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ORIGINAL ARTICLE

Survey on the use and behaviour of metal-on-metal hip replacements in Spain[☆]



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KEYWORDS

Total hip arthroplasty;
Metal-metal prosthesis;
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Hip surface replacement

Abstract

Background: Following medical device alerts published in different countries of problems with metal-on-metal total hip replacements, the Spanish Agency of Medicines and Medical Devices (AEMPS) in collaboration with the Spanish Hip Society Surgery designed a national survey to gather information on the use and behaviour of these hip implants.

Methods: The survey consisted of a questionnaire sent by e-mail to 283 clinical centre recipients of metal-on-metal hips to be filled in by surgeons with expertise in the field.

Results: A total of 257 questionnaires were completed. The response rate of the clinical centres was 36.7%. A total of 97.7% of the responses reported that clinical and radiological follow-ups are carried out, and 79.6% undertook metal ion analyses (chromium and cobalt). A large majority (83.6%) of the responders who had used surface implants, and 70% of those with large-head implants reported peri-operative complications. The most common complication was pain (25% with surface implants and 30.8% with large-head implants). Currently 80.8% of those responding were considering abandoning implanting of these hip replacements.

Conclusions: Despite the many limitations to this study, the survey has allowed us to obtain in a quick first view of the implant scenario of Metal on Metal hip implants in Spain, and to determine the type of patient implanted, the time of implantation, and the experience/expertise of the surgeons, and the type of follow-up carried out.

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PALABRAS CLAVE

Prótesis total de cadera;
Prótesis metal-metal;
Pares de fricción metal-metal;
Artroplastias de superficie de cadera

Encuesta sobre el uso y comportamiento de las prótesis de cadera metal-metal en España**Resumen**

Objetivo: La publicación de alertas en distintos países sobre posibles complicaciones del par metal-metal en las prótesis totales de cadera, indujo a la Agencia Española de Medicamentos y Productos Sanitarios en colaboración con la Sociedad Española de Cirugía de Cadera a diseñar una encuesta de ámbito nacional, con el objetivo de obtener información sobre el uso y comportamiento de estos implantes.

Material y método: La encuesta utilizó como instrumento un cuestionario que fue enviado por correo electrónico a 283 centros receptores de prótesis de cadera metal-metal para que fuese cumplimentado por los cirujanos con experiencia en este tipo de implantes.

Resultados: El número total de encuestas cumplimentadas fue 257. La tasa global de respuesta de los centros fue del 36,7%. El 97,7% de las encuestas refirieron realizar seguimientos clínicos y radiográficos y el 79,6% analíticos. El 83,6% de las encuestas que habían implantado prótesis de superficie y el 70% de las que habían implantado prótesis con cabeza grande refirieron complicaciones perioperatorias. El fallo más frecuente referido fue el dolor tanto en prótesis de superficie como en prótesis de cabeza grande. Actualmente el 80,8% de las encuestas han referido haber abandonado este tipo de implantes.

Conclusiones: A pesar de las numerosas limitaciones del estudio, la encuesta ha permitido obtener de forma rápida un primer contacto con la realidad de la implantación de prótesis de cadera metal-metal en España, y conocer así el perfil de pacientes intervenidos, el periodo de implantación, la experiencia de los cirujanos y el tipo de seguimiento realizado.

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Introduction

The theoretical advantages of hip prostheses with a metal-on-metal friction coupling and their widespread adoption in clinical practice^{1–6} have subsequently been questioned due to reports of local adverse effects,^{7–9} as well as an increase in the levels of metallic ions in blood and urine with possible systemic reactions.^{10–13} The potential hazards of these implants became better known after health alerts were published in various countries^{14–16} and at a national level,¹⁷ even causing significant public concern in some cases.¹⁸

The publication of these alerts about possible complications related to metal-on-metal couplings in total hip prostheses (THP) and their possible repercussion on the population, led the Spanish Drug and Healthcare Products Agency (*Agencia Española de Medicamentos y Productos Sanitarios, AEMPS*) to evaluate the use and behaviour of these implants in our country. Due to the variability in the results obtained by research studies, which hindered an analysis of both effectiveness and safety of metal-on-metal couplings in THP, as well as an absence of available information regarding the monitoring of implanted patients caused by the lack of a National Registry of Arthroplasties, AEMPS collaborated with the Spanish Hip Surgery Society (*Sociedad Española de Cirugía de Cadera, SECCA*) in the design of a survey on the use and performance of hip prostheses with metal-on-metal couplings in Spain.

The survey on the use and performance of hip prostheses with metal-on-metal couplings was conducted at a national level to obtain information about the behaviour of

metal-on-metal THP in our country. The specific objectives were to describe the characteristics of the intervened population and of the prostheses used, to know the experience in implantation, analyse some of the complications derived from their use and to know the type of monitoring conducted on implanted patients.

This work presents the main results obtained in the survey on the use and performance of metal-on-metal hip prostheses in Spain with the limitations inherent to this type of research procedure.

Material and methods**Design**

The survey was designed by AEMPS in collaboration with SECCA between the months of September and October 2013.

The target population of the survey were surgeons with experience in implantation of THP with metal-on-metal couplings who worked at public and private centres throughout the national territory.

The sample was calculated using the Registry of Healthcare Products of AEMPS, listing distributors of metal-on-metal coupling THP in Spain. Based on this registry, AEMPS identified 283 centres receiving hip prostheses with metal-on-metal couplings in Spain. All 283 centres were included in the study.

The questionnaire produced is structured into 15 questions, mainly with closed answers. The questions were defined to gather the following information:

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