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REVIEW ARTICLE

Information and advice for orthopaedic surgeons: a decision tree to a patient with prosthesis with metal-metal friction pair

Información y asesoramiento para cirujanos ortopédicos: árbol de decisiones ante un paciente portador de prótesis con par de fricción metal-metal

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The ASR surface prostheses and the XL heads by Depuy Johnson&Johnson® have been withdrawn from the market worldwide due to adverse outcomes that were greater than initially foreseen. In general, in the registries of the United Kingdom and Australia, there is a 5-year revision rate of 12% for the ASR and 13% for the XL heads.

The Spanish Society for Hip Surgery (Sociedad Española de Cirugía de Cadera, SECCA) suggests the following action guidelines for surgeons and, as a result, to benefit patients:

1. All patients carrying any of the prosthetic components that have been withdrawn should be identified and informed that they are carrying a prosthesis that has been removed from the market and that, henceforth, they will be included in a very strict monitoring and surveillance protocol.
2. They must undergo routine check-ups yearly, at which time they will receive the appropriate information regarding the clinical and radiological evolution of their hip arthroplasty, as well as the possible need to conduct other diagnostic tests, such as blood levels of metallic ions, to determine the degree of wear on the implant. This follow-up should continue throughout the life of the patient or until more data become available.
3. In patients with proper clinical function, there are no studies showing the need to carry out any special kind of monitoring, beyond the routine yearly check-ups. However, should the X-rays show certain extreme positions of the components, there may be a high rate of wear and special testing should be performed to verify proper functioning.
4. Should the implant of one of the models mentioned become painful, differential diagnosis should be made with other causes for the pain, such as infection, aseptic loosening of the components, tendonitis, or irritation of the psoas, trochanteric bursitis, fractures, osteonecrosis, referred pain from the spinal column, abdomen, and/or pelvis.
5. In certain patients, it may be necessary to measure ions such as chrome and cobalt in blood and urine so as to assess the rate of wear of the prosthetic surface. There is a long history of metal analysis and the results are

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reliable. It would also be wise to order concentrations in urine, since patients with good kidney function (such as all those carrying this type of prosthesis) are capable of maintaining relatively normal figures in blood, but present high figures in urine, putting them at risk.

In general, these values are low in patients in whom the prosthesis is functioning well. Cobalt or chrome levels of 7 ppb in blood (μg/L or ng/mL) can be considered to be the average value in these implants. Below this level, damage is less likely and there appears to be less of a risk of implant failure. Above this level, patients will require closer supervision and may need revision surgery if there is a correlation between poor clinical evolution and poor radiological evolution. There is no scientific evidence that an isolated increase in metal ion levels in blood, with good clinical or radiological evolution justifies revision surgery with removal of the prosthesis.

6. When, following routine examinations, there is a suspicion of implant failure, the most useful complementary examinations include computerized tomography (CT) with transversal slices or magnetic resonance imaging (MRI) with artefact attenuation software. These examinations may reveal peri-articular fluid collections or adverse cystic lesions in response to the particles released by the implants.
7. If the patient is asymptomatic, but the rest of the examinations yield progressively worse results, the convenience of revision surgery to remove the implant should be considered together with the patient. The decision as to when to perform the revision surgery should still be based on clinical parameters. The worsening of pain or presence of severe pain, increased metal ions in blood/ urine or and increase in the cystic or solid mass mandate revision surgery. The revision surgery may be challenging in the presence of an adverse event affecting peri-articular soft tissues, often demanding difficult debridement and reconstructions. It is important that all the abnormal tissue be debrided, similar to treatment for infection. An imaging study (MRI and/or CT) should be performed prior to the operation to see the extension of the diseased tissue. The surgery should be conducted by expert hip implant surgeons.
8. If the patient is asymptomatic and his/her complementary tests are normal, follow-up should be scheduled on a

Table 1 Clinical practice recommendations in the clinic for patients with a metal-metal friction pair prosthesis

A. If the patient is asymptomatic, the clinical examination is normal, and simple X-rays do not reveal any problem, blood/urine ion levels (chrome and cobalt) will be requested and will serve as control values.
—If these tests are normal, repeat one year later at follow-up.

B. If the patient is asymptomatic, the clinical examination is normal, and simple X-rays do not reveal any problem, but the patient is very concerned about the prosthesis, order blood/urine ion levels (chrome and cobalt) and imaging studies (CT and/or MRI with artefact attenuation techniques).
—If these tests are normal, carry out follow-up at one year
—If the tests are doubtful, repeat follow-up after 6 months (in the event of clinical deterioration, the check-up should be brought forward).

C. If the patient is asymptomatic, the clinical examination is normal, but the X-rays reveal that the acetabular component is poorly positioned (orientation greater than 55°), blood/urine ion levels (chrome and cobalt) should be ordered along with imaging studies with sagittal and coronal slices (CT and/or MRI with artefact attenuation techniques).
—If the tests are normal, repeat follow-up after 6 months (in the event of clinical deterioration, the check-up should be brought forward).
—If the tests are doubtful, repeat follow-up after 3 months (in the event of clinical deterioration, the check-up should be brought forward).
—If the tests are abnormal, seriously consider the possibility of prosthetic revision surgery (particularly high metal ion levels or the presence of cystic adverse reaction in the peri-articular soft tissues).

D. If the patient is symptomatic and other causes for the pain have been ruled out, order blood/urine ion levels (chrome and cobalt) and imaging studies (CT and/or MRI with artefact attenuation techniques).
—If symptoms are mild, but the tests are normal, repeat follow-up after 3 months (in the event of clinical deterioration, the check-up should be brought forward).
—If symptoms are mild, but the tests are abnormal (particularly high metal ion levels or presence of cystic adverse reaction in the peri-articular soft tissues), serious consideration should be given to the possibility of prosthetic revision surgery.
—If symptoms are severe, but the tests are normal, serious consideration should be given to the possibility of prosthetic revision surgery.
—If symptoms are severe or are getting worse and the test results are abnormal, consider immediate prosthetic revision surgery.

CT: computerized tomography.
MRI: magnetic resonance imaging.

yearly basis, although the patient should be informed that, if there is clinical worsening, he/she should see a physician immediately. The patient should be advised as to the symptoms that are of concern.

Clinical practice recommendations are as follows:

1. Contact patients and explain to them that they will be included in a protocol for close supervision and that they should contact their surgeon so that he/she can begin to study their situation (individualized in each case).
2. In the clinic with the patient carrying a prosthesis with a metal-metal friction pair (table 1).

Notes

—It is important for patients to receive the very best advice possible. Patients should have free access to return to the clinic at any time should their symptoms worsen.
—Prosthetic revision surgery with removal of the implant must be objectively evaluated after comprehensive analysis of the causes involved. The revision surgery may be complex and should be performed by surgeons who are experts in hip surgery. Once the indication has been established, the revision surgery should be performed promptly, so as to avoid damage due to progressive osteolysis in the peri-prosthetic bone tissue.
—The implants retrieved should be sent to an independent laboratory with the patient's knowledge. The information should not be sent to any commercial business without the patient's consent.
—This guideline represents the best practices at present to protect the patients, but it may change as scientific evidence is updated with respect to these implants.

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