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DOI
10.1016/j.arthro.2023.07.060

Publication date
2023

Document Version
Final published version

Published in
Arthroscopy - Journal of Arthroscopic and Related Surgery

Citation (APA)
Verweij, L. P. E., Sierevelt, I. N., van der Woude, H. J., Hekman, K. M. C., Veeger, H. E. J., & van den Bekerom, M. P. J. (2023). Surgical Intervention Following a First Traumatic Anterior Shoulder Dislocation Is Worthy of Consideration. *Arthroscopy - Journal of Arthroscopic and Related Surgery*, *39*(12), 2577-2586. https://doi.org/10.1016/j.arthro.2023.07.060

Level V Evidence

Surgical Intervention Following a First Traumatic Anterior Shoulder Dislocation Is Worthy of Consideration

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Abstract: Up to 60% of patients experience recurrence after a first traumatic anterior shoulder dislocation (FTASD), which is often defined as having experienced either dislocation or subluxation. Thus surgical intervention after FTASD is worthy of consideration and is guided by the number of patients who need to receive surgical intervention to prevent 1 redislocation (i.e., number needed to treat), (subjective) health benefit, complication risk, and costs. Operative intervention through arthroscopic stabilization can be successful in reducing recurrence risk in FTASD, as has been shown in multiple randomized controlled trials. Nevertheless, there is a large "gray area" for the indication of arthroscopic stabilization, and it is therefore heavily debated which patients should receive operative treatment. Previous trials showed widely varying redislocation rates in both the intervention and control group, meta-analysis shows 2% to 19% after operative and 20% to 75% after nonoperative treatment, and redislocation rates may not correlate with patient-reported outcomes. The literature is quite heterogeneous, and a major confounder is time to follow-up. Furthermore, there is insufficient standardization of reporting of outcomes and no consensus on definition of risk factors. As a result, surgery is a reasonable intervention for FTASD patients, but in which patients it best prevents redislocation requires additional refinement.

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Shoulder, or glenohumeral, dislocations are painful, and shoulder instability limits patients in performing activities of daily living, sports, and work.[1,2] The glenohumeral joint is the most frequently dislocated joint, of which > 95% of dislocations are traumatic and occur in the anterior direction.[3] Joint stability is maintained by the structures that form the glenohumeral joint (i.e., structural component) and muscle control (i.e., functional component), and the experienced degree of instability is related to fear/anxiety and coping (i.e., mental component). When the structural component is damaged, it becomes increasingly difficult for the functional component to compensate, which leads to a redislocation when compensation fails. Up to 60% of patients experience recurrence after a first traumatic anterior shoulder dislocation (FTASD), which is often defined as having experienced either a (complete) redislocation or subluxation of the shoulder

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The authors report that they have no conflicts of interest in the authorship and publication of this article. Full ICMJE author disclosure forms are available for this article online, as supplementary material.

Received July 30, 2023; accepted July 31, 2023.

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0749-8063/231077

https://doi.org/10.1016/j.arthro.2023.07.060

joint.[4,5] Operative intervention through arthroscopic stabilization can be successful in restoring the structural component and therefore reduces recurrence risk, as has been shown in multiple randomized controlled trials (RCTs).[6-9] Nevertheless, there is a large "gray area" for the indication of arthroscopic stabilization, and it is therefore heavily debated which patients should receive operative treatment. A Delphi consensus study among shoulder specialists in the United States showed that out of 162 clinical scenarios that included FTASD patients, only 8 (5%) reached a strong consensus for recommendation of operative treatment.[10] Basically, there is an effective operative intervention available, but it is unclear which patients should receive it. Despite the gray area and debate, there is a clear international increase of shoulder instability surgery, demonstrating a 77% increase between 1997 and 2014 in Finland and an 18% increase between 1994 and 2006 in the United States according to their national databases.[11-13] The justification of surgical intervention is based on a clinical and ethical discussion, which is guided by the number of patients who need to receive surgical intervention to prevent one redislocation (i.e., number needed to treat; generally acquired by performing RCTs), (subjective) health benefit, complication risk and costs.[14,15] Despite multiple RCTs patient selection criteria for FTASD therapy remain undetermined.

Design of Current RCTs

RCTs are a suitable study design to get an unbiased assessment of whether a specific treatment is more effective than the alternative in a specific patient group. A meta-analysis by Belk et al that included RCTs with 2-year follow-up demonstrated a (large) reduction in redislocation rates when patients were allocated to operative treatment compared to nonoperative treatment.[6] However, when looking at the redislocation rate of the individual RCTs, they varied between 2% to 19% in the operative and 20% to 75% in the nonoperative treatment group.[6] These varying proportions can probably be explained by length of follow-up and inclusion criteria and possibly by postsurgical rehabilitation, for which limited evidence is available. Length of follow-up should correspond with the duration of time that is needed for sufficient events to occur in both groups to accurately assess the primary outcome. Two prospective cohort studies followed up all FTASD patients who did not receive an operative intervention and registered whether they experienced a redislocation until 8 and 10 years after the first dislocation.[16,17] These studies demonstrated that 87% (general population) and 75% (adolescent population) of all redislocations occurred within 2 years.[16,17] However, 2 prospective cohort studies that both followed up patients until 10 years after operative treatment after FTASD demonstrated that only 40% (athlete population) and 69% (general population) of all redislocations occurred within 2 years.[18,19] It can therefore be questioned whether redislocation rates were underestimated in the operative treatment group at 2-year follow-up compared to nonoperative treatment, because there is a larger amount of redislocations that are still expected to occur. Fortunately, 2 RCTs confirmed the effectiveness of the intervention at long-term follow-up by reporting redislocation rates 10 years after treatment, after which the outcome is less likely to be biased by follow-up duration.[7-9]

The subject populations at study in RCTs can also lead to bias when the results of the study are extrapolated to a group that was not included in the trial or the results were underpowered for a specific subgroup. RCTs demonstrating relatively high redislocation rates in both intervention and conservative treatment groups evaluated a high-demand military population or a very young and active patient group, which are considered to have a high risk of failure after both operative (intervention) and nonoperative (control) treatment, and these results cannot be extrapolated to other patient groups.[4,20-23] Risk factors can help us define inclusion criteria and identify suitable candidates for RCTs by selecting patients who bear a specific risk profile for redislocation, which can be managed with the intervention of interest (Fig 1). Unfortunately, selecting patients is more complex than what is presented in Figure 1, because risk factors can influence each other and the effect of risk factors is often reduced and not absent after the intervention. This is also the rationale for randomization in trials, as randomization balances the effect of (unknown) risk factors in both groups. Furthermore, the effect of risk factors can drastically change based on patient behavior, for example, when patients quit or change sports.

When we aim to maintain the high reduction in redislocation rate in the intervention group, but also want to realize a low redislocation rate and prevent overtreatment, risk factors can assist in forming inclusion and exclusion criteria. For example, arthroscopic stabilization can be effective in young individuals, but less effective in specific young individuals, such as those participating in collision sports.[24] It is important to understand the effect of risk factors in specific patient groups and following specific treatment options to form strict inclusion criteria. The current evidence on risk factors is inconsistent after operative and nonoperative treatment and incomplete for nonoperative treatment FTASD patients, which hampers defining the inclusion criteria for new RCTs or nonrandomized comparative studies based on known risk factors.[9,20,21,23,25-29] Risk factors can be identified through RCT data; however, a large sample size is often needed to obtain sufficient power. Steyerberg[30] introduced the rule of thumb that at least 10 events need to occur per risk factor, which

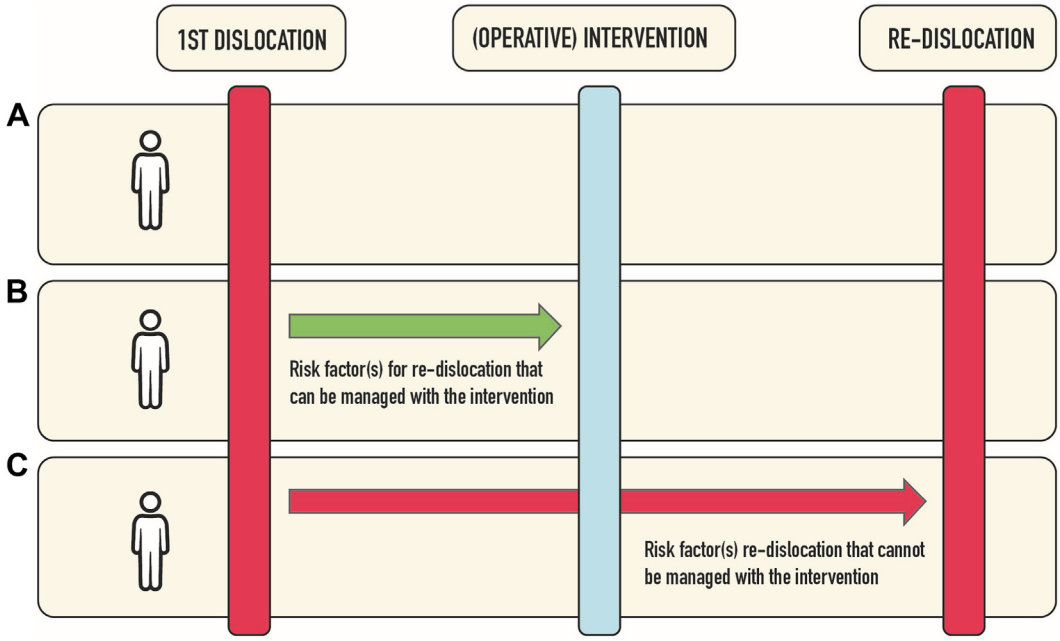

Fig 1. A redislocation or undesired event can be prevented when a patient bears specific risk factors (indicated by the arrows) that can be managed with an intervention (indicated by the blue bar). This can hypothetically lead to the following patient groups: patient A that bears no risk factors for redislocation where no treatment suffices, patient B that bears risk factors for redislocation that can be managed by performing the (operative) intervention, and patient C that bears risk factors that cannot be managed with the intervention, where an alternate (operative) intervention is needed. Inclusion criteria should focus on patient B as a suitable candidate for a randomized controlled trial to the determine the effectiveness of the (operative) intervention, because it is most likely effective in preventing redislocation.

generally leads to a large required sample size. This can be challenging to realize through RCT data and can be more easily acquired by performing cohort studies or combining data from previous studies.

Combining RCTs With Cohort Studies

When looking at studies that identified risk factors after operative, nonoperative, or no treatment, many inconsistencies and large heterogeneities ($I^2 > 50\%$) were observed in meta-analyses that pool risk factor data.[23,29,31] Important explanations for this heterogeneity include retrospective study designs that are prone to bias, dichotomization of continuous variables, differences in definition of redislocation or the factors that are used to predict redislocation and selection bias. In addition, underpowered analyses and pooling averages instead of using individual patient data can lead to inaccurate results.[5,30] Risk factors are not just associated with redislocation and can also influence each other. Barrow et al.[32] provided an excellent example of why this is important to consider in their study that assessed the association of the distance to dislocation (DTD) concept with redislocation. The DTD concept is an extension of the dichotomous on-track/off-track concept, which estimates whether the humeral head and glenoid can maintain contact based on the size and location of the Hill-Sachs lesion and available glenoid surface (on-track).[33,34] The DTD concept is a continuous variation that calculates how close a Hill-Sachs lesion is to being off-track and is defined as "the distance between the medial edge of the Hill-Sachs lesion and the anterior edge of the glenoid track."[35] Yamamoto et al.[36] showed that a smaller distance led to worse Western Ontario Shoulder Instability Index (WOSI) scores, but found no association with redislocation, whereas Li et al.[35] showed that a smaller distance was associated with redislocation following an arthroscopic Bankart repair.[37] Barrow et al.[32] were able to divide their cohort in collision and non-collision athletes and showed — despite an overall association between DTD and redislocation - that a smaller DTD did not lead to a higher redislocation rate (13% at 22mm to 16% at 0mm) in collision athletes, whereas the redislocation rate steadily increased with a smaller DTD (0% at 22 mm to 15% at 0 mm) in noncollision athletes (Table 1). A similar observation was done by Verweij et al., who showed that DTD was not predictive for redislocation in a military population, both supporting the hypothesis that the risk factor DTD shows a different effect in different patient groups, in this case possibly patients with "mid-range instability."[38] The included patients might therefore explain the different findings of Yamamoto et al.[36] and Li et al.[35] and show that when designing an RCT in which the glenoid track concept is used to include/exclude or stratify patients, it is important to take this patient group into account.

Table 1. Redislocation Rates*

DTD Threshold (mm)	Collision Athletes	Noncollision Athletes	P Value
0	10/61 (16.4%)	19/127 (15%)	.48
2	10/61 (16.4%)	18/126 (14.3%)	.43
4	10/61 (16.4%)	17/125 (13.6%)	.38
6	9/60 (15%)	16/122 (13.1%)	.45
8	7/57 (12.3%)	14/119 (11.8%)	.55
10	7/55 (12.7%)	7/102 (6.9%)	.17
12	7/50 (14%)	5/91 (5.5%)	.08
14	6/41 (14.6%)	1/74 (1.4%)	**.01**
16	5/34 (14.7%)	1/61 (1.6%)	**.02**
18	4/29 (13.8%)	0/51 (0%)	**.02**
20	3/23 (13%)	0/42 (0%)	**.02**
22	2/15 (13.3%)	0/17 (0%)	**.04**

DTD, distance to dislocation.

Data are presented as events observed in the cumulative total sample per 2 mm intervals of the DTD threshold and includes the corresponding percentage. The *P* values in bold indicate a statistically significant difference as found by the authors.

*As reported by Barrow et al. in collision and noncollision athletes according to DTD thresholds, where a smaller value indicates that the Hill-Sachs lesions is closer to be being off-track (32).

Exploring the effect of risk factors requires individual patient data and studies evaluating the same factors under the same conditions, which is currently inconsistent.[39] The benefit of cohort studies is clear, but acquiring a large sample size can be challenging and is often only reached by combining multicenter data that collected data for the same risk factors.[30] How should we design and facilitate cohort studies, improve the quality, and know where to look?

Outcomes: Defining "Subjective" Treatment Success

Treatment success is not only defined by redislocation but also includes the experience and goal of the patient. There has been a paradigm shift toward using more patient-reported outcome measures (PROM) in orthopaedic research, which led to many PROM tools for which a consensus has yet to be reached.[40] RCTs have demonstrated conflicting results, often showing a decrease in redislocation rates and no difference in PROM at final follow-up that measure overall clinical improvement, such as the WOSI.[6,7] When designing RCTs and cohort studies, it is important to consider why outcomes are chosen, whether they measure what is aimed to be measured and whether they align with what the patient aims to achieve when undergoing a specific treatment.

Timing, Reporting Averages, and Choosing Outcomes

RCTs often report the average outcome for a PROM at specific time points along with redislocation rates. However, when looking at the WOSI or American Shoulder and Elbow Score reported in RCTs that compared treatment options for shoulder instability, it can be observed that the average maximum improvement of the cohort is generally already reached at 6 months after any treatment.[26,27,41-46] The same is observed for return to sport, with return-to-sport criteria generally aiming at a return at around 6 months.[47] A follow-up of 2 years or longer is probably not necessary to measure these outcomes for the average patient.[26,27,41-46] However, monitoring patients at individual level could be useful to identify outliers because of redislocation, complications, or delayed recovery. The reported standard deviations are generally high, indicating that there is a considerable number of patients that follow a clinical improvement pattern that deviates from the average pattern. Besides from timing, it is important to determine what PROM should be measured to obtain the desired information and how it should be interpreted. The WOSI score is a validated and widely accepted instability-specific PROM tool but—as with most PROM tools—broadly assesses patient-centered therapeutic response after treatment.[36,48] Warth et al.[49] showed that the most important expectation of patients before shoulder surgery and reason for seeking treatment is for the "shoulder to be back to the way it was before the problem started." Simply asking this question through the single assessment numeric evaluation has shown to be reliable, valid, and responsive in patients with shoulder pathologies and correlated with the Rowe score.[50,51] Do we need 21 questions to evaluate whether the shoulder is "back the way it was," or is 1 question sufficient, and can we use the other questions to get a more detailed overview of other aspects, such as return to sport or level of function? This does not necessarily mean that the WOSI is redundant, but with 28 available PROM tools in shoulder instability research, it is necessary to reach a consensus on *why*, *what*, *when*, and *how* outcomes should be measured and interpreted to answer our research questions and to be able to pool and compare results.[40] This can also include current PROM tools or an adaption of these tools. Finally, as previously mentioned in the guideline for reporting clinical significance by Harris et al.,[52] determining clinical importance of the studied population and reporting the number of patients meeting minimal clinical important difference, patient-acceptable symptomatic state, substantial clinical benefit, and maximal outcome improvement can assist in the interpretation of PROM.

Relationship Between Redislocation and PROM

Patients can have a bad mindset or experience a lifestyle change when filling in a questionnaire. There has been more attention for the relationship between redislocation and PROM and factors that influence

treatment success that are not necessarily related to the effectiveness of the treatment. For example, (1) factors that predict whether patients are dissatisfied or experience redislocation do not align, (2) psychological readiness to return to sport is associated with a successful return, (3) lifestyle changes can influence a successful return to (the same level of) sport and (4) kinesiophobia is associated with a lower risk of redislocation.[53-56] The latter is an example of a paradoxical phenomenon in which patients are protected from experiencing a redislocation by an unfavorable aspect that we intent to treat, as it is associated with worse subjective outcomes.[2,57,58] Kinesiophobia can possibly be treated with physical therapy, for which little evidence is available about the approach or effectiveness in instability patients, but this treatment may reduce the protective effect. Appropriate timing of measurement and looking at individual patient data will be important to further explore this growing field of interest. Furthermore, it could contribute to patient selection for comparative studies and how treatment success is defined in the future.

Defining and Selecting Risk Factors and Outcomes

Considering the incidence of FTASD, we will need to rely on combining (inter)national multicenter data to obtain sufficient power in cohort studies.[30,59,60] To provide high-quality data and facilitate data sharing, professionals in biostatistics urge us to (1) measure the same risk factors and outcomes under the same definitions and (2) use parameters that can be measured with high precision.[30] Trasolini et al.[29] showed that in current risk factors studies there are many inconsistencies in outcomes—which is partly caused by different definitions—and different risk factors are evaluated. This hampers pooling data and obtaining sufficient power to evaluate the risk factors. There is no consensus on definitions for many risk factors and outcomes. Examples include (1) there being numerous glenoid bone loss measurement methods available, which have proven to lead to substantial differences in bone loss percentage; (2) a high variety in prevalence and definitions of pathological lesions associated with shoulder dislocations; and (3) simplified versions of complex outcomes such as return to (preinjury level of) sport, which can be influenced by (1) not all patients wishing to return, (2) patients changing sports, (3) patients being satisfied with returning to a different level, and (4) patients being unable to return for a reason that is not related to treatment or shoulder pathology.[61-63] These examples illustrate the need for a consensus when we aim to combine (inter)national data and prevent bias caused by differences in measurement and interpretation. Because unified international definitions can be difficult to realize, it is important for authors to report *what* was measured and *how* parameters and outcomes were defined.

Challenges and Opportunities in Cohort Studies

The challenges of (prospective) cohort studies to identify risk factors are clear: it can be costly and a large sample size is needed that involves multidisciplinary (inter)national multicenter collaboration. However, we believe the following opportunities outweigh these challenges and can assist in defining which patients benefit from (early) surgical intervention after FTASD: (1) the quality of existing cohort studies after both operative and nonoperative treatment can be improved by combining existing data—for example from the RCTs and prospective cohort studies that collected data for the same risk factors—and re-evaluating parameters under the same definitions; (2) there is a targetable imbalance between risk factors that have been identified after nonoperative or no treatment and operative treatment in favor of operative treatment, which could be explained by more easily accessible data, a preoperative magnetic resonance imaging (MRI) or computed tomography (CT) scan, easier patient identification, and easier management with an all-orthopaedic research team in cohort studies.[22,23,31]

Opportunities for Cohort Studies

As mentioned before, factors that are associated with failure after both nonoperative and operative treatment can be used to identify which patients are most likely to benefit from (early) surgical intervention. When defining the domains for risk factors, they can roughly be divided in demographic, pathological (or damage that is the result of the dislocation), and patient-specific factors, which also includes factors that make the patient biomechanically more vulnerable to experience a dislocation. Besides from the study by Salomonsson et al.[64] and Dyrna et al.,[65] who had a sample size of 51 and 54 patients, cohort studies with nonoperative FTASD patients only evaluated demographic data (mainly age), and data that can be acquired from a radiograph in a relatively small sample size.[4,16,17,22,54,66-76] An MRI or CT scan is often not performed after FTASD at the emergency department, but it can provide us with some essential information in a homogenous patient group: (1) to what extent pathological factors, such as bone loss, are associated with redislocation, (2) whether performing an MRI or CT is beneficial after FTASD to select patients for (early) surgical intervention, and (3) evidence for which factors that make a patient biomechanically potentially more vulnerable are associated with redislocation. This can only be acquired through prospective design, because the MRI/CT is not part of standard care when

FTASD patients are admitted to the emergency department. When the imbalance in data collection is addressed and the effect of the risk factors is clarified, they can provide crucial information for which patients should be included in future RCTs or which aspects are important to focus on in nonrandomized comparative studies.

Potential Risk Factors Based on Biomechanics

Understanding biomechanical vulnerability caused by morphologic differences between individuals may clarify why some patients experience a redislocation and allow more targeted surgical treatment.[77] Several studies contributed to the rationale that differences in glenoid morphology are associated with redislocation risk: (1) studies comparing glenoid morphology between patients who experienced a dislocation to healthy individuals found that the glenoid was more flat and anteverted in the dislocation group; (2) cohort studies following patients after surgical treatment demonstrated an association between glenoid version and inclination and redislocation and (3) a cadaver study by Eichinger et al.[78] showed that both anteversion and retroversion angles can lead to highly unstable shoulders.[79-83] Furthermore, there are conflicting results regarding altered scapular kinematics or hyperlaxity and the association with redislocation.[23,84,85] Finally, considering that glenoid bone loss is strongly associated with redislocation following operative treatment, it is likely that relatively narrow glenoids—or glenoids with a more oval shape, with relatively less width compared to the height—have a higher risk of redislocation.[23,34,86] To what extent these factors are associated with redislocation after both operative and nonoperative treatment is unclear. It would be clinically and scientifically valuable to perform CT/MRI in patients after FTASD that will not receive surgical treatment to determine the effect of these factors in a homogenous patient group that is not influenced by alterations that are the result of surgical treatment.

Conclusions

In summary, there is an effective operative intervention available for FTASD patients, but is it unclear in which patients it leads to both a reduction in redislocation rates and a low risk of redislocation. Cohort studies will need to identify risk factors and to what extent they are associated with redislocation or other undesired outcomes in both the intervention and control group to define inclusion criteria for RCTs. However, the following shortcomings need to be addressed to facilitate high-quality shoulder instability research: (1) there is insufficient awareness for standardization, timing, and reporting of both redislocation and PROM; (2) there are many inconsistencies in selection and definitions of risk factor and outcome parameters; and (3) the quality of cohort studies overall is low, inconsistent after operative and nonoperative treatment, and incomplete for nonoperative FTASD patients. There are currently 2 trials registered in the database www.clinicaltrials.gov that compare operative to nonoperative treatment after FTASD that have a follow-up of 1 year and 2 years, with the latter assessing WOSI and return to sport at 2 years and no prospective FTASD cohort studies, highlighting the importance of awareness for these shortcomings.[87] Using homogenous outcomes, risk factors, and definitions will allow for data comparison and data sharing to increase the sample size and facilitate comparability. Because this is difficult to realize on an international scale, it is important for authors to report *what* and *how* parameters and outcomes were measured. Finally, it is important that a consensus is reached with regard to how treatment success and outcomes are defined. The Core Outcome Measures in Effectiveness Trials initiative raises awareness for current problems with outcomes in scientific research and encourages development and uptake of core outcome sets, in which they promote patient and public involvement.[88,89] A core outcome set is a set of agreed standardized outcomes that should be measured and reported in clinical trials and includes *what* should be measured and reported and *how* this should be measured. We believe that when these points are addressed in future study designs, it may help us to determine which patients benefit from (early) surgical intervention after FTASD.

Acknowledgments

The authors thank T. H. Staal for designing the image presented in the article.

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