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The development of the National Arthroplasty Registry of Slovenia (RES) – from the idea to the results

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Introduction

The National Arthroplasty Registry of Slovenia (RES) was launched in 2019 as an upgrade of a Valdoltra hospital registry, which has been running for 21 years. The RES registry's goal is to analyze the quality of implants used in Slovenia. RES operates as a healthcare program with funding from the Health Insurance Institute of Slovenia.

Materials and Methods

The first data were inserted in the Excel file and the reports were made using Excel and Tableau. Since 2021, IBM SPSS Statistics 28.0 has been used for analysis. The company for the development of the application did address the requirements of specification, architecture design, coding, testing, validation, and product support. The structure and data from the Implant Library were adjusted from the hospital registry and added to the surgery data.

Results

In 2019, all the hospitals in Slovenia, performing knee or hip arthroplasties, were requested by RES to send the appropriate formularies with data about patients, surgeries and materials used in the hip or knee arthroplasty. In 2022, the computer application was ready, the files from 2019 were imported and data from 2022 on were entered directly into the application. In September 2022, the application was upgraded with PROMs, registered before and 6 months or/and 12 months after surgery. The information on the implants is checked from the labels with barcode readers and has a direct connection to the Implant Library. Now the real-time data, including the patient's vital status in the RES database are ready for the reports.

Discussion

RES is a new registry, but we learned from other registries and implemented good practices. Since 2023, RES has been completely digitalized, including PROMs monitoring. There is still a lot of work in automating data collection and upgrading the software to improve the existing application.

Keywords: National Arthroplasty Registry of Slovenia (RES), primary hip arthroplasty survival, primary knee arthroplasty survival, Patient Reported Outcome Measures (PROMs), Implant Library

Notes

No. 4

Catastrophic acetabular cup failure as a model of large amount of periprosthetic titanium alloy debris accumulation *in vivo*

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Introduction

The majority of contemporary total hip arthroplasty (THA) implants are constructed from Ti-alloys. Although Ti-alloys are generally believed to generate fewer adverse local tissue reactions (ALTR) compared to CoCr-alloys, trunnionosis has been linked to pain, ALTR, and aseptic loosening of implants. This study aims to present a case of primary THA where an extreme release of Ti-alloy debris was observed.

Materials and Methods

A 52-year-old active male underwent osteosynthesis for a femoral neck fracture in 2006. The patient subsequently developed aseptic necrosis of the femoral head and received THA eight months after the fracture treatment. Following THA, he noticed unusual sounds during weight-bearing but did not experience any pain. Seventeen years after the THA, the patient presented with groin pain and restricted range of motion.

Results

X-rays revealed protrusion of the alumina ceramic head through the Ti₆Al₄V acetabular cup. Trace element analysis indicated significantly elevated levels of serum Ti (891.4 µg/L; norm <6.0 µg/L), Al (11 µg/L; norm <10.0 µg/L), and V (6.33 µg/L; norm <0.14 µg/L). CT and MRI confirmed Ti-alloy cup failure and severe ALTR. During revision surgery, no acetabular liner was found, and the worn-out ceramic head was in direct contact with the acetabular cup, having protruded through the central hole it created over time. Tissue samples exhibited substantial metal debris and chronic inflammation. The presence of Ti, Al, and V elements was confirmed using micro Particle Induced X-ray Emission (micro-PIXE). Six months after the revision THA, the patient has experienced favorable outcomes, with declining Ti, Al, and V values.

Discussion

This case provides an instructive illustration for studying the consequences of substantial release of Ti-alloy debris from orthopedic implants. Given the remarkably elevated serum Ti values following THA failure, this patient will be vigilantly monitored for potential long-term effects associated with Ti-alloy debris.

Notes

No. 107**Impact of surgeon variability on septic revision rates following total hip arthroplasty: An analysis of the Valdoltra Arthroplasty Registry**

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Introduction

The rising prevalence of total hip replacement (THR) surgery, has led to a growing number of revisions due to periprosthetic infection. This study investigates the impact of individual surgeons on septic revisions within the first postoperative year, utilizing data from the Valdoltra Arthroplasty Registry.

Patients and Methods

A total of 13,265 THRs for primary osteoarthritis were performed from January 1st 2002 to December 31st, 2022. The average age at the surgery was 67.9 years and the average BMI was 28.9.kg/m². 7389 (55.7%) THRs were implanted in females and 5876 (44.3%) in males. There were 14 consultant surgeons with more than 500 surgeries performed in this period. Statistical analyses, utilizing a logistic mixed effect model with gender, age, BMI, and surgical approach as fixed variables, and surgeon as a random variable, was conducted using the R program, version 4.2.2.

Results

Out of the total, 50 THRs (0.4%) were revised for deep infection within the first year. The incidence of revisions on one surgeon ranged from 0/868 cases to 10/1060 cases (0,93%). The sex (female vs. male; OR 0.43, 95% CI 0.24 – 0.78, P=0.005) and BMI (OR 1.16, 95% CI 1.10 – 1.22, P<0.001) were significantly associated with infection. However, the surgeon variable did not prove to be a significant contributing factor for infection.

Discussion

Although the differences among surgeons were detected, the surgeon variability did not contributed significantly to postoperative infection in the first year. The study's limitations include a relatively low number of revisions for periprosthetic infection within the first postoperative year, making statistical analysis inconclusive. Consistent with previous findings, BMI and male gender were identified as factors increasing the probability of postoperative periprosthetic infection.

Notes

No. 85

Comparing the response rate of Patient Reported Outcome Measures (PROMs) in the National Arthroplasty Registry of Slovenia

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Introduction

Patient Reported Outcome Measures (PROMs) are widely used in clinical medicine, in order to determine the outcomes of surgeries reflected in their lives. At the National Registry of Slovenia (RES), which is managed by the Valdoltra Orthopaedic Hospital (OBV), we started to collect PROMs in September 2022. In this presentation, we will discuss the response rate.

Materials and Methods

Since September 2022 we have collected PROMs data about primary knee and hip arthroplasties, using OHS and OKS, EQ-5D-5L, and VAS, for patients of OBV. Data were collected at three points in time. First, patients are given the printed questionnaires upon their admission to the hospital. Administrators have been digitalising the collected data. The telephone number for each patient has been also recorded. Six and twelve months after surgery, administrators of OBV called the patients and collected again their data about PROMs, and inserted it in the application.

Results

From 2nd of September 2022 to 5th of December 2023, there have been 1537 primary hip and 1323 primary knee arthroplasties performed in OBV, inserted in the database. The response rate for the preoperative period for primary hip arthroplasties is 83,73 %, and for primary knee arthroplasties is 82,46 %. The response rate for the period of 6 months after primary hip arthroplasties is 56,36 %, and for primary knee arthroplasties is 52,39 %. The response rate for the period of 12 months after primary hip arthroplasties is 49,69 %, and for primary knee arthroplasties is 42,28 %.

Discussion

Results show that the response rate of patients undergoing primary hip and knee arthroplasties is above 80 % when the data is collected before surgery – at the time of the admission to the hospital. The response rate is between 40 and 60 %, when the patients are being called 6 and 12 months after surgery.

Keywords: Patient Reported Outcome Measures (PROMs), National Arthroplasty Registry of Slovenia (RES), primary hip arthroplasty, primary knee arthroplasty, EQ-5D-5L, Oxford Hip Score (OHS), Oxford Knee Score (OKS), Visual Analogue Scale (VAS)

Notes

No. 86

Comparing summarised and factor scores for Oxford Hip Score and Oxford Knee Score

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Introduction

Oxford Hip Score (OHS) and Oxford Knee Score (OKS) are widely used instruments for measuring the outcome of primary hip and knee arthroplasties. Up to now, the most common way to determine the overall score was to add all the answers to 12 different questions about pain and functionality of the affected hip or knee. In this presentation, we suggest using factor scores to obtain the overall score. Factor analysis is a multivariate statistical analysis that linearly reduces the number of variables and is frequently used in surveys.

Materials and Methods

The National Arthroplasty Registry of Slovenia (RES), which is managed by the Valdoltra Orthopaedic Hospital (OBV), was launched on the 1st of January 2019. On the 2nd of September 2022, data about PROMs have been also added. In this presentation, the focus is being made on preoperative OHS and OKS. In total, there are 2758 valid answers for OHS and 2787 valid answers for OKS in the database. A comparison between the traditional way of obtaining the final score and using factor analysis to calculate the final score is being made.

Results

In both cases, as for OHS and OKS, one factor is suggested, explaining 46 % and 47 % of total variance. The correlation with the summarised score is very high ($r > 0,9$) suggesting an appropriate measure. The distribution of the summarised and factor score is very similar.

Discussion

As results show no discrepancies between summarising the answers and using factor loadings to calculate the final OHS or OKS score, we suggest using the factor scores. The result in this case is more objective and the variable is measured on a ratio scale, compared to the summarised score, which is more subjective and the variable is measured on an interval scale.

Keywords: Patient Reported Outcome Measures (PROMs), National Arthroplasty Registry of Slovenia (RES), primary hip arthroplasty, primary knee arthroplasty, Oxford Hip Score (OHS), Oxford Knee Score (OKS), factor analysis

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Implementing PROMs to the computer application of the National Arthroplasty Registry of Slovenia (RES)

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Introduction

National arthroplasty registries have their role in monitoring the implants by calculating revision risks, technique-related factors and patient-related factors for inferior results. Nowadays, the active role of patient opinion is rising. In this presentation, we present how the PROMs were applied to the existing computer application of the National Arthroplasty Registry of Slovenia (RES).

Materials and Methods

RES was launched on the 1st of January 2019. The computer application started to run fully in 2022, so all the data from Excel files were imported and from then after the data were entered directly into the application. Since the state law added the monitoring of PROMs to the arthroplasty registry, we upgraded the application with validated Oxford Hip and Knee Questionnaires and EQ-5D-5L with VAS to measure quality of life.

Results

From 2019 on, all the hospitals in Slovenia, performing knee or hip arthroplasties, send the appropriate formulaires by regular mail. In September 2022, we started collecting PROMs. Patients are asked to fill in the PROM questionnaires at the time of admission. They also give a signed permission to use their telephone number for further data collection. The preoperatively PROM is added automatically to the patient data of the surgery. After 6 and 12 months the application creates the working list for the administrator, so she calls the patients and enters the answers directly into the computer. The application enables to export of data with SQL queries into the Excel and SPSS programs for further analysis.

Discussion

The National Arthroplasty Registry of Slovenia (RES) is relatively new. In its development, several modifications have been made. Adding the PROMs monitoring to the RES application has shown good results since patients are reporting PROMS with a high response rate.

Keywords: Patient Reported Outcome Measures (PROMs), National Arthroplasty Registry of Slovenia (RES), primary hip arthroplasty, primary knee arthroplasty, EQ-5D-5L, Oxford Hip Score (OHS), Oxford Knee Score (OKS), Visual Analogue Scale (VAS)

Notes