

**Official title:** Analysis of influencing factors and construction of prediction models of artificial joint replacement in China

**NCT number:** Not yet assigned.

**Date of the document:** December 27, 2017.

## **Introduction**

Joint arthroplasty (JA) is a safe and cost-effective musculoskeletal surgical procedure for relieving pain and improving function and health-related quality of life for patients with end-stage joint disease. As one of the most commonly performed procedures, more than 1.5 million knee arthroplasties (KA)<sup>1</sup>, more than 1 million hip arthroplasties (HA)<sup>2</sup> and over 100 thousand shoulder arthroplasties (SA)<sup>3</sup> were performed annually worldwide. In addition, more than 10 thousand elbow arthroplasties (EA) in Germany and has been rapidly increasing<sup>4</sup>. Moreover, the incidence of ankle osteoarthritis has been estimated to be 47.7/100,000, affecting approximately 1% of the world population<sup>5</sup>. The increased demands of JA pose a challenge for the health care system from a quality and finance perspective.

China is the most populated country in the world, and now has the second-largest economy in the world. As nearly 420 million Chinese are aged more than 50 years<sup>6</sup>, and the living standards and health system continue to improve, the demand for healthcare, including JA, is increasing<sup>7</sup>. However, the consequences of increased access to new medical technologies and their application to patient care is unknown. Description of epidemiological characteristics, risk factors, complications and resource utilization of JA<sup>8</sup>, can provide valuable information for healthcare planners in China and similar countries, and can guide care providers to develop effective and targeted preventive measures to minimize mortality from this procedure.

Therefore, in this study, investigators will use data from a mandatory patient-level

national database, i.e., the Hospital Quality Monitoring System (HQMS), to study the epidemiological characteristics, risk factors, complications and resource utilization of JA (i.e., KA, HA, SA, EA and ankle arthroplasty [AA]).

## **Methods**

### **Data source**

This nationwide retrospective study will be a review of the HQMS database. The HQMS database is a mandatory electronic inpatient database system developed by the National Health Commission of the People's Republic of China. Since 2013, tertiary hospitals have been required to upload their inpatient discharge records. By 2019, the HQMS database has included about 230 million standardized inpatient discharge records of more than 1,000 hospitals across all 31 provincial-level administrative regions in mainland China. Patient demographics, clinical diagnosis, procedures and operations, costs and complications are all recorded in the HQMS database. The diagnosis is coded in the form of International Classification of Diseases, Tenth Revision (ICD-10), and the procedures and operations are coded in accordance with International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). A more detailed description of this database can be found in previous studies<sup>7,9,10</sup>. This study was authorized by the HQMS Committee Board and approved by the institutional review board, with waiver of informed consent.

### **Study population**

Patients who were recorded in HQMS and underwent KA, HA, SA, EA and AA will be included in our study. Investigators will identify KA, HA, SA, EA and AA in HQMS based on the ICD-9-CM. To minimize the possibility of miscoding, other knee-related procedure, diagnosis codes and free texts will be also identified. Investigators will exclude: 1. Patients who didn't undergo these five types of JA; 2. Patients with missing demographics or medical data.

### **Study variables**

Patient demographics (e.g., age, sex, marital status and comorbidities), clinical diagnosis, procedures and operations, costs, complications and hospital characteristics will be all extracted from the HQMS database. Medical insurance, including Urban Employee-Based Medical Insurance (UEBMI), Urban Resident-Based Medical Insurance (URBMI) and New Cooperative Medical Scheme (NCMS), self-pay and others (e.g., commercial insurance) will be identified in our study. Preexisting comorbidities will be extracted<sup>11,12</sup>. The Charlson Comorbidity Index (CCI) will be calculate<sup>13</sup> and categorized<sup>7</sup>. Investigators will also extract the indication for KA. Hospital characteristics, such as region, volume of surgery will be extracted<sup>14</sup>.

### **Measurement of outcomes**

Five types of JA of our interest will be identified in HQMS, including KA, HA, SA, EA and AA. Epidemiological characteristics, risk factors, complications and resource utilization of these five types of JA will be analyzed.

## **Statistical analysis**

Line charts will be drawn to describe annual change in trends of JA. Basic information in different groups will be compared. For continuous variables, Mann-Whitney U test will be used for non-normally variables and Student t-test will be used for normally variables, while chi-square test or Fisher's exact test will be used for categorical data. Then, multivariable-adjusted logistic regression will be performed to examine the risk factors of complications following JA (e.g., year of surgery, patient demographics and region of hospitals) with the calculation of odds ratios (ORs) and 95% confidence interval (CI). To minimize the effect of potential confounders, the propensity-score matching or multivariable-adjusted regression will be performed to compare the incidence of complications and resource utilization in different groups<sup>15</sup>.

SAS 9.4 (SAS Institute Inc., Cary, NC, USA) will be used in all statistical analyses and  $P < 0.05$  will be considered as significant.

## Reference

1. Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991-2010. *JAMA*. 2012;308(12):1227-1236. doi:10.1001/2012.jama.11153
2. Ferguson RJ, Palmer AJ, Taylor A, Porter ML, Malchau H, Glyn-Jones S. Hip replacement. *Lancet Lond Engl*. 2018;392(10158):1662-1671. doi:10.1016/S0140-6736(18)31777-X
3. Lübbeke A, Rees JL, Barea C, Combescure C, Carr AJ, Silman AJ. International variation in shoulder arthroplasty. *Acta Orthop*. 2017;88(6):592-599. doi:10.1080/17453674.2017.1368884
4. Klug A, Gramlich Y, Buckup J, Schweigkofler U, Hoffmann R, Schmidt-Horlohé K. Trends in total elbow arthroplasty: a nationwide analysis in Germany from 2005 to 2014. *Int Orthop*. 2018;42(4):883-889. doi:10.1007/s00264-018-3818-x
5. Jeyaseelan L, Si-Hyeong Park S, Al-Rumaih H, et al. Outcomes Following Total Ankle Arthroplasty: A Review of the Registry Data and Current Literature. *Orthop Clin North Am*. 2019;50(4):539-548. doi:10.1016/j.ocl.2019.06.004
6. Feng B, Lin J, Jin J, Qian WW, Wang W, Weng XS. Thirty-day Postoperative Complications following Primary Total Knee Arthroplasty: A Retrospective Study of Incidence and Risk Factors at a Single Center in China. *Chin Med J (Engl)*. 2017;130(21):2551-2556. doi:10.4103/0366-6999.213071
7. Zeng C, Lane NE, Englund M, et al. In-hospital mortality after hip arthroplasty in China: analysis of a large national database. *Bone Jt J*. 2019;101-B(10):1209-1217. doi:10.1302/0301-620X.101B10.BJJ-2018-1608.R1
8. Shahian DM, Wolf RE, Iezzoni LI, Kirle L, Normand SLT. Variability in the measurement of hospital-wide mortality rates. *N Engl J Med*. 2010;363(26):2530-2539. doi:10.1056/NEJMsa1006396
9. Zhang L, Long J, Jiang W, et al. Trends in Chronic Kidney Disease in China. *N Engl J Med*. 2016;375(9):905-906. doi:10.1056/NEJMc1602469
10. Gu J, Shi Y, Zhu Y, et al. Ambient air pollution and cause-specific risk of hospital admission in China: A nationwide time-series study. *PLoS Med*. 2020;17(8):e1003188. doi:10.1371/journal.pmed.1003188
11. Perlas A, Chan VWS, Beattie S. Anesthesia Technique and Mortality after Total Hip or Knee Arthroplasty: A Retrospective, Propensity Score-matched Cohort Study. *Anesthesiology*. 2016;125(4):724-731. doi:10.1097/ALN.0000000000001248

12. Chu CC, Weng SF, Chen KT, et al. Propensity Score-matched Comparison of Postoperative Adverse Outcomes between Geriatric Patients Given a General or a Neuraxial Anesthetic for Hip Surgery: A Population-based Study. *Anesthesiology*. 2015;123(1):136-147. doi:10.1097/ALN.0000000000000695
13. Marchant MH, Viens NA, Cook C, Vail TP, Bolognesi MP. The impact of glycemic control and diabetes mellitus on perioperative outcomes after total joint arthroplasty. *J Bone Joint Surg Am*. 2009;91(7):1621-1629. doi:10.2106/JBJS.H.00116
14. Tang X, Wang S, Zhan S, et al. The Prevalence of Symptomatic Knee Osteoarthritis in China: Results From the China Health and Retirement Longitudinal Study. *Arthritis Rheumatol Hoboken NJ*. 2016;68(3):648-653. doi:10.1002/art.39465
15. Seeger JD, Williams PL, Walker AM. An application of propensity score matching using claims data. *Pharmacoepidemiol Drug Saf*. 2005;14(7):465-476. doi:10.1002/pds.1062