The Journal of Arthroplasty 30 (2015) 1317–1323

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Follow-Up of Metal-on-Metal Hip Arthroplasty Patients Is Currently Not Evidence Based or Cost Effective

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ARTICLE INFO

Article history:
Received 4 December 2014
Accepted 7 March 2015

Keywords:
metal-on-metal
hip resurfacing
total hip arthroplasty
follow-up
finance
guidelines

ABSTRACT

Over one-million patients worldwide have received metal-on-metal (MoM) hip arthroplasties with a significant proportion requiring revision surgery in the short-term for adverse reaction to metal debris (ARMD). Worldwide authorities have subsequently issued follow-up guidance for MoM hip patients. This article compares follow-up guidelines for MoM hips published by five worldwide authorities, analyses these protocols in relation to published evidence, and assesses the financial implications of these guidelines. A number of major differences exist between authorities regarding patient follow-up, with vast cost differences between protocols (£84 to £988/patient/year for stemmed MoM hips and £0 to £988/patient/year for hip resurfacing). Current worldwide guidance is neither evidence-based nor financially sustainable with most protocols lacking the sensitivity to detect asymptomatic ARMD lesions.

Over one-million patients worldwide have received large-diameter metal-on-metal (MoM) hip arthroplasties (hip resurfacing (HR) and total hip arthroplasty (THA)) [1]. Recently high short-term failure rates due to adverse reaction to metal debris (ARMD) have been observed with MoM hips [2–6]. ARMD is the sequelae of metal debris released from MoM articulations due to wear and corrosion [7], which can result in destructive soft-tissue masses often requiring revision [8]. In the United Kingdom (UK) the prevalence of ARMD revision surgery is increasing, accounting for 13% of all revisions performed in 2012 [9]. As ARMD can cause significant bone loss and muscle damage, short-term outcomes following revision are often poor [10,11]. These unsatisfactory outcomes are concerning given that most patients are young and active [12–14]. Early revision surgery for ARMD is currently recommended which may improve outcomes [15,16]. To identify patients with ARMD early, regulatory authorities worldwide have published follow-up guidance for MoM hip patients [16–20].

This article compares follow-up guidelines for MoM hip patients issued by five worldwide authorities, analyses these protocols in relation to published evidence, and assesses the financial implications.

Follow-Up Guidelines

Guidance for MoM hip follow-up has been issued by the: UK Medical and Healthcare Products Regulatory Agency (MHRA) [16], European Federation of National Associations of Orthopaedics and Traumatology (EFORT) [17], United States of America (USA) Food and Drug Administration (FDA) [18], Therapeutic Goods Administration of Australia [19], and Health Canada [20] (Table 1). Major differences in follow-up guidance exist between authorities.

HR and THA

The USA and Canadian authorities do not distinguish between the follow-up of HRs and THAs. Other authorities make this distinction and follow-up large-diameter (≥36 mm) THAs regardless of symptoms [16,17,19]. Furthermore, these three authorities stratify HR follow-up by symptoms, with some also using ARMD risk factors. Small HR femoral head sizes are a high-risk group requiring at least annual surveillance in European (<50 mm) and Australian (≤45 mm) guidance, but not by the MHRA. Although USA and Canadian guidance stratifies follow-up according to symptoms, both advise closer follow-up (review intervals not stated) for patients with ARMD risk factors.

The authors would like to thank The Royal College of Surgeons of England and The Arthritis Research Trust, which have provided one of the authors with funding in the form of a Surgical Research Fellowship.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.03.009.

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http://dx.doi.org/10.1016/j.arth.2015.03.009
0883-5403/

Table 1
Follow-Up Guidance for Large-Diameter Metal-on-Metal Hip Arthroplasty Patients Published by Worldwide Authorities.

	MHRA UK [16]	EFORT Europe [17]	FDA USA [18]	TGA Australia [19]	Health Canada [20]
Distinguishes between HR and large-diameter THA	Yes	Yes	No	Yes	No
Follow-up protocol	All THA ≥36 mm + symptomatic HR — annually for implant life Asymptomatic HR[a] — as per local protocol	All THA ≥36 mm and HR with risk factors[d] — annually for implant life All HR without risk factors — annually for first 5 years (then as per local protocol)	All MoM hips[c] Asymptomatic = every 1 to 2 years Symptomatic = at least every 6 months	All MoM hips with symptoms, & asymptomatic THA ≥36 mm or HR ≤ 45 mm — at least annually Other MoM hips with no symptoms — as per practice for non-MoM hips	All MoM hips with symptoms — no guidance given on regularity of follow-up All MoM hips without symptoms — annually for first 5 years (then as per local protocol)[c]
Follow-up for symptomatic patients	All MoM hips = ions + imaging	All MoM hips = x-ray + ions + imaging	All MoM hips = x-ray + ions + imaging	All MoM hips = x-ray + ions + imaging	All MoM hips = x-ray + ions + imaging
Follow-up for asymptomatic patients	THA = ions[b] HR = see above	All MoM hips = x-ray + ions Further imaging if x-ray abnormal or Co between 2 and 7 μg/l	Clinical review	Asymptomatic THA ≥36 mm or HR ≤ 45 mm = x-ray + ions + imaging Other MoM hips with no symptoms (see above)	Clinical review
Metal ion sampling	Whole blood (Co and/or Cr)	Whole blood (Co only)	Whole blood (Co and/or Cr)	Whole blood or serum (Co and Cr)	Whole blood or serum (Co and Cr)
Metal ion thresholds of concern	>7 μg/l	2-7 μg/l	None stated	None stated	>7 μg/l
Plain radiographs recommended for any patients	Not stated	All patients	Symptomatic patients only	All patients	Symptomatic patients only
Cross-sectional imaging recommended	MARS MRI or ultrasound	MARS MRI or ultrasound or CT	MARS MRI or ultrasound or CT	MARS MRI or ultrasound	MARS MRI or ultrasound
Consider need for revision surgery	If imaging abnormal and/or blood metal ion levels rising	(1) If imaging abnormal and/or blood metal ion levels raised or rising (2) If Co >20 μg/l	Decide in response to overall clinical scenario and test results, but consider early revision in patients with progressive lesions	If persistent symptoms, imaging abnormalities and/or where blood metal ions are rising	If symptoms and positive MRI (soft-tissue mass) If positive MRI (soft-tissue mass), increasing in size

Cr = chromium; Co = cobalt; CT = computed tomography; EFORT = European Federation of National Associations of Orthopaedics and Traumatology; FDA = Food and Drug Administration; HR = hip resurfacing; MHRA = Medical and Healthcare Products Regulatory Agency; MARS MRI = metal artefact reduction sequence magnetic resonance imaging; MoM = metal-on-metal; TGA = Therapeutic Goods Administration; THA = total hip arthroplasty; UK = United Kingdom; USA = United States of America.

[a] Excludes Articular Surface Replacement hip resurfacing.

[b] Imaging recommended if blood metal ion levels rising.

[c] Advises closer follow-up for patients at increased risk of device wear such as females, those with bilateral implants, suboptimal component alignment, or hip resurfacings with small femoral head sizes (less than or equal to 44 mm).

[d] Risk factors include small femoral head size (<50 mm), female gender, and low coverage arc.

Follow-Up Regularity

Only the FDA advocates universal follow-up for all MoM hips for the implant lifetime (six-monthly reviews if symptomatic, and 1–2 yearly if asymptomatic). All other authorities recommend at least annual follow-up for most MoM hips, including large-diameter THAs, HRs with ARMD risk factors, and all symptomatic patients. Asymptomatic HR patients and those without ARMD risk factors are reviewed either according to local protocol or annually for five-years followed by local protocol.

Investigations

All authorities stratify investigations according to patient symptoms. Symptoms are defined by three authorities as pain and abnormal gait (including limping) [16,18,20], whilst European and Australian guidance do not define symptoms. The FDA and Canadian guidance further define symptoms as noises from the hip, decreased range of motion, swelling, local nerve palsy, and dislocation. Although patient reported outcome measures such as the Oxford Hip Score [21] are reliable and responsive instruments, no guidance recommends their usage during follow-up.

For symptomatic patients blood metal ions and cross-sectional imaging are universally recommended. For asymptomatic patients recommendations include: clinical review only [18,20], radiographs with metal ions [17], metal ions alone for THAs [16], and radiographs, metal ions, and cross-sectional imaging for all THAs and HRs with small head sizes [19].

All authorities recommend whole blood for determining metal ion concentrations, with serum also acceptable in Australia and Canada. European guidance requires measurement of cobalt only, though all other authorities recommend both cobalt and chromium sampling.

The MHRA make no recommendations regarding hip radiographs, whilst the FDA and Canada suggest radiographs in symptomatic patients only. All authorities advocate either metal artefact reduction sequence magnetic resonance imaging (MARS MRI) or ultrasound for cross-sectional imaging, however both the FDA guidance and the European guidance consider computed tomography (CT) to also be acceptable.

Blood Metal Ion Thresholds

Blood metal ion concentrations above 7 μg/l are of concern in two authorities [16,20] with the MHRA recommending repeat testing within