

Health resource use and costs of symptomatic knee and/or hip osteoarthritis

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Health resource use and costs of symptomatic knee 1 and/or hip osteoarthritis 2 3 JH Salmon^{1,2}, AC Rat^{3,4}, H Achit⁴, W Ngueyon-Sime⁴, C Gard⁵, F Guillemin⁴, D Jolly^{2,6}, B Fautrel^{7,8} 4 5 ¹ Rheumatology Department, Maison Blanche Hospital, Reims University Hospitals, Reims, F-51092, 6 France. 7 ²University of Reims Champagne-Ardenne, Faculty of Medicine, EA 3797, REIMS, F-51095, France. 8 ³Rheumatology Department, CHRU de Nancy, Hôpitaux de Brabois, Vandoeuvre-lès-Nancy, France. 9 ⁴Université de Lorraine, APEMAC, F-54000 Nancy, France; CHRU-Nancy, INSERM, CIC-EC, 10 54000 Nancy, France. 11 ⁵Department of Pharmacy, Pitié-Salpêtrière Hospital, 47-83 Boulevard de l'Hôpital, 75013, Paris, 12 France. 13 ⁶Department of Research and Innovation, Robert Debré Hospital, Reims University Hospitals, Reims, 14 F-51092, France. 15 ⁷Sorbonne Université, Institut Pierre Louis de d'Epidémiologie et Santé Publique, GRC08, Paris 16 France. 17 ⁸AP-HP, Pitié-Salpêtrière Hospital, Rheumatology Department, 83 Boulevard de l'Hôpital, 75013, 18 Paris, France. 19 ihsalmon@chu-reims.fr. ac.rat@chru-nancy.fr, h.achit@chru-nancy.fr, w.ngueyon-sime@chru-20 nancy.fr, claudine.gard@aphp.fr, francis.guillemin@chru-nancy.fr, djolly@chu-reims.fr, 21 bruno.fautrel@psl.aphp.fr. 22 Correspondence and reprint requests to: Pr Bruno FAUTREL, Service de Rhumatologie, Groupe 23 Hospitalier Pitié-Salpêtrière, 83 boulevard de l'Hôpital, 75651 Paris cedex 13. Tel: +33 1 421 77801, 24 Fax: +33 1 421 77802. Email: bruno.fautrel@psl.aphp.fr. 25 26 Keywords: Osteoarthritis, Knee, Hip, Costs, Health Resources 27

Running title: Costs of symptomatic hip and knee OA

29 30	Abstract
31	Background: Data on the economic consequences of hip and knee osteoarthritis (OA) are
32	scarce. We aimed to estimate the annual direct and indirect costs for patients followed for hip
33	and/or knee OA in the KHOALA cohort.
34	Methods: The KHOALA cohort, set up from 2007 to 2009, is a French multicenter study of
35	878 individuals with symptomatic knee/hip OA who were 40 to 75 years old. Resources used
36	were collected annually for 5 years. Costs were assigned by using official sources and
37	expressed in 2018 euros per patient.
38	Results : The mean annual total costs per patient over the 5-year study period were 2,180 \pm
39	5,305€. The mean annual direct medical costs per patient were 2,120 ± 5,275€ and mean
40	annual indirect costs per patient 180 ± 1,735€ for people of working age. Costs increased
41	slightly over the study period. Drugs were the largest cost share, representing over 50% of all
42	direct costs. However, the proportion attributable to OA drugs accounted for only 10.5% of
43	drug costs. The second cost share was hospitalizations; hip and knee prosthetic surgery
44	accounted for 27% of surgery hospitalization costs. Health professional visits were the third
45	cost share, accounting for 3% of direct medical costs. The median costs induced could be as
46	high as 2 billion €/year (IQR 0.7–4.3) in France.
47	Conclusion: Hip and knee OA costs were substantial and increased over the study period in
48	France. However, the costs attributable to OA represented only a small fraction of overall
49	costs
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52 53	Word count: 245
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Introduction

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Osteoarthritis (OA) is one of the most frequent musculoskeletal diseases, often resulting in severe functional disability (1). The prevalence of symptomatic knee and hip OA ranges from 10% to 20% depending on the population studied and the methods used to elicit these estimates (2). The prevalence of radiographically knee OA in 2010 was estimated to be 3.8% (3). The age-standardised prevalence of radiographically hip OA in 2010 was 0.85% (3). In the United States, the annual incidence of symptomatic knee OA is estimated at 17% and symptomatic hip OA 10% (4,5). In Europe, the prevalence of radiological hip and knee symptomatic OA in people 40 to 75 years old was estimated at 1.9% and 4.7%, respectively, for men and 2.5% and 6.6% for women (2). The overall ageing of the population as well as the increasing prevalence of obesity will be associated with an increased prevalence of lowerlimb OA and its functional consequences on affected patients, for an impending public health issue in society (6). The mean total costs associated with knee and/or hip OA range from €500 to €10,900 per year (5). There is a substantial heterogeneity in the methods used to assess the costs of OA (7). Depending on the population studied (community or hospital recruitments, patient profiles, socioeconomic status) and mode of diagnosis (symptomatic vs radiographic OA), OA cost estimates were reported with a multiplication factor between the lowest and highest estimates of 22 for hip and knee OA and even 65 for all-site OA (7). For more accurate estimates from an epidemiologic and public health perspective, we need to assess health resource use in a representative and large population sample with extended follow-up. The Knee and Hip Osteoarthritis Long term Assessment (KHOALA) cohort is a French multicenter, population-based prospective cohort of prevalent cases of symptomatic hip and knee OA; it was the continuation of a population-based survey aiming to estimate the prevalence of hip and knee OA independent of access to care by patients (2,8). Patients were

- 81 included between 2007 and 2009, then followed regularly to collect information on general
- and joint health as well as health resource use (2,8).
- Here we aimed to estimate the annual direct and indirect OA costs incurred by patients in the
- 84 KHOALA cohort over 5 years to describe their distribution in terms of cost components.

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Participants and Methods

Participants

Individuals who were 40 to 75 years old and had uni- or bilateral symptomatic hip and/or knee OA (American College of Rheumatology [ACR] criteria (9,10)) with Kellgren and Lawrence (KL) stage ≥ 2 (11) were recruited from a French national prevalence survey for the multicenter KHOALA cohort study (2). The cohort and its methodology for data collection were previously described (2,8). Individuals were recruited from two-stage population-based national prevalence survey conducted in France from April 2007 to March 2009 (2). Patients have been recruited through a population-based poll aiming to assess knee and/or hip OA prevalence, independently of any visit to a physician. Briefly, the survey involved a random sample of households in six French regions obtained by random digit phone dialing and the next-birthday method in each household. OA diagnosis was confirmed by a rheumatologist. All people with OA identified were invited to participate in the 10-year KHOALA cohort prospective study. Inclusion criteria were both sexes; age 40 to 75 years; uni- or bilateral symptomatic hip and/or knee OA; clinical diagnosis confirmed and fulfilling ACR criteria for knee (10) and hip OA (9); and KL stage ≥ 2 on standard X-rays (11). Individuals were excluded if they had prosthesis for the symptomatic joint, previous osteotomy, severe comorbidity leading to significant deterioration of functional abilities and quality of life or major healthcare consumption, isolated patello-femoral OA, or other joint disease. The cohort study was approved by the Medical Ethics Committee CPP Est III and was registered at ClinicalTrials.gov (NCT00481338). All participants gave their written informed consent before inclusion in the study.

Health resource use data

This study is an analysis of data for the first 5-year cohort (2008-2012). Data were collected by use of a validated self-reported questionnaire including consultations with physicians (general practitioners, rheumatologists, orthopedic surgeons and other specialists) and other health professionals (physiotherapists, nurses, occupational therapists, podiatrists, dentists, speech therapists and alternative medicine practitioners), drug use, imaging [radiography (X-ray), CT scan, MRI, bone densitometry, scintigraphy and other work-ups], hospitalizations, biological investigations [i.e. 25-(OH) D3 levels, serum creatinin, parathormone, sensitive C-reactive protein, erythrocyte sedimentation rate, leucocyte count, platelet count, hemoglobin concentrations, albumin and coagulation parameter], technical aids and transportation. This method had previously demonstrated good agreement with administrative data in people with OA (12). The questionnaires were administered every year, exploring a period of 3 months for consultations, drugs, biological investigations, imaging, technical aids and transportation and 12 months for hospitalizations. If necessary, health resource use was annualized. The original questionnaire is available in supplemental data.

Direct medical costs and indirect costs assessment

Estimation of direct medical costs included all costs incurred via the National Health Insurance System (NHIS) and private supplementary health insurance and by patients. For specialists, general practitioners, nurses and physiotherapists, an average consultation fee was estimated by using the 2015 general classification system for treatments (13–15).. Transportation, lab and imaging work-ups as well as technical aids were estimated according

131 to the 2015 social health insurance reimbursement fee of the Classification Commune des 132 Actes Médicaux (www.ameli.fr/accueil-de-la-ccam/index.php) or the Nomenclature des Actes 133 de Biologie Médicale 134 (http://www.codage.ext.cnamts.fr/codif/nabm/index_presentation.php?p_site=AMELI) 135 (14,16,17).136 Drugs were grouped according to their international nonproprietary names, and their costs 137 were calculated by estimating the mean fee per milligram or per dose, according to the Vidal 138 2016 database (18). If dosage data were missing, standard dosages were imputed taking into 139 account the patient's weight when applicable. According to the therapeutic class, we 140 differentiated drugs related to OA (analgesics, non-steroidal anti-inflammatory drugs 141 [NSAIDs], symptomatic slow-acting drugs, corticosteroids, corticosteroid infiltration and 142 viscosupplementation) or not. 143 For each hospitalization, a primary diagnosis or action code was assigned according to the 144 reason for the hospitalization reported by participants. This coding enabled the identification 145 of the closest corresponding Diagnosis-Related Group and the associated fees for the year 2015 as reported by the Technical Agency for Information on Hospital Care (Agence 146 147 Technique de l'Information sur l'Hospitalisation) (19). The attribution to OA was determined 148 by the authors on the basis of the reason for hospitalization. 149 Indirect costs were calculated in terms of the number of days off work per year due to knee 150 and/or hip OA as reported by participants. The costs associated with one day of sick leave 151 corresponded to the mean daily salary of a French employee, on the basis of the national 152 global domestic product (GDP) per capita in 2016. 153 Total costs were the sum of direct medical costs and indirect costs.

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Statistical analysis

Patient characteristics at baseline and health resource use for each year of follow-up are described by mean (SD) or number (%) at baseline. Yearly costs are described by mean for each year (year 1, 2, 3, 4 and 5) and/or median (interquartile range [IQR]) if non-normal distribution. To assess the median annual total costs of hip and knee OA in the 40 to 75-year-old population, standardized prevalence estimates calculated according to the French age and sex distribution for 2006 (www.insee.fr/fr/statistiques) were used (2). All statistical analyses involved using SAS v9.4, (SAS Institute, Inc., Cary, NC).

Results

Patient characteristics

In total, 878 individuals were included in the KHOALA cohort, 222 with hip OA (mean age 61.2 ± 8.8 years), 607 knee OA (mean age 62.0 ± 8.5 years) and 49 both hip and knee OA (mean age 64.7 ± 8.0 years). Baseline characteristics of the 878 participants are in Table 1. Radiographic disease severity for KL (11) stages 2, 3 and 4 represented 69.8%, 26.1% and 4.1%, respectively, of hip OA patients and 44.5%, 30.3%, and 25.2%, respectively, of knee OA patients. Mean Functional Comorbidity Index (FCI) (20) was 3 ± 1.5 for hip OA; 3.1 ± 1.6 for knee OA and 3.1 ± 1.4 for hip and knee OA. Mean duration after first symptoms is higher compared to mean duration after diagnosis. Mean body mass index (BMI) was 26.9 ± 4.4 for patients with hip OA, 30.3 ± 6.2 for those with knee OA and 29.8 ± 6.2 for those with both hip and knee OA.

Health resource use

The proportions of patients using healthcare resources are shown in Table 2. General practitioners have a central role. Only 20% of patients consult a rheumatologist. Most of

181 health care use is stable over 5 years. The decrease in the number of patients is due to loss-to-182 follow-up (refusal to prosecute (60%), death (22%), other (18%)). 183 184 Costs 185 Direct medical costs 186 The mean and median annual direct medical costs per patient over 5 years were 2,120€ and 187 980€ (IQR 395-2,350) respectively. The mean annual direct medical costs per patient were 188 1,515€ in year 1; 1,945€ in year 2; 1,935€ in year 3; 3,270€ in year 4; and 2,140€ in year 5. 189 Although OA mean direct medical costs increased by 41% at the end of the follow-up, the 190 median decreased by 33% from 515€ in year 1 to 345€ in year 5. This decrease was explained 191 by the fact that 50% of the patients accounted for 89% of the total direct medical costs over 192 the 5 years. The mean annual direct medical costs per patient over 5 years were 1,805€ for hip 193 OA; 2,230€ for knee OA; and 2,195€ for hip and knee OA (Table 3). 194 195 **Indirect costs** 196 The mean annual indirect costs per patient over 5 years were 60€ (180€ for the 554 patients 197 who were still on the market place). These costs were 95€ in year 1; 65€ in year 2; 40€ in year 198 3; 70€ in year 4; and 45€ in year 5. Hip and knee OA patients did not differ in indirect costs: 199 60€ for hip OA; 65€ for knee OA and 40€ for hip and knee OA (Table 3). 200 201 Total costs 202 The mean and median (IQR) annual total costs per patient over 5 years were 2,180€ and 203 1,115€ (400–2,385), respectively. They ranged from 1,615€ in year 1; to 2,010€ in year 2;

1,975€ in year 3; 3,340€ in year 4; and 2,190€ in year 5 (Figure 1). The mean annual total

costs per patient over 5 years were 1,865€ for hip OA; 2,295€ for knee OA; and 2,235€ for hip and knee OA (Table 3).

Costs over 5 years by patient characteristics (Table 3)

The affected joint, KL stage and FCI seemed associated with consumption of care. Indeed, the mean annual total costs over 5 years were increased for patients with knee OA and increased KL grade and FCI but not body mass index.

Cost share (or cost structure) and costs attributable to OA

The estimated costs of health resource use are shown in supplemental data. Drugs were the largest cost share, representing over 50% of all direct medical costs across the years. Annual drug costs ranged from 905€ in year 1 to 1,760€ in year 4 and 1,130€ in year 5. However, the proportion attributable to OA-specific agents (analgesics, NSAIDs, symptomatic slow-acting drugs, corticosteroids, corticosteroid infiltration and viscosupplementation) accounted for only 10.5% of drug costs over 5 years (i.e., annual mean of 110€ per patient and per year). Hospitalizations were the second largest component of health resource utilization. Costs of OA-related hospitalizations in medicine accounted for 9% of the total hospitalizations costs over 5 years (i.e., annual mean 20€ per patient and per year). Direct medical costs of OA-related hospitalizations in surgery accounted for 43% of surgery hospitalization costs over 5 years (i.e., annual mean 280€ per patient and per year). Hip and knee prosthetic surgery was the main reason for surgery (23%) but accounted for 27% of surgery hospitalization costs over 5 years (i.e., annual mean 177€ per patient and per year). The other reasons for surgery were less frequent but more expensive (according to the 2015 coding of the Technical Agency for Information on Hospitalization).

Health professional visits were the third direct medical cost component of health resource utilization, mainly for physiotherapy. They accounted for 3% of direct medical costs over 5 years (i.e., annual mean 150€ per patient and per year). Physiotherapy accounted for 1% to 2% of the direct medical costs over 5 years (i.e., annual mean 8€ per patient and per year). Annual cost distribution per resource user and average annual direct medical costs per patient and per resource are available in supplemental data.

The economic burden of hip and knee OA in France

On standardization to the French population 40 to 75 years old, the prevalence of hip and knee symptomatic and radiological OA was 2.5% and 6.5% for men and 1.0% and 2.7% for women, respectively [i.e. 1.8 million patients in 2017 (2)]. From these prevalence estimates, the median annual total costs of hip and knee OA in the 40- to 75-year-old population would be approximately 2 billion €/year (IQR 0.7–4.3), with direct medical costs of 1.7 billion €/year (IQR 0.7–4.2).

Discussion

This study described costs related to healthcare use among a representative sample of individuals with symptomatic hip and/or knee OA over 5 years. The mean and median annual total costs per patient over 5 years were 2,180€ and 1,115€ (IQR 400–2,385) respectively. Direct medical costs accounted for 97% of the total cost. Our findings highlight the burden of drugs, which represented the largest cost component among KHOALA patients.

Worldwide, the mean estimated annual total costs for knee and/or hip OA are heterogeneous: €1,000 in Europe, €6,200 in Asia (Singapore) and €10,000 in North America (7). The difference in costs we observed could be related to several points. First, published studies showed substantial methodological heterogeneity. Our economic study is innovative in its

method of recruitment and duration of follow-up. Indeed, the multi-center recruitment of individuals independent of any medical consultation is a major strength because it potentially allowed for including individuals who never consulted any physician (2). Regardless, OA diagnosis was ascertained by physicians on the basis of clinical and radiological features. Second, we included patients who had a prosthesis during follow-up. Prosthetic surgery is not always included in the direct medical costs of studies even though joint surgery is considered an important cost driver in hip and knee OA (7). Also, the follow-up of our study was 5 years, whereas the median follow-up for previous studies was 1 year (range 3 months to 2 years) (7). Third, the health resources studied in KHOALA are quite exhaustive, unlike in some studies, in which costs such as physiotherapy, hospitalizations, biology and imaging are not systematically included in direct cost estimates (7). In terms of all elements, the KHOALA cohort can be considered representative of the reality of people living with knee and hip OA. The social burden of OA is expected to be high and increasing in France. Indeed, in 1993, 3 million people had symptomatic OA, with direct medical costs of about 0.6 billion €/year (21). In 2003, 4.6 million people had symptomatic OA, with direct medical costs of about 1.6 billion €/year (22). These studies included patients with symptomatic general OA, including those over 75 years old. From the standardized prevalence, 1.8 million people 40 to 75 years old would have symptomatic and radiological hip and/or knee OA in 2017. Median annual direct medical costs would be about 1.7 billion €/year (IQR 0.7–4.2). The prevalence of OA is increasing with the aging of the population as well as obesity, which is becoming more common (23). The costs of the disease have increased even further, owing to an increase in patient demand for care and more frequent use of prosthetic surgery (24,25). Previous studies reported high rates of comorbidities and heathcare utilization among OA

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patients (26–28)

However, specific costs attributable to OA represented only a small fraction of overall costs. Our patients had a substantial number of comorbidities, which was expected due to the population demography. As a result, the main cost share was related to these comorbidities rather than OA. The importance of costs attributable to OA-related comorbidities has been discussed (26) but never clearly demonstrated. The limitations of the study include the observational design, missing data and lack of comparison. The presence of a control group (a cohort of patients matched for age, sex and co-morbidities, without knee and / or hip osteoarthritis) would reduce confounding bias. Moreover, use of self-reported questionnaires can imply memory bias and inaccurate data. However, the observational design have the advantage of better meeting the needs of daily practice and including subjects often excluded from randomized controlled trials and on a larger number of subjects and time much longer observation time. Using a patient-completed questionnaire was a feasible and valid way to capture health resource use and costs for patients with OA as compared with data from administrative databases (12). To conclude, in the KHOALA cohort, healthcare consumption costs over the first 5 years after inclusion in the cohort were heterogeneous and substantial. The costs might be related to a high proportion of patients with comorbidities. The follow-up of the cohort is 10 years, we will can study annual direct and indirect OA costs over 10 years and if the use of the replacement joints allows a costs reduction in long-term. These data are important for describing the healthcare costs of a representative sample of patients with symptomatic OA of the hip and/or knee recruited from the general population in France.

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309	writing. All have read and approved the final version of the manuscript for publication.
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Figure Legends:

Figure 1: Average annual total costs per patient over 5 years

Supplemental data: Mean annual direct medical costs per patient and per resource