Patients Lost to Follow-up in Shoulder Arthroplasty: Descriptive Characteristics and Reasons

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Background: The purpose of this study was to determine the number of patients lost to follow-up yearly in shoulder arthroplasty and investigate the characteristics of the patients lost to follow-up that may differ from those not lost to follow-up.

Methods: All shoulder arthroplasties performed from January 2008 to December 2014 were retrospectively reviewed. The number of patients lost to follow-up was determined yearly. Independent variables included age, sex, body mass index (BMI), diagnosis, type of prostheses, living condition, smoking, alcohol intake, American Society of Anesthesiologists (ASA) score, in-hospital length, surgery length, living area, preoperative Constant score, last Constant score available, and complications. Number of deaths was recorded.

Results: This study included 251 patients. There was an accumulation of 86 patients (34.3%) lost to follow-up after a maximum of 8 years. During the first year, 9.9% of the patients were lost to follow-up, 18.3% in the second year, 25.1% in the third year, 28.7% in the fourth year, 31.5% in the fifth year, 33.9% in the sixth year, and 34.3% in the seventh year. Patients with severe obesity had 2.44 times greater risk of being lost to follow-up (hazard ratio [HR], 2.44; p < 0.001). Elderly patients were also at higher risk (HR, 1.05; p < 0.001). Increases in the ASA score raised the risk of being lost (HR, 1.93; p < 0.001). Patients with complications had a lower risk (43%) of being lost (HR, 0.57; p = 0.018) at the 8-year follow-up. At the 2-year follow-up, the patients with acute fractures and fracture sequelae had a higher risk of being lost to follow-up (HR, 2.44; p = 0.002), and the patients with complications were not significantly different from those without complications (HR, 0.54; p = 0.12).

Conclusions: The longer the follow-up in shoulder arthroplasty, the greater the number of patients lost to follow-up, reaching 34.3% by the seventh year. Patients lost to follow-up were not random in shoulder arthroplasty: older patients, severely obese patients, and those with higher ASA scores were at higher risk of being lost to follow-up, but reasons for being lost to follow-up changed through time and depending on when they were assessed.

Keywords: Follow-up, Outcomes, Shoulder arthroplasty

Many study limitations have been described in observational studies. Among them, incomplete follow-up represents one of the major sources of bias. Patients lost to follow-up may differ from those that do not drop out and the rate of patients lost may differ between study groups. This potentially creates a bias as patients lost are not random. Patients lost to follow-up may have poorer outcomes than respondent patients, thereby making for an overestimation of the outcomes when only respondents are included. Moreover, the characteristics of the patients lost to follow-up may differ among patients with different pathologies such as an acute trauma, a rotator cuff tear, a degenerative disorder of the lumbar spine, a total hip or total knee arthroplasty, or a displaced intra-articular...
calcaneal fracture.\(^\text{12}^\) Following the recommendations of Sackett et al.,\(^\text{13}^\) major orthopedic journals recommend that there be no more than 20% of the patients lost to follow-up. But even 20% can dramatically affect outcomes as it has been demonstrated that a simulated loss to follow-up of 20% can change the statistical significance in 28% of a simulated series.\(^\text{14}^\)

Observational studies require a minimum follow-up period to be able to report consistent results. However, the longer the follow-up, the greater the number of patients lost to follow-up.\(^\text{15}^\) To minimize the number of patients lost, several strategies have been tested, such as selecting outcomes that can be obtained without an in-person visit, clinical sites with research coordinators, flexible scheduling, verification of contact information, reducing the requirements for participation in the study, locating patients labeled lost to follow-up, or using telephone and postal reminders.\(^\text{6,15,16}^\) Then again, many factors have been implicated in contributing to follow-up loss. They include financial barriers, logistical problems, language barriers, or adverse outcomes.\(^\text{17,18}^\)

The objective of this study was to determine the number of patients lost to follow-up yearly in shoulder arthroplasty and investigate the characteristics of the patients lost to follow-up that may differ from those not lost to follow-up. This objective was different from the common survival analysis, in which end points are usually death or revision surgery. The hypothesis of the study was that characteristics of the patients lost to follow-up would be different from those not lost to follow-up in shoulder arthroplasty.

### METHODS

The study received the approval of the Comité Etic d’Investigació Clínica (CEIC-Parc de Salut Mar) with the number 2016/7110/I. Informed consent was obtained from all the patients included.

All the shoulder arthroplasties performed in a single tertiary university hospital by a single shoulder surgeon (CT) from January 2008 to December 2014 were retrospectively reviewed. In January 2008, the medical records in the hospital were computerized, so any appointment from then and onward could be checked to determine whether the postoperative follow-up had been completed or not. The standard regime for follow-up appointments after a shoulder arthroplasty includes appointments at 1 and 3 weeks after surgery, at 3, 6, and 12 months after surgery, and yearly, subsequently. Patients who did not come to an appointment and had no other visit since the shoulder arthroplasty were deemed lost to follow-up. The number of deaths was recorded. If the death happened during the year after the last visit and before the following yearly visit, the patient was not deemed lost to follow-up. All the patients included had a minimum follow-up of 2 years and a maximum follow-up of 8 years. No specific strategy was put in place to reduce the number of patients lost to follow-up, but all the patients included were controlled because of their participation in different prospective and retrospective studies during the follow-up period.

The number of patients lost to follow-up was determined yearly. With the loss to follow-up being the dependent variable, the independent variables included and the missing data for each variable are presented in Table 1. In all the patients, the Constant score at the last available visit was also recorded.\(^\text{19}^\) Complications such as infections, revision surgeries, spine fractures, and dislocations were also recorded. The Constant score, range of motion, and complications were recorded by the senior author (CT) and subsequently obtained by reviewing the medical charts.

### Statistical Methods

Cox regression analyses were used to identify risk factors for lost to follow-up: for complete follow-up, as well as

### Table 1. Independent Variables Analyzed and Percentage of Missing Data

| Variable                                           | Missing data (%) |
|----------------------------------------------------|------------------|
| Age                                                | 0                |
| Sex                                                | 0                |
| Body mass index                                    | 19.6             |
| Type of prostheses                                 | 0                |
| Living condition (alone or with family support)    | 7.8              |
| Smoking                                            | 1.7              |
| Alcohol intake                                     | 2.1              |
| American Society of Anesthesiologists score        | 0                |
| In-hospital length                                 | 0                |
| Surgery length                                     | 1.4              |
| Living area (area belonging to the hospital/ referred from other community) | 0          |
| Preoperative Constant score                        | 18.2             |
| Last Constant score                                | 14.6             |
| Complication                                       | 0                |
| Variable                        | HR (95% CI)          | p-value |
|--------------------------------|----------------------|---------|
| **Univariate at 2-year follow-up** |                      |         |
| Age                            | 1.06 (1.02–1.11)     | 0.003   |
| Sex                            | 0.77 (0.30–1.96)     | 0.592   |
| BMI > 35 kg/m²                  | 1.83 (1.02–3.28)     | 0.042   |
| **Treatment**                   |                      |         |
| Anatomical                      | 0.29 (0.03–2.27)     | 0.241   |
| Reverse                         | 1.35 (0.68–2.67)     | 0.378   |
| Living condition                | 1.27 (0.66–2.46)     | 0.465   |
| ASA score                       | 1.97 (1.22–3.19)     | 0.005   |
| In-hospital length              | 1.03 (0.95–1.12)     | 0.384   |
| Surgery length                  | 0.87 (0.37–2.03)     | 0.758   |
| Living area                     | 0.64 (0.32–1.27)     | 0.210   |
| Preoperative Constant score     | 0.96 (0.92–1.00)     | 0.057   |
| Last Constant score             | 0.97 (0.95–1.00)     | 0.064   |
| With complications              | 0.54 (0.25–1.17)     | 0.122   |
| **Univariate for the whole period** |                      |         |
| Age                            | 1.05 (1.02–1.08)     | < 0.001 |
| Sex                            | 0.74 (0.37–1.47)     | 0.393   |
| BMI > 35 kg/m²                  | 2.44 (1.60–3.73)     | < 0.001 |
| **Treatment**                   |                      |         |
| Anatomical                      | 2.11 (0.64–7.02)     | 0.219   |
| Reverse                         | 2.39 (0.74–7.65)     | 0.141   |
| Living condition                | 1.40 (0.86–2.28)     | 0.174   |
| ASA score                       | 1.93 (1.33–2.78)     | < 0.001 |
| In-hospital length              | 1.03 (0.96–1.10)     | 0.314   |
| Surgery length                  | 1.00 (1.00–1.00)     | 0.036   |
| Living area                     | 1.08 (0.70–1.68)     | 0.709   |
| Preoperative Constant score     | 0.98 (0.95–1.01)     | 0.225   |
| Last Constant score             | 0.98 (0.97–1.00)     | 0.066   |
| With complications              | 0.57 (0.36–0.90)     | 0.018   |

HR: hazard ratio, CI: confidence interval, BMI: body mass index, ASA: American Society of Anesthesiologists.
Truncating at two years. The proportional hazard assumption, checked by examining Schoenfeld residuals (for overall model and variable by variable), was not violated. Stata ver. 15 (StataCorp., College Station, TX, USA) was used for statistical analysis.

RESULTS

This study included 251 patients who underwent shoulder replacement between January 2008 and December 2014. Twenty-one of those patients underwent bilateral shoulder replacement, but only data from the first surgery were analyzed. Most of the patients were women (85.7%) and the mean age was 72.5 years (range, 33–88 years). There were 158 reverse shoulder arthroplasties, 74 hemiarthroplasties, and 19 total shoulder arthroplasties of anatomical design. Rotator cuff arthropathy was the most common indication for surgery (43.1%), followed by acute fractures (21.1%), primary arthropathy (18.4%), fracture sequelae (7.3%), revision surgery (6.5%), and tumoral surgery (0.7%).

There was an accumulation of 86 patients (34.3%) lost to follow-up after a minimum follow-up of 2 years and maximum of 8 years. During the first year, 9.9% of the patients were lost to follow-up. The percentage of patients lost to follow-up was 18.3% in the second year, 25.1% in the third year, 28.7% in the fourth year, 31.5% in the fifth year, 33.9% in the sixth year, and 34.3% in the seventh year.

During the 8-year follow-up period, there were 39 deaths (15.5%). Twelve of them happened during the follow-up period and were not classed as lost to follow-up, while 27 of them happened after being lost to follow-up. There were 35 patients with complications (13.9%). They included 17 infections (6.7%), 12 revision surgeries (4.7%), 4 spine fractures (1.6%), and 2 dislocations (0.8%). Smoking and alcohol intake involved only 15 patients (5.9%) and 16 patients (6.3%), respectively, out of the 251 patients included and could not be analyzed as independent variables.

Patients with severe obesity (body mass index [BMI], > 35 kg/m²) had a 2.44 times greater risk of being lost to follow-up (hazard ratio [HR], 2.44; 95% confidence interval [CI], 1.60–3.73; p < 0.001). Elderly patients were at a higher risk. With every year of increase in age, the odds of being lost increased 5% (HR, 1.05; 95% CI, 1.02–1.09; p < 0.001). Increases in the American Society of Anesthesiologists (ASA) score raised the risk of being lost 1.9 times (HR, 1.93; 95% CI, 1.33–2.78, p < 0.001). Patients with complications had a lower risk (43%) of being lost (HR, 0.57; 95% CI, 0.36–0.90; p = 0.018). Patients with better forward elevation were at the least risk (2%) of being lost to follow-up (HR, 0.98; 95% CI, 0.98–0.99; p < 0.001). Detailed data of all independent variables are shown in Table 2.

At the 2-year follow-up, the patients with acute fractures and fracture sequelae had a higher risk of being lost to follow-up than patients with other diagnoses (HR, 2.44; 95% CI, 1.37–4.36; p = 0.002). This condition was lost if the whole period was considered, and the diagnosis did not significantly affect loss at follow-up (p = 0.11). At the 2-year follow-up, the patients with complications were

| Table 3. Cox Regression Analysis for Loss to Follow-up at 2-Years and for the Whole Period |
|------------------------------------------|-------------------|-----------------|
| Covariate | HR (95% CI) | p-value |
| 2-Year follow-up | | |
| Age | 1.07 (1.00–1.14) | 0.029 |
| BMI > 35 kg/m² | 1.48 (0.67–3.26) | 0.324 |
| ASA score | 1.66 (0.87–3.16) | 0.123 |
| Last Constant score | 0.99 (0.94–1.05) | 0.898 |
| Whole period | | |
| Age | 1.02 (0.98–1.07) | 0.202 |
| BMI > 35 kg/m² | 1.04 (0.98–1.11) | 0.160 |
| ASA score | 1.63 (0.87–3.03) | 0.121 |
| With complications | 0.08 (0.01–0.68) | 0.020 |
| Last Constant score | 1.02 (0.96–1.07) | 0.439 |

HR: hazard ratio, CI: confidence interval, BMI: body mass index, ASA: American Society of Anesthesiologists.
not significantly different from those without complications (HR, 0.54; 95% CI, 0.25–1.17; \( p = 0.12 \)). This condition turned out to be significant in favor of patients with complications if the whole period was considered (\( p = 0.018 \)). An increase in the ASA score increased the risk of being lost to follow-up at the 2-year follow-up (HR, 1.97; 95% CI, 1.22–3.19; \( p = 0.005 \)). Elderly patients were at a significantly higher risk of being lost to follow-up at all the follow-up points (2, 3, and 5 years of follow-up, \( p = 0.003 \), \( p = 0.003 \), and \( p = 0.002 \), respectively). Patients with severe obesity were at higher risk of being lost to follow-up at 2 years of follow-up (HR, 1.83; 95% CI, 1.02–3.28; \( p = 0.04 \)) (Table 2).

The regression analysis for the whole period showed that having a complication was an independent factor affecting the condition of being lost to follow-up (Table 3). Among the 86 patients lost to follow-up, 64 patients came back to the same tertiary hospital for other department appointments for other reasons after being lost to follow-up while 22 never came back to the same hospital.

In 81 of the 86 patients lost to follow-up, several telephone contacts were tried at the end of the present study. Fourteen patients did not respond to the calls. Sixteen patients died during the time of data collection and analysis. Ten of the 47 patients that responded to the call (21.2%) agreed to have another visit if they could, 36 did not agree (76.6%), and 4 (8.5%) declined to respond. Among the reasons that the patients or their relatives gave for not going to their appointments, 8 patients were too old to make the trip, 15 were in a bad state, 18 thought there was no reason to come back for the visit, 6 did not go due to administrative problems, and 5 had other reasons.

**DISCUSSION**

The results of this study show that the longer the follow-up, the higher the rate of patients being lost to follow-up in shoulder arthroplasty, reaching 34.3% at the seventh year of follow-up. It also shows that increases in age, BMI, and the ASA score were associated with greater odds for being lost to follow-up. Conversely, patients with complications such as infection, revision surgery, dislocation, or spine fracture had lower odds of being lost to follow-up.

It has been shown that the length of follow-up correlates with the number of patients lost to follow-up. Many of the studies addressing the consequences of patients lost to follow-up in orthopedics have been done with a short-term follow-up ranging from 1 month to 24 months. In the present study, it was shown that the number of patients lost to follow-up increased year-to-year during the period analyzed. The critical years are the first 3 years, in which the number of patients lost to follow-up reached 25.1%. In the second year of follow-up, it almost arrived at 20% of the patients. That percentage is considered the maximum acceptable number of patients lost to follow-up for most orthopedic journals. Form the third year and on, the number of patients lost continued to rise, but at a slower rate. When the condition to be studied is an arthroplasty, long-term follow-up studies are needed to ensure that outcomes maintain through time and reflect all possible complications that may appear over time. However, the longer the follow up after arthroplasties, the higher the rate of patients lost to follow-up and thus the greater the risk of bias. An accurate description of the number and characteristics of the patients lost to follow-up is strongly recommended, especially in long-term studies, to better understand possible sources of bias. This is so as it has been shown that only 9.7% of the trials had enough description of the patients lost to follow-up.

Patients lost to follow-up are not random, they usually respond to one or another condition, normally having different prognoses and thus creating a bias when interpreting the results. The characteristics of the patients lost to follow-up may depend on the population subjected to study and may be different among the different specialties such as psychiatry, pulmonology, urology, and trauma. In trauma studies, the characteristics may include male sex, smoking, alcohol intake, younger age, and lower baseline scores. In the present study, in an elderly population with a mean age of 72.5 years, the older patients were at higher risk of being lost to follow-up. In the same manner, patients with severe obesity and a higher ASA score were also at a higher risk of being lost to follow-up. Smoking and alcohol intake were so infrequent among this older population that it could not be analyzed. Other independent variables that could affect elderly population such as living alone without support needed to get to hospital appointments or the distance to the hospital did not have an influence. It is interesting to note that characteristics of the patients lost to follow-up can change over time. In previous studies, analysis was done at a certain point of the follow-up, but the analysis was done yearly in the present study, reflecting the changes over time. Thus, in the first 2 years of follow-up, elderly patients and those having an acute or old fracture were at higher risk of being lost while patients having a complication were not at higher risk. After the third year of follow-up, the diagnosis no longer influenced the odds of being lost while conditions such as severe obesity and the ASA score were shown to have significant influence. Addition-
ally, patients presenting complications were at lower risk of being lost. This is of special interest when interpreting the results of studies. Depending on the time of follow-up, the population at risk of being lost, as well as the bias created by it, may be different.\textsuperscript{26}

Loss to follow-up has been associated with poorer outcomes. After knee arthroplasty, non-responders presented poorer results in terms of function.\textsuperscript{5} After hip replacement, they complained of greater pain and less movement and had lower satisfaction scores.\textsuperscript{9,11} Subsequent to surgical and non-surgical management of rotator cuff tears, there were lower daily living activities scores (Simple Shoulder Test).\textsuperscript{7} In the present study, patients lost to follow-up had slightly worse forward elevation, abduction, and internal rotation. However, no significant differences were noted in terms of pain or in the complete Constant score value. Conversely, patients having complications were less likely to be lost to follow-up. Patients undergoing knee or hip arthroplasty with poorer results are probably at higher risk of being lost to follow-up because they cannot attend appointments due to displacement problems, but such problems may not be the cause of nonattendance in patients undergoing shoulder arthroplasty.

Many strategies have been tried to minimize the number of patients lost to follow-up. Some strategies need to be used according to the population studied and the length of follow-up.\textsuperscript{6} Identifying patients at risk of being lost and excluding them from the trial design may create a non-representative population.\textsuperscript{7} Other options include reducing some of the requirements for participation in the study,\textsuperscript{7} using telephone or postal reminders, selecting primary outcomes that can be obtained without an in-person visit, and applying flexible scheduling.\textsuperscript{6,16} In the present study, no specific strategies were used to prevent losses to follow-up. All patients included were participating in different studies and because of this, the patients lost to follow-up were able to be contacted during the study, thereby minimizing losses. Moreover, at the end of the present study, the patients lost to follow-up were contacted again to identify the reasons why they stopped going to the appointments. Most of them would not accede to another visit. In most cases, it was because they were too elderly and in poor condition. Another important group of patients simply thought there was no reason to come back for the visit. Administrative problems seemed to account for just a small number of patients. In this selected elderly population, the main reason for being lost to follow-up was probably because attendant conditions did not make the visit possible. In the future, the follow-up will probably be more easily done via online, especially in this selected elderly population.

In light of the results of the present study, the sample size of a study has to be determined according to the length of follow-up because an increased number of patients might be lost from year to year. In addition, the results of long-term studies have to be handled with care because elderly patients and those having more comorbidities may not be present at the end of the follow-up, giving an optimistic appearance of the results.

One of the limitations of the present study is its retrospective design even though there was minimal missing data for most of the independent variables. In addition, the results were obtained from a single surgeon at a single institution, which may not reflect the general population. Among its strengths are the number of patients included and the length of follow-up.

In conclusion, the longer the follow-up in shoulder arthroplasty, the greater the number of patients lost to follow-up, reaching 34.3% by the seventh year. Patients lost to follow-up are not random in shoulder arthroplasty: older patients, severely obese patients, and those with higher ASA scores were at are higher risk of being lost to follow-up, but reasons for being lost to follow-up changed through time and depending on when they were assessed. The main reasons for missing appointments included the patients were elderly and they felt no need to go back for follow-up visits.

**CONFLICT OF INTEREST**

No potential conflict of interest relevant to this article was reported.

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