Evidence-Based Medicine: A Case Study of Its Application to Innovative Surgical Procedures in the United Kingdom

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OBJECTIVES

The objectives of this case study were as follows:

- To illustrate the application of evidence-based medicine (EBM) to an innovative surgical procedure, arthroscopic surgery for hip impingement syndrome
- To highlight how the recommendations for use of arthroscopic surgery changed as additional evidence was generated

BACKGROUND

- Hip impingement, or femoroacetabular impingement, results from skeletal abnormalities and leads to restriction of movement and pain. Some evidence suggests that femoroacetabular impingement may lead to the development of osteoarthritis.
- Arthroscopic femoroacetabular surgery is a procedure performed under general anesthesia to improve range of motion and reduce pain.
- EBM is frequently used as the basis for clinical guidelines and reimbursement recommendations. The hierarchy of evidence is as follows:
  - Level I: randomized controlled trials (RCTs)
  - Level II: nonrandomized prospective cohort studies
  - Level III: case-control studies
  - Level IV: case series
  - Level V: expert opinion
- RCTs are generally required during the development of clinical guidelines or reimbursement recommendations for new drugs; however, RCTs evaluating the efficacy of innovative surgical procedures (e.g., arthroscopic surgery for hip impingement syndrome) typically are not available.

METHODS

- National Institute of Health and Clinical Excellence (NICE) data summaries and guidelines for arthroscopic surgery for femoroacetabular impingement syndrome were reviewed.
- This case study was selected because the treatment modality represents an innovative surgical technology. NICE recommendations for coverage of this procedure, first promulgated in 2007,[1] were later changed in 2011,[2] illustrating the impact of additional evidence generation.

RESULTS

- In 2007, the only evidence regarding the efficacy and safety of femoroacetabular impingement that NICE considered was from two case series, one with 158 patients and one with 10 patients (Table 1).[3]

Table 1. Evidence Considered in the 2007 NICE Guidance on Femoroacetabular Impingement[3]

Study Details	Efficacy	Safety
Sampson, 2005[4] Case series, United States; 22 months maximum follow-up N = 158 hips Arthroscopy with labral debridement All procedures by 2 surgeons	Resolution of impingement clinical signs in nearly all patients In most patients, pain was reduced by 50% at 3 months, by 75% at 5 months, and by 95% at 12 months (pain measure was not stated in the study) 2% of patients required total hip replacement at a mean follow-up of 22 months	Pathological nondisplaced fracture that required closed pinning occurred in 1 patient
Guanche and Bare, 2006[5] Case series, United States; 16 months follow-up N = 10 hips Arthroscopy with labral debridement All procedures by 1 surgeon	Mean nonarthritic hip score on the McCarthy scale improved from 75 to 95 points at 14 months follow-up	None reported

- In 2011, NICE considered efficacy and safety evidence comprising data from 1,126 patients participating in the following studies (Table 2)[6]:
  - Three nonrandomized controlled studies (none compared with natural history or nonarthroscopic surgical techniques)
  - Five case series (with 100 to 200 hips)
  - One case report
- NICE summarized the evidence considered in 2011 as follows[6]:
  - "Little controlled data are available comparing the procedure with other interventions or against natural history.
  - A range of outcome assessment scales are used; validation of these scales is often not reported.
  - The description of hip impingement pathology/lesions is not well defined in all studies.
  - The intervention required is usually individualised to each patient, making comparison between studies difficult.
  - Study quality is poor with little prospective data collection in case series."
- In addition to the data presented in Table 2, NICE also identified 28 other publications that provided additional data.[6]
- In addition to the evidence review, NICE consulted five specialists in 2011, whose perspectives on femoroacetabular impingement included the following[6]:
  - Four of five specialist advisors viewed the procedure as established, whereas one advisor considered the efficacy and safety still to be uncertain.
  - The main comparators for arthroscopic surgery were conservative management or open femoroacetabular surgery.
  - There is a well-recognized learning curve for the arthroscopic procedures and a concern about surgeons receiving adequate training and experience.
  - An arthroscopic approach to treatment has provided a considerable improvement in surgical morbidity.
  - There is no proof yet, but the procedure might prevent development of osteoarthritis of the hip in some patients.
- In 2007, NICE concluded the following: "Current evidence on the safety and efficacy of arthroscopic femoro-acetabular surgery for hip impingement syndrome does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research."[1]
- In 2011, NICE concluded the following: "Current evidence on the efficacy of arthroscopic femoro-acetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term. With regards to safety, there are well recognised complications. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance. . . . The Committee noted that the available evidence was from observational studies. While this was considered adequate for the present recommendation, further studies would be useful. The Committee recognised the difficulties of comparative research and acquisition of long-term data on this procedure."[2]

Table 2. Evidence Considered in the 2011 NICE Guidance on Femoroacetabular Impingement[6]

Study Details	Key Efficacy Findings			Key Safety Findings
Larson and Giveans (2009)[7] Nonrandomized controlled study, US, 2004-2007; 1 year minimum follow-up; 19 months mean follow-up n = 36 hips with labral debridement; n = 39 hips with labral refixation Historical control before and after labral refixation technique available All procedures performed by same surgeon—learning curve for arthroscopy for femoroacetabular impingement may explain better outcomes for labral refixation	**Measure**	**Labral Debridement**	**Labral Refixation**	Rate of heterotopic bone development was 8.3% in labral debridement and 0% in labral refixation
	Efficacy outcomes			
	HHS—baseline	63	63	
	HHS—1 year	88.9	94.3 ($P = 0.029$)	
	HHS > 80—19 months	66.7%	89.7%	
	SF-12—1 year	No difference		
	Pain—1 year	No difference		
	Offset angle—1 year	No difference		
	Degenerative changes—1 year	No difference		
	Clinical failures			
	Revision osteochondroplasty	5.6%	0%	
	THA	0%	2.6%	
	Reinjury	0%	2.6%	
Nepple et al. (2009)[8] Nonrandomized controlled study, US; 2 years mean follow-up n = 23 arthroscopic only; n = 25 arthroscopy + limited open osteochondroplasty; no labral refixation in either group Historical control before and after combined technique available	**Measure**	**Arthroscopy Only**	**Arthroscopy + Limited Open Osteochondroplasty**	Not reported
	Efficacy outcomes			
	HHS—baseline	61.6	66.0 ($P = 0.179$)	
	HHS—1 year	84.7	95.7 ($P = 0.019$)	
	HHS—2 year	82.5	93.5 ($P = 0.056$)	
	ΔHHS > 10	65.2%	96.0% ($P = 0.009$)	
	Clinical failures			
	THA	2	0	
	Revision osteochondroplasty	1		
	Repeat arthroscopy	1		
	Repeat arthroscopy + limited open osteochondroplasty	1		
Randelli et al. (2010)[9] Nonrandomized controlled study, Italy, 2006-2009; 18 months mean follow-up n = 15 arthroscopy with no NSAID; n = 285 arthroscopy + NSAID; no details on surgical technique Patient assignment not reported	Efficacy outcomes not reported			Rate of heterotopic ossification, occurring between 2 and 12 months after surgery, was: • 0% in those taking NSAID • 33.3% in those not taking NSAID
Byrd and Jones (2009)[10] Case series, US, 2003-2007; 16 months mean follow-up n = 207 hips arthroscopy with labral debridement	**Measure**	**Outcomes**		**Outcome** / **Rate per Hip** Transient neurapraxia of pudendal nerve—resolved at 2 weeks / 1 out of 207 Partial neurapraxia of lateral femoral cutaneous nerve—resolved at 1 month / 1 out of 207 Heteroscopic ossification / 1 out of 207
	Efficacy outcomes			
	Mean ΔHHS	20 (range, –17 to 60)		
	Improvement in HHS	83%		
	Clinical failures			
	THA	0.5%		
	Repeat arthroscopy with labral debridement	1.5%		
Sampson (2006)[11] Case series, US, 2002-2006; 29 months maximum follow-up n = 194 hips arthroscopy with labral debridement All procedures by 2 surgeons	**Measure**	**Outcomes**		**Outcome** / **Rate** Pathological fracture / 1.1%
	Efficacy outcomes			
	Impingement sign on test eliminated	94%		
	Improvement in pain by 50% 2-5 weeks, 75% by 5 months, and 95% at 1 year	"Most patients"		
	Clinical failures			
	THA	3.3%		
Philippon et al. (2009)[12] Case series, US, 2005; 2.3 years mean follow-up n = 112 hips arthroscopy with labral debridement	**Measure**	**Outcomes**		No reports of infection, pulmonary embolism, deep vein thrombosis, fracture, or paresthesia following the procedure
	Efficacy outcomes			
	HHS—baseline	58.0		
	HHS—2.3 years	84.3 ($P < 0.001$)		
	ADL—baseline	70.0		
	ADL—2.3 years	87.8 ($P < 0.001$)		
	Sport activities—baseline	43.0		
	Sport activities—2.3 years	69.0 ($P < 0.001$)		
	Clinical failures			
	THA at mean 16 months	8.9%		
Laude et al. (2009)[13] Case series, France, 1999-2004; 58 months mean follow-up n = 100 hips arthroscopy plus osteochondroplasty with labral refixation in 40 hips All procedures by 1 surgeon	**Measure**	**Outcomes**		**Outcome** / **Rate per Hip** Femoral neck fracture at 23-week follow-up / 1 out of 97 Deep wound infection / 2 out of 97 Heterotopic ossification at 33 months / 1 out of 97 Avascular necrosis / 0 out of 97
	Efficacy outcomes			
	Nonarthritis hip score—baseline, 94 hips	54.8 ± 12		
	Nonarthritis hip score—58 months, 94 hips	83.9 ± 16 ($P < 0.001$)		
	Nonarthritis hip score—58 months, with refixation	86.0 ± 11		
	Nonarthritis hip score—58 months, with debridement	82.0 ± 19 ($P < 0.13$)		
	Clinical failures			
	THA	11.0%		
	Repeat arthroscopic debridement—at mean 30 months	13.4%		
	Refixed labrum failure	8.2%		
Gedouin et al. (2010)[14] Case series, European, 2008-2009; 10 months mean follow-up n = 111 hips arthroscopy with labral suturing in 14 hips Multicenter study, operative technique not standardized	**Measure**	**Outcomes**		**Outcome** / **Rate per Hip** Femoral neck fracture / 1 out of 111 Femoral neurapraxia / 1 out of 111 Pudendal neurapraxia / 1 out of 111 Heterotopic ossification / 3 out of 111 Labium major skin necrosis / 1 out of 111
	Efficacy outcomes			
	WOMAC osteoarthritis index—baseline	60.3 ± 14.8		
	WOMAC osteoarthritis index—10 months	83.0 ± 16.4 ($P < 0.001$)		
	WOMAC osteoarthritis index—10 months, labral debridement	82.7		
	WOMAC osteoarthritis index—10 months, labral refixation	86.3 ($P = 0.4$)		
	Very satisfied or satisfied	77.3%		
	Moderately satisfied	27.3%		
	Disappointed	12.0%		
	α angle—baseline	64.6 ± 12.0		
	α angle—10 months	50.6 ± 6.3 ($P < 0.001$)		
	Clinical failures			
	THA	4.5%		
Scher et al. (2010)[15] Case report, US; 3 months follow-up n = 1 hip arthroscopy plus labrum debridement	At 12 months, after repeat arthroscopy at 3 months because of femoral head osteonecrosis, the patient still had pain and decreased range of motion			Femoral head osteonecrosis at 3 months

ADL = activities of daily living; HHS = Harris hip score; NSAID = nonsteroidal anti-inflammatory drug; SF-12 = Short-Form 12-item health survey; THA = total hip arthroplasty; US = United States; WOMAC = Western Ontario and McMaster Universities.

CONCLUSIONS

- For innovative surgical procedures in the UK, nonrandomized controlled studies and large case series, supported by specialist recommendation, may be sufficient for a positive recommendation for use by NICE.
- This level of evidence is much less demanding than that required for approval by the European Medicines Agency or a reimbursement recommendation by NICE for new drugs.

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