ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ
ΠΜΣ «Μεθοδολογία Βιοϊατρικής Έρευνας,
Βιοστατιστική και Κλινική Βιοπληροφορική»

Θέμα:

«Ποιοτική αξιολόγηση Τυχαιοποιημένων Κλινικών Μελετών για την Αρθροσκόπηση Ισχίου στην Μηριαιοκοτυλιαία Πρόσκρουση από το 2008 έως το 2018»

"Assessment of the reporting quality of RCTs for Hip Arthroscopy in Femoroacetabular Impingement published from 2008 to 2018"

Τριμελής επιτροπή:

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Έτος υποβολής ΜΔΕ: 2018

Α. Περίληψη

Εισαγωγή: Το σύνδρομο της μηριαιοκοτυλιαίας πρόσκρουσης είναι μια από τις σημαντικότερες αιτίες άλγους του ισχίου σε νέους ενήλικες. Χαρακτηρίζεται από μη φυσιολογική επαφή της κεφαλής του μηριαίου και της κοτύλης. Η χρήση της αρθροσκόπησης του ισχίου ως θεραπεία έχει αναπτυχθεί πολύ τα τελευταία χρόνια λόγο των μειωμένων επιπλοκών σε σύγκριση με άλλες χειρουργικές τεχνικές.
Σκοπός: Σκοπός της εργασίας είναι να αξιολογηθούν τυχαιοποιημένες ερευνητικές μελέτες που συγκρίνουν την αρθροσκόπηση του ισχίου με άλλες θεραπευτικές προσεγγίσεις για την αντιμετώπιση του συνδρόμου.
Μεθοδολογία: Ελέγχθηκαν οι ηλεκτρονικές βιβλιοθήκες των Pubmed, Cochrane Library, Science Direct, Google scholar και το αρχείο των Clinical trials των Ηνωμένων Πολιτειών από το 2008 έως σήμερα. 16 άρθρα εμφανίστηκαν από τα οποία κρίθηκαν κατάλληλα για να συμπεριληφθούν στην μελέτη τα 5. Για την αξιολόγηση των τυχαιοποιημένων κλινικών μελετών χρησιμοποιήθηκε το CONSORT Checklist
Αποτελέσματα: Μια μελέτη δεν δημοσίευσε τα αποτελέσματα της δοκιμής και αξιολογήθηκε μόνο για τα υπόλοιπα κριτήρια. Δύο από τις πέντε δοκιμές πέτυχαν μέτρια σκορ (21/37 και 20/37) ενώ οι δύο άλλες πολύ υψηλά (31/37 και 30/37)
Συμπεράσματα: Παρόλο που ο αριθμός των τυχαιοποιημένων κλινικών μελετών για την σύγκριση της αρθροσκόπησης με άλλες θεραπείες είναι ακόμα περιορισμένος τα αποτελέσματα τα οποία βασίζονται στο CONSORT checklist ήταν πάνω από το μέτριο, δείχνοντας από μέτρια έως μεγάλη συμμόρφωση.

Λέξεις κλειδια: Μηριαιοκοτυλιαία, πρόσκρουση, αρθροσκόπηση, ισχίου, τυχαιοποιημένη, δοκιμή

A.Abstract

Introduction: Femoroacetabular impingement syndrome is an important cause of hip pain in young adults. It is characterized by excess contact between the femoral neck and head and the anterior rim of the acetabulum.
Purpose: The purpose of this study is to assess the reporting quality of randomized controlled trials (RCTs) for Hip Arthroscopy effectiveness, in Femoroacetabular Impingement, compared to other therapeutic methods.
Methods: Electronic databases of MEDLINE (Pub Med), Cohrane Library, Science Direct, Google scholar and United States Clinical trials registration from 2008 until today. From 16 scientific papers, 5 were selected as appropriate for the study. For the assessment of the randomized controlled trials the CONSORT Checklist was used assessing the report of the 37 key terms.
Results: One study was not reporting results yet but in the rest of the sections complied with the checklist in 21 out of the 25 items. Two out of five of the trials achieved moderate score (21/37 and 20/37) and two trials achieved high scores (31/37 and 30/37).
Conclusions: Although there are limited RCT's, that compare hip arthroscopy to other treatments for FAI, the results based the CONSORT checklist have been more than adequate indicating moderate to high compliancy.

Key words: Femoroacetabular, impingement, arthroscopy, hip, randomized, trial

B. Introduction

Femoroacetabular Impingement (FAI) syndrome is a recently described pathology of the hip and a cause of hip pain in young adults (1). It is a result of shape and size mismatch between the femoral head-neck and the acetabulum. There are two types of FAI: cam and pincer. Cam type, where the morphology of femoral neck-head junction is thicker and with insufficient concavity and pincer type, where acetabulum extends beyond its normal depth and over-covers the femoral head (2). Many patients have a combination of these two types of impingement (mixed type). Both types are range of movement related disorders and they are characterized by symptoms, clinical signs and imaging findings (3). The repetitive compressive and shear forces within the joint can cause damage to the acetabular labrum and cartilage, which is believed that can lead to hip osteoarthritis (OA) (2,4). Alpha angle greater than 83 degrees has an odds ratio 9.66 for the development of hip osteoarthritis within 5 years follow up (6).

Hip osteoarthritis is an important factor of reduced quality of life and high healthcare costs (5). Current concepts for the treatment of FAI are surgical and non-surgical approaches. Conservative treatment involves physiotherapy, hip corticosteroid injections and anti-inflammatory drugs (7). The surgical approaches are either open or arthroscopic. Regardless of the technique used the recommended surgical intervention includes the correction of bony anomalies through osteoplasty, as well as debridement or repair of chondral, labral, and soft tissue defects (8). Open approaches consist by either the Safe Surgical Dislocation approach described by Ganz in 2001(9) and the mini-open anterior approach of the hip described by Hartmann in 2009 (10). The arthroscopic surgery to treat FAI (11,12) is an increasing trend and is performed at a growing rate worldwide the last decade (13). Initially, open surgery was the most frequently used method to treat FAI, but since many case series published positive outcomes from hip arthroscopy for FAI (14,15), hip arthroscopy is used more often. Hip arthroscopy proves to be safer, with less complications and a shorter recovery time than open surgery (16). Until few years ago there was minimum evidence from randomised controlled trials (RCTs) that compare hip arthroscopy with other interventions (17). RCTs can help clinicians to clear out whether arthroscopic surgery of the hip has a beneficial effect on patient's symptoms or can prevent osteoarthritis. However, randomized trials can yield bias if they lack methodological thoroughness. The purpose of this study is to assess the reporting quality of randomized controlled trials (RCTs) for Hip Arthroscopy effectiveness in Femoroacetabular Impigment comparing to other treatments.

C. Methods

A search was made of English-language randomized controlled trials published in MEDLINE (Pub Med), Cohrane Library, Science Direct, Google scholar and United States Clinical trials registration from 2008 until today. To ensure the inclusion of all relevant trials, there was a terminology search to electronic databases defined by the following terms: ("femoroacetabular" OR "femoro-acetabular" OR "femoro acetabular") AND (impingement OR "impingement syndrome") AND (arthroscopy OR arthroscopic) AND (randomised OR random) AND (controlled OR control) AND (trial OR trials).

Eligibility criteria for including, clinical trials in the study, were phase III clinical trials that compare hip arthroscopy surgery to any other possible treatment for femoroacetabular

impingement. This included physiotherapy, anti-inflammatory drugs, hip injections, open surgery and/or navigated surgery. Studies should compare patient of FAI with no previous

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

surgery of the hip and not established osteoarthritis of the hip. Studies eligible for assessment were not limited to blinding of the participants and to follow up of the patients.

The assessment of the randomized controlled trials conducted with the help of the CONSORT Checklist. The CONSORT Checklist is a worldwide used assessment tool that helps to improve the reporting quality of randomized control trials (RCTs). The latest version described by Schulz et al (18), in 2010, updates the reporting guidelines based on the latest methodological evidence and accumulating experience. It includes a checklist of 25 items categorized in 6 sections: "Title and Abstract", "Introduction", "Methods", "Results", "Discussion" and finally "Other information". 12 items are divided into a and b parts, giving a total of 37 points to score per paper. All items were investigated in terms of whether they were reported and not whether they were actually carried out during the trial. An item was characterised with a "yes" if it was clearly reported and with a "no" if it is partially reported or not reported at all.

Data were analysed using Microsoft Excel. The total quality of the reporting score on the CONSORT checklist was calculated as a proportion of the "yes" rated applicable items with a possible range of 0 to 37 points. For every negative answer the word "no" was applied.

D. Results

From the Medline (Pubmed) search, 16 articles were listed. From them, only 4 of them were suitable for this study (19-22) (6 studies were only describing the protocol, 2 were feasibility studies, 3 were review studies and 1 was not comparing arthroscopic surgery for FAI, but conservative treatments). One of the four eligible for inclusion studies (21) was not published with results (although this was not highlighted in the title of the study) but finally was picked off for assessment, to the point that it was concluded, because of lack of any other completed clinical trials. One more study, eligible for inclusion, was found from clinical trials registration and Google scholar (23). No other completed clinical trials were found that could be included in the analysis in the study. Additional search from 2005, when the first arthroscopic treatment for FAI was reported (12), did not provide more clinical trials than the initial search (Figure 1). The causes may be attributed to the recently described pathophysiology of femoroacetabular impingement and the even more recent development of hip arthroscopy for FAI. This specificity makes the development of this study, the first that assess the quality of the clinical trials for FAI with the CONSORT statement.

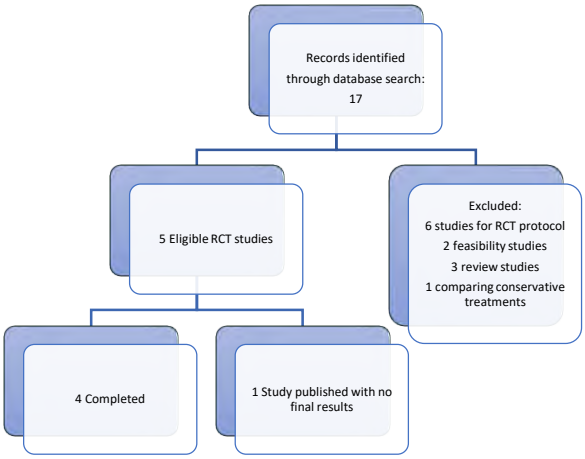

Figure 1. Flow chart of the selection process

From the eligible trials two were examining the effectiveness of hip arthroscopy, compared to conservative treatment (drugs, hip injections, physiotherapy) (19,23), one compared to physical therapy alone (22), one compared hip arthroscopy with arthroscopic lavage of the hip alone (21) and the final one compared the classic hip arthroscopy with the computer navigated procedure (20).

Following the steps of the consort statement assessment, the "Title and Abstract" category in all of the studies concluded the identification as a randomised trial in the title. The structured summary of the trial was following the appropriate sequence in all studies except the one made from the FIRST investigators (21) that is not completed yet and is not reporting results and conclusions (even that the article was published in 2015).

In the "Introduction" category the background and the objectives were examined. The explanation of the rationale and the background, that the study was based on, explained in all studies along with specific objectives and hypotheses.

According to the date the trials were published, the first study that was assessed was published (23) in 2013 (Figure 2). "Methods" is the biggest part of the CONSORT Checklist. In this trial, the design was based on a parallel, randomised intervention model. No changes in eligibility criteria was made but the sample size and the duration of the follow up changed. From 2 years, the follow up ended in 6 months and the size of the sample from the starting 140 patients ended up in 10. The eligibility criteria for participants and the places and time where the data collected were reported also. HOS (Hip Outcome Score) was the primary outcome measures and SF-12, LEFS (Lower extremity functional scale), MHHS (modified Harris hip score), NAHS (Non-arthritic hip score) and range of movement were the secondary measures. The sample size was determined with statistical power of 80% and 0.05 alpha error rate to detect a moderate effect size of 0.5 standard deviation. All interventions were explained with detail but there was no explanation about the mechanism and the method used to generate the random allocation sequence and the type of randomization of the patients. The random allocation sequence has been made by two surgeons and during the trial there was no blinding.


Electronic Thesis and Dissertation Repository

August 2013

A Randomized Controlled Trial Comparing Arthroscopic Surgery to Conservative Management of Femoroacetabular Impingement

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Figure 2.

In section "Results" from a total of 280 patients at the beginning, only 13 participated and out of them only 10 were analysed. No dates were defining the periods of recruitment and no information about the end of the trial was given. Baseline data and demographics of the

participants was presented. The participants in each group were analysed by original assigned groups. The confidence interval was set in 95% and for each group the primary but not all the secondary outcomes were analysed (range of motion wasn't analysed). Harms and unintended effects were mentioned but no other analysis was performed.

Trial limitations were presented in "Discussion" section, together with the reasons why the trial failed to reach the number of participants that required and of course generalisability was not applicable.

Registration number was not published, although there was a registry in United States clinical trials registry Library. The full protocol of the trial was available but not any sources of founding were mentioned.

The next eligible trial was published in 2015 (21) (Figure 3). As mentioned before this was the fifth trial that participated in the study and can only be assessed for sections that are published. Results will be published in the near future.

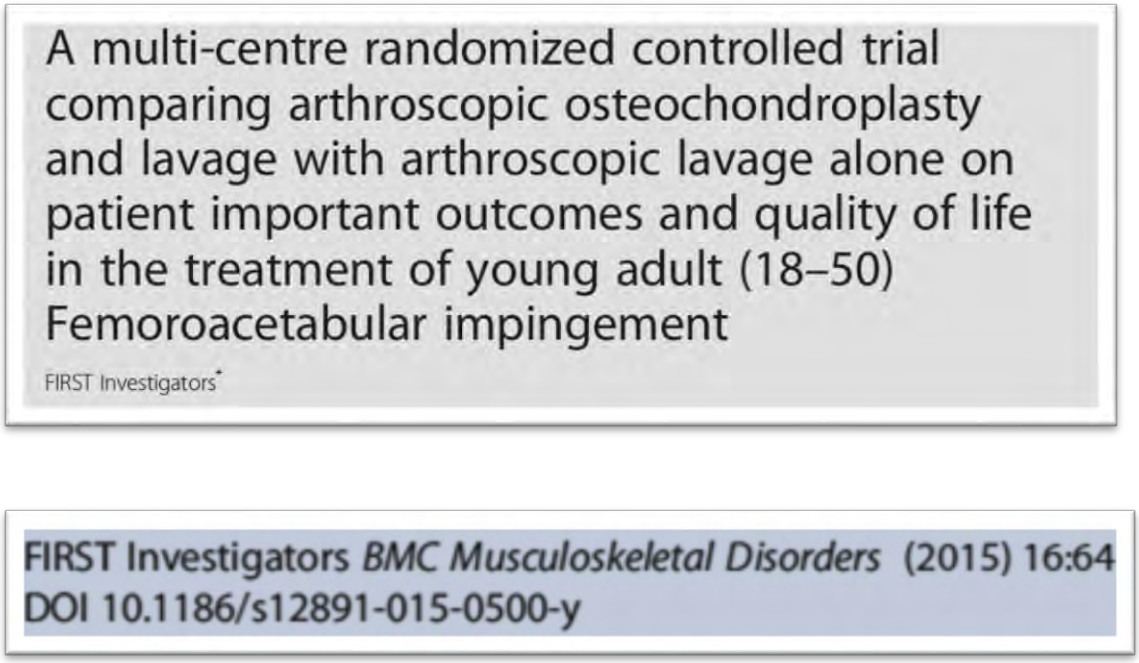


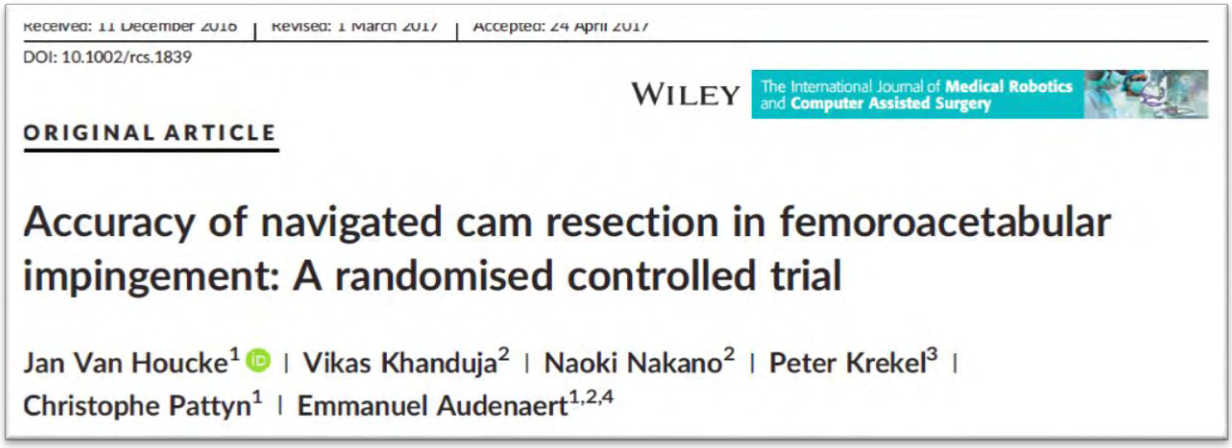
Figure 3.

In section of "Methods", the design of the trial was not described but in the trial registry page the term "parallel" can be found. Eligibility criteria mentioned in detail and remained the same during the trial. Dates, settings, and locations where the data collected were also included. The intervention in each group was presented in detail with pre-specified primary and secondary outcome measures. Primary outcome measures were using the Visual Analog Scale (VAS) while for the secondary outcome measures HOS, SF-12, iHOT-12 (International Hip Outcome Tool), EuroQol-5D, adverse events, cost and urinary (and sexual) function were measured. The randomisation was made by centralized 24-hour computerized system that allows for automated, internet based allocation patients to the control or intervention group in random block sizes of 4 and 8 prior to intervention. Patients, outcomes assessors and data analysts were blinded. All analyses were made according to intention to treat principle and the statistical was presented in detail.

The category of "Results" cannot be assessed in this trial but some information from the "Discussion" and "Other" topic was available. Some of the trial limitations included the

unavailability of the surgeons to be blind. Registration number of the trial was given, together with the access to the full trial protocol and funding sources.

The third trial assessed was published in 2016 (20) (Figure 4). In this trial, the classic hip arthroscopy for FAI was compared with the navigated method. Description of the trial was included and together there were information about eligibility criteria for the patients, the sample size, the interventions for each group, the similarity between the interventions and pre-specified primary and secondary outcomes. The randomisation type was tailored block based but neither the method used to generate the random allocation nor the mechanism (steps of concealment) was presented. The statistical method and additional analyses was sufficiently described.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WILEY The International Journal of Medical Robotics and Computer Assisted Surgery
ORIGINAL ARTICLE

Accuracy of navigated cam resection in femoroacetabular impingement: A randomised controlled trial

Jan Van Houcke[1] | Vikas Khanduja[2] | Naoki Nakano[2] | Peter Krekel[3] | Christophe Pattyn[1] | Emmanuel Audenaert[1,2,4]

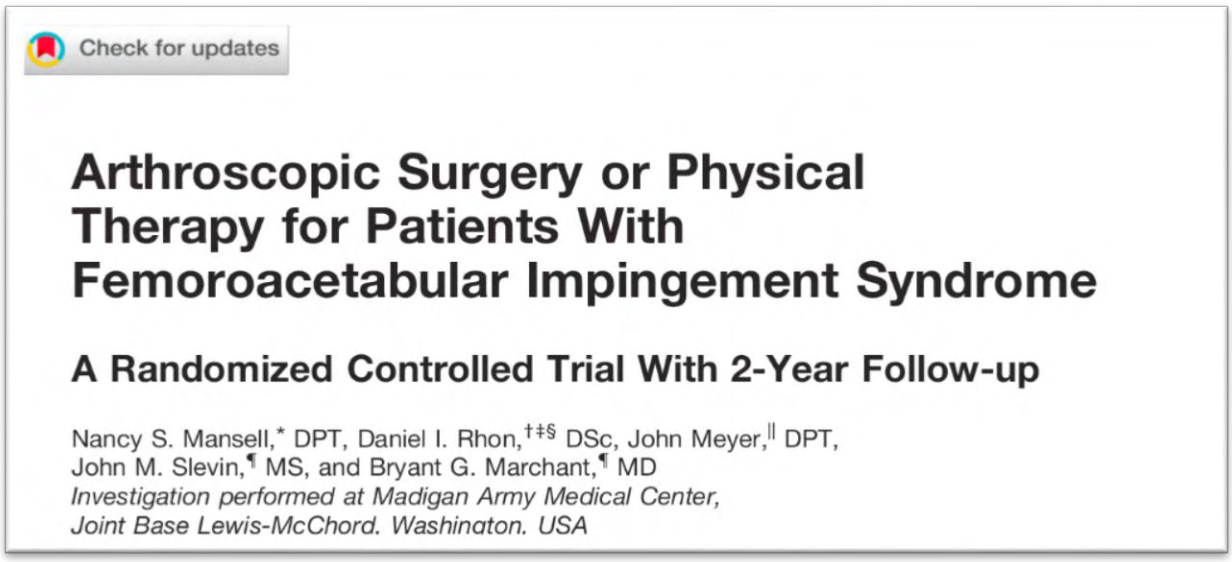
Figure 4.

In "Results" section the trial didn't include any follow up information. The primary and secondary outcomes and results for each group were analysed in a 95% confidence interval but no subgroup or adjusted analyses performed. The participant flow was mentioned (despite not in a diagram) with loses and exclusions alongside with baseline data and demographics.

The trial had limitations that the writers included in the "conclusion" topic. All participants were male, the range of movement assessment was computer simulated, the surgeries performed by a single surgeon, in supine position and there was no assessment of the clinical value of the interventions. There was an interpretation consistent between harms and benefits but no discussion made about generalisability. The registration number and the protocol of the trial was not provided. While the sources of founding were mentioned.

The forth trial (22) (Figure 5) was between patients who treated with hip arthroscopy or physiotherapy. The writer describes in the part of "methods" the design of the trial, the eligibility criteria for participants and the data collection settings. The intervention in each group was described in detail in the study protocol and the same apply for the outcomes of the trial (primary and secondary). The primary outcome was measured with the HOS scale, while the secondary outcomes with the GRC and the iHOT-33. The sample size was determined based on power 80% and the randomization was performed electronically by an independent person in blocks of 2 or 4. The mechanism of the random allocation was mentioned and blinded were the assessors. Statistical methods for the comparison of groups outcomes along with additional sensitivity analyses were also reported.

The participant flow was described with a diagram (including losses and exclusions) and baseline data was presented. During the trial, many patients decided to change group from physical therapy to surgery. The analysis of the outcomes was made in both the original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Arthroscopic Surgery or Physical Therapy for Patients With Femoroacetabular Impingement Syndrome

A Randomized Controlled Trial With 2-Year Follow-up

Nancy S. Mansell,* DPT, Daniel I. Rhon,†‡§ DSc, John Meyer,‖ DPT, John M. Slevin,¶ MS, and Bryant G. Marchant,¶ MD

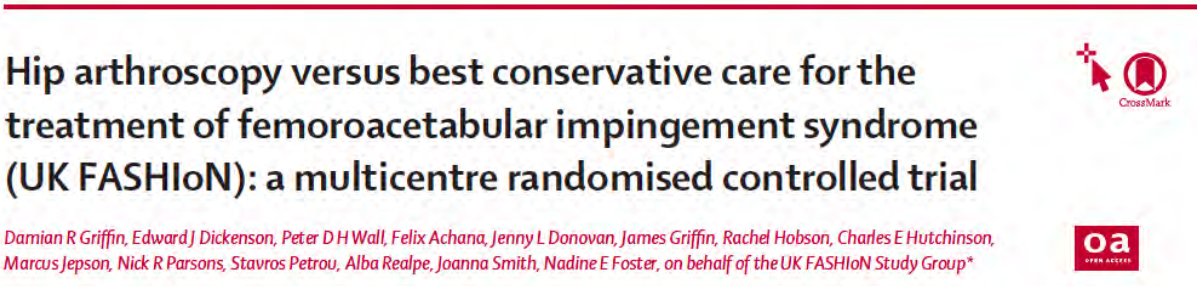
Investigation performed at Madigan Army Medical Center, Joint Base Lewis-McChord, Washington, USA

Figure 5.

randomization and based on the type of the final intervention. Harms and unintended effects were also presented.

The limitations of the trial were mentioned and they were the high rate of crossover, no masking of the therapists, the one sight that the trial took place and a single surgeon, the low final number of the physical therapy group and that the sample was consisted only by military population. These were the reasons why the writer admitted that no generalizability could be applied. The full trial protocol could be accessed through the trials registration number but the role of the founders wasn't specified.

The final trial (19) (Figure 6) was 23 centres, assessor-blinded randomised trial that was published in 2018. During the trial design, no changes to methods and outcomes measures took place. The eligibility criteria along with way the sample size determined was presented. The statistical methods for the analysis of the outcomes in both groups were described thoroughly. Unfortunately, the mechanism and the type of randomisation were not available and the same applies for the person or persons who generated the random allocation.


Hip arthroscopy versus best conservative care for the treatment of femoroacetabular impingement syndrome (UK FASHIoN): a multicentre randomised controlled trial

Damian R Griffin, Edward J Dickenson, Peter D H Wall, Felix Achana, Jenny L Donovan, James Griffin, Rachel Hobson, Charles E Hutchinson, Marcus Jepson, Nick R Parsons, Stavros Petrou, Alba Realpe, Joanna Smith, Nadine E Foster, on behalf of the UK FASHIoN Study Group*

Figure 6.

In this big multi-centre trial, in the "results" section all the criteria of the checklist were met. The participant flow (with a diagram), the way the recruitment of the patients took place, the baseline data and analysis of the results were all published in the study. The limitations of the trial were also described. The participants and the treating clinicians were not blinded to treatment allocation, there was no control group and there was a delay in the time the surgery,

in many patients, took place. The last one resulted in the follow up examination (12 months after randomization) some patients not to have enough time to recover from the surgery. During the discussion parameters that should have been added to the trial were reported so that it could be generalised. The interpretation of the results was consistent with the trials hypothesis. The trial registry number was published and the full trial protocol could be reached through that. The sources of founding were reported but there was no role for the founders in the trial.

Item No	*Klaus et al (2013)*	*FIRST Team (2015)*	*Houcke et al (2016)*	*Mansell et al (2018)*	*Griffin et al (2018)*	*Proportion*
1a	Yes	Yes	Yes	Yes	Yes	5/5(100%)
1b	Yes	No	Yes	Yes	Yes	4/5(80%)
2a	Yes	Yes	Yes	Yes	Yes	5/5(100%)
2b	Yes	Yes	Yes	Yes	Yes	5/5(100%)
3a	Yes	Yes	No	Yes	Yes	4/5(80%)
3b	Yes	Yes	No	No	No	2/5(40%)
4a	Yes	Yes	Yes	Yes	Yes	5/5(100%)
4b	Yes	Yes	No	Yes	Yes	4/5(80%)
5	Yes	Yes	Yes	Yes	No	4/5(80%)
6a	Yes	Yes	Yes	Yes	Yes	5/5(100%)
6b	No	No	No	Yes	No	1/5(20%)
7a	Yes	Yes	Yes	Yes	Yes	5/5(100%)
7b	No	No	No	No	Yes	1/5(20%)
8a	No	Yes	No	Yes	Yes	3/5(60%)
8b	No	Yes	Yes	Yes	No	3/5(60%)
9	No	Yes	No	Yes	No	2/5(40%)
10	No	No	No	Yes	No	1/5(20%)
11a	No	Yes	No	Yes	Yes	3/5(60%)
11b	No	Yes	Yes	Yes	No	3/5(60%)
12a	Yes	Yes	Yes	Yes	Yes	5/5(100%)
12b	Yes	Yes	Yes	Yes	Yes	5/5(100%)
13a	No	N/A	Yes	Yes	Yes	3/4(75%)
13b	Yes	N/A	Yes	Yes	Yes	4/4(100%)
14a	No	N/A	No	Yes	Yes	2/4(50%)
14b	No	N/A	Yes	Yes	Yes	3/4(75%)
15	Yes	N/A	Yes	Yes	Yes	4/4(100%)
16	Yes	N/A	Yes	Yes	Yes	4/4(100%)
17a	Yes	N/A	Yes	Yes	Yes	4/4(100%)
17b	No	N/A	No	No	Yes	1/4(25%)
18	No	N/A	No	Yes	Yes	2/4(50%)
19	Yes	N/A	No	Yes	Yes	3/4(75%)
20	Yes	Yes	Yes	Yes	Yes	5/5(100%)
21	No	N/A	No	No	Yes	1/4(25%)
22	No	N/A	Yes	No	Yes	2/4(50%)
23	No	Yes	No	Yes	Yes	3/4(75%)
24	Yes	Yes	No	Yes	Yes	4/5(80%)
25	No	Yes	Yes	No	Yes	3/5(60%)
Total	20/37	21/25	21/37	31/37	30/37	

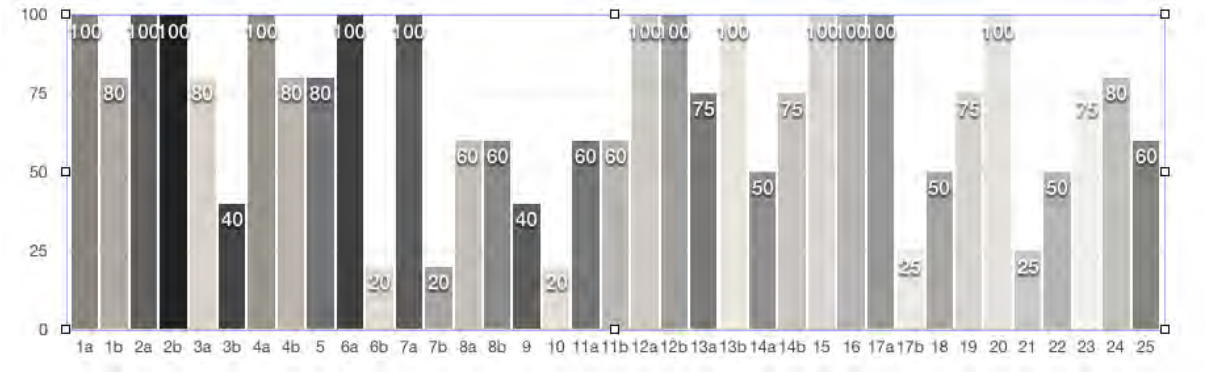


Chart 1.

E. Conclusions

The CONSORT checklist does not actually assess the quality of the methodology of a RCT, but rather assess the reporting of key items that are crucial in determining the validity and quality of the RCT. The CONSORT checklist was developed as a guideline, not as an actual scale for assessing methodology of an RCT. A well-designed and well-reported RCT should meet all of the criteria of the CONSORT statement. With adequate reporting, readers will understand what was actually done, rather than assume what was done.

There is no evidence that the failure to mention methodological details equates to the lack of methodological knowledge or skills: a method of a trial that is not reported does not mean actually that it has not been performed. The reporting of methodological aspects of RCTs does not necessarily reflect the conduct of the trial. The responsibility for reporting lies not only with the authors. Peer reviewers and editors are at fault for not insisting on complete description of the studies as dictated by the CONSORT statement.

In the present study, we assessed the quality of reporting of randomized controlled trials that compared the Hip Arthroscopy with other therapeutic methods for the treatment of Femoroacetabular Impingement published from 2008 to 2018. During our search, we discovered that there are limited RCT's that compare the hip arthroscopy with other therapies for FAI. This is a result of the recently described pathology of femoroacetabular impingement and the even more recent development of hip arthroscopy for FAI.

All RCT's reported satisfactorily on many important items (i.e. structure of the RCT, scientific background, eligibility criteria, outcome measures, sample size calculation, statistical methods used to compare groups, participant flow, baseline data, intention-to-treat analysis and precision of measurement and limitations of the studies), making it easy for any reader to determine the quality and validity of results without needing to make various assumptions.

Compliance was poorest for items relating to randomization (60%), implementation of randomization (40%), allocation concealment mechanism (20%) and generalisability (25%). Good randomization protocols aim to produce treatment groups that are comparable and have an equal distribution of both known and unknown confounders. Achieving patient randomization suitable for a clinical trial is a complex issue. The fact that items related to the previous topics were poorly adhered to, highlights the need for further education regarding this aspect of trial design.

Two out of five of the studies achieved moderate score (21/37 and 20/37), two studies achieved high scores (31/37 and 30/37) and the study that was not yet completed 21 out of 25 items, suggesting that many journals have adopted the CONSORT checklist and have improved levels of compliance in their trial reports. There are good evidence in the literature that the

adoption of CONSORT statement improves the quality of both the conduct and reporting of trials in journals that have taken the decision to make it a requirement for submission acceptance. Researchers also need to design research with full understanding of the CONSORT reporting guidelines and full consideration of items whose reporting quality is low.

In conclusion, although there is a limited number of RCT's regarding hip arthroscopy for FAI, the results based the CONSORT checklist have been more than adequate. During a period of rapid transition in the healthcare delivery system (where cost and effectiveness of every treatment matters more and more) and especially during a period of new therapeutic modalities, higher quality reports are likely to improve RCT interpretation, minimize biased conclusions, and ultimately facilitate decision-making about treatment effectiveness.

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