



Differences in the baseline characteristics, management and outcomes of patients with hip fractures depending on their pre-fracture place of residence: the Spanish National Hip Fracture Registry (RNFC) cohort

Peggy P. Ríos-Germán^{1,2} · Alicia Gutierrez-Misis^{2,3} · Rocío Queipo^{2,4} · Cristina Ojeda-Thies⁵ · Pilar Sáez-López^{2,6} · Teresa Alarcón^{1,2} · Angel Otero Puime^{2,3} · Paloma Gómez-Campelo² · Laura Navarro-Castellanos² · Juan Ignacio González-Montalvo^{1,2,3} · the participants in the Spanish National Hip Fracture Registry (RNFC)

Received: 3 January 2021 / Accepted: 15 April 2021
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Key summary points

Aim Comparing the characteristics of hip fracture patients as per their pre-fracture place of residence, patients from aged care facilities vs. community dwellers, at baseline, during hospitalization and 1-month post-fracture in 75 hospitals in Spain.

Findings The results suggest that their baseline situation, the care process during hospitalization and the therapeutic recommendations at discharge are all different, and that at 1-month follow-up, older adults admitted from aged care facilities fare disproportionately worse.

Message New studies are needed to evaluate whether a common protocol emphasizing the characteristics of each group can reduce the differences regarding post-fracture decline of ambulatory status between individuals from aged care facilities and community dwellers.

Abstract

Purpose One in four hip fracture patients comes from an aged care facility. This study aimed to compare the characteristics of these subjects with their community-dwelling counterparts at baseline, during hospitalization and 1-month post-fracture.

Methods We analyzed data from a cohort of older adults admitted with hip fractures to 75 Spanish hospitals, collected prospectively in the Spanish National Hip Fracture Registry between 2016 and 2018.

We classified participants according to pre-fracture residence: community dwellers vs. aged care facilities residents. We collected demographic records at baseline, along with variables relating to in-hospital evolution and discharge to geriatric rehabilitation units. Patients or relatives were interviewed at 1-month follow-up.

Results Out of 18,262 patients, 4,422 (24.2%) lived in aged care facilities. Aged care facilities residents were older (median age: 89 vs. 86 years), less mobile (inability to walk independently: 20.8% vs. 9.4%) and had more cognitive impairment

✉ Peggy P. Ríos-Germán
peggyaola.rios@salud.madrid.org

¹ Department of Geriatric Medicine, Geriatric Service, Hospital Universitario La Paz, Paseo La Castellana 261, 28046 Madrid, Spain

² La Paz University Hospital Institute for Health Research (IdiPAZ), Madrid, Spain

³ Department of Medicine, Universidad Autónoma de Madrid, Madrid, Spain

⁴ European University of Madrid, Madrid, Spain

⁵ Department of Traumatology and Orthopaedic Surgery, Hospital Universitario, 12 de Octubre, Madrid, Spain

⁶ Department of Geriatric Medicine, Hospital Universitario Fundación de Alcorcón, Madrid, Spain

(Pfeiffer's SPMSQ > 3, 75.3% vs. 34.8%). They were more likely to receive conservative treatment (5.4% vs. 2.0%) and less likely to be mobilized early (58.2% vs. 63.0%). At discharge, they received less vitamin D supplements (68.5% vs. 72.4%), less anti-osteoporotic medication (29.3% vs. 44.3%), and were referred to geriatric rehabilitation units less frequently (5.4% vs. 27.5%). One-month post-fracture, 45% of aged care facilities residents compared to 28% of community dwellers experienced a severe gait decline. Aged care facilities residents had a higher one-month mortality (10.6% vs. 6.8%).

Conclusion Hip fracture patients from aged care facilities are more vulnerable than their community-dwelling peers and are managed differently both during hospitalization and at discharge. Gait decline is disproportionately higher among those admitted from aged care.

Keywords Hip fracture · Functional decline · Aged care facilities · Rehabilitation · National audit

Introduction

Hip fractures are a considerable public health problem, with severe personal, social and economic repercussions [1, 2]. Their incidence stands at 1.7 million cases per year worldwide [3], of which around 620,000 in Europe [4], and 300,000 in the United States [5]. One-year mortality following a hip fracture varies between 12 and 35% [6, 7]. A significant decline in function and walking ability can occur following the fracture, with stern consequences for both the patient and his/her environment [1].

The institutionalisation of older adults, on the other hand, is a complex phenomenon associated with demographic, social and economic factors [8]. The number of people over the age of 85 is expected to grow worldwide. This age group has greater comorbidity, functional decline, cognitive impairment and dependence [9, 10], all features linked with institutionalisation [11]. Currently, in the United States, 3.1% of adults over the age of 65 and 10.6% of those over the age of 85 live in aged care facilities [12]. In Spain, 3.3% of those aged 65 and above live in such facilities; these percentages increase to 11.8% of men and 18.1% of women aged 90 and above [13].

Residents of aged care facilities have a higher annual incidence of hip fractures than their community-dwelling peers, representing approximately 17–40% of hip fracture patients [14–16]. Studying patients with hip fractures according to their place of residence is fundamental, to audit their course during and after hospitalisation and to implement strategies to improve clinical practice [7]. In spite of institutionalised older adults comprising a large proportion of the total number of individuals admitted due to hip fractures, few studies analyse the baseline, in-hospital and follow-up differences between these patients and those not institutionalised prior to the fracture [17–19].

There are few studies which compare both groups, and they usually consist of a limited number of cases or do not include sufficient variables to make allowance for the fact that being institutionalised at the time of a hip fracture is an aggravating factor. They conclude that, compared to community-dwelling adults, older adults residing in aged

care facilities are older and more likely to present geriatric syndromes such as functional decline, cognitive impairment, polypharmacy or sarcopenia [7, 20, 21]. Furthermore, they are less likely to be sent to rehabilitation units [7, 18]. Mortality following hospitalisation is not always higher among residents of aged care facilities, though these present higher rates of gait decline [7, 18, 21–24].

The goals of this study were to compare two groups of older adults suffering hip fractures: those coming from aged care facilities, and those which were community dwellers, with regards to the following aspects: (1) baseline functional and clinical status; (2) medical and surgical management, as well as rehabilitation care and in-hospital mortality; and (3) mortality and functional decline 1 month after the fracture. These aspects were selected to highlight the aggravation of circumstances arising when an aged care facility resident suffers a hip fracture.

Methods

Study design

Between the years 2017 and 2018, there were 873 public and private hospitals in Spain which registered data in the database of Hospital Discharges of the Spanish National Health System (CMBD for the Spanish acronym for the Minimum Basic Data Set). Out of all of these, in this time frame only 275 operated on hip fracture patients older than 75 years of age. The data of this prospective observational study were obtained from the Spanish National Hip Fracture Registry (*Registro Nacional de Fracturas de Cadera*, or RNFC, in Spanish), a multicentre, observational, prospective database previously described [25, 26]. This registry, in which public hospitals participate on a voluntary basis, was set up in July 2016 with 10 hospitals. As of December 2018, 75 public hospitals had participated in the registry. For this study, we used data from this entire time period.

In this paper, pre-fracture residence refers to the place of residence, where the hip fracture occurred. Aged care facilities included sheltered housing, residential housing and

nursing homes, and community-dwelling patients lived in their own homes or together with relatives [9].

Study subjects

Subjects were selected through convenience sampling based on inclusion and exclusion criteria. The inclusion criteria were: having been admitted to one of the RNFC participating hospitals with the diagnosis of low-energy hip fracture (due to a fall from standing height), being aged 75 or older, and providing informed consent (by the patient or by their next of kin). Exclusion criteria were: hip fractures occurring as a result of high-energy trauma, pathologic fractures due to cancer, unknown pre-fracture place of residence or living in a location different from the usual place of residence at the time of the fracture.

Data collection

Data collection took place in two phases:

1. Acute hospitalisation phase:

The variables, collected by the physician in charge during acute hospitalisation, were age, gender, date of admission, surgery and hospital discharge, pre-fracture place of residence, mobility according to the Functional Ambulation Categories [FAC] scale (FAC 0: Non-functional ambulator; FAC 1: Ambulator, dependent on physical assistance—level I; FAC 2: Ambulator, dependent on physical assistance—level II; FAC 3: Ambulator, dependent on supervision; FAC 4: Ambulator, independent level surface only; FAC 5: Ambulator, independent) [27], cognitive status (Pfeiffer's Questionnaire) [28], calcium and vitamin D supplementation, anti-osteoporotic medication (antiresorptive and bone-forming drugs) prescribed before the fracture and at hospital discharge, anaesthetic risk (ASA Score), non-operative treatment, surgical delay, type of anaesthesia used, early mobilisation (during the first postoperative day), length of hospital stay, hospital-acquired pressure sores, vital status at the time of hospital discharge and destination of hospital discharge.

Participation was authorised by the patient or next of kin by means of informed consent during this phase, and contact details for the 1-month follow-up were recorded.

2. Follow-up phase,

Data were collected 1 month after the fracture by telephone interview or during a follow-up visit by the corresponding healthcare professional. Those interviewed were the patients themselves, their relatives or even the healthcare personnel in charge, in the case of phone calls made to an aged care facility. Variables collected were vital status,

place of residence, calcium or vitamin D supplementation, anti-osteoporotic medication taken (antiresorptive or bone-forming drugs), the existence of surgical readmissions and reoperations in the month following the fracture, patient mobility (as per the FAC scale), and change in ambulatory status. For the last two variables, data were only used from individuals who had registered their vital status and known place of residence at 1 month.

Ethical considerations

This research project was approved by the Ethical Review Board of the Hospital Universitario La Paz, Madrid (IdiPAZ project, number 2574) and was ratified by the review boards of all participating hospitals.

Statistical analysis

Quantitative variables are described using the mean and standard deviation (SD) for variables with normal distribution, and using the median and interquartile range for those distributed non-normally. Qualitative variables are described using frequencies. We established two groups of subjects according to their place of residence prior to the hip fracture: community dwellers and residents of aged care facilities. The variable “change in ambulatory status” was created using the FAC scale, comparing the baseline ambulation with that 1 month after the fracture. It was classified in three categories: “without change” if there was no change on the FAC scale 1-month post-fracture; “moderate decline” if there was a gait decline of one point (FAC 5 to FAC 4, FAC 4 to FAC 3, and so on), and “severe decline” if a gait decline of more than one point occurred (FAC 5 to FAC 3, FAC 4 to FAC 2, and so on) [7]. The analysis “change in ambulatory status” was performed on subjects alive at the 1-month follow-up which had a pre-fracture capacity between FAC 2 and 5.

The association of each variable with the pre-fracture place of residence was calculated using the Chi-squared test for qualitative variables, the Student's *t* test for normally distributed quantitative variables, and the Mann–Whitney *U* test for variables with non-normal distribution. Normality was confirmed by means of the Kolmogorov–Smirnov test. The statistical package used for the analysis was SPSS, version 25 (IBM, Armonk, NY, USA).

Results

Baseline characteristics of the patients

Of the 19,008 persons aged 75 and over admitted with fragility hip fractures, 18,262 accepted participation in the

registry. Those that declined participation had a similar age and gender distribution to that of those included in the study. Residents of aged care facilities comprised 24% of study participants (4422 individuals). Demographic, clinical and functional differences between hip-fracture patients living in aged care facilities and those living in the community are summarised in Table 1. Those living in aged care facilities were older, their ambulatory status was worse, and they were more likely to present cognitive decline; their anaesthetic risk was higher, and they were treated more commonly with vitamin D supplements and less frequently with antiresorptive medication, compared to their community-dwelling peers.

Acute hospitalisation

The differences between both groups during the acute hospitalisation phase are shown in Table 2. Individuals living in aged care facilities were more likely to receive conservative treatment (5.4% vs. 2.0%, $p < 0.001$), and those that were operated were less likely to be mobilised on the first post-operative day (61.4% vs. 64.1%, $p < 0.001$). They did not, however, develop more pressure sores. In this study, 35 individuals from aged care facilities (0.8%) and 440 community

dwellers (3.2%) were treated with total hip arthroplasty, $p < 0.001$.

In-hospital mortality was higher for patients admitted from aged care facilities than for community dwellers. At discharge, they were prescribed fewer calcium and vitamin D supplements, as well as less anti-osteoporotic medication, and were less frequently sent to geriatric recovery units.

One-month follow-up

Evolution at 1-month follow-up for both groups is shown in Table 3. The distribution of the 611 (3.5%) subjects in whom vital status could not be ascertained was similar, vis-à-vis age and gender, to those who survived at 1 month. Older adults living in aged care facilities before the fracture were less likely to be in geriatric rehabilitation units, and took fewer calcium and vitamin D supplements, as well as less anti-osteoporotic medication, compared to their community-dwelling counterparts. There was little difference between the two groups regarding readmission or reoperation rates. One-month mortality was higher among patients originating from aged care facilities than among community dwellers (10.6% vs. 6.8%, respectively, $p < 0.001$).

Table 1 Baseline differences between community-dwelling patients and those admitted from Aged Care Facilities from the Spanish National Hip Fracture Registry (RNFC)

Characteristic	Aged care facilities <i>N</i> = 4422	Community-dwelling <i>N</i> = 13,840	<i>p</i> value
Demographic variables			
Age	89 (85–92)	86 (82–90)	<0.001
Female gender	3420 (77.4)	10,405 (75.3)	0.03
Clinical and functional assessment			
Baseline FAC			<0.001
FAC 4–5	2883 (65.9)	12,144 (88.4)	
FAC 1–3	911 (20.8)	1288 (9.4)	
FAC 0	581 (13.3)	310 (2.2)	
Pfeiffer's SPMSQ > 3	2586 (73.5)	4052 (34.8)	<0.001
Clinical variables			
Fracture type			0.001
Intracapsular	1827 (41.8)	5366 (39.3)	
Intertrochanteric	2257 (51.6)	7199 (52.5)	
Subtrochanteric	299 (6.6)	1113 (8.1)	
ASA classification ≥ III	3393 (81.0)	9114 (69.1)	<0.001
Anti-osteoporotic medication			
Antiresorptive	174 (3.9)	759 (5.5)	<0.001
Bone forming	17 (0.4)	82 (0.6)	0.064
Calcium	522 (11.8)	1556 (8.6)	0.342
Vitamin D	856 (19.4)	2169 (15.8)	<0.001

^aData were expressed as number (percentage) except for the age, expressed as median (interquartile range)

^bFAC=Functional Ambulation Categories

^cSPMSQ=Short Portable Mental Status Questionnaire (Pfeiffer's Questionnaire)

^dASA = American Society of Anaesthesiologists Score

Table 2 In-hospital differences between community-dwelling patients and those admitted from Aged Care Facilities from the Spanish National Hip Fracture Registry (RNFC)

Variable	Aged care facilities N=4422	Community-dwelling N=13,840	p value
Process			
Non-operative treatment	233 (5.4)	270 (2.0)	<0.001
Type of surgery			
Cannulated screws	98 (2.4)	311 (2.3)	0.657
Intramedullary nail	2460 (60.2)	8034 (60.2)	
Arthroplasty	1524 (37.2)	4951 (37.1)	
Others	10 (0.2)	50 (0.4)	
Type of anaesthesia			
General	256 (6.2)	843 (6.3)	0.029
Spinal	3792 (92.6)	12,257 (91.9)	
Other regional	32 (0.8)	183 (1.4)	
Unknown	17 (0.4)	55 (0.4)	
Surgery in > 48 h	2313 (56.4)	7318 (54.8)	0.067
Length of stay in days, median (SD)	9.0 (5.4)	10.8 (6.5)	<0.001
Mobilization on the first postoperative day	2519 (61.4)	8556 (64.1)	<0.001
Results			
Pressure ulcers	264 (6.1)	827 (6.0)	0.700
In-hospital mortality	248 (5.6)	576 (4.2)	<0.001
Destination at discharge			
Home	72 (1.6)	6963 (50.4)	<0.001
Nursing home	3795 (85.9)	2134 (15.4)	
Acute hospitalization	37 (0.8)	139 (1.0)	
Geriatric Rehabilitation Unit	239 (5.4)	3796 (27.5)	
Long-term hospital care	24 (0.5)	201 (1.5)	
Unknown	7 (0.2)	31 (0.2)	
Anti-osteoporotic treatment at discharge			
Antiresorptive	1168 (28.0)	5501 (41.5)	<0.001
Bone forming	55 (1.3)	365 (2.8)	<0.001
Any (Antiresorptive or bone forming)	1223 (29.3)	5866 (44.3)	<0.001
Calcium	2045 (49.5)	6862 (52.3)	0.002
Vitamin D	2830 (68.5)	9504 (72.4)	<0.001

^aData were expressed as number (percentage), except for Length of stay in days, expressed as mean and standard deviation (SD)

^bSD = standard deviation

One month after the fracture, independent ambulation (FAC 4 and 5) amid community-dwelling older adults was nearly double that of those living in aged care facilities. As can be observed in Table 3, there was a severe gait decline in 54.6% of institutionalised individuals, compared to 29.1% of community dwellers ($p < 0.001$).

Discussion

In this large nationwide multicentre inception cohort study, we observed that, among individuals with hip fractures, those living in aged care facilities were older, more likely to be cognitively impaired and have worse ambulatory status than their community-dwelling peers. In addition, they did

not receive the same medical, surgical or rehabilitation treatment. Older adults coming from aged care facilities received non-operative treatment more frequently, were sent to geriatric rehabilitation units less often and were prescribed less anti-osteoporotic medication. Severe decline of ambulatory status was more common and mortality was higher in this group 1 month after the fracture.

1. Over-representation of subjects from aged care facilities among hip fracture patients.

Our results have several implications for clinical practice. First, we would like to underline the proportion of patients living in aged care facilities admitted for hip fractures. According to the Spanish National Institute of Statistics, 5.5% of people aged 75 or older were living in

Table 3 Differences at 1-month follow-up between community-dwelling patients and those admitted from Aged Care Facilities from the Spanish National Hip Fracture Registry (RNFC)

Variable	Aged care facilities	Community dwelling	<i>p</i> value
One-month mortality	468 (10.6)	944 (6.8)	<0.001
Among those alive:	3814	12,425	
One-month place of residence			<0.001
At home	124 (3.3)	7626 (61.4)	
Nursing home	3457 (90.6)	2250 (18.5)	
Acute hospitalization	75 (2.0)	304 (2.4)	
Long-term hospital care	11 (0.3)	183 (1.5)	
Geriatric Rehabilitation Unit	69 (1.8)	1779 (14.3)	
Unknown residence	78 (2.0)	283 (2.3)	
One-month anti-osteoporotic treatment			
Antiresorptive	1074 (28.5)	5280 (42.8)	<0.001
Bone forming	76 (2.0)	460 (3.7)	<0.001
Any (Antiresorptive or bone forming)	1150 (30.5)	5740 (46.5)	<0.001
Calcium	1898 (50.5)	6692 (54.7)	<0.001
Vitamin D	2587 (68.9)	9122 (74.5)	<0.001
Readmission at 30 days related to the hip fracture	100 (2.6)	329 (2.7)	0.495
Reoperation at 30 days	80 (2.1)	282 (2.3)	0.285
Ambulation at 30 days (FAC)			<0.001
Independent (FAC 4–5)	1292 (35.4)	7944 (66.2)	
With help or supervision (FAC 1–3)	917 (25.1)	1885 (15.7)	
Does not walk (FAC 0)	1442 (39.5)	2163 (18.0)	
Unknown ambulation	163 (4.2)	433 (3.5)	
Deterioration of ambulation at 30 days			<0.001
No change (0 points difference)	801 (29.5)	4410 (40.3)	
Moderate decline (1 point difference from initial FAC)	432 (15.9)	3351 (30.6)	
Severe decline (> 1 point difference from initial FAC)	1485 (54.6)	3195 (29.1)	

^aData were expressed as number (percentage)

^bFAC = Functional Ambulation Categories

aged care facilities in 2011. However, our results showed that institutionalised adults amounted to one quarter of all cases included in our National Hip Fracture Registry. Other national registries, such as those from England, Australia and New Zealand report between 23 and 29% of hip fracture patients from aged care facilities [29, 30], decreasing to around 10% for Italy and Ireland [31, 32].

Previous literature indicates that the incidence of hip fractures among those living in aged care facilities can be 3.3 times that among community dwellers [14, 15]. The three risk factors most associated with hip fractures are age, risk of falling and osteoporosis. People living in aged care facilities are older and have more risk factors for falls [7, 20, 33]. Osteoporosis is also more prevalent and more severe among individuals living in aged care facilities than among community dwellers [34].

Our results agree with these facts, and hence our first recommendation is to direct more efforts towards strategies to study and reduce the risk of falling and ensuing

fractures among older adults living in aged care facilities. Special attention should be paid to subjects having been recently institutionalised, and to those who walk independently. Anti-osteoporotic treatment and calcium and vitamin D supplementation should be prescribed in a timely manner when deemed necessary [15, 35, 36].

2. *In-hospital evolution.*

The results of this study suggest that hip fracture patients living in aged care facilities are more likely to be treated non-operatively, and that, among those managed surgically, postoperative mobilisation occurs later than with community dwellers. It should be noted that the total percentage of patients who were treated surgically is in line with the one in other national registries [26]. With regard to issues which can interfere with initiating rehabilitation, some authors have observed that residents of aged care facilities are more likely to present adverse events such as electrolyte imbalance, arrhyth-

mias, anaemia, severe pain, delirium or infections [7, 18, 24].

The shorter length of acute hospital stay and the lower proportion of institutionalised older adults referred to geriatric rehabilitation units have been observed persistently by authors in several countries [17, 18, 21, 22]. After adjusting for age, gender, marital status, social support, pre-fracture function, comorbidity index and cognitive status, Beaupre et al. concluded that coming from an aged care facility was linked to not returning to pre-fracture functional status [21]. In that study, all patients were operated on in the first 24 h, and started rehabilitation on the second postoperative day; however, only 10% of subjects from aged care facilities were sent to geriatric rehabilitation units, compared to 79% of community dwellers, with the authors admitting that this could have influenced recovery.

In a nationwide study, Burleigh et al. observed that, following a hip fracture, older adults residing in aged care facilities were less likely to receive fall assessments, nutritional assessments, nursing care plans, or evaluation by an occupational therapist [17]. They were also less likely to begin anti-osteoporotic treatment during either acute hospitalisation or during rehabilitation. It is known that institutionalised individuals are treated less often for osteoporosis, both before and after a hip fracture [22, 37, 38]. Although residents of aged care facilities were excluded from the first studies carried out using bisphosphonates, it has recently been proven that these reduce hip fracture rates in institutionalised adults, without increasing the adverse events associated with their use [36]. The characteristics of these subjects (older age, greater functional decline and cognitive impairment, with a higher risk of falls and ensuing fractures) place them at a higher risk of imminent fracture. To improve the in-hospital process and outcome for both institutionalised and non-institutionalised patients, a protocol should be implemented, trying to meet quality indicators from which both groups could equally benefit. In that sense, as suggested by Condorhuamán et al., a common protocol with multidisciplinary facets is needed, including: (1) at the surgical level, a swift appraisal by the Departments of Orthopaedic Surgery and Anaesthesiology, to make prompt surgery possible; (2) at the medical level, an assessment including nutrition, anaemia, evaluation of pain and oral or parenteral anti-osteoporotic treatment, depending on the patient's characteristics, and (3) at the rehabilitation level, timely actions in the acute phase as well as during subsequent weeks [39].

3. One-month follow-up.

In this study, we observed that both decline of ambulatory status and mortality were higher after a hip fracture for older adults coming from aged care facilities. In a different study performed by our group using a common multi-domain orthogeriatric treatment protocol, with few differences between institutionalised individuals and those admitted from private homes, there was little divergence in mortality rates between groups, whether in-hospital or at 1 year [7]. However, that study also observed that community dwellers were more likely to be referred to geriatric rehabilitation units at discharge from acute hospitalisation, and that severe deterioration of ambulatory status was greater among those coming from aged care facilities, as also observed in the 1-month results of the present study.

A Danish group applied an orthogeriatric protocol during acute hospitalisation, which was continued after discharge by visiting the patients' aged care facilities [40]. They achieved a reduction of mortality from 40 to 19% during the first 3 months following a hip fracture among residents of the facilities which they visited, as well as a decrease in readmissions to hospital during the first month. Another recently published study applied a multidisciplinary treatment in the aged care facilities themselves, including rehabilitation, nutritional assessment and a care plan [41]. Residents showed improved results with regards to mobility, mortality and quality of life, compared to those receiving standard care in their facilities.

Taking into account the proven benefit of geriatric rehabilitation units, and given that health resources are limited, it would be interesting to analyse and develop a decision tree about which patients to transfer to geriatric rehabilitation units, emphasising the subjects' functional and mental status, as well as their personal or family preferences, over their pre-fracture place of residence. Moreover, periodic visitations of aged care facilities by professionals from Orthogeriatric Units have been shown to improve post-fracture function, mortality, readmission rates and quality of life of residents, and could, therefore, be considered a valid alternative [40, 41].

This study has several strengths. Regarding the number of participants, it is one of the largest clinical studies analysing this topic to date, and both groups are widely represented, thanks to the large number of cases included. In addition, it is a multicentre study with participation of 75 hospitals distributed across most regions of the country.

Among the limitations of the study is the fact that, being carried out at national and multicentre level, participating hospitals did not necessarily apply the same care protocol everywhere. Furthermore, due to the fact that a large number of hospitals participated in this registry, the number of variables included could not be very extensive and was limited to those that were most representative of the quality of the care process.

Conclusions and implications

In conclusion, this study, carried out at national level, highlights the differences in patients hospitalised following a hip fracture, between those admitted from aged care facilities and those which were community dwellers. The results suggest that their baseline situation, the care process during hospitalisation and the therapeutic recommendations at discharge are all different, and that at 1-month follow-up, older adults admitted from aged care facilities fare disproportionately worse.

New studies are needed to evaluate whether a common protocol emphasising the characteristics of each group can reduce the differences regarding post-fracture decline of ambulatory status between individuals from aged care facilities and community dwellers.

Declarations

Conflict of interest The authors declare that they have neither conflicts of interest nor competing interests related to this work.

Ethical approval This research project was approved by the Ethical Review Board of the Hospital Universitario La Paz, Madrid (IdiPAZ project, number 2574) and was ratified by the review boards of all participating hospitals.

Informed consent Subjects provided informed consent (the patient or their next of kin).

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