Global Orthopaedic Registry

GLORY

Assessing Today's Practice Patterns to Enhance Tomorrow's Care

Introduction

Over one million total knee arthroplasty (TKA) and total hip arthroplasty (THA) surgeries are performed throughout the world every year. Although a few countries, such as Sweden, have national joint arthroplasty registry programs, a majority of countries do not. Surgical practices, hospital resources, patient demographic factors, and outcomes may vary widely depending on the surgeon, hospital, and country. However, little or no data have been available to compare clinical practices and outcomes from a multinational perspective.

The Global Orthopaedic Registry (GLORY) is a multinational, multicenter, observational study that will gather and analyze data on THA/TKA patients with respect to treatment practices and patient outcomes, including assessment of rapidly evolving clinical practice guidelines for the prevention of venous thromboembolism (VTE). Data captured and reported in this registry will reflect a "real-world" approach to the treatment and management of THA/TKA and their complications. Such data may be more representative of patients with THA/TKA than data collected in the context of controlled clinical trials, in which restrictive inclusion/exclusion criteria may limit generalizability.

It is envisioned that each year GLORY will enroll at least 5000 patients with elective primary THA/TKA **(Figure 1)**. This sample will provide sufficient statistical power to test a number of impor-

Figure 1. Global Site Network

tant hypotheses, and the duration of the registry will provide an opportunity to observe temporal trends in clinical practice and short-term outcomes.

Objectives of the Registry

GLORY is intended to measure and improve outcomes in a real-world setting, to develop benchmarks of routine quality-of-care outcomes, and to provide confidential quarterly reports of their data to each participating surgeon. It will also create opportunities to develop scientific publications and presentations for major scientific meetings. Additionally, GLORY will afford participating surgeons the opportunity to demonstrate the quality of their outcomes. Specific objectives are to:

- Provide expanded data to orthopaedic surgeons to characterize existing and evolving practice patterns, delivery of care, and resource utilization in the management of THA/TKA patients
- Provide data to allow benchmarking of treatment patterns and patient outcomes
- Analyze data and design ancillary studies to address unanswered clinical questions
- Disseminate findings through publication in peer-reviewed scientific journals

The ultimate goal of GLORY is to improve patient care through a better understanding of patient management and outcomes.

History

GLORY grew out of the merger of two registries, the International Orthopaedic Registry (IOR), and The North American Hip and Knee Registry (THKR). **(Figure 2)**

IOR: Like GLORY, the IOR was an international observational study of practices and outcomes in patients receiving total joint

Figure 2.

replacement, particularly with respect to prevention of VTE. The IOR Scientific Advisory Committee met for the first time in February 2001 in Philadelphia, Pennsylvania, to formulate objectives, map out a study design, and develop a study protocol and case report form (CRF). Following that meeting, a pilot study was conducted to assess (1) the feasibility of the project, (2) data collection methods, and (3) use of a standardized data abstraction instrument, and to identify and correct any problems associated with implementing the study. The CRF and protocol were refined at the second Advisory Board meeting, which took place in Paris in July 2001, and the registry was formally launched in December 2001.

THKR: In January 2002, it was decided to merge IOR and the 8-year-old Aventis-sponsored THKR. THKR, which involved surgeons from the United States and Canada, brings to the new international registry a legacy of over 40,000 cases and more than 200 US and Canadian orthopaedic surgeons. Several members of the former THKR Scientific Advisory Board now sit on the GLORY Scientific Advisory Committee.

The first meeting of the GLORY Scientific Advisory Committee was held in April 2002 in Philadelphia, Pennsylvania, and the second in Florence, Italy, in July 2002. The CRFs and protocols of the two registries were similar and have now been merged, preserving the most useful elements of both.

Challenges for GLORY

Historically the use of registry findings to assess patient outcomes has met with varying degrees of success. One reason for this is the participation primarily of large academic medical centers. Because patients seen in these centers may have characteristics that are different from those seen in smaller, community-based hospitals, the generalizability of the findings has been limited. Conversely, studies conducted in smaller community-based centers may fail to reflect the broader pool of patients and management strategies. These patients may have less access to acute care facilities. Also, community-based physicians must practice with the diagnostic and treatment options available to them, which may limit patient management and affect outcomes findings. GLORY is committed to enrolling hospitals that represent the demographics of each country or region enrolled in the registry, in order to obtain a generalizable, representative view of both clinical practices and patient outcomes.

Patient characteristics, such as age, gender, health status, and comorbid conditions can also affect both the interpretation and external validity of study outcomes, through “pre-selection.” In order to avoid selection bias, all patients undergoing primary THA or TKA procedures, including those who may die during surgery, will be considered as potentially eligible to be enrolled in GLORY, provided they meet study inclusion criteria and have given consent or are exempt from consent requirements. A predetermined number of consecutive eligible patients will be enrolled at participating hospitals each month. For smaller cen-

ters, this may mean enrolling all patients who meet entry criteria. In this way, GLORY expects to collect management patterns and outcomes data that accurately reflect representative, real-world practice patterns in a variety of care environments in each participating country.

Inclusion/Exclusion Criteria

To be enrolled in GLORY, patients must be:

- Undergoing a primary, elective THA or TKA, either unilateral or bilateral.
- At least 18 years of age

Excluded are patients undergoing revision surgery or surgery for traumatic fracture.

Key Outcomes

Key outcomes include:

- Clinically recognized VTE
- Bleeding
- Infection
- Dislocation
- Functional status
- Death

Follow-up

Routine follow-up will be obtained at 3 months and 1 year following surgery. For patients who are unavailable for an office visit, telephone follow-up can be used. In order for GLORY to have the highest level of scientific validity, an important goal of the registry is to achieve at least an 80% rate of follow-up.

Patient Forms

Prior to hospitalization, patients will complete a pre-operative quality-of-life self-assessment questionnaire consisting of the Short Form-8 Survey (SF-8) and the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index, reflecting self-assessed functional status and quality-of-life before their surgery. A similar questionnaire will be administered at follow-up.

Data Collection and Confidentiality

Data will be collected at each registry hospital on a standardized CRF, either by the surgeon or by a designated study coordinator who has been trained to abstract and record data. CRFs will then be submitted to the Center for Outcomes Research (COR) at the University of Massachusetts Medical School for entry into the registry database. As the scientific coordinating center for the registry, COR is responsible for its compliance with appropriate scientific and ethical standards.

Study data may be submitted by fax, mail, or via the Internet. At the discretion of each participating surgeon, study data may also be submitted through the secure website at the University of Massachusetts Medical School. Patient identities will remain confidential to the participating surgeon and hospital. No patient names or other identifiers that could be used to identify individual study patients will be submitted to or held by COR. Patients will be identified through a unique number assigned to them at enrollment by the study coordinator at each hospital. COR will protect the confidentiality of surgeon- and hospital-specific clinical data by using passwords for electronic data and by storing all paper copies of data and reports in a secure facility. Aventis Pharma will have access to aggregate reports only, and not to individual patient, physician, or hospital data. The sponsor will be unable to link physicians with their outcomes.

All patients are told that information about them is being entered into the registry database and, if required by the Ethics Committee, their consent is obtained and recorded. They are informed that they are free to refuse to answer follow-up questions without any effect on their medical care. Measures to ensure protection of the rights of patients, physicians, and sites have been reviewed and approved by the Institutional Review Board of the University of Massachusetts Medical School.

Ethics Committee review of this project may not be legally mandated in some regions. However, individual hospitals have the right to require local Ethics Committee review of this research. Thus, investigators are responsible for notifying their local hospital research Ethics Committee of the intention to enroll patients and for obtaining all required permissions prior to doing so.

Quality Assurance Self-Study: Quarterly Reports

An important goal of GLORY is to empower surgeons to perform regular self-assessment of their practices and outcomes and to use these data to improve patient care. A confidential Quarterly Report, prepared by COR, is provided to the Scientific Advisor at each participating site. This report will provide comparative data for a list of variables for the site, identified by ID number, vs the country and the world. It will enable physicians to see how their practices resemble or differ from others in their country and other GLORY sites throughout the world.

Variables in the Quarterly Report include:

- Enrollment statistics
- Demographics
- Preoperative data (primary diagnosis, pre-existing comorbid conditions)
- Surgical data (length of stay, type of approach, type of anesthesia)
- Prevention of VTE (prophylaxis, including type and duration)
- In-hospital complications
- Discharge disposition
- Patient self-reported quality of life (WOMAC and SF-8) and satisfaction with their health care.

Legacy data from over 40,000 patients submitted to THKR since 1995 will strengthen the comparisons provided in the GLORY Quarterly Reports. Surgeons practicing in smaller community hospitals will find participation in GLORY particularly useful, because it will allow them to benchmark their practices and outcomes against those of a number of types of practices, including academic vs community centers and high-volume vs low-volume practices.

Clinical Notes

The Clinical Notes are provided to each site along with the Quarterly Report, and represent another educational tool. These notes will cover a variety of current topics related to the management of patients with THA/TKA.

Publications

A Publication Committee, composed of four members of the Scientific Advisory Committee of the Registry, is responsible for approving and coordinating publications to be developed by GLORY. All new projects must be reviewed and approved by this committee before they may go forward with data analysis, presentation, or publication.

Authorship of abstracts and manuscripts is open to all GLORY investigators and coordinators. Publication proposals will be solicited semi-annually. The Publication Committee will review new project proposals and will be responsible for scoring each proposal according to published review criteria. All projects will be ranked; the number approved each year will depend on budgetary constraints. Upon approval of a proposal, a request for database analysis from COR may be initiated. Such a request may come from a member of the Scientific Advisory Committee or any enrolled physician at a participating hospital, provided that he or she is working in collaboration with one or more members of the Scientific Advisory Committee.

THKR has brought to GLORY a legacy of 10 publications, with several others currently in development or scheduled for publication. Although GLORY is in its infancy, 2 posters were presented at SICOT in August 2002. In most cases, future publications will go forward under the GLORY name.

Registry Organization

GLORY is organized into a 2-tiered system **(Figure 3)**. A core group of approximately 40 orthopaedic surgeons from participating countries has agreed to assume an extra measure of commitment to the registry. Extra commitments include (1) enrolling a representative sample of THA/TKA patients; (2) collecting 3-month and 1-year follow-up data on at least 80% of enrolled patients; and (3) allowing a periodic independent audit

Figure 3. Two-Tier Registry Concept

of the medical records of their patients. The subset of GLORY data from hospitals that meet these standards will be considered publication quality and will be used in key scientific publications.

Website

(Figure 4) GLORY has its own web address at the COR website (www.outcomes.org). All participants will be issued passwords to enter the Members' Room on the website. The website will provide an overview of the registry, a listing of all mem-

Figure 4. GLORY Website Home Page

bers of the Scientific Advisory Committee, and some useful links for orthopaedic surgery. All meeting materials will be posted there, as will the full Instruction Manual, registry protocol, and CRFs. Summary slides about the registry will also be available for downloading.

Enrollment Policy and Projections

In order to ensure that GLORY will reflect a representative sample of hospitals, we are actively seeking the participation of nonacademic and community-based hospitals to complement the primarily large academic centers at the advisor sites. With the addition of these sites, and building on the legacy of THKR, it is envisioned that GLORY may include as many as 250 sites worldwide.

Study Management

As a service to physicians, Aventis Pharma has provided an unrestricted educational grant to COR for management of GLORY. Located at the University of Massachusetts Medical School in Worcester, Massachusetts, COR has served as coordinating center for THKR for the past 8 years and continues to serve as the study coordinating center for GLORY. Questions related to scientific content or data management should be directed to COR, including study implementation, protocol clarifications, form completion instructions, instruction manuals, and data analysis/interpretation (eg, Quarterly Reports).

The Registry is governed by a Scientific Advisory Committee, which includes orthopaedic surgeons, anesthesiologists, and hematologists representing each participating country and clinical scientists with experience in the design and analysis of registry data from joint arthroplasty patients. It is the duty of the Scientific Advisory Committee to ensure that the data analysis methods and assumptions used in interpreting the data are valid and that confidentiality is maintained.

Value of GLORY

GLORY will be the only multinational orthopaedic registry using standard data collection instruments, definitions, and patient selection criteria across many different healthcare systems. The registry will provide an opportunity to examine real-world practice and will compare current practices in participating countries with evidence-based reviews. Finally, GLORY should provide sufficient data to allow participating orthopaedic surgeons to monitor and ensure compliance with national and hospital-specific protocols.

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