Institutional Registry of Hip Fracture in the Elderly

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Study protocol

BACKGROUNG

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 and its quality depends directly on the completeness and validity of the data contained [1]. Hip fracture is a frequent complication of osteoporosis in elderly patients [2]. The elderly have weaker bones and are more likely to fall due to comorbidities, instability, polypharmacy, and difficulty maneuvering around environmental hazards. Hip fractures substantially increase the risk of death and major morbidity in this population [3]. 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. Moreover, 13.5% of patients die within 6 months [4]. Of those who survive at 6 months, only 50-60% recover the ability to walk, and 40-50% regain their previous level of independence in basic activities of daily life [5]. Worldwide, the total number of hip fractures is expected to surpass 6 million/year by the year 2050 [5,6], with more than 70% of the new fractures occurring in Asia, Latin America, the Middle East and Africa [7]. Limited data regarding hip fractures is available from Latin America [8]. Several hip fracture registries have been developed worldwide: the National Hip Fracture Database (NHFD) and the Irish Hip Fracture Database in Europe; the Australian and New Zealand Hip Fracture Registry (ANZ HFR) in Oceania; the British Columbia Hip Fracture Registry (IHFD) in North America. Currently, there are no hip fracture registries on-going in Latin America [9]. 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 over 65's population reaching over 10 million14. Each year approximately 5700 patients are hospitalized due to hip fractures in Argentina. 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 [10]. The mean annual rate of hip fractures, is 488/100 000 inhabitants aged above 50 years, with a 2.6:1 female to male ratio [11]. 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. We hope this registry will reveal how this disease affects the elderly in our environment, allowing us to evaluate different strategies of care and outcomes.

Primary Objective 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 co-management, 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 clinically relevant outcomes such as in-hospital and long-term morbidity and mortality.

METHODS

The RIAFC takes place at the Hospital Italiano de Buenos Aires, 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 include patients over 65 years, with hip fracture, admitted to any medical or surgical unit in the Hospital Italiano de Buenos Aires (HIBA) from July 2014 onwards. We exclude patients who refuse to participate in the RIAFC or to give oral informed consent. We exclude patients with periprosthetic, subtrochanteric and pelvic fracture, hip fracture caused by traumatic injury and pathologic hip fracture.

Hip Fracture Definition We define hip fracture as a femur fracture above the distal part of the lesser trochanter.

Design Prospective registry with consecutive incident cases capture, standardized evaluation, monitoring, and follow up at 12 months. This study is not a clinical trial clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes, as stated 42 CRF part 11).

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 (ASA) 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, Social Support Inventory.

Chirurgic type of fracture was evaluated according to the Müller AO classification. Relevant clinical information prior 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 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 two 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 the sensitivity and specificity of the alert. A trained research fellow assesses eligible patients and determines inclusion and exclusion criteria. Patients that meet the 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, including oral questionnaires and forms, is performed and completed. All data collectors have a training period in which they attend academic discussions 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 is collected with secondary databases and information from the hospital's 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 three and twelve months. The follow-up call has two different instances; the clinical and the orthopedist follow-up. As the patients reach 12 months since the inclusion the clinical evaluation includes a telephone follow-up where we ask for any post operatory comorbidities and the orthopedist follow-up consists on patient's visit to the orthopedist clinic. An integrated electronic system ensures at least one of both types of follow up for all patients included. The electronic 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.

Indicators: performance indicators are monitored weekly. Weekly reports are performed in order to detect alterations in the number of included and excluded patients, loss of patients' evaluation, number of patients for follow-up. This strategy aids early detection of any problem in the recruitment and inclusion process.

Operations Manual: Acts 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 inter-observer variation in data collection, assuring the accuracy of the registry data.

Statistical Analysis Continuous variables are shown as mean and standard deviation or median and interquartile range, according to the observed distribution. Categorical variables are expressed as absolute numbers and percentages. Prevalence rates are expressed with its 95% confidence interval (95% CI). Comparisons between groups are made with Chi-Square test for categorical variables and the Mann–Whitney U test for continuous variables. Survival at one year is estimated with the Kaplan–Meier estimator. Median survival is expressed with its 95% confidence interval (95% CI). Significance will be defined as $p<0.05$. All data analyses will be performed with Stata 14 software.

Ethics: Each patient give 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. This study is not a clinical trial clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes, as atated 42 CRF part 11).

This study is eligible for written informed consent exemption according to CIOMS rule 10; besides it is not an applicable clinical trial for which registration information is required to be submitted.

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study. Epidemiol Rev 1980;2:210–20.
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