The Geneva Hip Arthroplasty Registry

Why do we need hospital-based registries? The Geneva Hip Arthroplasty Registry

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Contents

Abstract

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Introduction: In the field of joint replacement surgery, large registries exist at the regional, national and international level. These large registries provide important information on the long term effectiveness and quality of implants through direct feedback from surgeons, publications and annual reports. In this context, do we still need hospital-based registries?

Objective: We discuss strengths and limitations of hospital-based arthroplasty registries. We describe our own registry (patient-, implant- and technique-related characteristics, outcome instruments, areas of research), evaluate mortality and follow-up rates, response rates for questionnaires, and describe the effort necessary to maintain the registry.

Results: National registries provide information on a very large number of patients, many different implants and techniques and from surgeons of all levels of experience within a short period of time. Nevertheless, they are limited with respect to the number of variables they can collect for each individual patient without compromising the quality of their data, and they usually focus on "revision" as their end-point. These limitations do not apply to hospital-based registries. The Geneva Hip Arthroplasty Registry has prospectively enrolled all primary and revision total hip arthroplasties (THA) since March 1996, and now includes 4,165 primary and 385 revision THAs. Patients have a clinical and radiological follow-up visit at 5-year intervals. The following outcome measures are used: Harris Hip, Merle d'Aubigné and UCLA scores, WOMAC and SF-12 questionnaires, and satisfaction evaluation. Radiological analysis, specifically looking at osteolysis and wear, is performed by an independent Orthopaedic surgeon. Follow-up rates are 84.7% at 5 years and 85.5% at 10 years among all those who have not died or left the area. Mortality is 13.5% at 5 years and 29.6% at 10 years. Questionnaire response rates are 77% pre-operatively, 77% at 5 years and 71% at 10 years post-operatively. Maintenance of the registry necessitates continuous data input from the operating surgeons, two medical secretaries, an informatics specialist, and a physician trained in epidemiology and statistics.

Conclusion: There is an increasing need and demand to provide data on how an implant/technique works in the real world, and under which circumstances. Both small and large registries can make contributions towards this goal.

Introduction

Introduction

Registries have been recognised as powerful tools in supporting medical decision making, and even more so when long-term follow-up is required as in the field of joint replacement. Large total joint arthroplasty (TJA) registries exist at the regional, national and even supra-(inter-) national level[1-4]. They provide important information on long-term effectiveness and quality of TJA through direct feedback from surgeons, scientific publications and annual reports. In this context, the question arises whether hospital-based registries are still useful. If yes, why are they useful? What are their strengths and limitations?

The advantage of large registries is that they involve large numbers of patients, as well as a great variety of different implants and techniques used by surgeons of all levels of experience. Their usefulness has been proven in numerous instances[5-7]. Nevertheless, they are limited with respect to the number of variables they can collect for each individual patient without compromising the quality of their data[8]. In contrast, smaller area hospital- or community-based registries have the potential to collect much more information for each patient by history (e.g. patient information such as co-morbidities, patient activity), by questionnaires, or by including radiographs and other complementary examinations (e.g. gait analyses). This flexibility allows for more in-depth evaluation of questions that may have surfaced in large registries. The larger number of variables collected facilitates the evaluation of possible associations or causal relationships between adverse events and factors related to the patient, the environment, the implant or the technique applied using modern epidemiologic and statistical approaches[9]. Another important advantage is the ability to analyse outcomes among patient sub-groups beyond the age-, gender- and diagnosis-based stratification provided by national registries, which may serve as a basis for a more personalised treatment approach[10]. However, obtaining information on a sufficient number of patients per sub-group may require collecting data over a long period of time.

Registry data reflect the local patient population and local implant-, technique- and surgeon-related particulars, as well as the local healthcare system, access to care, and the specific hospital, operating room and rehabilitation environment. With respect to these determinants, larger registries may cover a broader range of characteristics than a small registry. On the other hand, variation in these population characteristics may entail confounding in studies conducted from large registries, whereas the homogeneity of a small registry may avoid that kind of bias, offsetting to some extent the more limited generality of results from small registry studies.

The end-point commonly evaluated in large registries is implant revision. In contrast, hospital-based registries have the potential advantage to report on clinical outcomes, such as the occurrence of complications (dislocation or prosthesis infection), patient satisfaction and quality of life, as well as radiographic outcomes (e.g. development of osteolysis)[11-16]. Thus, they provide essential additional information on clinical failures that is commonly not obtained from revision-based national registry data[14].

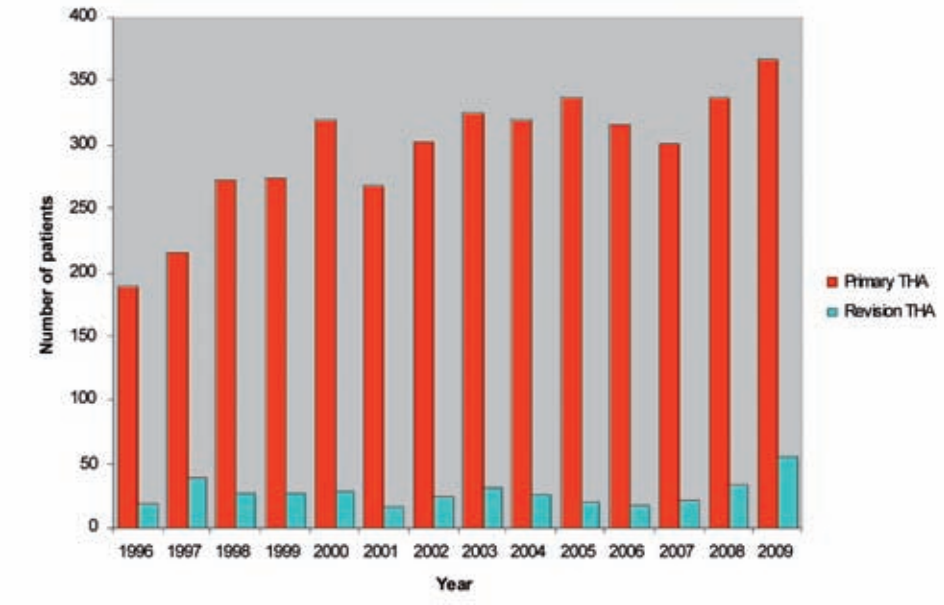
The Geneva Hip Arthroplasty Registry

Objectives and Study Population

The registry's objectives are the improvement of the patients' quality of life, and the surveillance of the quality of implants and techniques through continuous monitoring of their clinical performance and complete documentation of complications (revision, infection, dislocation, peri-prosthetic fractures, etc.). The analysis of protective factors and of risk factors (related to patient, environment, implant, technique, surgeon), the detection of trends, and the evaluation of the impact of specific interventions are part of the strategies employed to achieve this goal.

Study population: Since March 1996 all patients undergoing primary or revision THA at the Division of Orthopaedics and Trauma Surgery of the Geneva University Hospitals have been routinely enrolled in the Geneva Hip Arthroplasty Registry and followed longitudinally. The registry has been approved by the Institutional Ethics Review Board. Overall, 4,522 THAs (4,141 primary and 381 revision THAs) have been included from March 1996 to December 2009 (Fig. 1).

Figure 1: Annual number of primary and revision THAs



The Geneva University Hospital, the only public hospital in the city, is a 2032-bed tertiary teaching hospital. The Division of Orthopaedics and Trauma Surgery has five Orthopaedic wards with 105 acute care beds and a septic ward with 24 beds. Between 40 and 50 Orthopaedic surgeons of varying levels of experience are working in the centre. They perform both Orthopaedic and Trauma surgery. 6,034 annual admissions, 5,740 interventions and 34,122 ambulatory consultations were recorded in 2009.

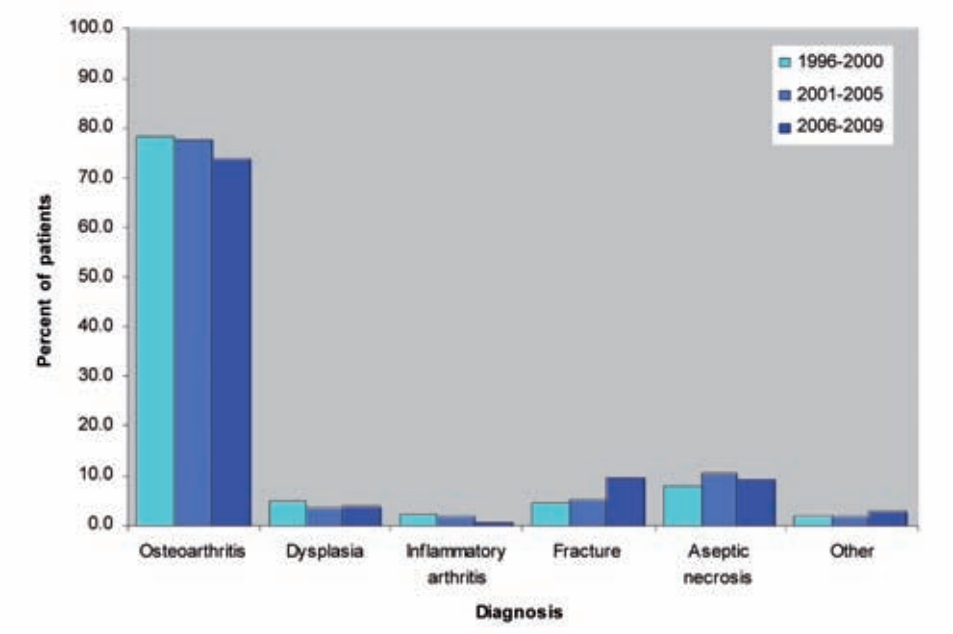
The Geneva Hip Arthroplasty Registry

Baseline Characteristics

- Our participants are comparable with those in the Swedish and Danish registry with respect to the baseline characteristics such as mean age, sex ratio and diagnosis (Table 1). The mean body mass index in our cohort is 26.7 kg/m². 37% of the patients presenting for primary THA are overweight and 24% are obese.

- In the majority of patients the diagnosis is primary osteoarthritis. In recent years there has been an increase in THAs for acute fracture (especially proximal femur fractures) and a decrease in THAs for inflammatory arthritis (Fig. 2).

Figure 2: Trends in diagnosis distribution over three time periods



The Geneva Hip Arthroplasty Registry

Table 1. Comparison of baseline characteristics Geneva Hip Arthroplasty Registry, Swedish Hip Register and Danish Hip Register

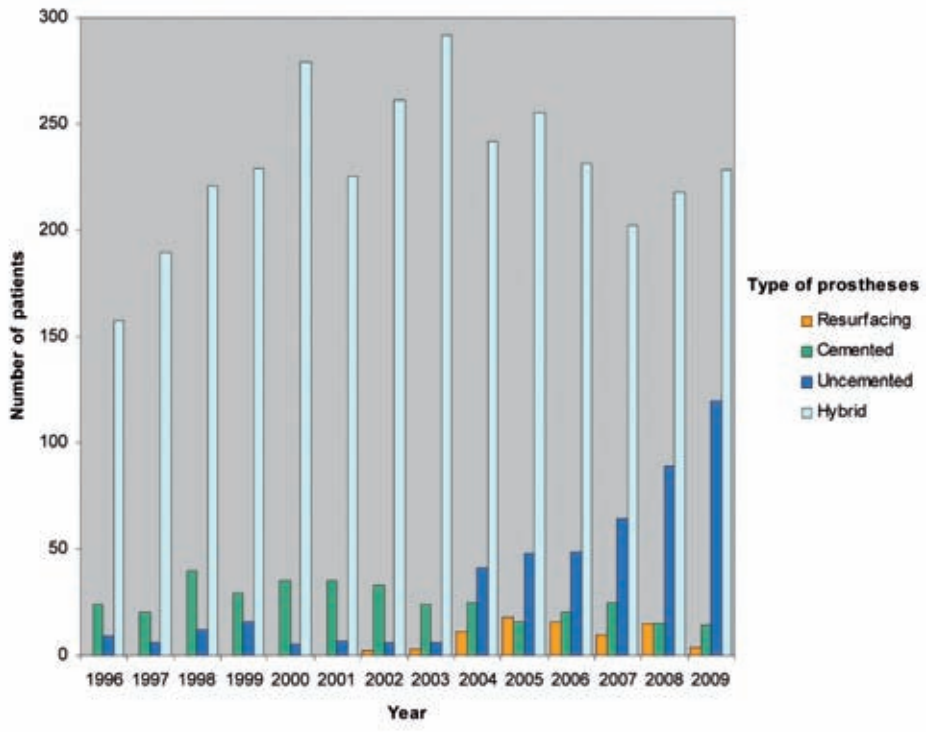
	Geneva	Sweden*	Denmark
Since	1996	1979	1995
Type of registry	Hospital based	National	National
	Multi-surgeon	Multi-surgeon	Multi-surgeon
Women (%)	55.6%	60.2%	58.2%
Age, mean	69 years	69 years	68 years
Diagnosis			
Primary OA	76.7%	77.7%	77.5%
Type of prostheses			
Uncemented	9.5%	4.9%	29.6%
Cemented	9.0%	87.7%	43.9%
Hybrid/Reverse hybrid	79.5%	6.6%	26.5%
Revision burden	8.6%	10.6%	13.6%

From: Annual reports 2007 of the Swedish and the Danish Hip Register, and Lucht U: The Danish Hip Arthroplasty Register, Acta Orthop Scand 2000
*Only including prostheses operated on between 1992 and 2006

Implant- and Technique-Related Factors

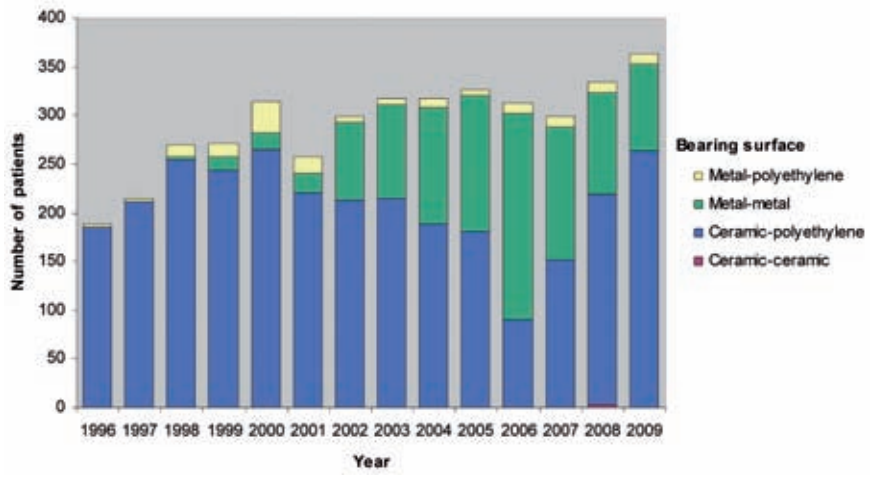
The types of implants used from 1996 to today were hybrid, cemented and uncemented prostheses, as well as hip resurfacing implants, the majority being hybrid THAs (78%). The annual distribution is presented in Fig. 3.

Figure 3: Types of protheses used in primary THA 1996-2009



With respect to bearing surfaces, the surgeons most often implemented a ceramic-polyethylene bearing (70%) followed by a metal-on-metal bearing (25%) Fig. 4.

Figure 4: Bearing surface used in primary THA 1996-2009



The Geneva Hip Arthroplasty Registry

Implant- and Technique-Related Factors

- The vast majority of interventions were performed via the lateral transgluteal approach (91%). During the last few years other approaches, such as the anterior approach by Hueter and the posterior approach, have been used increasingly.

- All patients receive a single-dose second generation cephalosporin before induction as well as standard thrombo-prophylaxis. The procedures are performed in an ultra-clean air laminar flow operating room using an outflow exhaust system. Gentamycin-loaded bone cement is employed in all cases with cemented implants.

The Geneva Hip Arthroplasty Registry

Outcome Instruments

- The following clinical scores and questionnaires are routinely used:

  a. Harris Hip Score (HHS)[17], a hip-specific, physician-assessed instrument
  b. Merle d'Aubigné and Postel score[18], a hip-specific, physician-assessed instrument
  c. Charnley disability grades[19]
  d. Western Ontario and Mc Master Universities Osteoarthritis Index[20] in its Likert 5-point scale version (WOMAC 3.0), a disease-specific, patient-assessed score. We use a shortened 12-item scale, which includes all five original items for pain and seven of the 17 original items for function[21]. Results are presented separately for pain and function on a scale from 0-100 (0=worse, 100=best).
  e. 12-Item Short-Form Health Survey (SF-12), a general health status instrument[22]. It is a self-administered 12-item questionnaire comprising two summary measures, the physical and the mental health component score.
  f. University of California Los Angeles (UCLA) activity scale, an outcome measure for activity assessment in THA patients, which has proven to be both reliable and valid[23-25].
  g. Visual analogue scale (1-10) to evaluate patient satisfaction scaled between 0 (lowest satisfaction) and 10 (highest satisfaction).

- In addition, medical and musculo-skeletal co-morbidities (back and lower limb) are evaluated pre-operatively and at follow-up.

- During the first years, the pre-operative assessment comprised only the Merle d'Aubigné and Postel score and the Charnley disability grades. Since July 2002, all patients additionally receive the WOMAC and the SF-12 questionnaire one week pre-operatively. Similarly, the Harris Hip score is assessed pre-operatively since December 2001. At follow-up we routinely assess the Harris Hip Score, Merle d'Aubigné and Postel score, Charnley disability grades, WOMAC, SF-12, and patient satisfaction evaluation. Starting in April 2006, we additionally introduced activity level assessment (UCLA scale) at the follow-up visits.

The Geneva Hip Arthroplasty Registry

Data Collection

- Information about the pre-operative status and surgical intervention, including implant- and technique-related details, is routinely documented by the operating surgeon on specifically designed data collection forms. Information about co-morbidities is retrieved from the anesthesia record and the discharge summary by a medical secretary. The treatment of any main complication or arthroplasty revision performed at our hospital or reported either to the Orthopaedic surgeon during one of the follow-up visits or during the telephone interview is systematically included in the database. The data entry of any main complication (including infections, dislocations and peri-prosthetic fractures), re-operation (e.g. removal of cerclage wires or cables, abductor avulsion repair) or prosthesis revision is double-checked by the physician in charge of the hip registry (AL). Furthermore, we periodically verify any main complication related to THA by comparing the hospital diagnosis coding system and our medical records.

- As part of our routine protocol, all participants are contacted by a trained medical secretary at five year intervals for a follow-up visit to include a clinical and radiological examination, patient satisfaction evaluation and questionnaire assessment. Additional controls are scheduled for patients who are clinically symptomatic and/or develop linear or focal osteolysis. A telephone interview is conducted with patients who are unable (poor general health or very old age) or unwilling to come for follow-up. Information about the current address, death, or move outside the area is obtained from the Census bureau. Patients are contacted by mail (two letters) and telephone. Those patients due for a control visit who have not responded at the end of the year are contacted once again by mail.

The Geneva Hip Arthroplasty Registry

Radiographic Analysis

Standardised antero-posterior pelvic and lateral radiographs are systematically collected from the pre- and immediately post-operative period and from each follow-up visit. The radiographs are analysed by the surgeon performing the follow-up visit, and independently by an experienced Orthopaedic surgeon. Evaluation is performed on digitised radiographs, and quantitative measurements are performed using specific templates and DICOMeasure™ software (ViewTec, Maison-Alfort, France). The diameter of the femoral head is used for calibration. Main radiological outcomes are acetabular and femoral osteolysis, wear, implant migration, and aseptic loosening. For osteolysis at the acetabular side, evaluation involves the analysis of the peri-acetabular zones described by DeLee and Charnley[26], while analysis at the femur is performed in the zones described by Gruen et al[27]. Polyethylene wear is measured using the dual-circle technique based on vector analysis as described by Martell and Berdia[28]. Cup migration is measured as the distance between a line joining the inferior aspect of the teardrop and the highest point of the cup. The position of the cup is obtained by measuring the angle at the intersection of the line joining the inferior aspect of the teardrop and the line joining the highest and the lowest point of the ellipse projected on the radiograph, as described by Sutherland et al[29].

Registry Maintenance

The registry relies on the continuous participation of the surgeons, who routinely contribute data related to the peri-operative period and to complications, as well as re-operations and implant revisions. One full-time medical secretary tracks the patients, organises follow-up visits, and performs telephone interviews and data entry regarding post-operative complications and follow-up results. Two part-time medical secretaries are involved in data collection regarding the peri-operative period and in radiographic archiving. Follow-up examinations are performed by three physicians not involved in the operation. Radiographic analysis is performed by an independent senior Orthopaedic surgeon. Finally, a computer specialist (programming and data management) and an epidemiologist (data management, statistical analysis, publications including annual reports, and grant applications) are working for the hip registry. Maintaining a high-quality registry requires a continuous effort from all surgeons and from staff with various areas of expertise, and it is costly and time-consuming.

The Geneva Hip Arthroplasty Registry

Main Outcomes and Feedback to Surgeons

- Main outcomes evaluated yearly are implant survivorship (survival for any reason and for sub-groups of revision causes; Fig. 5) and 2-year revision rates (especially important for newer implants).

- Complication rates and trends are analysed for prosthetic infection, dislocation, peri-prosthetic fractures, nerve lesions and abductor avulsion, as well as for medical complications (e.g. pulmonary embolism, urinary infections, etc.). Clinical outcomes (including clinical score and questionnaire results, and patient satisfaction), are reported overall (Table 2) and for specific patient sub-groups and different implants at 5 and 10 years post-operatively. All evaluations are performed separately for primary and revision THAs. Regular feedback is provided to the surgeons and the staff on results from published work and through the annual report (oral and written distribution). This information is available on-line for all our surgeons on the hip registry website.

Follow-up and Questionnaire Response Rates

- Obtaining a high follow-up rate is crucial and also very challenging, especially with the long time period necessary for joint replacement evaluation (Table 3). The rate of follow-up depends on the patients' age. Mortality rates increase substantially after 80 years of age, 31.5% of the patients had died at 5 years post-operatively and 61.7% at 10 years post-operatively. Moreover, the percentage of patients unable to attend because of poor general health is also highest in this age group. In contrast, younger patients are more likely to be lost to follow-up. At 5 and 10 years, respectively, 84.7% and 85.5% of all patients remaining for control either had a follow-up examination or a telephone interview. The others either refused to participate or were in poor general health. In accordance with the experiences from the Mayo Clinic Hip Registry[11] our clinical follow-up rates are higher than the radiographic follow-up rates. Berry et al. reported radiographic follow-up rates at 5 years varying from 35-65%, depending on the patients' age. In our 5-year cohort the comparable rate (all operated patients included) was 60% (1256 of 2108 THAs). Pre-operatively, clinical scores were obtained in 87.5% of the interventions. Questionnaires were returned by 76.6% of the patients pre-operatively, by 76.9% at 5 years and by 70.8% of the patients at 10 years post-operatively.

Table 2

Clinical evaluation and questionnaire results pre-operatively and at follow-up for all primary THAs operated between 3/1996 and 12/2008 (n=3775)

	Pre-operative	5-year follow-up	10-year follow-up
Clinical scores (mean, SD)			
Harris Hip score	49.0 (±16.0)	88.1 (±13.6)	85.6 (±14.8)
80–100 (%)	-	78	71
70–80 (%)	-	12	16
<70 (%)	-	10	13
Merle d'Aubigné	9.9 (±2.1)	15.9 (±2.1)	15.7 (±2.3)
UCLA score	-	5.6 (±1.9)	5.3 (±2.1)
Patient satisfaction (VAS scale)	-	8.9 (±1.6)	9.1 (±1.4)
Questionnaires (mean, SD)			
WOMAC pain	38.3 (±18.1)	72.5 (±23.8)	70.7 (±24.7)
WOMAC function	38.5 (±18.0)	69.6 (±23.4)	68.8 (±24.2)
SF-12 physical component	33.0 (±7.6)	41.1 (±9.9)	40.5 (±9.4)
SF-12 mental component	43.6 (±11.5)	46.3 (±10.9)	46.3 (±10.7)

Table 3

Parameters of follow-up according to four age groups at operation for all primary THAs operated between 3/1996 and 12/2003 (5-year control) and 12/1998 (10-year control)

	<60 years	60–69 years	70–79 years	≥80 years	Total
5 years post-operatively (n)	407	600	711	390	2108
Had died (%)	4.7	7.3	13.8	31.5	13.5
Attended visit (%)	69.1	70.5	61.0	35.3	60.6
Telephone interview (%)	4.1	4.3	7.9	12.9	7.0
Lost to follow-up (%)	11.1	7.7	4.2	2.1	6.1
Refused to participate (%)	8.5	6.5	6.7	9.8	7.6
Poor general health (%)	2.5	3.7	6.4	8.4	5.2
	100%	100%	100%	100%	100%
Remaining patients (n)*	340	504	581	258	1683
Visit/interview, n (%)	298 (87.6)	449 (89.1)	490 (84.3)	188 (72.9)	1425 (84.7)
X-rays obtained, n (%)					1256 (74.6)
10 years post operatively (n)	117	200	233	128	678
Had died (%)	13.7	16.0	31.8	61.7	29.6
Attended visit (%)	66.7	60.6	41.6	15.6	46.8
Telephone interview (%)	3.4	4.9	9.1	7.8	6.5
Lost to follow-up (%)	10.3	9.0	3.9	1.6	6.0
Refused to participate (%)	3.4	5.0	6.4	5.5	5.3
Poor general health (%)	2.5	4.5	7.2	7.8	5.8
	100%	100%	100%	100%	100%
Remaining patients (n)*	85	145	145	47	422
Visit/interview, n (%)	82 (96.5)	131 (90.3)	118 (81.4)	30 (63.8)	361 (85.5)
X-rays obtained, n (%)					308 (73.0)

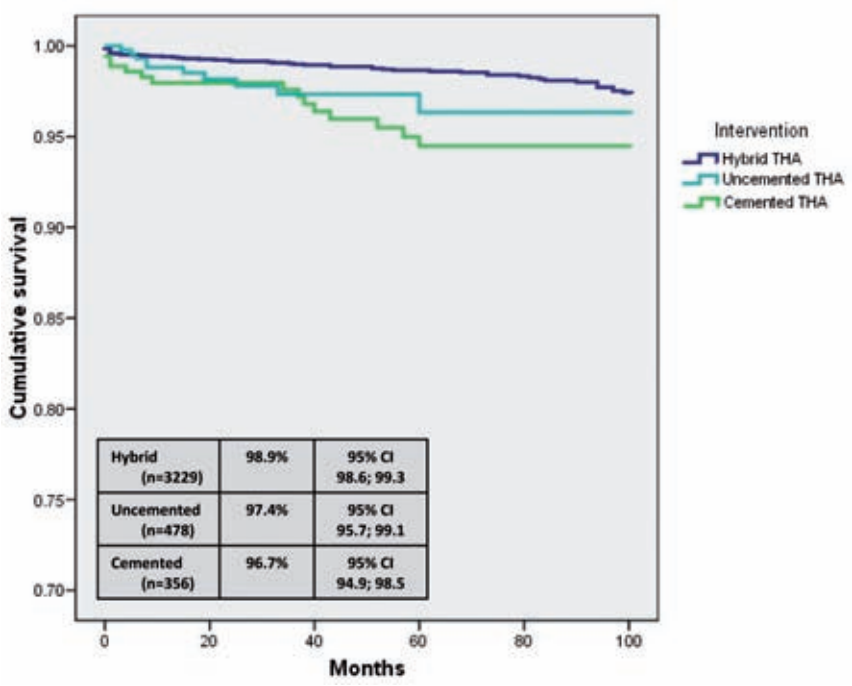
*Included are all patients except for those who had died or were lost to follow-up.

The Geneva Hip Arthroplasty Registry

Clinical Impact

Information obtained from hospital-based as well as regional or national registries can have an important impact on clinical practice, as has been shown repeatedly[5,6,11,13,14,30-33]. We use data from our own registry[34] (Fig. 5), as well as data from other registries to guide the choice of implant.

Figure 5: Survivorship according to the type of implant



The registry has been very important in monitoring and reducing the risk of dislocation. We have been able to show that the introduction of a pre-operative patient education session in 2002 substantially reduced the risk of dislocation in our registry[35]. Furthermore, a recent analysis on the influence of cup diameter on the occurrence of dislocation revealed an increased risk of dislocation with a larger cup–head ratio, which led to a modification of our current cup–head diameter choice[36]. Moreover, information obtained through the registry has prompted us to modify the treatment protocol of patients with abductor avulsion[37].

Another research focus has been the evaluation of clinical and radiographic outcomes, as well as short- and long-term complications in obese patients. This has increased our awareness of a greater risk of post-operative complications after primary and revision THAs, especially in obese women[38,39]. At the same time, results obtained with respect to long-term implant survival[15], functional improvement, pain relief and patient satisfaction[38,39] have been very encouraging in obese patients.

Finally, a precise registry is also useful to inform the hospitals' administration as to the activities and results of hip arthroplasty operations. It serves as a quality assurance tool for informing future patients, health care providers, administrators, and politicians.

The Geneva Hip Arthroplasty Registry

Conclusion

The small size of hospital-based registries is a disadvantage, but it is partially offset by the freedom to collect substantially more information per individual patient. This additional information enables them to provide a more in-depth evaluation of causes for questions identified in large registries. Moreover, small registries are well-suited to evaluate a variety of end-points, as opposed to focusing on implant revision only. The need and demand for comparative effectiveness research is increasing. Comparative effectiveness studies provide data on how an implant/technique works in the real world, and under which circumstances. Registries of all sizes will be useful in this process.

Disclosure

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