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Development of the Italian fractures registry (RIFra): A call for action to improve quality and safety

Giovanni Vicenti[a,*], Davide Bizzoca[a,**], Raffaele Pascarella[b], Ferdinando Delprete[c], Federico Chiodini[d], Walter Daghino[e], Alessandro Casiraghi[f], Giulio Maccauro[g], Francesco Liuzza[g], Emanuele Boero[h], Alberto Belluati[i], Carlotta Pari[i], Marco Berlusconi[j], Filippo Randelli[k], Federico Bove[l], Ettore Sabbetta[m], Massimiliano Carrozzo[a], Giuseppe Solarino[a], Biagio Moretti[a]

[a] *School of Medicine, University of Bari Aldo Moro, AOU Consorziale "Policlinico", Department of Basic Medical Sciences, Neuroscience and Sense Organs, Orthopaedic & Trauma Unit, Bari, Italy*
[b] *Orthopaedic and Trauma Unit, Ospedali Riuniti, Ancona, Italy*
[c] *Orthopaedic and Trauma Unit, Ospedale "San Giovanni di Dio", Firenze, Azienda USL Toscana Centro, Italy*
[d] *Orthopaedic and Trauma Unit, Ospedale Civile di Legnano, A.S.S.T. OVEST MILANESE, Legnano, Italy*
[e] *Orthopaedic and Trauma Unit, Ospedale di Biella, ASL Biella, Italy*
[f] *Orthopaedic and Trauma Unit, Ospedali Civili di Brescia, Brescia, Italy*
[g] *Orthopaedic and Trauma Unit, Fondazione Policlinico Universitario "Agostino Gemelli", Rome, Italy*
[h] *Orthopaedic and Trauma Unit, Ospedale Camposampiero (Padova), AULSS 6 Euganea, Italy*
[i] *Orthopaedic and Trauma Unit, Ospedale "Santa Maria delle Croci", Ravenna, AUSL Romagna, Italy*
[j] *Orthopaedic and Trauma Unit, Humanitas Research Hospital, Milano, Italy*
[k] *Orthopaedic and Trauma Unit, Gaetano Pini Hospital, Milano, Italy*
[l] *Orthopaedic and Trauma Unit, Niguarda Hospital, Milano, Italy*
[m] *Orthopaedic and Trauma Unit, Arcispedale S. Maria Nuova, Azienda Ospedaliera di Reggio Emilia, Italy*

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ABSTRACT

In recent years, there has been an increasing interest in the development of arthroplasty registries, therefore, in our country, the Italian Arthroplasty Registry (RIAP), was issued by the National Law No. 221/2012.

In the last decade, however, some European countries -namely Sweden, Denmark, Norway, and Germany (in development)- have introduced another nationwide orthopaedic registry than arthroplasty registers: the fracture registry. The development of this new tool aims to improve quality and safety in fracture management, thus trying to provide a better postoperative quality of life in trauma patients.

Based on these findings, the AO-Trauma Italy Council encouraged the development of a national fracture registry in Italy. The present study aims to (1) provide an overview of the fracture registries in Europe and (2) to develop, for the first time, a pilot Italian Fracture Registry (RIFra).

Thirteen AO-Trauma Italy members, chairmen of Level-I orthopaedic and trauma centres, diffused throughout Italy, were involved in the RIFra project. The RIFra form, developed between November 2019 and March 2020, consists of 5 main sections, namely: epidemiologic data, previous surgical procedure (if any), patient and fracture features, surgical procedure, surgical implant details. This study constitutes the first step to start, in future years, the bureaucratic procedure leading to the final establishment of a RIAP-like fracture registry in Italy.

Introduction

Medical registries are databases longitudinally collecting health-related information. They provide an observational assessment of diseases prevalence and treatment, surgical performed techniques and employed surgical implants, in a specific geographic area in a selected period [1,2].

** Co-first authors.
* Corresponding author at: School of Medicine, University of Bari Aldo Moro, AOU Consorziale Policlinico, Department of Basic Medical Sciences, Neuroscience and Sense Organs, Orthopaedic & Trauma Unit, Piazza Giulio Cesare 11, 70100 Bari, Italy
E-mail address: dott.gvicenti@gmail.com (G. Vicenti).

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These tools are extremely useful to improve safety and quality in surgical procedures and, at the same time, they also provide a significant number of data useful to realize observational studies [3]. Although observational studies are lower ranked than randomized clinical trials (RCTs), in the level of evidence hierarchy, they are based on a "real-world" population of patients, thus providing results more applicable in everyday clinical practice, compared with RCTs, and focus on a longer-term follow-up [3,4].

Based on these findings, in Orthopaedics and Traumatology, there has been an increasing interest in the development of surgical registries, in the last decades. The first nationwide orthopaedic register, the Swedish Knee Arthroplasty Register, was established in 1975 in Sweden, to collect data on total knee arthroplasty (TKA) implants [5]. In the following 2–3 decades, several arthroplasty registries have been established either in European countries (i.e., Finland, Norway, Denmark, the UK, Netherlands, Germany) and extra-European countries (New Zealand, Australia, Canada and the USA) [6,7].

In Italy, Health Monitoring Systems (HMSs) and Medical Registries (MRs), including the Implanted Medical Devices Registries (IMDRs) and the Italian Arthroplasty Registry (RIAP), were issued by the National Law No. 221/2012. Nonetheless, they only entered into force after the approval of the Decree of the President of the Council of Ministers (DPCM) of March 3rd, 2017 [8,9]. HMSs and MRs are currently defined as tools aiming to systematically gather personal, health-related, and epidemiologic data [10]. They are also intended to record and characterize all the health-related risks of a specific disease, including either its treatment strategies and the clinical outcome [10].

However, the milestone for the RIAP development was put in 2005, when all the Italian regions agreed on the creation of a national arthroplasty registry, aiming to gather all the data collected in the regional registries, under the supervision of the Italian National Institute of Health (ISS). The Italian Ministry of Health subsequently supported this project by funding, several pilot studies on Total Joint Replacement (TJRs), performed under the ISS supervision. One of the senior authors of the present paper (BM) took part in these studies that constituted the basis for the final RIAP development.

In recent years, some European countries have introduced another nationwide orthopaedic registry than arthroplasty registers: the fracture registry [7,11]. The development of this new tool aims to improve quality and safety in fracture management, thus trying to provide a better postoperative quality of life in trauma patients [12–14]. The fracture registries are useful in the evaluation of treatment methods, currently employed in orthopaedic trauma surgery, since RCTs comparing surgical and conservative managements, for the same fracture patterns, are often not feasible in trauma surgery.

Based on the above-mentioned findings, the AO-Trauma Italy Council decided to support the development of a national fracture registry in Italy. This is the first step to start, in future years, the bureaucratic procedure leading to the final establishment of a RIAP-like fracture registry in our country.

The present study aims to (1) provide an overview of the fracture registries in Europe and (2) to develop, for the first time, a pilot Italian Fracture Registry (RIFra), thus creating the basis for the establishment of this new national registry in Italy.

Overview of fracture registries in Europe

Norwegian hip fracture register (NHFR)

The Norwegian Hip Fracture Register (NHFR, http://nrlweb.ihelse.net/) was developed in 2004 in cooperation with the Norwegian Orthopaedic Association. Since January 2005, the NHR has been collecting data concerning only hip fractures surgically managed: other fracture types and conservatively managed hip fractures are not involved in the present registry. Currently, 55 orthopaedic departments are involved in the present registry; each participating centre has a reference surgeon who coordinates the data collection. This registry aims to gather epidemiological data, to compare the results of the different surgical procedures currently used in the management of hip fractures and to assess patients' functional and psychological outcome, using the EuroQol questionnaire. Every year, an annual report is shared between all the participating centres. The NHFR has contributed to the realization of a relevant number of studies concerning several clinical and surgical aspects of hip fractures, including implant choice, surgical timing and mortality, the role of comorbidities and drugs assumption on the outcome and reoperation risks [15–17].

Swedish fracture register (SFR)

The Swedish Fracture Register (SFR, https://sfr.registercentrum.se/sfr-in-english/the-swedish-fracture-register/p/HyEtC7VJ4) was developed in 2009–2010 and started collecting data in 2011. Since its introduction, the SFR has been continuously implemented and improved [18]. Currently, more than 80% of all Swedish departments treating fractures regularly record data about fractures, either surgically or conservatively managed, on a web-based form [18]. In the SFR is also available a section focusing on the Patient-Reported Outcome Measures (PROM). Another interesting feature of the SFR is the link between all the recorded data and the personal identity number, i.e. a unique number for each Swedish citizen: all the fractures and/or complications procedures that will occur later will be added to the same patient's sheet, even if they will be managed in different hospitals. Furthermore, all the collected data is always available for each participating centres.

The SFR has contributed to the production of several high-quality papers [19–24], thus significantly improving the orthopaedic trauma knowledge and clinical practice.

Danish fracture database (DFDB)

The Danish Fracture Database (DFDB, https://www.danishhealthdata.com/find-health-data/Dansk-Frakturdatabase) was established in 2011 and currently collect data concerning all types of fractures, surgically managed [25]. The DFDB consists of an online database completed by the operating surgeon at the end of the surgical procedure. The DFDB aims to assess the outcome of the orthopaedic trauma surgical procedures performed, identify risk factors influencing the clinical outcome and monitor the survival of the implants used. The DFDB also supported orthopaedic trauma surgery evolution, by contributing to the production of several high-quality papers [25–29].

German fracture register (in development)

Several orthopaedic registers are currently used in Germany, including the Trauma Register of the *Deutsche Gesellschaft für Unfallchirurgie* (DGU®, established in 1993), the *BeckenRegister DGU®* (i.e., the pelvic trauma register, established in 2004), the *Endoprothesenregister Deutschland* (i.e., the German Arthroplasty Registry, established in 2010), the *Deutsche Wirbelsäulengesellschaft* (i.e., the German Spine Registry, established in 2012), the *HandTraumaRegister DGH* (i.e., the hand trauma register, established in 2014), and AltersTraumaRegister DGU® (i.e., the Orthogeriatric registry, established in 2016) [30].

Nonetheless, the German Fracture Register (GFR), i.e. a unique registry collecting data about all fractures type is still in development [11]. As recently reported by Beirer et al., in a feasibility

Table 1
Centres participating in the RIFra project.

1.	AUO "Policlinico" di Bari-University of Bari "Aldo Moro" (Leader centre)
2.	Ospedali Riuniti di Ancona
3.	Ospedale di Biella, ASL Biella
4.	Ospedali Civili di Brescia
5.	Ospedale Camposampiero (Padova), AULSS 6 Euganea
6.	Ospedale "San Giovanni di Dio", Firenze, Azienda USL Toscana Centro
7.	Ospedale Civile di Legnano, A.S.S.T. OVEST MILANESE
8.	Humanitas Research Hospital, Milano
9.	Niguarda Hospital, Milano
10.	Gaetano Pini Hospital, Milano
11.	Ospedale "Santa Maria delle Croci", Ravenna, AUSL Romagna
12.	Arcispedale S. Maria Nuova, Azienda Ospedaliera di Reggio Emilia
13.	Fondazione Policlinico Universitario "Agostino Gemelli", Roma

study, the GFR will be a national registry aiming to record the patient-centred outcome of either non-surgical and surgical fracture treatment, in all the anatomical districts [11].

The Italian fractures registry (RIFra) project

Based on the above-mentioned encouraging European examples, in 2019 the AO-Trauma Italy Council decided to promote the development of a national fracture registry in Italy, aiming to collect all relevant data concerning the fractures surgically managed in our country. Thirteen AO-Trauma Italy members, chairmen of Level-I orthopaedic and trauma centres, diffused throughout Italy, were involved in the RIFra project (Table 1).

Therefore, an Italian Fracture Registry (RIFra) form was developed and approved by all the involved centres. To further assess the feasibility and sustainability of this project, a pilot prospective data collection started in all the participating centres.

The RIFra form development strategy

The RIFra form was developed between November 2019 and March 2020 at the Orthopaedic and Trauma Unit of the University of Bari *"Aldo Moro"* by two authors, VG and DB, supervised by one of the senior authors (BM). The development strategy involved the following steps.

The first step consisted of a scoping literature search on PubMed database to select potentially relevant parameters to be included in the RIFra. The search strategy, using PubMed database, included the following terms: ((fractures[MeSH Terms] OR "orthopaedic trauma"[*All Fields*]) OR (musculoskeletal injuries[MeSH Terms] OR "AO classification"[*All Fields*]) AND ("registry"[MeSH Terms] OR (surgery[All Fields] AND techniques[*All Fields*]) OR ("outcome"[All Fields] OR measures[All Fields] OR quality[*All Fields*]) AND ((reoperation[MeSH Terms] OR "function"[All Fields] OR satisfaction[*All Fields*])).

The second step consisted of the choice of the most relevant parameters to be included in the RIFra form; a RIAP-like form was used as an example. Two authors (BM and GV), based on literature analysis, proposed to the AO Trauma Council the parameters to be included in the RIFRA form. All the parameters were discussed using Delphi method. Only parameters accepted by >80% of AO Trauma Council members, were included in the proof-version of the RIFra form.

In the third step, the proof-version of the RIFra form was realized and shared between the involved centres. In each centre, the proof of the RIFra form was evaluated by one referent surgeon, who was also allowed to suggest changes aiming to improve the form quality. All the proposed changes were finally discussed between the thirteen centres. The definitive version of the RIFra form, unanimously approved by all the participating centres, was finally obtained.

Table 2
The RIFra form.

Section 1: epidemiologic data	Age Gender Body Mass Index (BMI) Comorbidities Drug history Smocking status Hospital performing surgery
Section 2: previous surgical procedure (if any)	Date and hospital of previous surgical intervention Fracture type Implanted devices details
Section 3: patient and fracture features	Mechanism of injury Type of trauma patient (single fracture/ multiple fractures/ polytrauma) AO fracture pattern (use of other classifications is also allowed) Affected side Gustilo classification (if open fracture) Types of imaging examinations
Section 4: surgical procedure	Trauma to surgery time Type of surgery (Damage control/ definitive surgery/ re-operation/hardware removal/other) American Society of Anaesthesiologists score (ASA) Charlson Comorbidity Index (CCI) haematocrit (before surgery) Platelet count (before surgery) Antibiotic prophylaxis Thromboembolic prophylaxis Type of anaesthesia Tourniquet employment (yes, no, not applicable) First surgeon (senior surgeon vs resident surgeon) Reduction type (direct/indirect) Surgical approach Type of AO technique (absolute stability/relative stability) Intraoperative fluoroscopy duration Bone graft type (if used) Blood transfusion Surgical procedure time Associated non-orthopaedic procedures Intra-operative complications
Section 5: implanted devices details	Type of device Reference number (REF) Lot number (LOT) CND number (Classificazione Nazionale Dispositivi Medici) (to be filled in for each implanted device)
Section 6: long-terms complications and outcomes (in development)	Type of complication Clinical orthopaedic scores Numeric Rate Scale for pain (NRS)

Features of the definitive RIFra form

The RIFra form consists of 5 main sections, namely: epidemiologic data, previous surgical procedure (if any), patient and fracture features, surgical procedure, surgical implant details (Table 2). All the data were collected in accordance with the General Data Protection Regulation, EU No. 2016/679.

In section one, relevant epidemiologic data are recorded, including gender, age, Body Mass Index (BMI), comorbidities, drug history, smocking status and hospital performing surgery.

Section two focuses on fracture previous surgical procedure details, to correctly define patients undergoing definitive surgery after damage control orthopaedics (DCO) strategy, or patients undergoing hardware removal and patients undergoing reoperation for local complications.

Section three provides several useful information to correctly classify the patient complexity, i.e. mechanism of injury, affected side and type of trauma (single fracture, or multiple fractures or polytrauma), and the fracture pattern, i.e.AO fracture pattern and Gustilo classification, in presence of open fractures, and type of imaging exams performed.

Section four focuses on the surgical procedure and includes several items that could be divided into the following domains:

(1) general information: trauma to surgery time (minutes) and type of surgery (damage control/ definitive surgery/ re-operation/hardware removal/other), preoperative haematocrit and platelet count;
(2) pharmacologic and anesthesiologic features: American Society of Anaesthesiologists score (ASA), Charlson Comorbidity Index (CCI), antibiotic prophylaxis, thromboembolic prophylaxis, type of anaesthesia, tourniquet employment (yes, no, not applicable);
(3) surgical details: first surgeon experience (senior surgeon/ resident surgeon); surgical approach; reduction type (direct/indirect); type of AO technique (absolute stability/relative stability); intraoperative fluoroscopy duration; eventual use of bone graft type; type of intraoperative blood transfusion (if applicable); surgical procedure time; associated non-orthopaedic procedures and intra-operative complications.

Section five focuses on the implanted devices features; for each device, the following elements should be detailed: type of device; reference number (REF); lot number (LOT) and CND (i.e., *Classificazione Nazionale Dispositivi Medici*) number.

Finally, section six is still under development; it will aim at recording patients' complications and clinical outcome.

Data collection strategy

After the definitive approval, an online editable form containing all the RIFra sheet items was developed and shared between the involved centre. The pilot prospective data collection started in April 2020 and the data will be recorded after the fracture surgical treatment. The collected data, gathered and analysed by the leader centre, will be always available for all the participating centre. A semesterly report will be provided for the first year. These reports will be then used to develop a national fracture registry.

Expected practical implications in daily clinical practice

The RIFra introduction could behave several positive implications in daily clinical practice. Firstly, it will depict a picture of the current orthopaedic trauma surgery in Italy, detailing the epidemiology of the different fracture patterns, the antibiotic thromboembolic prophylaxis choices, the Italian orthopaedic surgeons' implant choices, the Italian surgeons' compliance to AO surgical techniques, the number of surgical procedures performed by Italian residents, the number and type of complications following orthopaedic trauma surgery. All these data could be useful to improve the current clinical practice.

Secondly, the data provided by the RIFra could be useful in solving the current controversies in preoperative imaging workout [31,32] trauma implant choice and configuration [33–42], fracture features influencing healing time [43–46] and in perioperative infection prevalence [47–52].

Finally, the data collected in the RIFra database will contribute to building evidence in orthopaedic trauma surgery, thus supporting the decision-making process performed in daily clinical practice.

Future developments

We hope this pilot study could be useful to realize a national fracture registry in Italy, to improve the quality and the safety of orthopaedic trauma surgery in our country.

Furthermore, we are currently working on the development of the section 6 of the RIFra form, centred on the patients' clinical outcomes and complications. This section will include the clinical orthopaedic scores specific for each district, pain level assessment, using the Numeric Rating Scale for Pain (NRS) and the Patient-Reported Outcome Measures (PROM) will be assessed using the EuroQuality five dimensions index (EQ-5D). This section will be used at each follow-up to assess patients' function and satisfaction about the received surgical treatment.

Conclusion

Fracture registries are useful tools aiming to collect data about fractures epidemiology and management. In the present study, we have presented the adopted strategy to develop the Italian Fracture Registry (RIFra) pilot project. The data collected using the RIFra form, described for the first time in the present study, will lay the basis for the future establishment of a national fracture registry in Italy.

Declaration of Competing Interest

None

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2020.10.052.

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