. The dynamometer was internally rotated to 20º and tilted to 50º. The arc of motion was fixed at 60º (30º external rotation and 30º of internal rotation). An explanation of the testing procedure was given before the test began. A correction for gravity was used and the equipment was calibrated according to the manufacturer's guide.

Strength was measured sequentially in the following order in a concentric mode: 5 maximal repetitions at 60º/s, 5 maximal repetitions at 180º/s and 20 maximal repetitions at 240º/s. The participants were verbally encouraged to reach their maximal capacity. A rest period of three minutes between trials was given. The isokinetic parameters evaluated were peak torque to body weight (PTBW), average peak torque (APT), agonist to antagonist ratio (AGON/ANTAG) and range of motion (ROM).

Statistical methods

Independent-samples T test or Mann-Whitey as an alternative were used to compare surgeries (Bankart vs Latarjet). Paired-Samples T test or Wilcoxon as an alternative were used to compare shoulders (involved vs uninvolved). The Shapiro-Wilk test was performed to study normal sample distribution.

Software SPSS (Statistical Package for the Social Sciences) v25.0 was used to perform statistical analysis. A *p*-value of less than 0.05 was considered significant.

Results

The mean age of all individuals in the study was 26.1 ± 8.4 years. Of the 9 patients submitted to Bankart repair, 6 were male (66.7%) and 3 were female (33.3%). All the 5 patients submitted to Latarjet procedure were male (100%). Mean time from surgery to evaluation of all individuals in the study was 23,4 ± 13,1 months. The remaining population characteristics are summarized in **Table I**.

No significant differences between surgeries were found for concentric rotator cuff muscles PTBW (peak torque divided by body mass [Nm/Kg]) and average peak torque (peak torque, measured as APT [Nm]), during internal or external rotation, at either 60º/s, 180º/s or 240º/s. We found no significant differences in AGON/ANTAG and ROM between surgeries. No significant difference was found in the Rowe score between surgeries. We found a mean value of 85.2 for AGON/ANTAG in the Latarjet group (**Table II**).

All the isokinetic parameters measured were higher in the uninvolved shoulder group, although not always with significant difference. Significant differences were found between the involved and uninvolved shoulders for PTBW during ER with lower mean values for the involved shoulder at 60º/s (p=0.002), 180º/s (p=0.013) and 240º/s (p=0.015). A significant lower PTBW was also found in the involved shoulder group at 60º/s during IR (p=0.034) but no significant differences were found at either 180º/s and 240º/s during IR for this parameter between the involved shoulder group and the uninvolved shoulder group. The APT was significantly lower during ER at 60º/s (p=0.010), 180º/s (p=0.015) and 240º/s in the involved shoulder (p=0.015). No significant differences were found between the involved shoulder and the uninvolved shoulder during IR at 60º/s and 180º/s. The APT of the involved shoulder was significantly lower

at 240º/s (p=0.043) when compared to the uninvolved shoulder. No significant differences were found in ROM and AGON/ANTAG between the involved and uninvolved shoulders (**Table III**).

When comparing individually the shoulder submitted to Bankart surgery to the uninvolved shoulder at the parameters where a significant difference was found between the involved and the uninvolved shoulders, we found a significantly lower PTBW in ER at 60º/s (p=0.021) in the shoulder submitted to Bankart surgery, comparing to the uninvolved shoulder and no significant differences were found at 180º/s and 240º/s in ER and at 60º/s in IR. We found a significantly lower APT in the shoulder submitted to Bankart surgery at 60º/s (p=0.021), 180º/s (p=0.018) and 240º/s (p=0.011) when comparing to the uninvolved shoulder in ER and no significant difference was found in IR at 240º/s (**Table IV**).

We found a significantly lower PTBW at 180º/s (p=0.043) and 240º/s in ER (p=0.043) and at 60º/s in IR (p=0.043) in the shoulder submitted to Latarjet procedure comparing to the uninvolved shoulder. No significant difference for PTBW was found at 60º/s in ER. No significant differences were found in the APT between the shoulder submitted to Latarjet procedure and the uninvolved shoulder in ER at either 60º/s, 180º/s and 240º/s. A significant lower APT was found in the shoulder submitted to Latarjet procedure at 240º/s (p=0.043) in internal rotation (**Table V**).

Discussion

Average peak torque and peak torque to body weight

The APT in ER was significantly lower in patients who had Bankart surgery and PTBW was significantly lower in ER at a slower angular velocity of 60º/s. The lower APT in ER agrees with the results of the study of Szuba *et al.*, although, in this study, the APT was significantly lower in both ER and IR and a lower PTBW was found in ER and IR[39] A recent study by Amako *et al.* showed that the PTBW on the shoulder submitted to arthroscopic Bankart repair was only significantly lower until 6 months after surgery for ER and 4,5 months follow-up for IR.[2] These results agree partially with ours since our patients have all been operated for more than 6 months and the only deficit in PTBW we found was in ER at 60º/s. However, Amako *et al.* demonstrated that at 60º/s in ER the values were significantly lower than those at 180º/s at 1,5 months and 3 months after surgery when compared with the uninvolved shoulder.[2] In our study, the deficit in ER at 60º/s seems to have been extended. One possible explanation for the significant difference found in PTBW at 60º/s in ER but not at higher velocities could be the only fair reproducibility for velocities greater than 180º/s.[15] Also, functional tasks can be better represented at slower speeds.[41]

The Latarjet procedure provokes a disruption of the subscapularis which can lead to muscle atrophy and imbalance of the strength of the shoulder's muscles.[3,12] The manipulation of the subscapularis could lead particularly to weakness of IR.[38] In our study, we found mainly deficits in PTBW at the higher angular velocities of 180º/s and 240º/s in ER in patients submitted to Latarjet procedure when comparing the involved and uninvolved shoulders. In IR, the only deficit we found in PTBW was at 60º/s. Caubère *et al*. found a deficit in Peak Torque of both the IR and ER at both 60º/s and 180º/s.[10]

We used 20 repetitions at 240º/s as a fatigue test. We found a deficit in IR at the angular velocity of 240º/s in APT. Edouard *et al.* showed that after Latarjet procedure, there was a significant higher IR fatigability in the involved shoulder, followed by recovery at 6 months and a long-time maintenance at 21 months.[16] In another recent study, a very significant higher fatigability of the IR was found after Latarjet procedure, when compared to the uninvolved shoulder.[10] These studies are not directly comparable to ours because they used a fatigue index, different angular velocities and a different number of repetitions to find the fatigability. Our study shows that the patients submitted to Latarjet procedure still maintain some degree of fatigability of IR due to the result we found in APT at 240º/s. However, at low repetitions, the IR does not seem to be compromised since there are no significant deficit when comparing to the uninvolved shoulder. The PTBW in IR is altered too but only at 60º/s, which might represent an incomplete recovery of subscapularis muscle.

Internal and external rotation

In our study, we found no significant difference in total ROM when comparing patients submitted to Bankart repair and Latarjet procedure. However, we measure the total ROM and did not discriminate the external or internal ROM. In the present study, the total ROM was higher in patients operated with Latarjet procedure, although, the difference was not statistically significant. There are several studies where arthroscopic Bankart repair seems to lead to more limitation of ER than the Latarjet procedure. An *et al.* reported in their systematic review comparing the Bankart repair and Latarjet procedure, a loss of 11.5º in external rotation ROM for the Latarjet procedure and a loss of 20.9º following Bankart repair.[4] Hovelius *et al.*, showed a loss in outward rotation of 11º in patients submitted to Latarjet surgery compared to a loss of 19º in patients submitted to Bankart repair. All the significant differences we found in isokinetic parameters when comparing the shoulders

submitted to Bankart repair with the uninvolved shoulder were in ER, which might be due to the tension that is created by pulling the retracted anterior capsule and labrum to their original position at the glenoid margin.[28] We also found some deficits in isokinetic parameters for ER strength in shoulders submitted to Latarjet. We consider that some ER strength deficit might be happening due to the period after surgery where our patients get the operated shoulder immobilized in internal rotation which is leading to a loss of ER strength. Therefore, directed rehabilitation protocols should be utilized to correct this deficit in strength instead of focusing mainly in the restoration of the ROM.

Agonist to antagonist ratio

Following anterior shoulder instability, one of the main goals is to restore the dynamic stability of the glenohumeral joint. The rehabilitation program should assess the involved AGON/ANTG strength and the goal for rehabilitation should be a ratio between 66% and 75% ER to IR strength, which has been found to be normal.[19,27] There are also specific values for different type of sports.[6,31,33] In our study, we found no significant differences in AGON/ANTG between patients submitted to Bankart repair and patients submitted to Latarjet procedure. Furthermore, the values for AGON/ANTG were between the normal range value of 66% and 75% stated above, with the exception at 240º/s for patients submitted to Latarjet procedure that had a mean value of 85.2%. This reflects that, for both surgeries, the balance of the muscles is maintained. The higher ratio found after the fatigue repetitions at 240º/s in patients submitted to Latarjet procedure might be due to a decrease in IR strength and, therefore, represents a greater external rotation eccentric force compared to the internal rotation concentric force. These results are important since different studies showed that ER/IR muscle imbalance may be a contributing factor to shoulder injuries.[36,37,42]

Rowe score

The Rowe score is a clinical international scoring system often used for the postoperative assessment of anterior shoulder surgery. In the present study, we found no significant difference in the Rowe scores between shoulders submitted to Bankart repair or Latarjet procedure. The Rowe score range from 0 to 100 points and include the possible ratings of excellent, good, fair and poor. The patients included in this study submitted to either Bankart repair or Latarjet procedure achieved a rating considered good with a mean value of 86.7±11,9 and 87±12 respectively. Hurley *et al.*, reported in their systematic review of long-term outcomes of the Latarjet procedure, a Rowe score with a mean average of 88.5.[26] In another systematic review, the long-term outcomes of the Bankart and Latarjet repairs were studied, where they found four studies that reported the results of arthroscopic Bankart repair with reported Rowe scores with an average of 85.5 and seven studies about open Latarjet procedure with reported Rowe scores with an average score of 87.9.[35] Although the Rowe score is frequently used, the relationship between shoulder function and the level of strength recovery has not been well characterized.[3,20] The Rowe score is not useful as an index of when it is the best time to start activities that require a higher performance because it is calculated after the patients started practicing sports or other activities. We think that the isokinetic strength measure of the rotator cuff muscles could give an indication about the better time to resume activities. Therefore, no surgery could be recommended solely by its reported Rowe scores.

Implications

Our results suggest an impairment of the external rotators for the APT in patients submitted to Bankart surgery and an overall impairment of the rotator cuff muscles for PTBW in patients submitted to Latarjet procedure. These results might have implications

in the type of activity that either group should be able to perform. The peak torque is a commonly studied parameter when performing isokinetic measurements but might represent an exceptional situation which not reflects a normal function. The APT provides information about the average production of force and gives an idea to what extent the maximum torque is close to the mean. The impaired capacity to maintain the APT in shoulders operated with Bankart repair could have implications when recommending between the Latarjet procedure and the Bankart repair through the type of activity the patient would want to perform. Sports where a more constant use of the force is needed, such as rowing or swimming, might benefit from the use of Latarjet procedure since, in the present study, the APT seems to be better preserved in the shoulders submitted to this surgery. However, in the present study, muscle fatigue in IR seems to be an important factor to consider in patients submitted to the Latarjet procedure and the difference in fatigability between the agonist and antagonist muscles could be a potential factor of shoulder instability during sports practice, in case of insufficient passive stabilizers.[21,40] On the other hand, patients that would want to practice some throwing sports where the maximal peak torque seems to play a more important role, especially those where higher angular velocities are achieved, like baseball, might benefit from the Bankart repair.

Limitations

The findings of this study did not demonstrate a significant deficit in isokinetic strength when directly comparing the shoulders submitted to Bankart repair versus Latarjet procedure. To the best of our knowledge, there are no previous studies comparing directly the isokinetic strength of the shoulders submitted to one of these two surgical techniques. The reduced number of evaluated patients contributed as a limitation to the statistical analysis as well as to find any significant association between the 2 surgeries. The low participation of patients in our study could be explained by difficulties with dislocation

to the location where the measurements took place as well as the lack of any financial support or justification for absence from work. Several parameters might have affected the isokinetic evaluation, e.g. age, gender, sports and activity level.[22,24] However, we believe a fair comparison between surgeries can be made as we compared the isokinetic measurements of the involved shoulder with the uninvolved contralateral shoulder to exclude individual differences.

Conclusion

This study showed a deficit in ER for both surgeries, particularly in APT in the Bankart group. Direct rehabilitation protocols should be performed to assess this loss of strength.

The IR strength was not completely recovered in tasks involving fatigability of the subscapularis in the Latarjet group and the difference in fatigability between the agonist and antagonist muscles could be a potential factor of shoulder instability during sports practice.

The Latarjet procedure seems to be a better option to recommend for patients that want to practice activities where a more constant use of force is needed and the Bankart repair might be better for patients wanting to practice activities that require an optimal peak torque such as those involving throwing at high velocities.

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Figures and Tables

Table I Population characteristics

Table II Isokinetic parameters and Rowe scores of the shoulders submitted to Bankart repair or Latarjet procedure

Table III Isokinetic parameters of the involved and the uninvolved shoulders

Table IV Isokinetic parameters of the shoulders submitted to Bankart repair and the uninvolved contralateral shoulders

Table V Isokinetic parameters of the shoulders submitted to Latarjet procedure and the uninvolved contralateral shoulders

Table I

	Total (N=14)		Bankart (N=9)		Latarjet (N=5)	
Sex (N;%)						
Male	11	78.6	6	66.7	5	100.0
Female	3	21.4	3	33.3	0	0.0
Age, years (M;SD)	26.1	8.4	27.6	8.6	23.4	8.2
Height, cm (M;SD)	174.3	6.8	173.8	7.8	175.2	5.7
Weight, Kg (M;SD)	70.1	10.8	68.4	12.1	73.0	8.5
BMI, Kg/m^2 (M;SD)	22.9	2.7	22.6	3.1	23.7	2.0
Elapsed time from surgery, months	23.4	13.1	22.7	14.4	24.6	12.0
Sports and activity level (N;%)						
Recreational	9	64.3	8	88.9	1	20.0
Federate	3	21.4	1	11.1	2	40.0
Competitive	2	14.3	0	0.0	2	40.0
Dominant side (N;%)						
right	12	85.7	7	77.8	5	100.0
left	2	14.3	2	22.2	0	0.0
Involved shoulder (N;%)						
right	6	42.9	4	44.4	2	40.0
left	8	57.1	5	55.6	3	60.0

M, mean; SD, standard deviation

Table II

	Bankart		Latarjet		
	M	SD	M	SD	*p*
Agonist to antagonist ratio [%]					
60º/s	72.9	20.8	70.1	15.6	.801
180º/s	73.5	16.1	75.9	23.1	.825
240º/s	70.4	13.4	85.2	13.2	.070
Range of motion [Deg]					
60º/s	55.9	6.2	58.7	1.9	.356
180º/s	56.9	3.1	58.2	0.8	.361
240º/s	57.3	1.6	58.3	0.6	.239
Peak torque to body weight [Nm/Kg]					
External Rotation					
60º/s	32.1	8.7	37.1	8.5	.321
180º/s	33.1	10.4	35.4	9.1	.687
240º/s	36.0	11.8	44.1	9.0	.213
Internal Rotation					
60º/s	46.7	20.0	48.4	11.6	.869
180º/s	46.9	16.1	47.3	5.1	.951
240º/s	52.0	16.4	49.0	12.5	.732
Average peak torque [Nm]					
External Rotation					
60º/s	20.2	7.6	24.9	7.3	.291
180º/s	19.9	6.7	23.7	6.3	.323
240º/s	20.5	7.5	25.9	5.8	.186
Internal Rotation					
60º/s	30.1	15.6	34.5	4.6	.553
180º/s	29.7	14.0	31.0	3.6	.839
240º/s	31.1	12.0	30.5	7.5	.923
Rowe score	86.7	11.9	87.0	12.0	.961

Deg, degrees; M, mean; SD, standard deviation

Table III

	Involved		Uninvolved		
	M	SD	M	SD	*p*
Agonist to antagonist ratio [%]					
60º/s	71.88	18.51	74.71	9.86	.363
180º/s	74.39	18.04	79.31	7.38	.240
240º/s	75.69	14.75	78.50	12.04	.423
Range of motion [Deg]					
60º/s	56.90	5.15	58.86	56.90	.109
180º/s	57.36	2.56	58.33	57.36	.058
240º/s	57.67	1.35	57.98	57.67	.509
Peak torque to body weight [Nm/Kg]					
External Rotation					
60º/s	33.89	8.62	41.89	9.11	.002**
180º/s	33.91	9.62	42.20	11.83	.013*
240º/s	38.92	11.28	45.24	13.29	.015*
Internal Rotation					
60º/s	47.33	16.99	54.22	16.95	.034*
180º/s	47.04	12.95	53.31	14.71	.079
240º/s	50.91	14.70	55.88	14.07	.099
Average peak torque [Nm]					
External Rotation					
60º/s	21.89	7.57	27.60	9.25	.010**
180º/s	21.29	6.55	27.19	9.55	.015*
240º/s	22.42	7.22	27.51	10.49	.015*
Internal Rotation					
60º/s	31.66	12.68	37.19	13.90	.052
180º/s	30.14	11.15	34.11	13.59	.169
240º/s	30.84	10.34	34.71	11.47	.043*

Deg, degrees; M, mean; SD, standard deviation

* $p < 0.05$ ** $p < 0.01$ *** $p < 0.001$

Table IV

	Involved		Uninvolved		
	M	SD	M	SD	*p*
Peak torque to body weight [Nm/Kg]					
External Rotation					
60º/s	32.12	8.66	38.27	8.08	.021*
180º/s	33.09	10.35	36.79	9.60	.093
240º/s	36.04	11.84	38.94	10.55	.066
Internal Rotation					
60º/s	46.73	20.03	49.17	14.58	.374
Average peak torque [Nm]					
External Rotation					
60º/s	20.23	7.60	24.16	7.64	.021*
180º/s	19.94	6.66	23.31	7.28	.018*
240º/s	20.48	7.47	23.43	7.75	.011*
Internal Rotation					
240º/s	31.06	12.05	31.48	9.85	.953

M, mean; SD, standard deviation

* $p < 0.05$

Table V

	Involved		Uninvolved		
	M	SD	M	SD	*p*
Peak torque to body weight [Nm/Kg]					
External Rotation					
60º/s	37.08	37.08	48.40	7.54	.080
180º/s	35.38	35.38	51.94	9.26	.043*
240º/s	44.10	44.10	56.56	10.10	.043*
Internal Rotation					
60º/s	48.40	11.56	63.32	18.65	.043*
Average peak torque [Nm]					
External Rotation					
60º/s	24.86	7.32	33.80	9.31	.078
180º/s	23.70	6.27	34.18	9.77	.080
240º/s	25.92	5.83	34.86	11.52	.080
Internal Rotation					
240º/s	30.46	7.54	40.54	12.95	.043*

M, mean; SD, standard deviation

* $p < 0.05$

Agradecimentos

Ao Prof. Manuel Gutierres pela sua orientação. Sem dúvida a sua dedicação, apoio e confiança foram essenciais na execução deste trabalho.

Ao Engenheiro Pedro Fonseca por toda a ajuda prestada na avaliação isocinética dos doentes e ao Dr. Bernardo Nunes pela disponibilidade e pela partilha de conhecimentos.

Aos meus pais, à minha família e aos meus amigos pelo apoio prestado ao longo destes anos.

À minha avó Maria Luísa, a minha melhor amiga desde sempre.

À minha namorada Samanta, pela paciência, pela calma transmitida, pela amizade e pelo companheirismo.

Anexos

Comissão de Ética para a Saúde do IISJ
Parecer

Projeto de investigação: "Tratamento da instabilidade anterior do ombro com Bankart vs Latarjet: estudo isocinético comparativo".

Promotor:

- Não aplicável.

Concepção e pertinência do estudo

- Trata-se de um estudo sem intervenção, que tem como objectivos: avaliar a possibilidade de existirem diferenças na força de rotação interna e externa do ombro após a cirurgia por instabilidade; comparar os procedimentos de Bankart vs Latarjet relativamente à força isocinética.

- Serão incluídos doentes que tenham sido submetidos a cirurgia de correcção de instabilidade do ombro (Bankart ou Latarjet), com *follow-up* mínimo de 6 meses e máximo de 4 anos.

- Serão recolhidos dados demográficos, dados sobre o Rowe Instability score, actividade desportiva, nível competitivo e tempo decorrido desde a cirurgia.

- Será avaliada a força isocinética dos rotadores internos e externos com recurso ao dinamómetro Biodex System 4 Pro.

- O estudo não terá encargos financeiros para o Centro Hospitalar de S. João.
  - O estudo é importante, pertinente e está bem fundamentado.
- O Investigador Principal, o Prof Manuel Gutierres, docente da FMUP e especialista de Ortopedia do CHSJ, dispõe das competências técnicas e científicas para a realização do estudo.
  - O estudo será realizado no Serviço de Ortopedia do Hospital S. João EPE e no Labiomep, que dispõem das condições necessárias para a realização do estudo, e tem autorização para a sua realização pelo Diretor de Serviço, o Prof. António Sousa.

– **Benefício/Risco**

- Dada a natureza não intervencional do estudo, não haverá procedimentos adicionais nem benefícios, riscos ou incómodos relacionados com a participação do doente no estudo.

– **Respeito pela liberdade e autonomia do sujeito do ensaio**

- A folha de informação submetida à CES contém a informação relevante relacionada com o tipo de estudo proposto.
- Estão consignados os direitos e referenciadas as (não) consequências para o sujeito do estudo em não participar e, uma vez dado o seu consentimento, ter a possibilidade de exercer o direito de não continuar no estudo sem que daí resulte qualquer modificação dos cuidados médicos a prestar.

– **Confidencialidade dos dados**

A confidencialidade dos dados está garantida.

– **Indemnização por danos**

Não aplicável.

– **Continuação do tratamento**

Não aplicável.

- **Propriedade dos dados**

- Não aplicável.

Conclusão

Em face da análise do protocolo do estudo "Tratamento da instabilidade anterior do ombro com Bankart vs Latarjet: estudo isocinético comparativo", proponho a sua aprovação pela CES do HSJ/FMUP.

Porto, 19 de outubro de 2018

O Relator
Prof. Manuel Vaz Silva

Unidade de Investigação

Tomei conhecimento. Nada a opor.

03 de Janeiro de 2019

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

n.º 275/18

DIRECÇÃO CLÍNICA

Aprovado. Ao CA. 4/01/2019

(Prof.ª Doutora Ana Azevedo)

SÃO JOÃO

PEDIDO DE AUTORIZAÇÃO

Realização de Investigação

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

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Nome do Investigador Principal:

Manuel António Pereira Gutierres

Título da Investigação:

Tratamento da instabilidade anterior do ombro com Bankart vs Latarjet: estudo isocinético comparativo

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

Ortopedia e Traumatologia

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, 17 *de* setembro *de* 2018 .

assinatura

Centro Hospitalar São João
Centro de Epidemiologia Hospitalar
26/12/2018

CES-IM005-0

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)
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- [x] Informação dos orientadores
- [x] Informação ao participante
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- [ ] Protocolo financeiro
- [ ] Outros:

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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, 17 *de* setembro *de* 2018

Nome legível: Manuel António Pereira Gutierres

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 Filipe Almeida
Presidente da Comissão de Ética

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Type of Study	Treatment Study	Prognosis Study	Study of Diagnostic Test	Cost Effectiveness Study
LEVEL I	Randomized controlled trials with adequate statistical power to detect differences (narrow confidence intervals) and follow up >80%.	High-quality prospective cohort study with >80% follow-up, and all patients enrolled at same time point in disease	Testing previously developed diagnostic criteria in a consecutive series of patients and a universally applied "gold" standard	Reasonable costs and alternatives used in study with values obtained from many studies, study used multi-way sensitivity analysis
LEVEL II	Lower quality randomized trials (follow up <80%, improper randomization techniques, no masking Prospective comparative study	Lower quality prospective cohort study (<80% follow-up, patients enrolled at different time points in disease) Retrospective study Untreated controls from a randomized controlled trial	Development of diagnostic criteria in a consecutive series of patients and a universally applied "gold" standard	Reasonable costs and alternatives used in study with values obtained from limited studies, study uses multi-way sensitivity analysis
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Appropriate consents, permissions and releases must be obtained where authors wish to include case details or other personal information or images of patients and any other individuals in their JSES submission. It is generally *not sufficient* to anonymise a photograph simply by using eye bars or blurring the face of the individual concerned. Consent documents should be uploaded in the document category Figure Permissions, thus NOT seen by reviewers and NOT unblinding your submission.

PREPARATION OF MANUSCRIPTS

The *Journal* adheres to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (the Vancouver style) developed by the International Committee of Medical Journal Editors as described in the Journal of the American Medical Association (1993;269:2282-6) (also may be retrieved at http://www.icmje.org/ (http://www.icmje.org/)), with the exception that the references must be placed in alphabetic order by author(s) name, numbered sequentially, and appear as superscript numbers in the text but without brackets (see section on "References").

Formatting Manuscripts: The *Journal* suggests that authors follow these guidelines when writing and formatting their work:

Randomized controlled trials should follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines (http://www.consort-statement.org (http://www.consort-statement.org)).

Case reports, case series, cross-sectional and other observational studies should follow the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (http://www.strobe-statement.org (http://www.strobe-statement.org)). If the detailed methods are explicitly stated in the manuscript for single case studies, STROBE is not needed.

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Type the manuscript with margins of at least 25 mm (1 inch). Use double-line spacing throughout the entire manuscript, typing in Times New Roman font size 12, **and include continuous line numbering**. Please use Insert Page Break and begin each of the following sections on a new page: Abstract; Introduction; Materials and Methods; Results; Discussion; Conclusion; References; and Figure and Table Legends. **Figures and Tables should be uploaded separately and individually** (see below). Number the pages consecutively in the lower right-hand corner of each page beginning with the Title Page as number 1. Place a six-word short-form/running title in the header space of the manuscript document. The manuscript file must be in a Word format. Manuscripts without continuous line numbering will be returned to the author.

Word Count Submissions of review and original articles (including abstract, introduction, materials and methods, results, discussion and conclusion) should have a maximum word count of 4,750; submissions which exceed this limit **will be returned to the author** for further revision without being reviewed. Case reports should not exceed 2,250 words.

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The *Journal* has limited space to publish numerous review and technique articles and these are usually solicited by the Review Article and Special Projects Editors. Authors must remember the *Journal* only publishes one review paper per issue, or about 12 per year. In a typical year, the *Journal* receives in excess of 200 review articles submitted in consideration for publication. Hence, the acceptance rate of review articles for the *Journal* is usually around 3%-4%. Authors considering submission of a review article are encouraged to read "What is the value of a systematic review? (*J Shoulder Elbow Surg* 23:1-2, 2014; http://dx.doi.org/10.1016/j.jse.2013.09.001 (http://dx.doi.org/10.1016/j.jse.2013.09.001))" to critically evaluate whether their submission may be suitable for publication in the journal. Please contact the Review and Special Projects Editor (T. Bradley Edwards, M.D.) via ✉ jsesedit@gmail.com (mailto:jsesedit@gmail.com) outlining your proposed article. Video Technique Articles are acceptable but will be published only on the website.

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The first text page of observational and experimental articles and review articles should be an abstract of no more than 250 words. This abstract should state the purpose of the study, basic procedures, essential findings, and principal conclusions, and should be formatted into: Hypothesis and/or Background; Methods; Results; and Discussion and/or Conclusion. The abstract should emphasize new and important aspects of the observation or study, but may not contain data that are not presented in the main text.

Case reports do not require an abstract and are published without abstracts.

For full research articles, include the Level of Evidence of the study performed (see above) and Keywords at the end of the abstract. The authors should assign their own Level of Evidence although this will be reviewed by the *Journal*'s Editorial Staff and should also list 6-8 Keywords that highlight the topic of the article, allowing for easier electronic retrieval.

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The text of observational and experimental articles is divided into 5 sections with the headings: Introduction; Materials and Methods; Results; Discussion; and, Conclusions. Each section should start on a new page. Longer articles may need subheadings within headings to clarify their content. Other articles, such as reviews, case reports and editorials need not take the form of manuscripts describing observational or experimental studies. A case report should include Keywords at the end of the Introduction.

All manuscript texts should be blinded for review purposes. Blind institute location, author initials and references by same authors. To blind an item, use Black Text Highlight Color to black-out the text.

Introduction. The purpose of the article should be stated and the rationale for the study or observation summarized. Pertinent references should be given, but the subject should not be reviewed extensively.

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The Reference List should be in alphabetical order by authors' last name, in double-line spacing, and numbered sequentially. At the end of each reference, please include the Digital Object Identifier (DOI) (http://www.doi.org/ (http://www.doi.org/)) or ISBN number for all references dating from 2002 to today. References with identical author(s) should be listed by youngest first. If there is more than one reference with the same first author, use 2nd, 3rd author etc to decide the alphabetical order. When a reference citation has 6 or fewer authors, list all the authors; when there are 7 or more authors, list the first 6 then "et al." Identify references in the text, tables, and illustration legends by superscript Arabic numerals without brackets. References must conform to Vancouver style. Abbreviate titles of journals according to the style used in *PubMed*.

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2006;15:436-439. doi:10.1016/j.jse.2005.03.008

Book chapter: 2. Zarins B, Prodromos CC. Shoulder injuries in sports. In: Rowe CR, editor. The shoulder. New York: Churchill Livingstone; 1988. p. 411-33. (ISBN No. 978-0443084577)

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Authors are requested to upload their full databases of studies, both clinical and basic science, as Supplemental Files. This information should be both blinded and anonymized. At present this is not mandatory, but recommended. Please use standard files types. Supplemental Files are published online as a link; the JSES print edition includes details of links.

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Measurements of height, length, weight, or volume should be reported in metric units. Temperatures should be given in degrees Celsius; blood pressures should be given in millimeters of mercury. All laboratory measurements should be reported in the metric system.

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Only standard abbreviations should be used, and abbreviations should be avoided in the title or abstract. The full term for an abbreviation should precede its first use in the text unless it is a standard unit of measurement.

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Letters to the Editor should be sent to the Editor-in-Chief of the *Journal* via the EES system following the guidelines for all other submissions. Letters should be no longer than 2 pages in length. Letters should be signed by all authors and concern only articles that have been published recently in the *Journal of Shoulder and Elbow Surgery*. A response to the letter will be requested from the author of the article in question, and both the letter and response will be published together if there is a response.

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Announcements of participating society activities must be received at least 10 weeks before the desired issue of publication. Send announcements to the office of the Editor-in-Chief.

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