Evidence in focus

Publication summary

Reito A, et al. *Acta Orthop* (2017)*

smith&nephew

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The BIRMINGHAM HIP◇ Resurfacing (BHR◇) System was gradually introduced into practice supported by clinical evidence from peer-reviewed literature

Conversely, introduction of the ASR™ Hip Resurfacing System (ASR) and ASR™ XL Total Hip Replacement (ASR XL) was rapid and disproportionate compared to the clinical evidence base

Study overview

- A systematic literature review assessing whether the introduction of three metal-on-metal hip implants (BHR, ASR [DePuy Orthopaedics] and ASR XL [DePuy Orthopaedics]) followed IDEAL Collaboration proposals for step-wise, evidence-based introduction of orthopaedic implants:
  - Step 1: preclinical testing
  - Step 2: clinical studies published in peer-reviewed literature
  - Step 3: real-world use recorded in registries
- The annual number of implanted BHR, ASR and ASR XL from 2002 (BHR), 2006 (ASR) and 2010 (ASR XL) through to 2013 was extracted from:

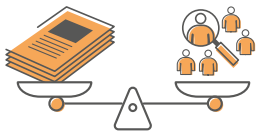
89 peer-reviewed clinical studies (BHR, 65; ASR, 17; ASR XL, 13; some studies assessed >1 implant)

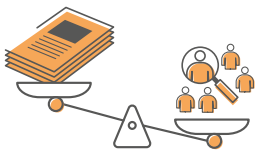
7 hip arthroplasty registries from 8 countries (Australia, Denmark, England, Finland, New Zealand, Norway, Sweden and Wales)

- The cumulative proportion of implanted hips in clinical studies was compared over time to the cumulative proportion of implanted hips in registries. When the two cumulative proportions grow at a comparable rate over time, it can be inferred that the implant was introduced in a gradual, step-wise, evidence-based manner

Key findings

- BHR was introduced gradually
  - The cumulative proportion of implanted hips in clinical studies and in registries grew proportionally over time
- Introduction of ASR and ASR XL was rapid
  - Over time, the cumulative proportion of implanted hips in registries grew disproportionately faster compared to clinical studies
  - ASR: only one peer-reviewed study was published prior to its peak use (2007)
  - ASR XL: the first peer-reviewed study was published the year ASR was recalled (2010)





Conclusion

BHR was introduced gradually thorough preclinical and clinical testing, in line with the step-wise, evidence-based introduction of orthpaedic implants proposed by the IDEAL Collaboration. The introduction of ASR and ASR XL was rapid, with regulatory approval based on preclinical proof of similarity studies, and did not follow the recommended step-wise introduction.

Study citation

*Reito A, Lehtovirta L, Lainiala O, Mäkelä K, Eskelinen A. Lack of evidence—the anti-stepwise introduction of metal-on-metal hip replacements. *Acta Orthop*. 2017;88(5):478–483.

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