Arthroscopic hip surgery compared with personalised hip therapy in people over 16 years old with femoroacetabular impingement syndrome: UK FASHIoN RCT

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Declared competing interests of authors: Damian R Griffin is a surgeon with a hip preservation practice that includes treating femoroacetabular impingement syndrome and hip arthroscopy, and he reports consulting and teaching fees from Stryker UK (Newbury, UK) and Smith & Nephew UK (Watford, UK), outside the submitted work. Joanna Smith is a physiotherapist who treats patients with femoroacetabular impingement syndrome. Peter DH Wall is a hip surgeon who treats patients with femoroacetabular impingement syndrome. Nadine Foster is a member of Clinical Trial Units that were funded by the National Institute for Health Research until 2021 and was a member of the Health Technology Assessment Primary Care, Community and Preventive Interventions Panel (2010–15). Jenny Donovan reports membership of the Rapid Trials and Add-on Studies Board (2012 to present) and the Health Technology Assessment Commissioning Committee (2006–12).

Published February 2022
DOI: 10.3310/FXII0508

Scientific summary

The UK FASHIoN RCT

Health Technology Assessment 2022; Vol. 26: No. 16
DOI: 10.3310/FXII0508

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Scientific summary

Background

Femoroacetabular impingement (FAI) syndrome is a painful disorder of the hip. FAI syndrome is caused by a premature contact between the femur and acetabulum during hip movements. This premature contact typically occurs as a result of certain hip shapes, for example cam or pincer morphology. Cam morphology refers to a flattening or convexity at the femoral head–neck junction, whereas pincer morphology refers to a focal or global overcoverage of the femoral head by the acetabulum. FAI syndrome leads to progressive damage within the joint, including the acetabular labrum and articular cartilage, and is associated with the development of osteoarthritis of the hip.

Surgery has become an established treatment for FAI syndrome and hip arthroscopy, in particular, is widespread. The aim of surgery is to reshape the hip joint to prevent impingement. Intra-articular injury, such as a cartilage and labral damage, can be resected, repaired or reconstructed. Non-operative treatments for FAI syndrome include exercise-based packages of conservative care delivered by a physiotherapist.

Many case series report improvement in patients with FAI syndrome after open or arthroscopic surgery, or physiotherapy. However, a 2014 Cochrane review of surgery for treating FAI syndrome showed that there was no randomised controlled trial (RCT) evidence to support these treatments [Wall PD, Brown JS, Parsons N, Buchbinder R, Costa ML, Griffin D. Surgery for treating hip impingement (femoroacetabular impingement). *Cochrane Database Syst Rev* 2014;**9**:CD010796].

Our aim was to assess the effectiveness of hip arthroscopy in treating patients with FAI syndrome. In a feasibility study, we established that patients were prepared to be recruited, and that surgeons were in equipoise and willing to recruit patients to a trial that compared hip arthroscopy with best conservative care. In this pragmatic, multicentre RCT, we assessed the clinical effectiveness and cost-effectiveness of hip arthroscopy compared with best conservative care in patients with FAI syndrome.

Methods

We conducted a pragmatic, multicentre, two-arm, assessor-blind RCT. An initial feasibility study was treated as an internal pilot so that participants who took part were included in the main trial recruitment. The study was performed in 23 NHS hospitals in the UK.

Participants were recruited from the specialist hip arthroscopy services at 23 NHS hospitals. Participating surgeons identified eligible patients during routine diagnostic consultations. Assessments included history, clinical examination, plain radiographs and cross-sectional imaging [i.e. magnetic resonance imaging (MRI) or computerised tomography, or both]. The surgeon classified patients as having cam impingement (defined as an alpha angle of $> 55°$), pincer impingement (defined as a lateral centre-edge angle of $> 40°$ or a positive crossover sign) or mixed-type impingement (i.e. a combination of both).

Qualitative research to understand recruitment as it occurred was integrated into the trial. Findings were used to design a recruiter training and centre support programme that was implemented to optimise recruitment.

Inclusion and exclusion criteria

Patients were eligible to participate if they had hip pain, had radiographic features of cam or pincer morphology, were aged ≥ 16 years old and were able to give informed consent, and if the treating surgeon believed that they were likely to benefit from hip arthroscopy. Patients were excluded if they had hip osteoarthritis (i.e. Tönnis grade > 1 or loss of > 2 mm of superior joint space on an anteroposterior radiograph), a history of hip pathology (such as Perthes' disease, slipped upper femoral epiphysis or avascular necrosis) or of previous hip injury (such as acetabular fracture, hip dislocation or femoral neck fracture) or if they had already had undergone shape-changing surgery (open or arthroscopic) of the hip. Patients with bilateral FAI syndrome were eligible and the most symptomatic hip was randomised and followed. Trained research associates (RAs) approached eligible patients to explain the trial and to invite them to participate. All participants gave written informed consent.

Interventions

Surgical intervention

Hip arthroscopy was performed by a senior surgeon who was trained and experienced in hip arthroscopy. Trial surgeons reported that they performed a mean of 12 [standard deviation (SD) 55] hip arthroscopies per year during the study. Shape abnormalities and consequent labral and cartilage pathology were treated. Adequacy of bony reshaping was assessed by intraoperative image intensifier views or by arthroscopic visualisation of a satisfactory impingement free range of movement of the hip, or both. Patients were referred to outpatient physiotherapy services for a course of rehabilitation, as per usual care for that surgeon. These postoperative physiotherapists were distinct from those providing conservative care to avoid contamination between groups. Patients had a scan of their hip at least 6 weeks after surgery. A panel of international experts assessed the fidelity of the surgery. They reviewed operation notes, intraoperative images and postoperative scans to subjectively assess whether or not adequate surgery, according to the protocol, had been undertaken.

Best conservative care

Personalised hip therapy (PHT) is a package of physiotherapist-led rehabilitation for FAI syndrome. Although the name for this intervention is new, the care offered was based on a consensus of what physiotherapists, physicians and surgeons regarded as best conservative care for FAI syndrome. Care was delivered by at least one physiotherapist at each centre who was trained formally in this protocol via a 1-day workshop and supported to deliver PHT through refresher workshops. At their initial assessment, participants received a PHT information pack that described what to expect during the course of their treatment. Participants then had between 6 and 10 contacts with the physiotherapist over 12–24 weeks. Some of the contacts were conducted by either telephone or e-mail if geographical distance prevented all contacts being carried out face to face. Exercise diaries were available for physiotherapists to monitor compliance. Physiotherapists recorded full details of their advice and treatments, number and type of treatment contacts, and any non-attendance on case report forms (CRFs). These CRFs were reviewed for accuracy in comparison to the usual physiotherapy records at each treatment centre and then assessed for fidelity to the protocol by a panel comprising members of the core group who developed the protocol for PHT.

Outcomes

The primary outcome was hip-related quality of life measured by the International Hip Outcome Tool-33 (iHOT-33) at 12 months after randomisation. The instrument has been validated in a relevant population for this trial and has a minimum clinically important difference (MCID) of 6.1 points. Secondary outcomes were health-related quality of life measured using the EuroQol-5 Dimensions,

five-level version (EQ-5D-5L) and the Short Form questionnaire-12 items (SF-12) v2, adverse events and resource use. Patients reported complications 6 weeks following the start of their intervention. iHOT-33, EQ-5D-5L, SF-12, complications and health-care resource use were collected by questionnaires that were administered centrally. Scores for these measures were collected at the time of consent and again by postal questionnaire at 6 and 12 months after randomisation. Information on further procedures was collected at 2 and 3 years post randomisation.

Randomisation

Participants were randomised (1 : 1) to receive either hip arthroscopy or best conservative care using a minimisation algorithm for centre and type of impingement. All baseline data were collected prior to randomisation, which was performed by the recruiting RA. Allocation concealment was ensured by using a secure telephone randomisation service. It was not possible to blind patients or the treating clinicians to their allocation. Researchers who collected outcome assessments and analysed the results were blind to allocation.

Analyses

The planned sample size was 172 participants in each group, based on a SD iHOT-33 score of 16 points and a MCID of 6.1 points, giving a standardised effect size of 0.38. We designed the trial to have 90% power to detect an effect of this size at a two-sided 5% significance level, allowing for up to 15% loss to follow-up at the primary outcome time point.

The primary analysis investigated differences in the primary outcome measure (i.e. iHOT-33 score) between the two treatment groups at 12 months after randomisation on an intention-to-treat basis. We assessed the primary outcome 12 months from randomisation rather than from intervention because this was a pragmatic trial design of two different treatment strategies. A mixed-effects regression analysis was used to assess the effects of the interventions on 12-month iHOT-33 scores, after adjusting for the fixed effects of impingement type, sex and baseline iHOT-33 score, with recruiting centre included as a random effect to model any potential associations within the recruiting centres. No interim analyses were planned.

Our primary inferences were drawn from an intention-to-treat analysis, irrespective of compliance and without imputation for missing data. Prespecified subgroup analyses were performed for different impingement types (i.e. cam, pincer and mixed) and for patients aged < 40 years and > 40 years.

An economic evaluation was conducted from a UK NHS and Personal Social Services perspective. Economic costs associated with the delivery of the two interventions were estimated. Resource use questions completed by participants at each assessment point provided a profile of all hospital inpatient and outpatient service use, community health and social care encounters, prescribed medications and NHS supplies, such as crutches and home adaptations.

Results

A total of 648 patients attending the participating surgeons' hip clinics between 20 July 2012 and 15 July 2016, were deemed eligible of whom 351 (54%) agreed to participate. Three participants were randomised but subsequently found not to meet the eligibility criteria and, therefore, were excluded from further analysis. In total, 171 participants were allocated to hip arthroscopy and 177 to PHT.

Participants in the two groups were well matched in terms of both demographics and pre-randomisation hip-related quality of life, having had symptoms for approximately 3 years. Fourteen (8%) participants who were allocated to PHT had all or part of this intervention, but then, at their request, went on to have hip arthroscopy within 12 months after randomisation. No patients allocated to hip arthroscopy had PHT. The median time from randomisation to treatment was 122 [interquartile range (IQR) 80–185] days for hip arthroscopy and 37 (IQR 22–60) days for PHT. Twenty-seven (16%) participants allocated hip arthroscopy did not receive it by the 12-month time point. Of those participants who did receive hip arthroscopy, 84% (121/144) had postoperative MRI and their case was assessed by the surgical review panel. Among these participants, surgery was deemed to have been performed with high fidelity for 87% (105/12) and to be unsatisfactory for 13% (16/121). The most common reason for unsatisfactory surgery was an inadequate bony resection ($n = 7$) and a sharp transition from the femoral head to neck ($n = 5$) as a result of reshaping surgery. Five per cent (9/177) of participants allocated to PHT did not receive any treatment by 12 months. Of those participants who received PHT, 69% (107/154) were judged to have received the intervention to a high fidelity. The most common reason for lack of PHT fidelity was participants not receiving the minimum of six PHT sessions (34/46, 74%).

A total of 319 (92%) participants completed questionnaires at 12 months after randomisation; seven participants withdrew from follow-up and 22 participants were lost to follow-up. The iHOT-33 score increased between baseline and 6 months and between 6 and 12 months, indicating an improvement in hip-related quality of life. In the primary intention-to-treat analysis at 12 months, the adjusted estimate of treatment effect measured with the iHOT-33 was 6.8 [95% confidence interval (CI) 1.7 to 12.0; $p = 0.009$] in favour of hip arthroscopy compared with PHT.

In the as-treated (per-protocol) analysis at 12 months, including participants who received PHT ($n = 154$) or hip arthroscopy ($n = 144$), the adjusted estimate of the between-group difference on the iHOT-33 was 8.2 (95% CI 2.8 to 13.6) points in favour of hip arthroscopy. In the exploratory secondary analysis based on those participants whose treatment was deemed to have been of high fidelity (hip arthroscopy, $n = 105$; PHT, $n = 107$), the adjusted estimate of between-group difference on the iHOT-33 was 5.8 (95% CI −0.7 to 12.2) points in favour of hip arthroscopy.

In the prespecified subgroup analysis, the between-group difference on the iHOT-33 was 5.0 (95% CI −1.2 to 11.3) points in participants aged < 40 years and 10.9 (95% CI 1.7 to 20.1) points in participants aged > 40 years. In addition, in the prespecified subgroup analysis, the between-group difference on the iHOT-33 was 8.3 (95% CI 2.5 to 14.2) points in participants with cam morphology, 1.1 (95% CI −11.5 to 13.7) points in participants with mixed cam and pincer morphology and 4.0 (95% CI −14.6 to 22.7) points in participants with pincer morphology, in favour of hip arthroscopy. There were no statistically significant between-group differences in SF-12 or EQ-5D-5L scores at 6 or 12 months post randomisation.

At 6 weeks post intervention, the most frequently reported complication was muscle soreness. At 12 months, seven serious adverse events had been reported. Six of these serious adverse events were among the participants in the hip arthroscopy group (one failed discharge from the day surgery unit and required an overnight admission, one scrotal haematoma necessitated the patient's readmission, two superficial wound infections required treatment with oral antibiotics, one deep wound infection led to further surgery and ultimately a total hip replacement, and one participant had a fall that was unrelated to the hip arthroscopy). One participant in the PHT group developed biliary sepsis that was unrelated to PHT.

The level of missing item-level data was low (iHOT-33 0.6%) for all patient-reported outcome measures at all time points. After imputation for missing data, the adjusted estimate of treatment effect was almost unchanged at 6.6 (95% CI 1.7 to 11.4) points in favour of hip arthroscopy. There was no difference in iHOT-33 scores at 12 months for hip arthroscopy patients treated within 6 months of randomisation or later (0.9, 95% CI −10.7 to 8.8). The mean cost of hip arthroscopy was £3042 (35% staff time, 28% surgical devices and anaesthetic drugs, 19% theatre running costs and 18%

bed-day costs). Participants in the PHT group attended a mean of six physiotherapy sessions (average duration of 30 minutes), generating a mean total treatment cost of £155 per participant. The adjusted incremental cost of hip arthroscopy compared with PHT during the 12-month follow-up was £2483, with incremental quality-adjusted life-years (QALYs) of –0.018 (representing a net QALY loss).

Conclusion

We have shown that offering hip arthroscopy to patients with FAI syndrome leads to better clinical outcomes at 12 months than best conservative care. However, this improvement comes at a cost. Our study does not demonstrate cost-effectiveness of hip arthroscopy compared with conservative care within the first 12 months, and further follow-up is required (5 and 10 years are planned) to establish clinical effectiveness and cost-effectiveness in the longer term. Future work should include characterisation of those patients who gain most from surgery compared to best conservative care. A qualitative recruitment intervention was able to maximise recruitment of eligible participants by improving research nurse and clinicians communication with patients.

Trial registration

This trial is registered as ISRCTN64081839.

Funding

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 26, No. 16. See the NIHR Journals Library website for further project information.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

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The research reported in this issue of the journal was funded by the HTA programme as project number 13/103/02. The contractual start date was in April 2014. The draft report began editorial review in November 2019 and was accepted for publication in August 2021. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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