


Institutional Registry of Elderly Patients With Hip Fracture in a Community-Based Tertiary Care Hospital in Argentina (RIAFC)

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Abstract

Background: A clinical registry encompasses a selective set of rigorously collected and stored clinical data focused on a specific condition. Hip fracture is a common complication of osteoporosis in elderly patients. Hip fracture substantially increases the risk of death and major morbidity in the elderly patients. Limited data regarding hip fracture are available from Latin America and Argentina. The purpose of this project is to create an institutional registry of elderly patients with hip fracture in order to obtain data that reveal the impact of this disease in our environment, allowing us to evaluate different strategies of patient's care and clinical outcomes. **Objective:** To describe the implementation of an institutional registry of elderly patients with hip fracture in Argentina. **Methods:** In this article, we described the creation, implementation, and data management of a prospective registry of elderly patients with hip fracture. The registry contains information on baseline demographics, comorbidities, laboratory, and radiological data. Follow-up at 3 and 12 months postfracture is done by phone interview to assess physical function, readmissions, and morbi-mortality. Clinical Trials registry number NCT02279550. **Conclusion:** In this project, we have created a hip fracture registry. We hope that this registry will provide valuable data that can lead us to new lines of research, addressed to answer questions raised in clinical practice.

Keywords

hip fracture, elderly, institutional registry

Introduction

Clinical registries comprise a set of selectively collected and stored data focused on a specific condition. The information stored in a registry is generated through a process of prospective data collection focus on data quality to detect errors and thus ensure data integrity. Systematic data collection is characteristic of a well-designed registry,¹ and its quality depends directly on the completeness and validity of the data contained.²

Hip fracture is a frequent complication of osteoporosis in elderly patients.³ The elderly patients have weaker bones and are more likely to fall due to comorbidities, instability, polypharmacy, and difficulty maneuvering around environmental hazards.⁴ Hip fractures substantially increase the risk of death and major morbidity in this population.⁵ In-hospital, 30-day mortality in patients admitted for hip fracture is around 6.5%, considering heart and respiratory failure as the main causes of death.⁶ Moreover, 13.5% of patients die within 6 months.⁷ Of those who survive at 6 months, only 50% to 60% recover the ability to walk and 40% to 50% regain their previous level of independence in basic activities of daily life.^{8,9} Worldwide, the

total number of hip fractures is expected to surpass 6 million/year by the year 2050,¹⁰ with more than 70% of the new fractures occurring in Asia, Latin America, the Middle East, and Africa.¹¹ Limited data regarding hip fractures are available from Latin America.¹²

Several hip fracture registries have been developed worldwide: the National Hip Fracture Database and the Irish Hip Fracture Database in Europe; the Australian and New Zealand

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Hip Fracture Registry in Oceania; and the British Columbia Hip Fracture Registry in North America. Currently, there are no hip fracture registries ongoing in Latin America.¹³

In 2015, the total population of Argentina is estimated to be close to 43.5 million, with 5 million inhabitants aged ≥ 65 years. The population is expected to increase 28% by 2050 and will reach 53 million, with the population aged older than 65 reaching over 10 million.¹⁴ In Argentina, each year approximately 5700 patients are hospitalized due to hip fractures. The incidence of hip fractures is increasing in our country due to the advancing age of the population, with an interannual growth rate of 1.4%, resulting in an increasing demand on the health services.¹⁵ The annual incidence among inhabitants older than 65 years was 646 per 100 000 (847 for women and 343 for men; ratio: 2.47).¹⁶

In this scenario, due to the large number of patients with hip fracture in our hospital, and the high rate of complications associated, we propose the creation of an institutional registry of elderly patients with hip fracture called "Registro Institucional de Ancianos con Fractura de Cadera (RIAFC)," which was established and initiated at the Hospital Italiano de Buenos Aires (HIBA) in July 2014.

In this article, we describe the methodology that we developed to ensure data completeness and accuracy of the RIAFC. We hope this registry will reveal how this disease affects the elderly patients in our environment, allowing us to evaluate different strategies of care and outcomes.

Primary Objective

The objective of this article is to report the creation, implementation, and data management of the RIAFC. The main aim of the RIAFC is to collect epidemiological and clinical data on elderly population with hip fractures regarding risk factors, diagnosis, treatment, prognosis, follow-up, and mortality as a basis for improved orthogeriatric comanagement, enhancing patients' outcomes, safety, and quality of attention. Secondary objectives for RIAFC are to describe the population with hip fractures in the HIBA, predisposing factors and triggers for hip fracture, rate of complications associated with hip fracture, and their treatment and to describe the clinical relevant outcomes such as in-hospital and long-term morbidity and mortality.

Methods

The RIAFC takes place at the HIBA, a community-based tertiary care hospital with 650 beds. Information about the patient, the fracture, and the treatment is collected prospectively from personal interviews and from the hospital's electronic clinical records. We included patients older than 65 years, with hip fracture, admitted to any medical or surgical unit in the HIBA from July 2014 onward. We excluded patients who refused to participate in the RIAFC or to give informed consent. We excluded patients with periprosthetic, subtrochanteric, and pelvic fracture; hip fracture caused by traumatic injury; and pathologic hip fracture

Hip Fracture Definition

We defined hip fracture as a femur fracture above the distal part of the lesser trochanter. Intracapsular fracture occurs proximal to the point at which the hip joint capsule attaches to the femur. Extracapsular fracture occurs distal to the hip joint capsule.

Design

Prospective registry with consecutive incident cases capture, standardized evaluation, monitoring, and follow-up at 3 and 12 months.

A pilot study was performed to assess the validity of the registry's instruments for data collection. This allowed us to calculate the time needed to complete the form, the completeness and comprehensiveness of the included questions, the accuracy of data entry, and missing data detection.

The registry contains information on patient's baseline demographics, American Society of Anesthesiologists, and Charlson comorbidity index. To evaluate variables proper of elderly population, we included the Barthel index of activities of daily living, Lawton and Brody instrumental activities of daily living scale, Clinical Frailty Scale, physical status classification, Mini Nutritional Assessment, Parker Mobility Score, EuroQol-5 Dimension Questionnaire, and Social Support Inventory. Chirurgical type of fracture was evaluated according to the Müller AO classification. Relevant clinical information previous to the fracture includes bone mineralization disorders, circumstances around the fall, and regular medication. Treatment-related variables include fracture treatment, postoperative complications, and rehabilitation outcomes.

Follow-up at 3 and 12 months postfracture is performed by telephone interview using structured evaluation to assess physical function, health perception, venous thromboembolism prophylaxis, late postoperative complications, readmissions, and mortality.

Data Collection and Management: Quality Control Strategies

All hip fracture incident cases are captured by an automatic real-time alert. This alert is generated on the moment the patient is admitted to the hospital with a hip fracture diagnosis, encoded (SNOMED CT) in the hospital's computerized clinical record chart. During the first 2 months from the beginning of the recruitment, we performed a double checked system, where every potentially included patient was reported by physician in charge who actively assessed patients with hip fracture in admission wards. The rules that trigger the alert were modified using the information generated by this manual/automatic double check in order to improve sensitivity and specificity of the alert.

A trained research fellow assesses eligible patients and determines inclusion and exclusion criteria. Patients who meet inclusion criteria and none of the exclusion criteria are included if they agree to participate through the informed consent process. A standardized and structured interview that includes oral questionnaires and forms is performed and completed. All data

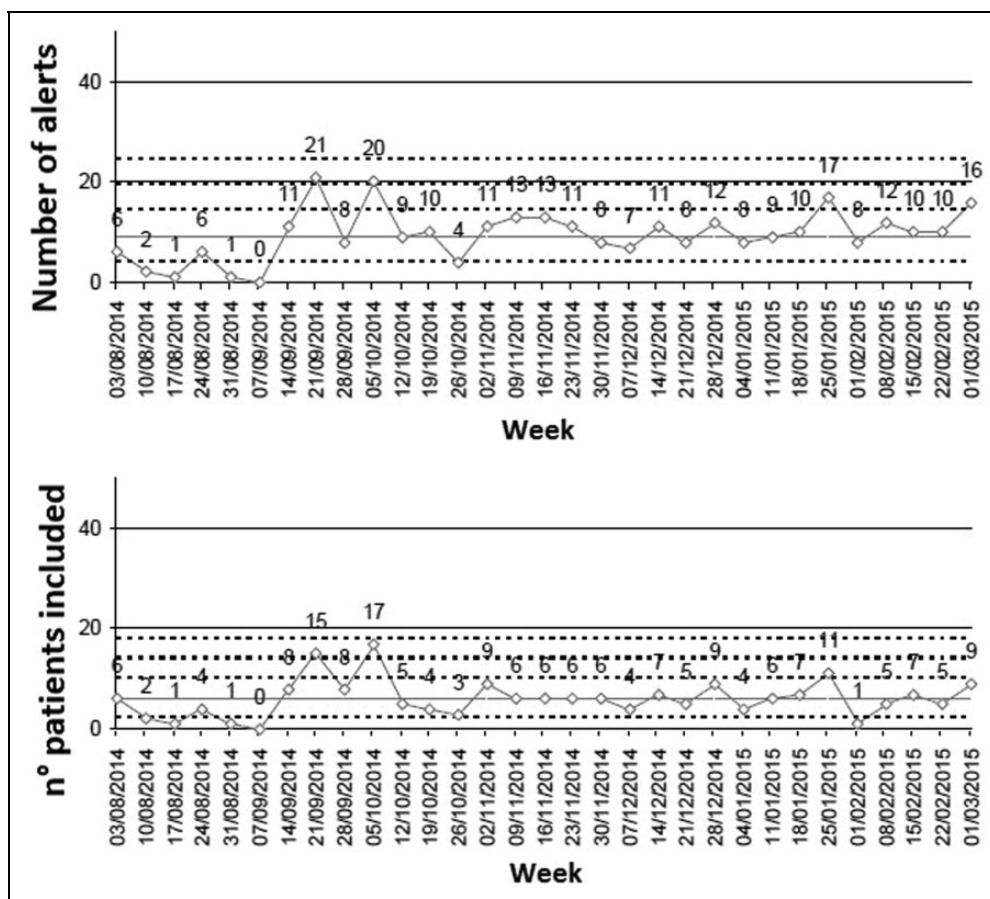


Figure 1. Control charts.

collectors have a training period in which they attend academic discussion with the physicians and orthogeriatrics involved. They are trained in data collection, electronic databases, and data entry. They receive coaching to perform the follow-up evaluation by telephone calls, supervised by a research fellow.

Data collectors check the completeness of the records of each patient. A data cleaning process is frequently performed to identify and correct all discrepant data. Missing values, inconsistencies, outliers, and other data problems are identified using queries and completed reassessing the patient and the original clinical records.

Laboratory results and ancillary tests are obtained from secondary databases using the higher quality validated sources available. Administrative and hospitalization data are collected with the secondary databases and information from the hospital computerized clinical health records. All data are automatically backed up daily with redundant storage in a protected off-site location. To protect the patient’s confidentiality, the database assigns an external unique administrative subject identifier (subject ID).

Follow-up is established every 3 and 12 months. The first follow-up has 2 different instances, the clinical and the orthopedist follow-up. As the patients fulfill 3 months since the inclusion, the clinical evaluation includes a telephone follow-up where we ask for any postoperative comorbidities

(cardiovascular events, thrombosis, infections, readmission, rehabilitation status, and death). If the patient is unreachable, we perform a systematic review of their medical records.

The orthopedist follow-up consists on patient’s visit to the orthopedist clinic where patients are evaluated in hip parameters and bone/prosthesis status.

This dual instance has a quality control in order to detect causes of loss of follow-up. A united electronic system ensures at least one of both the types of follow-up for all patients included.

All data collected in paper forms are submitted to the electronic database as shortly as possible after the data collection to ensure fidelity of the transcription and the chance to correct erroneous data using primary data. The electronic case report form (CRF) was encoded in an exhaustive and mutually exclusive way limiting responses to a range of coded values. Data entry is made by a different research fellow who collects clinical data. In this instance, we perform a second check of data quality. Weekly meetings with medical staff specialized in orthogeriatrics are placed to discuss ambiguous or difficult cases. Attending physicians helped in the interpretation of clinical issues to improve data quality.

Additionally, we created a system of performance indicators that are graphed and monitored weekly through control charts (Figure 1). Weekly reports are performed in order to detect

alteration in number of included and excluded patients, loss of patients' evaluation, and number of patients for follow-up. This strategy helps to early detect any problem on the recruitment and inclusion process. Every week, team meetings are focused on monitoring the behavior of indicators, detecting potential causes for changes in recruitment, and developing strategies to improve it.

Operations Manual

We developed an operations manual that functions as a guide to define evaluation strategies and quality control of all the processes involved in collecting and maintaining registry cases. This document standardizes the procedures and processes of the registry to reduce interobserver variation in data collection, assuring the accuracy of the registry data.

Statistical Analysis

Descriptive analysis for continuous variables will be shown as mean and standard deviation or median and interquartile range, according to the observed distribution. Categorical variables will be expressed as absolute number and percentage. Prevalence rates will be expressed with its 95% confidence interval (CI). Comparisons between groups will be performed with the χ^2 test for categorical variables and the Mann-Whitney *U* test for continuous variables. Survival at 1 year will be calculated with the Kaplan-Meier estimator. Median survival time will be expressed with its 95% CI. Significance will be defined as $P < .05$. All data analyses will be performed with Stata 14 software.

Brief Summary of Inclusion Process

Since July 2014 till nowadays, we included more than 450 patients. The evaluation is performed within 48 hours of perioperative management. Each evaluation takes about 30 minutes. We evaluate 5 to 10 patients per week. In the beginning of the implementation, we estimated 1 to 2 patients lost per week. This was related to the improvement in automatic reporting and operational procedures. At present, the loss rate is virtually zero.

Ethics

Each patient gives oral consent to be included into the registry. The patient's family consent is required if the patient is not able to give or withhold consent. The registry was approved by an ethics review board and registered in Clinical Trials with the number NCT02279550.

Discussion

The RIAFC is an opportunity to study all hip fractures cases admitted to our hospital. The registry will provide valuable data on incidence of fracture types, patients' characteristics, and different treatments and prognosis over time.

In our setting, we would give useful information about elderly patients. This specific population is a big concern in

public health, for this is a growing population in the past years. There are few reports that could establish a possible different prognosis in this subgroup.^{17,18}

This registry can lead to new lines of research and relevant information to focus on an orthogeriatric comanagement of hip fractures improving patients' outcomes, safety, and quality of attention. We aim to generate information to establish clinical and local guidelines and quality indicators of clinical management based on the RIAFC. The creation of a specific registry for hip fracture in elderly population in a high-complexity hospital in a city such as Buenos Aires, Argentina, represents an important contribution, primarily for including geriatric variables that include both clinical and social aspects.

Clinical geriatric variables include comorbidities, functional aspects, fragility and mobility, and nutritional and health status prior to the fracture. Gait disorders and fall characteristics are also assessed. All these aspects allow us to evaluate their quality of life, the possibility to incorporate into their daily activities as well as the autonomy to continue living independently or requiring assistance from caregivers or institutionalization. Social variables are focused on describing their place of residence (home or institutionalized), cohabitants, caregivers, and social support.

In comparison with other registries of hip fracture, this includes other dimensions that impact on results in the short, medium, and long term. There are studies in our country that engaged hip fractures: a case-control study that evaluates proximal femur fractures to osteoporosis and other associated risk factors in people older than 50 years,¹⁵ a study that reports incidence of hip fractures in the city of Rosario,¹⁶ and another study that reports the effect of age and sex on the incidence of hip fractures or fracture types and their variabilities over time for 4 years in Argentina.¹⁹ None of these gather all the characteristics of our registry. Although in Argentina there are some research groups that report patients with hip fractures in international studies, this information is limited and fragmented in the scopes of interest of each group. This registry information would enable clinicians to compare populations and therapeutic strategies and establish new local health policies.

On the other hand, there are many problems associated with developing registries in general, such as the cost, the organization and staff involved, and data quality.² Our registry is an institutional one, where costs and motivational interest are essential in the highly complex university institution setting where this registry takes place. This supports the sustainability implied on the registry's maintenance. In this scenario, members from different specialties hold the registry by working as an integrated team.

Regarding the problem of organization and staff, difficulties for agreements and collaboration between principal investigators (different objectives pursued by the different specialties) are described as problems to address in the conduction of registries. We scheduled meetings regularly, where all participants contribute with new ideas and resources to promote teamwork. The human resource is especially important, the registry counts with researchers specialized in different functions; researchers specialized in methodology in the data management (collection of

data, data entry, and management of computerized databases) and specialists from the principal disciplines: internal medicine, geriatrics, and orthopedic surgery. These members of the team gather their interests to define the variables for collection and the possible questions and analysis that might arise.

The last problem described in conducting registries is to ensure the quality of the data. Many authors suggest the need to strengthen this aspect.²⁰ Two components can possibly threaten quality of data, the completeness (integrity) and validity. We implement several quality measures regarding data integrity: the data collector and the registry's supervisor check the database weekly for early detection of missing data and to evaluate the opportunity to recover the missing information. Validity of the data is defined as truly possessing the attribute measured. Our records defined meticulously how patient's information is collected in order to avoid bias and investigators are frequently certificated on this process. Potential discrepancies on the interpretation of clinical information from each included patient are discussed on the weekly meetings. Collected information is evaluated to certify the quality of data.

Conclusion

This registry may provide information of great importance about elderly population in Argentina that has suffered hip fracture. Besides, it may serve as a source to develop new research questions and an efficient way to improve the assessment of these patients.

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Declaration of Conflicting Interests

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