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Pilot Study of an e-Cohort to Monitor Adverse Event for Patient with Hip Prostheses from Clinical Data Warehouse

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Abstract. Hip arthroplasty represents a large proportion of orthopaedic activity, constantly increasing. Automating monitoring from clinical data warehouses is an opportunity to dynamically monitor devices and patient outcomes allowing improve clinical practices. Our objective was to assess quantitative and qualitative concordance between claim data and device supply data in order to create an e-cohort of patients undergoing a hip replacement.
We performed a single-centre cohort pilot study, from one clinical data warehouse of a French University Hospital, from January 1, 2010 to December 31, 2019. We included all adult patients undergoing a hip arthroplasty, and with at least one hip medical device provided. Patients younger than 18 years or opposed to the reuse of their data were excluded from the analysis. Our primary outcome was the percentage of hospital stays with both hip arthroplasty and hip device provided. The patient and stay characteristics assessed in this study were: age, sex, length of stay, surgery procedure (replacement, repositioning, change, or reconstruction), medical motif for surgery (osteoarthritis, fracture, cancer, infection, or other) and device provided (head, stem, shell, or other).
We found 3,380 stays and 2,934 patients, 96.4% of them had both a hip surgery procedure and a hip device provided. These data from different sources are close enough to be integrated in a common clinical data warehouse.

Keywords: Data Warehousing; Data Management; Arthroplasty, Replacement, Hip; Equipment Safety

1. Introduction

The number of Total Hip Arthroplasty (THA) is constantly increasing in France [1]. With the reinforcement of the European regulatory constraints, there is a need to improve follow-up of patients with hip prostheses with an efficient post-marketing surveillance [2]. Complications are rare but have important consequences on the patients' quality of life (surgical site infection, deep vein thrombosis, dislocation).

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In France, there is no national cohort of hip replacement patients of sufficient quality to be reused for surveillance purposes [3]. This lack of data makes it difficult to combine clinical information on patients and technical data on devices to identify the determinants of rare and/or delayed but severe complications such as surgical site infection or luxation. Moreover, the classic manual constitution of a cohort is a long expensive process requiring a high workload for the teams. Moreover, a dynamic link between patients and outcomes could allow real-time updated surveillance [4–6].

The digitization of medical records and health examinations represents now a large re-usable data sources to monitor adverse event. These digital data could be stored following FAIR principles, in clinical data warehouses in order to provide a technical, regulatory, interoperability and security framework adapted [7,8]. The use of our data warehouses already makes it possible to track drug complications and it seems necessary to study the possibility of tracking complications after an joint replacement [9,10]. Since the 2007 regulation, the references of implanted medical devices are listed and linked to the identification of the patient for device safety purposes [11]. Our hypothesis was that the device data were comprehensive and of sufficient quality to track the different components of a hip device to monitor adverse event through a clinical data warehouse.

Our objective was to assess quantitative and qualitative concordance between claim data and device supply data in order to integrate them into a data warehouse.

2. Method

We performed a single-centre pilot cohort study between January 1, 2010 and December 31, 2019, using the clinical data warehouse of one University Hospital using a large data warehouse software eHOP [12]. We included all patients' stays of hip arthroplasty procedure or with at least one hip medical device provided. Patients younger than 18 years or opposed to the reuse of their data were excluded from the analysis.

The coverage obtained by hospital stays from matching two different sources was assessed: the surgical procedure data came from claim data (hospital discharge database PMSI), completed with a French version of the Current procedural terminology (CPT) and the medical device data came from the pharmacy supply software. The consistency of using inclusion criteria from different sources was measured by identifying the percentage of hospital stays having both a hip replacement procedure and a hip device provided.

A descriptive analysis of the main characteristics was performed: age, sex, length of stay, surgery act (replacement, repositioning, change, or reconstruction), surgery motif (arthrosis, fracture, cancer, infection, osteonecrosis or other main diagnosis) and device provided (head, stem, shell, or other) following Giori et al [6]. This descriptive analysis specifically specified the source of each of these data and missing data.

In order to know in which medical and surgical situation we were able to obtain each component, we crossed the hospital stays according to the main cause of surgery and the presence of a head, a stem and a shell device. In the same way we crossed the type of surgical procedure and the presence of a head, a stem and a shell device to evaluate the completeness according to the type of surgical procedure.

3. Results

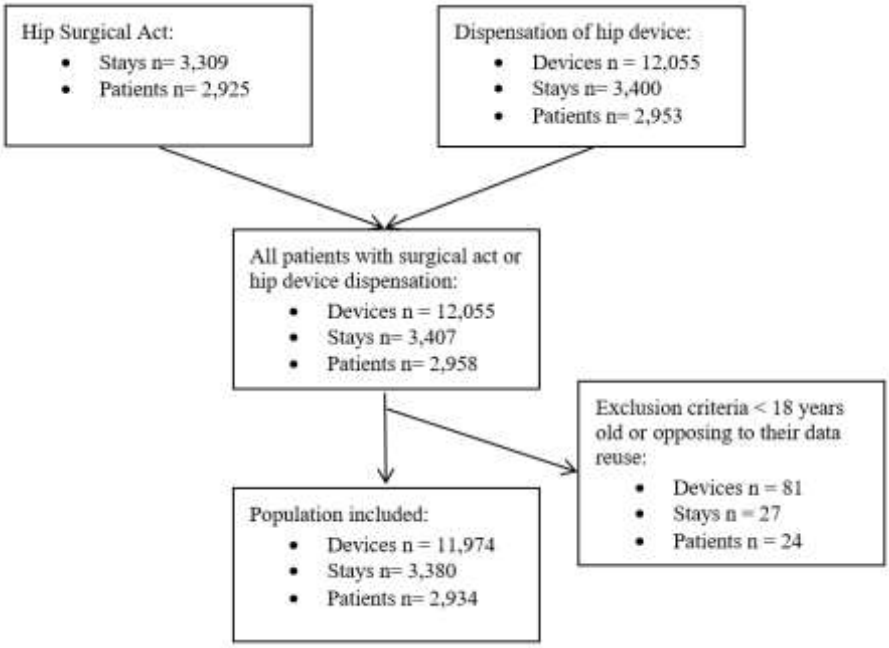

Figure 1. Flow chart

Table 1. Main characteristics of the population

Features	Descriptive Data	Source of Data
Stays (N = 3,880)		
Age (mean (sd))	71.3 (13.8)	Hospital discharge database
Sex		
- Female (%)	1,910 (43.5%)	
- Male (%)	1,470 (56.5%)	
Length of stay (mean (sd))	10.3 (10.5)	
Surgery procedure		Claim data French CPT
- Replacement (%)	2,642 (78.2%)	(Common procedure terminology)
- Change (%)	475 (14.1%)	
- Reconstruction (%)	86 (1.7%)	
- Repositioning (%)	57 (1.7%)	
- Missing value (%)	120 (3.5%)	
Cause of surgery		Claim data ICD-10
- Arthrosis (%)	1,864 (55.1%)	
- Fracture (%)	875 (25.9%)	
- Infection (%)	153 (4.5%)	
- Cancer (%)	85 (2.5%)	
- Osteonecrosis (%)	58 (1.7%)	
- Other (%)	327 (9.7%)	
- Missing value (%)	18 (<1%)	
Device (N = 11,974)		Device supply data
- Femoral Head (%)	3,444 (28.8%)	
- Femoral Stem (%)	3,055 (25.5%)	
- Acetabular Cup (%)	4,952 (41.3%)	
- Others (%)	523 (4.4%)	

Over the study period, 3,407 hospital stays corresponded to a hip replacement; of which 3,309 have a medical / surgical procedure and 3,400 have a medical device provided. Moreover, 27 stays were excluded because they were under 18 years old or opposed to the data reuse. We obtained 3,380 hospital stays, including 11,974 hip devices implanted.

The coverage between the medical / surgical procedure and the device supply data was 96.4%. Among the 3,380 hospital stays, 120 (3.6%) stays without hip surgery procedure were found.

The mean age of the patients was 71.3 years old years with 56.5% women and 43.5% men. The mean length of stay was 10.3 days. 55.1% of the stays were for hip arthrosis and 25.9% for femoral neck fracture (table 1).

Table 2. Presence of hip devices according to the main cause of surgery.

	Arthrosis	Fracture	Infection	Cancer	Osteonecrosis	Others
N	1,864	875	153	85	58	327
Device						
Head (%)	1,843 (98.9%)	871 (99.5%)	150 (98%)	84 (98.8%)	58 (100%)	293 (89.6%)
Stem (%)	1,801 (96.6%)	851 (97.3%)	84 (54.9%)	32 (37.6%)	56 (96.6%)	168 (51.4%)
Shell (%)	1,844 (98.9%)	864 (98.7%)	143 (93.5%)	80 (94.1%)	58 (100%)	299 (91.4%)

Table 3. Presence of hip devices according to the surgical procedure.

	Replacement	Change	Reconstruction	Repositioning
N	2,642	475	86	57
Device				
Head (%)	2,633 (99.7%)	428 (90.1%)	85 (98.8%)	56 (98.2%)
Stem (%)	2,608 (98.7%)	263 (55.4%)	47 (54.7%)	49 (86%)
Shell (%)	2,632 (99.6%)	425 (89.5%)	84 (97.7%)	57 (100%)

Over 90% of the hospital stays had a femoral head and shell references. The presence of femoral stems was more inconstant, especially in procedures performed for surgical site infections or cancer. Similarly, we found device references in over 98% of joint replacement procedures. In more complex procedures such as prosthesis change, reconstruction and repositioning the references were found in 50 to 100% of the cases (table 2-3).

4. Discussion

With 96.4% coverage, we obtained close data between the hospital stays obtained by medical-surgical procedures and those obtained by medical devices. The devices were found for more than 90% of the heads and shells and almost entirely for the most common clinical cases such as joint replacement in first intention for osteoarthritis.

In the case of change or repositioning surgery, the prosthesis stems were not systematically replaced and the procedure might concern only the head and the acetabulum, which might explain the procedures without stem. In the reconstructive surgery scenario, devices data included batch devices, but did not include custom prostheses, which may explain the missing stem devices in some femoral cancer reconstruction.

These results are obtained from a single centre, but these data might also be close in other centres because claims data are collected in the same way for all French healthcare facilities and device data are subject to the same traceability regulations in France. The data obtained are subject to the usual bias of information, when handling

the hospital discharge database, and in the same way the device supply data the errors of information are ever possible. The number of medical records with missing device data was reasonable to be manually reviewed and corresponded to case-by-case situations, either due to data input errors or surgery where one of the pieces was actually not dispensed. The data reuse of medical device dispensed for a post-marketing surveillance and epidemiological purposes seemed possible.

The reliability of these data seemed high enough to be integrated in our clinical data warehouse. Among the next challenges, the organization of devices according to a common thesaurus seems complex considering the heterogeneous characteristics of medical devices and the lack of international common thesaurus.

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