



# Incidence and Determinants of Adverse Events among Older Inpatients in Post-Acute Rehabilitation Care: A Prospective Observational Study

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## Abstract

**Objective:** The aim of this study was to determine the incidence rates and determinants of adverse events during patients' hospital stays. In addition, the incidence rates of adverse events between elderly patients aged  $\geq 75$  and  $< 75$  years were compared.

**Material and Methods:** This was a prospective cohort study conducted in the rehabilitation unit of a public hospital among a sample of 216 inpatients aged  $> 65$  years. Adverse events were reported and briefly described. Variables potentially associated with the occurrence of adverse events were measured at baseline.

**Results:** Twenty-six patients (12%) experienced an adverse event. The most frequent were fall-related events (8.3%). Patients aged  $\geq 75$  years experienced a higher number of adverse events than those aged  $< 75$  years (15.6% vs. 4.3%, respectively;  $p=0.02$ ). Multivariable logistic regression models showed that age was strongly associated with fall-related events (odds ratio=1.1; 95% confidence interval=1.02–1.17) and all types of events combined (odds ratio=1.06; 95% confidence interval=1.03–1.12).

**Conclusion:** This study provides evidence for the occurrence of adverse events (particularly fall-related events) in elderly patients receiving post-acute care in the rehabilitation units of acute care hospitals. It also shows that some elderly patients (particularly those aged  $\geq 75$  years) are more likely to experience adverse events. There is room for improvement to reduce these experiences to facilitate patient safety.

**Keywords:** Accidental falls, patient care, patient safety, rehabilitation, risk management

## Introduction

Several studies have shown that a substantial number of elderly patients in acute care hospitals experience adverse events (AEs) (1-3), and that AEs are known to contribute in part to negative consequences on mortality, longer hospital stays, and functional status at discharge (4,5). Based on these findings, there is a growing interest in improving patient safety and reducing the number of AEs (6). Recent studies conclude that in addition to

interventions to improve overall patient safety within a hospital, tailored interventions for specific units (e.g., cardiology, neurology, rehabilitation, etc.) are necessary because procedures vary widely among the services that they offer (7).

Many hospitalized elderly patients often require early post-acute rehabilitation for optimizing functioning after acute care (8). This post-acute care may be provided either in specialized rehabilitation facilities or in dedicated units of an acute care hospital (8). Despite of the high levels of this type of care, little

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is known about the frequency and consequences of AEs and factors that predict their occurrence in post-acute rehabilitation care. Several predictive factors for AEs in the acute care of hospitalized seniors have been described, including demographic (age, gender), clinical (number of comorbidities, number of drugs prescribed), and functional (level of consciousness and functional status) factors at the time of admission (3-5). However, although existing literature provides some insights into the types of patient that are likely to experience AEs, the factors associated with AEs in rehabilitation units are likely to differ.

To investigate these issues further, a cohort of elderly patients admitted to a rehabilitation unit in a French acute care hospital was assessed over their stay. The main objectives of this study were to determine the incidence rates and determinants of AEs so that clinicians might use the findings to guide efforts to reduce AEs and therefore improve older-patient safety. Additionally, we compared the incidence rates of AEs between elderly patients aged  $\geq 75$  and  $< 75$  years. Based on previous studies (6,9,10), we hypothesized that older patients would be at a greater risk of AEs in early rehabilitation units.

## Material and Methods

### Study Design and Setting

We conducted a prospective cohort study at a public hospital in Castelnaudary, France. This hospital, with its 268-bed capacity, provides acute and post-acute care. It has a rehabilitation unit for the early post-acute rehabilitation of patients transferred either from its acute services or from other acute care hospitals. All in patients in the hospital are included in a post-acute rehabilitation program, which usually requires a standard stay of 4 weeks. An interdisciplinary team of physicians, nurses, and therapists specialized in rehabilitation care cooperate to manage the demands of early post-acute rehabilitation. The institutional review board of the hospital (ethics committee) approved the protocol used in this study.

### Study Population and Recruitment

Inpatients  $> 65$  years were recruited to the study if they were admitted to the rehabilitation unit and included in a post-acute rehabilitation program. Patients were excluded if they had an uncorrected visual impairment or an inability to understand simple instructions, which were required for filling questionnaires.

During a 11-month period, a provider who assessed eligibility criteria recruited a consecutive sample of the entire accessible population within the first 24 h of their inclusion in the rehabilitation program. The number and reasons for exclusion were documented. An informed consent form was obtained from all participants. Demographic data (age and gender) and reasons for hospitalization (diagnostic) were provided by means of medical records. The participants were classified into three major diagnostic groups: musculoskeletal (e.g., joint replacements, fractures, etc.), cardiopulmonary conditions (e.g., pneumonia, pulmonary edema, etc.), and medically complex (e.g., debility resulting from illness, stroke, or other complex neurologic conditions).

## Measurements

### AEs

For this study, the hospital used the indicators for patient safety in the Organisation for Economic Co-operation and Development (OECD) countries as a framework for reporting AEs (11). This framework included the following four types of relevant AEs: 1) Infections (ventilator pneumonia, wound infections, infections due to medical care, decubitus ulcers), 2) Postoperative complications (complications of anesthesia, postoperative hip fracture, postoperative pulmonary embolism or deep venous thrombosis, postoperative sepsis, technical difficulty with procedure), 3) Sentinel events (transfusion reaction, wrong blood type, wrong site surgery, foreign body left in during the procedure, medical equipment-related AEs, medication errors), and 4) Other care-related AEs (patient falls, in-hospital hip fracture or fall), henceforth defined as "fall-related events" or "fall events."

Members from the multidisciplinary health team were trained to report the occurrence of any AE during the hospital stay at the rehabilitation unit. Thus, AEs were reported and briefly described by the observer. In weekly meetings, two clinical researchers reviewed each patient's medical records to evaluate AEs that occurred during their hospital stay. When the two researchers disagreed about the presence of AE, they interviewed the clinical staff and started a process to achieve a consensus.

### Demographic, Clinical, and Functional Characteristics

Seven variables were selected from literature research based on their potential association with the occurrence of AEs in hospitalized seniors. The variables were measured at baseline and were classified into three domains: demographic, clinical, and functional factors. The demographic domain included age (years) and gender. The clinical domain included diagnostic group, number of prescription drugs used at the beginning of the rehabilitation program, and number of co-morbidities, measured by using the Functional Comorbidity Index (12). The functional factors domain included independence in cognitive functions and disability during mobility activities. Independence in cognitive functions was measured using the cognitive domain of the Functional Independence Measure (which has a scale of 5-35, where higher scores denote greater functional independence) (13). The Functional Independence Measure is broadly applied in various rehabilitation services for outcome assessment (14). To estimate the extent of disability, we used qualifiers ("no limitation", "mild", "moderate", "severe", and "complete disability") from the International Classification of Functioning, Disability and Health (ICF) (15). The level of disability for mobility activities was initially measured with the Mobam-in instrument (16), and later, patients' scores were used to estimate the disability ICF qualifier according to a previously validated procedure and using the ICF category interval scale (0-100) (17).

Mobam-in is an instrument developed for use with inpatients only, and it consists of activities typically performed in this environment. Mobam-in covers two domains of functioning in mobility activities: upper and lower body mobility (18). The lower body domain was selected as the main outcome measure in the present study. The upper body domain was used as an

**Table 1. Patient characteristics at admission (n=216)**

Characteristics	Number (%) or Mean $\pm$ SD <sup>†</sup>
<b>Demographic</b>	
Age, (years)	79.4 $\pm$ 8.5
Female	130 (60.2)
<b>Clinical characteristics</b>	
Diagnostic group	
Musculoskeletal	143 (66.2)
Cardio-respiratory	19 (8.8)
Medically complex	54 (25.0)
Number of medications ( $\geq$ 5 drugs per day)	16 (7.4)
Number of comorbidities	0.67 $\pm$ 0.8
<b>Functional characteristics</b>	
Cognitive status, (range 5–35)	34.1 $\pm$ 0.9
Disability levels, (n=215)	
No disability	0 (0)
Mild disability	9 (4.19)
Moderate disability	63 (29.30)
Severe disability	139 (64.65)
Complete	4 (1.86)

<sup>†</sup>Standard deviation

**Table 2. Type of adverse events experienced by 216 hospitalized older patients**

	Total (n=216)	Age-based groups		p value*
		<75 years (n=69)	$\geq$ 75 years (n=147)	
Overall	26 (12.0)	3 (4.3)	23 (15.6)	0.02 <sup>†</sup>
Infections	4 (1.9)	2 (2.9)	2 (1.4)	0.59 <sup>†</sup>
Sentinel events	4 (1.9)	1 (1.4)	3 (2.0)	1.00 <sup>†</sup>
Fall-related events	18 (8.3)	0 (0)	18 (12.2)	0.00 <sup>†</sup>

\*Comparison between patients aged <75 and  $\geq$ 75 years

<sup>†</sup>Fisher's exact test

alternative only if patients had exclusive musculoskeletal impairments in their upper extremities. Mobam-in scores range from 0 to 100, with lower scores implying greater limitations. Patients who obtained a score between 0 and 4 were assigned to the complete disability qualifier; those with a score between 5 and 49.9 were qualified as severe; those with a score between 50 and 74.9 were allocated to the moderate qualifier; those with a score between 75 and 94.9 were qualified as mild; those with a score between 95 and 100 were allocated to the no disability qualifier.

### Statistical Analyses

Descriptive statistics were used to characterize the cohort at the baseline and to describe the incidence rates of AEs. We used Fisher's exact test or Pearson's  $\chi^2$  test of significance to investigate the incidence rates of AEs between the age-based groups ( $\geq$  and <75 years). We initially examined factors associated with experiencing specific types of AEs and overall AEs (i.e., where all types were combined) by means of univariate logistic regression analyses. Due to the small incidence rates, the types of AEs were grouped as follows: "fall events" and "other" (infections/sentinel events). Subsequently, we entered variables with  $p < 0.10$  into a multivariable logistic regression model for each type of AE and overall AEs. Analyses were performed using the Statistical Package SPSS version 19.0 (SPSS, IBM Corp., Armonk, New York, USA).

### Results

In total, 230 subjects were identified during the study period. Of these, 12 were excluded (3 had visual impairment, whereas 9 were not able to understand simple instructions). Two patients refused to participate. Thus, 216 subjects were considered; 65.7% (142 patients) were admitted from acute services of other referral hospitals.

Participants' characteristics at baseline are described in Table 1. The mean age  $\pm$  standard deviation of participants was 79.4 $\pm$ 8.5, and participants aged  $\geq$ 75 years represented 68.1% of the sample. The sample included 60.2% female participants, and the musculoskeletal system was an issue in 66.2% of participants (40 of these had impairments exclusively in their upper extremities). In total, 49.5% of the sample showed one or two comorbidities, whereas 3.2% had three or more health conditions. The most common comorbidities were hypertension (20.1%), diabetes (18.7%), and osteoporosis (16.7%). Disability measures at the baseline revealed that 93.9% of participants admitted to the rehabilitation program showed moderate to severe levels of disability.

Twenty-six patients (12.0%) experienced at least one AE during their hospital stay. Most of these (25) experienced only one AE. Fall-related events were the most frequent AEs (8.3%), while infections (1.9%) and sentinel events (1.9%) were reported less often (Table 2). Among the 17 types of studied AEs, the most frequent were patient falls (16 subjects, i.e., 7.4%) and medication errors (4 subjects, i.e., 1.9%). No post-operative complications were identified.

Overall, patients aged  $\geq$ 75 years tended to experience a higher number of AEs than those aged <75 years (15.6% versus 4.3%, respectively;  $p = 0.02$ ). When comparing data by the types of AE, only fall-related events were statistically significant ( $p = 0.001$ ), particularly in patients aged  $\geq$ 75 years, who tended to experience a higher rate of fall-related events.

In the univariate logistic regression analyses, age ( $p = 0.002$ ) and diagnostic group, especially the medically complex group ( $p = 0.008$ ), were associated with fall-related AEs, and the number of co-morbidities was associated with other AEs ( $p = 0.014$ ). Based on these results, these three variables were entered in an "overall" multivariable logistic regression model that combined all AEs.

**Table 3. Summary of multivariable logistic regression models of specific adverse events (AEs) and overall AEs**

	Fall-related AEs			Other AEs <sup>†</sup>			Overall AEs <sup>‡</sup>		
	OR	95% CI	p value	OR	95% CI	p value	OR	95% CI	p value
Age	1.1	1.02–1.17	0.01	NI <sup>§</sup>	1.06	1.03–1.12	0.04		
Diagnostic group				NI <sup>§</sup>					
Musculoskeletal <sup>§</sup>	-	-	-		-	-	-		
Medically complex	2.31	0.79–6.75	0.13		1.65	0.65–4.14	0.29		
Number of comorbidities	NI <sup>§</sup>	1.91	1.02–3.69	0.04	1.6	0.97–2.62	0.06		

<sup>†</sup>The “Other AEs” category includes infections and sentinel events

<sup>‡</sup>The “Overall AEs” category includes all adverse events

<sup>§</sup>Reference category

<sup>¶</sup>Not included in the multivariable analysis

Table 3 shows the results of the multivariable models. Age was associated with fall-related AEs (OR=1.1 [95% CI=1.02–1.17]), but diagnostic group was not significant. Thus, for every 1-unit increase in years, a 10% increase concerning the odds of experiencing a fall-related event is expected. The number of co-morbidities was associated with other AEs (OR=1.9 [95% CI=1.02–3.69]). However, in the overall model, age was the only determinant associated with AEs.

## Discussion

To our knowledge, this is the first study to report the incidence rates of AEs among older patients during their stay in a rehabilitation unit for post-acute care. The results showed that AEs were experienced by nearly 12% of the older patients in the sample. These rates are consistent with other studies of elderly patients hospitalized in non-surgical departments (1,6) and therefore imply that patient safety at rehabilitation units could be improved. This study also provides insights into patient groups with a higher risk of experiencing AEs in rehabilitation units. The rates of AEs varied significantly between patients aged ≥75 years and those aged <75 years, particularly in relation to fall-related events. This variance is consistent with that in previous studies conducted in other departments of acute care hospitals (6). Age seems to be a major determinant when all types of AEs are combined. Thus, patient safety interventions in rehabilitation units should be focused on vulnerable elderly patients.

Nearly two out of three patients who experienced AEs were reported to have had a fall-related event. This incidence rate seems counterintuitive within a rehabilitation unit where patients attend with the goal of optimizing their functioning. Fall-related events were not determined by clinical or functional characteristics, rather they were associated with age in the multivariable model. Fall rates were significantly more common in patients aged ≥75 years. A similar difference between age-based groups has been reported in community environments (19), and fall rates represent an important target for prevention and reduction of injuries in facilities for older patients (20). Although positive changes have been confirmed in the incidence of fall-induced injuries among the elderly (21), our study supports the requirement for all feasible fall prevention actions to be taken to

reduce the incidence of injury further, especially because the at-risk population will grow rapidly in the near future.

Infections and sentinel events were the following most common AEs, mostly in reference to decubitus ulcers and medication errors, respectively. Although decubitus ulcers and drug-related AEs are more frequent in acute services for elderly patients (1,3,6), this study highlights a need to also pay attention to these AEs during rehabilitation programs. The number of comorbidities seems to be a major determinant for these “other” (i.e., non-fall-related) AEs. Although causation cannot be inferred from this result, patient safety interventions on comorbidity may be a promising means of avoiding these other AEs for some patients. This study does not identify factors that connect multiple comorbidities with these AEs; however, subjects with comorbidities probably have less mobility, take more medication, and are therefore more likely to experience decubitus ulcers and medication errors. However, neither mobility limitations nor the number of medications were significantly associated with other AEs in our univariate analyses.

## Strengths and Limitations of the Study

A strong aspect of the present study is its prospective design. These types of studies have advantages over retrospective studies for estimating AEs because of their power to determine more events and their reliability (22). Studies based on the retrospective assessment of information in medical records are more common, but they may underestimate the true rate of AEs. For example, some medication errors are not always recognized by hospital staff and are therefore not always noted in the medical records (1).

Our findings should be interpreted in light of our study’s methodological limitations. First, the types of studied AEs were those proposed by the framework of the OECD, which was designed for acute care hospitals. Although our study was conducted in an acute care hospital, it is possible that our results represent an overly optimistic view of the extent of AEs in rehabilitation units if additional and unit-specific AEs also occurred. Second, the exploratory analyses of determinants in this study were restricted to patient characteristics identified from a literature review that did not include studies performed in rehabilitation units. Therefore, we assume that these variables partly

included all patient-related determinants. Exploratory analyses of determinants are also limited because few patients experienced fall-related and other types of AE. However, this does not represent a major problem for the validity of the logistic regression models conducted here because the rule of thumb of 10 events per predictor variable can be relaxed when the number is close to 10 (23).

Finally, our findings are based on data from a large public French hospital, and the external validity of our results is limited by the fact that the patients of this study may differ from other older patients receiving rehabilitation in other post-acute care settings or in other health care systems. Therefore, until further research is conducted on a broader sample, these results should be generalized with caution.

### Implications of our Results

The findings of our study have implications for improving older patient safety in the rehabilitation units of acute care hospitals. Our results show that there is more room for improvement in the prevention of falls, beyond the increasing number of varied and specific interventions (24-26), within the current framework of increasing research production that supports the association between falls and factors such as musculoskeletal pain (27), medication-related issues (28,29), or gait-based chaotic behaviors (30). However, in addition to patient safety interventions to improve fall-related AEs, interventions are necessary to reduce the other AEs discussed here. Our study highlights the importance of age and comorbidity in patients' experiences of AEs. Nevertheless, to formulate more tailored interventions, new research will be necessary to create a better understanding of other modifiable factors that may explain the incidence of AEs.

The exploratory analyses of this study were restricted to patient characteristics. Other unmeasured patient characteristics and organizational factors should be explored in future studies. Some organizational factors that could probably be relevant are the level of experience and skill of staff (31), the amount and variety of total staffing, and the referral hospital that transferred the patient. In addition, future studies on the variation of AEs could be extended to multilevel analyses to examine variations between specific units of a rehabilitation department, such as physiotherapy or medical care. However, these studies should be accompanied by the inclusion of more cases.

### Conclusion

In summary, this study shows that some older patients receiving post-acute care in the rehabilitation units of acute care hospitals experience AEs, particularly fall-related events. It also provides evidence that some older patients are more likely to experience AEs than others, in particular those  $\geq 75$  years. These results suggest that improvements could be made to reduce these types of experience and thereby facilitate patient safety. Further research is required to identify the specific AEs that occur in rehabilitation units and to understand the relevance of other factors.

**Ethics Committee Approval:** Ethics committee approval was received for this study from the ethics committee of the hospital of Castelnau (France).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept - F.M.M.; Design - M.G.S.; Supervision - F.M.M.; Resource - F.M.M.; Materials - F.J.J.S.; Data Collection and/or Processing - M.G.S.; Analysis and/or Interpretation - P.E.R.; Literature Review - P.E.R.; Writer - F.M.M., M.G.S.; Critical Review - F.M.M., M.G.S., F.J.J.S., P.E.R.; Other - F.J.J.S.

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