ISSN: 2785-7263 DOI: 10.54103/dn/28125

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COHORT STUDY

Innovative model for inpatients falls predictors assessment: a prognostic cohort study

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Findings:

The study identified key predictive factors for in-hospital falls and proposes an innovative model for the early assessment of fall risk in older hospitalized patients.

ABSTRACT

BACKGROUND: In-hospital falls are avoidable accidents, but continue to be a high prevalent and incident patient safety issue. The 60% of falls are caused by more than one factor. An early identification and assessment of inpatients' high risk of falling, at the beginning of hospitalization, is unclear. **AIM**: The study evaluates prognostic factors that predict inpatients' falls in a consecutive cohort of subjects.

METHODS: A prospective multicentric prognostic cohort study was conducted between April 2015 and December 2016. The study involved 12 wards of Northern Italy. A total of 11,768 hospitalized patients, potentially at risk of falling, were included. The variables evaluated included gender, age, difficulty getting out of bed, history of falling, vertigo or dizziness, physical impairments, going to the bathroom more than two times for a nurse shift, patients with cardiovascular or neurological drug treatment and risk of falling. The Conley Scale was also assessed.

RESULTS: Multivariate regression analysis showed that female gender, difficulty getting out of bed, history of falling, dizziness or vertigo in the last three months, physical impairments, as balance and impaired gait, judgement/lack of safety awareness, cardiovascular or neurological drug treatment were associated risk factors of falling.

CONCLUSIONS: This study identifies key predictors of in-hospital falls and proposes an innovative model for the early assessment of older in-patients' fall risk. These findings can guide the development of risk assessment models and inform future research on leveraging electronic medical records to enhance fall prevention strategies.

KEYWORDS: *Prognostic cohort study, Older in-patients, Risk of falling, Conley scale, Model*

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Milano University Press

Submission received: 28/01/2025
End of Peer Review process: 30/05/2025
Accepted: 04/06/2025

ISSN: 2785-7263 DOI: 10.54103/dn/28125

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JOURNAL HOMEPAGE: HTTPS://RIVISTE.UNIMI.IT/INDEX.PHP/DISSERTATIONNURSING

STUDIO DI COORTE

Modello innovativo per la valutazione dei predittori di cadute nei pazienti ospedalizzati: uno studio di coorte prognostico

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Riscontri:

Lo studio ha identificato fattori predittivi chiave delle cadute in ospedale e propone un modello innovativo per la valutazione precoce del rischio di caduta nei pazienti anziani ricoverati.

ABSTRACT

BACKGROUND: Le cadute ospedaliere sono incidenti evitabili ma continuano a rappresentare una problematica rilevante e frequente per la sicurezza dei pazienti. Il 60% delle cadute è causato da più di un fattore. L'identificazione e la valutazione precoce del rischio elevato di caduta nei pazienti ricoverati, all'inizio del ricovero, rimane poco chiara.

OBIETTIVI: Questo studio valuta i fattori prognostici che predicono le cadute nei pazienti ospedalizzati in una coorte consecutiva di soggetti.

METODI: Uno studio prospettico multicentrico di coorte è stato condotto in 12 reparti del Nord Italia tra aprile 2015 e dicembre 2016, includendo 11,768 pazienti ricoverati a rischio di caduta. Sono state analizzate variabili come sesso, età, difficoltà ad alzarsi dal letto, storia di cadute, vertigini, limitazioni fisiche, frequenza di utilizzo del bagno, trattamenti farmacologici cardiovascolari o neurologici e il punteggio della Scala di Conley.

RISULTATI: L'analisi di regressione multivariata ha mostrato che il sesso femminile, la difficoltà ad alzarsi dal letto, una storia di cadute, vertigini o capogiri negli ultimi tre mesi, le limitazioni fisiche (ad esempio equilibrio e deambulazione compromessi), il giudizio compromesso/mancanza di consapevolezza del pericolo e l'assunzione di farmaci cardiovascolari o neurologici sono fattori di rischio associati alle cadute.

CONCLUSIONI: Questo studio identifica i principali predittori delle cadute ospedaliere e propone un modello innovativo per la valutazione precoce del rischio di caduta nei pazienti anziani ricoverati. Questi risultati possono guidare lo sviluppo di modelli di valutazione del rischio e informare future ricerche sull'utilizzo delle cartelle cliniche elettroniche per migliorare le strategie di prevenzione delle cadute.

KEYWORDS: *Studio di coorte prognostico, Pazienti anziani ricoverati, Rischio di caduta, Scala di Conley, Modello.*

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BACKGROUND

A fall is defined as an event, which results in a person coming to rest inadvertently on the ground or floor or other lower levels [1]. Globally, falls are the most serious health care problem in the elderly in terms of mortality and direct and indirect costs [2], common in the over 65 years old population, more vulnerable and frailty than others [3]. In-hospital falls are avoidable accidents, but continue to be a high prevalent and incident patient safety issue [4] with a negative impact on health systems and with fatal (about 24,190 falls in USA) and non-fatal (overall 3.2 million in USA) consequences [2]. The Joint Commission, in 2002, established its National Patient Safety Goals program (NPSGs), which includes the goal of reducing falls and the consequent risk of injury [5]. According to the 2017 Guideline of the Centre for Disease Control and Prevention (CDC), 60% of falls are caused by more than one factor.

Literature identifies, among falls risk factors, intrinsic ones related to patients characteristics, as age over 65 years old [6], longer length of stay [7], cognitive impairment, including agitation and confusion [6,8], physical impairments, such as balance and gait decay [8], the use of manual transfer aid [7], sensory deficits (vision and hearing) [7,9], urinary incontinence [7,8], fatigue and a history of falls [8], even if, in 2019, it was found not to be associated with falling in hospitals [10]. A 2018 prospective study has shown the association between impaired judgement/lack of safety awareness and falls, as predictive in terms of poorer balance and slower reaction time [11]. Moreover, comorbidities [8] and frailty [3] were identified as intrinsic risk factors, along with medication-related issues [8,10,12]. Callis and colleagues' review in 2016 [13], have identified that one of the predictive falls factors is the use of drugs which have action on the brain or with a cardiovascular effect, because of a possible orthostatic hypotension and vertigo or dizziness. Moreover, literature has opposing evidence about the association between poly pharmacotherapy and falls [7,13].

Furthermore, extrinsic factors influencing the environment, organizational and social factors have also been identified, including the registered nurses staffing ratio, although this factor has sometimes been found not to be significant [7,8,10,14]. Early identification and assessment of inpatients at risk of falling at the beginning of hospitalization are thus crucial first steps toward the implementation of proactive in-hospital fall prevention strategies [15]. Additionally, Usi and colleagues [14] discussed the role of environmental modifications in reducing fall risk, emphasizing that simple interventions, such as installing grab bars and improving lighting, can significantly enhance safety for at-risk individuals. The study underscores the ongoing need for healthcare facilities to implement comprehensive fall prevention programs that address both intrinsic and extrinsic risk factors. Despite the substantial body of evidence [16], there remains room for future studies to explore innovative strategies and interventions to mitigate fall risks further and enhance patient safety.

The common scale, used in Italian hospitalized contexts, is the Conley scale, considering only individual risk factors due to the poor appropriacy [17,18]. In addition, literature pays attention to multiple preventive interventions [19], which could influence risk factors. As result of this extremely extended literature, it has not been defined yet, which are effective predictors for identifying inpatients' falls risk. For this purpose, we have assumed that an observational prospective study could have been useful to analyse the whole risk factors separately identified by previous different studies. Because of these assumptions, this study aims to evaluate risk factors that predict inpatients' falls in a consecutive cohort of subjects.

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Submission received: 28/01/2025
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Accepted: 04/06/2025

Milano University Press

DISSERTATION NURSING V.4, N.2, (31/07/2025)

ISSN: 2785-7263 DOI: 10.54103/dn/28125

DISSERTATION NURSING®

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METHODS

Study design

This is a prospective multicentric prognostic cohort study. This study was conducted according to the STARD guideline.

Setting and participants

The study was conducted in 12 wards of two hospitals of Northern Italy. Specifically, the included divisions were geriatric, internal medicine acute care, rehabilitation, and post-acute care. All patients consecutively admitted to these wards, between April 2015 and December 2016, were eligible to participate in the study, if they were aged 75 years or older, with or without a confirmed risk of falling or aged under the age of 75 (adults only), but only in the presence of a confirmed risk of falling. The Conley scale and the medical history (history of falls, cognitive impairment, increased need to go to the bathroom and cardiovascular or neurological drug treatment) were used to evaluate the risk of falling. Out of 11,881 hospitalized patients admitted during the study period, 113 were excluded.

Measures

During the 21-months study period, data on the demographic and medical history of the attended patients were collected. The evaluated variables included gender, age, difficulty getting out of bed, going to the bathroom more than two times for a nurse shift, cardiovascular or neurological drug treatment, which have an influence on the brain and/or cardiovascular system and risk of falling. The Conley Scale, which is widely used in the clinical risk evaluation, related to patient safety at hospital admission, was also assessed [17,20,21]. This scale is based on six items: history of falling in the last three months, dizziness or vertigo in the last three months, wetting or soiling on the way to the bathroom in the last three months, impaired gait, shuffle, wide base, unsteady walk, agitation and impaired judgement/lack of safety awareness.

Data Analysis

Data were entered anonymously into a dedicated database and were analysed by using the statistical package IBM-SPSS Statistics (Ver. 21 for Windows, IBM Co., Armonk, NY, USA). Checking for normality was done using Kolmogorov-Smirnov (K-S) test. Mean, standard deviation (SD), ranges and frequencies were used as descriptive statistics. Possible associations between patients' falls and features have been assessed using the Pearson chi-squared that was applied to nominal variables, the Fisher's exact test to dichotomous variables and the independent t-test to analyse the differences among group means. Binomial logistic regression analyses were performed to evaluate significant variables associated with falling. Our dependent variable is falling and falls' occurrence is dichotomous (yes or no). The Hosmer and Lemeshow test was used to assess how well the model fit with the data (the null hypothesis is that the model is an adequate fit). The 95% confidence interval for odds ratio was assessed for every predictor. Deviance was used to compare the logistic regression model (the higher the deviance, the less adequate the model is). Predicted probabilities of the model were included in receiver operating characteristics (ROC) curve analysis. The area under the ROC curve, sensitivity, and specificity were calculated with 95% confidence intervals. The area under the ROC curve was used to assess prognostic accuracy for model, which ranges from 0.5 to 1.0, 0.5 indicating no discriminative ability and 1.0 indicating highest detection accuracy. It is considered outstanding if the area under the ROC curve is bigger than 0.9, excellent if the area is between 0.80 and 0.89, and acceptable if the area is between 0.7 and 0.8 [22]. Kaplan–Meier survival analysis was used to plot the survival curve. The software STATA (Ver. 13 for Windows, StataCorp, College Station, TX) was used

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Submission received: 28/01/2025
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Accepted: 04/06/2025

Milano University Press

DISSERTATION NURSING V.4, N.2, (31/07/2025)

ISSN: 2785-7263 DOI: 10.54103/dn/28125

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for survival analysis. Two-tailed P values less than 0.05 were considered statistically significant.

Ethical approval:

The study followed the principles of the Declaration of Helsinki and was approved by the Ethical Committee register n° 76/2014/O/Sper of May 13th 2014. All participants gave informed written consent.

RESULTS

During the 21-months' data collection period, 11,881 patients (6232 women, 52.5%, 5633 men, 47.5%) were followed; 11,768 of these patients (99.0%) met the inclusion criteria (6184 women, 52.5%, 5584 men, 47.5%). Their mean age was 79.6±12.0 years. Complete characteristics of participants are described in Table 1.

Table 1. Characteristics of participants classified by in-hospital falls

CHARACTERISTICS OF PARTICIPANTS	Not fall n (%)	Fall n (%)	Overall n (%)	p-value
Age (years)				
mean±SD	79.4±12.3	77.8±11.5	79.4±12.3	.013 [a]
Age (subgroups)				
< 75 years	2787 (96.5)	100 (3.5)	2887 (24.5)	.040 [b]
≥ 75 years	8643 (97.3)	242 (2.7)	8885 (75.5)	
Gender				
Female	6044 (97.8)	136 (2.2)	6180(52.5)	<.001 [b]
Male	5376 (96.3)	206 (3.7)	5582 (47.5)	
Difficulty getting out of bed				
Yes	4380 (97.9)	96 (2.1)	4476 (38.1)	<.001 [b]
No	7021 (96.6)	245 (3.4)	7266 (61.9)	
Being able to get up to chair easily				
Yes	6632 (97.0)	204 (3.0)	4899 (41.7)	.577 [b]
No	4762 (97.2)	137 (2.8)	6836 (58.3)	
Going to bathroom more than two times for nurse shift				
Yes	4579 (96.8)	153 (3.2)	4732 (40.2)	.082 [b]
No	6857 (97.3)	189 (2.7)	7046 (59.8)	
Orthostatique hypotension				
Yes	2144 (96.9)	69 (3.1)	2213 (18.8)	.530 [b]
No	9292 (97.1)	273 (2.9)	9565 (81.2)	
Cardiovascular or neurological drug treatment				
Yes	9601 (96.9)	306 (3.1)	9907 (85.4)	.005 [b]
No	1667 (90.2)	31 (1.8)	1698 (14.6)	
Conley Scale				
Positive for risk of falling	7633 (96.6)	270 (3.4)	7903 (67.4)	<.001 [b]
Negative for risk of falling	3759 (98.1)	72 (1.9)	3831 (32.6)	

[a] *T-Student test*

[b] *Fisher's exact test*

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Three-hundred and forty-two falls were reported (2.9%), among those the majority participants (91.8%, n=315) fell at least once and 8.2% (n=28) fell two or more times. An average of 87.1% (n=298) of falls resulted in minor injury and 12.9% (n=44) resulted in serious injury. Overall, scores on the Conley Scale showed 67.4% (n=7903) patients to be at risk of falling (40.3% men; 56.7% women) and 32.6% (n=3831) not to be at risk (56.1% men; 43.9% women). Table 2 shows the Conley Scale items. In addition, participants with impairment of judgment/lack of safety awareness were more likely to fall two or more times compared with who fell at least (64.3% versus 30.4%; p=.001, Fisher's exact test). Other features considered were not statistically significant.

Table 2. Patients' characteristics according to the Conley Scale

CONLEY SCALE ITEMS	FALLEN YES	*P value*
C1: History of falling in the last 3 months		
Yes	190(3.8)	*.040*
No	150(2.3)	
C2: Dizziness or vertigo in the last 3 months		
Yes	179(4.3)	*.000*
No	161(2.2)	
C3: Wetting or soiling on the way to the bathroom in the last 3 months		
Yes	133(3.1)	*.030*
No	207(2.8)	
C4: Impaired gait, shuffle, wide base, unsteady walk		
Yes	230(3.4)	*.000*
No	110(2.2)	
C5: Agitation		
Yes	64(5.0)	*.005*
No	276(2.7)	
C6: Impaired judgement/lack of safety awareness		
Yes	113(3.9)	*.000*
No	227(2.6)	

Regarding survival analysis, it was considered the time since the admission until fall/end of the study as the study time variable. When evaluating the Kaplan–Meier survival function, 97.2% of survival probability in the 10th-day, 95.9% in the 20th and 94.8% in the 30th, was observed (Figure 1a-1b). The univariate and multivariate logistic regression analyses were used for the analysis of variables which influence falling, and Odds Ratio was used to quantify the effect of each variable on falling (Table 3). In the univariate logistic regression analysis, all variables considered were decisive risk factors for falls (Table 3). A significantly higher risk was found for women compared with men [OR 1.703 (95% CI 1.367-2.121)], for patients who were able to get up to bed easily [OR 1.592 (95% CI 1.254-2.022)], for patients with history of falling [OR 1.712 (95% CI 1.378-2.128)], for patients with dizziness or vertigo [OR 2.015 (95% CI 1.623-2.502)], for patients with unsteady walk [OR 1.541 (95% CI 1.224-1.940)], for patients with agitation [OR 1.932

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(95% CI 1.462-2.552)], for patients with impaired judgement/lack of safety awareness [OR 1.526 (95% CI 1.213-1.919)] and for patients with cardiovascular or neurological drug treatment [OR 1.714 (95% CI 1.180-2.489)].

Figure 1a. Overall survival of the entire cohort (last observed exit t=118)

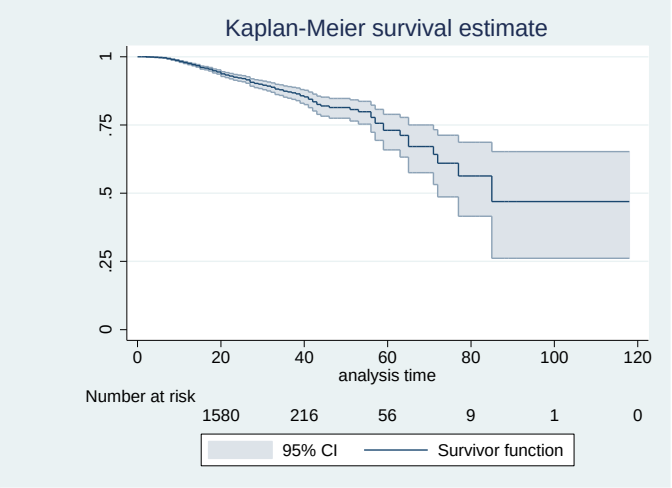
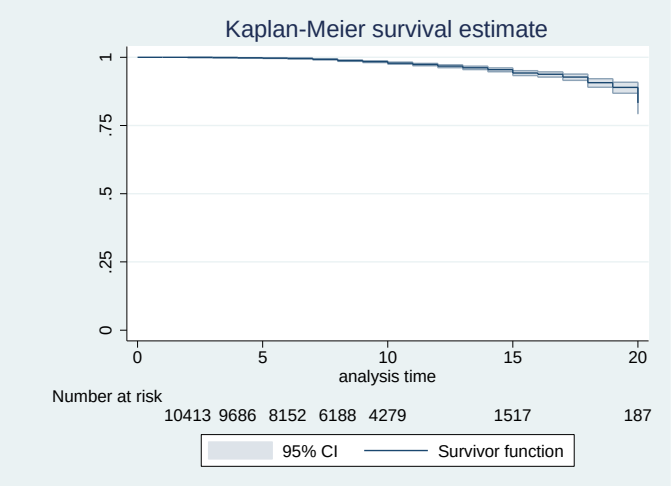


Figure 1b. Overall survival of the entire cohort (last observed exit t=20)



Variables that were detected as risk factors in univariate analysis were evaluated by multivariate analysis. The logistic regression model was statistically significant, x^2 (8) = 357.293, p<0.001. The model explained 25.6% (Nagelkerke R^2) of the variance in falling and correctly classified 98.8% of cases. Of the eight predictor variables, seven were statistically significant (as shown in Table 3). The risk of falling remained higher for women [OR 4.665 (95% CI 3.073-7.083)], for patients who were able to get up to bed easily [OR 5.065 (95% CI (3.210-7.993)], for patients with history of falling [OR 2.828 (95% CI (1.879-4.255)], for patients with dizziness or vertigo [OR 6.020 (95% CI 3.816-9.496)], for patients with physical impairments, as balance and gait decay [OR 2.999 (95% CI 1.763-5.099)], for patients with impaired judgement/lack of safety awareness [OR 3.192 (95% CI 2.108-4.834)] and for patients with cardiovascular or neurological drug treatment [OR 5.286 (95% CI 1.660-16.838)]. Predicted probabilities of this model were included in ROC curve analysis (Figure 2). The area under the ROC curve has shown an excellent level of discrimination with .916 (95% CI, .898-.934).

DISCUSSION

This is a multicentric large cohort study, which reports a model using a large combination of possible risk factors of falls. It could be fundamental for helping us to have a much more whole evidence for the in-patients' risk of falling evaluation. In fact, the main aim of this manuscript is to evaluate prognostic factors, which predict inpatients' falls. Our multivariate regression analysis showed that female gender, difficulty getting out of bed, history of falling, dizziness or vertigo in the last three months, physical impairments, as balance and gait decay, impaired judgement/lack of safety awareness, cardiovascular or neurological drug treatment were predictors.

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Table 3. Evaluation of falling risk factors by binomial logistic regression analysis

VARIABLES	UNIVARIATE		MULTIVARIATE*	
	OR [95% CI]	***P-value***	**OR [95% CI]**	***P-value***
Gender				
Female	1.703 [1.367-2.121]	*<.001*	4.665 [3.073-7.083]	*<.001*
Difficulty getting out of bed				
Yes	1.592 [1.254-2.022]	*<.001*	5.065 [3.210-7.993]	*<.001*
Being able to get up to chair easily				
Yes	1.069 [0.858-1.332]	*0.551*	-	-
C1: History of falling in the last 3 months				
Yes	1.712 [1.378-2.128]	*<.001*	2.828 [1.879-4.255]	*<.001*
C2: Dizziness or vertigo in the last 3 months				
Yes	2.015 [1.623-2.502]	*<.001*	6.020 [3.816-9.496]	*<.001*
C3: Wetting or soiling on the way to the bathroom in the last 3 months				
Yes	1.081 [0.866-1.348]	0.492	-	-
C4: Impaired gait, shuffle, wide base, unsteady walk				
Yes	1.541 [1.224-1.940]	*<.001*	2.999 [1.763-5.099]	*<.001*
C5: Agitation				
Yes	1.932 [1.462-2.552]	*<.001*	1.392 [0.888-2.182]	0.149
C6: Impaired judgement/lack of safety awareness				
Yes	1.526 [1.213-1.919]	*<.001*	3.192 [2.108-4.834]	0
Going to bathroom more than two times for nurse shift				
Yes	1.212 [0.976-1.505]	0.081	-	-
Orthostatic hypotension				
Yes	1.714 [0.838-1.432]	*0.506*	-	-
Drug treatment with an effect on their central nervous system and/or cardiovascular system				
Yes	1.714 [1.180-2.489]	0.005	5.286 [1.660-16.838]	*0.005*

* The gender, being able to get up to bed easily, C1, C2, C4, C5, C6, swelling medicine that have an effect on their central nervous system and/or cardiovascular system, which were significant variables in univariate analysis, were analyzed with multivariate binomial logistic regression.

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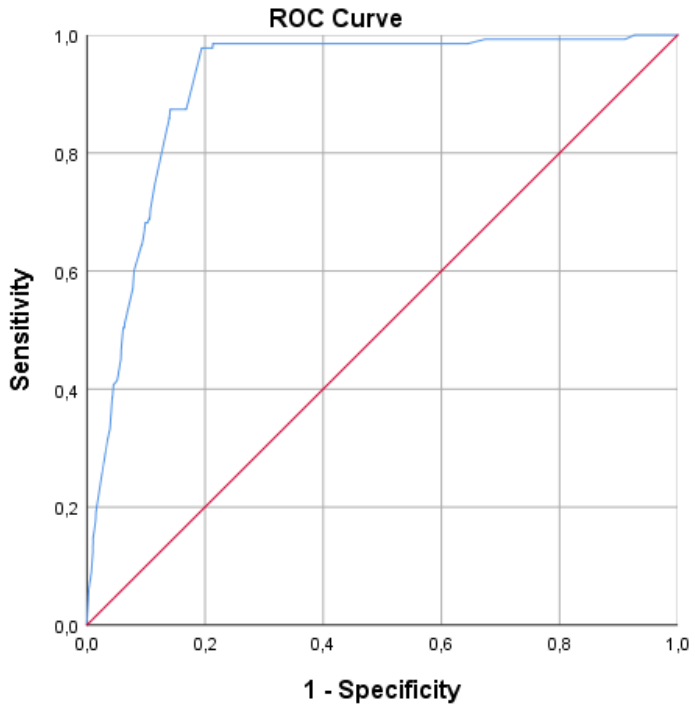
Figure 2: Receiver-operating characteristic (ROC) curve calculated from the binomial logistic regression



DISCUSSION

This is a multicentric large cohort study, which reports a model using a large combination of possible risk factors of falls. It could be fundamental for helping us to have a much more whole evidence for the in-patients' risk of falling evaluation. In fact, the main aim of this manuscript is to evaluate prognostic factors, which predict inpatients' falls. Our multivariate regression analysis showed that female gender, difficulty getting out of bed, history of falling, dizziness or vertigo in the last three months, physical impairments, as balance and gait decay, impaired judgement/lack of safety awareness, cardiovascular or neurological drug treatment were predictors. It is also verified by the ROC curve analysis, which has .916 as area under the curve and indicates these factors as the best valuable predictors for falling.

According to what literature describes, the first step for preventing with proactive strategies this significant in-patients adverse event is an early identification of predictors [23]. We have evaluated them through the medical history and the Conley scale which it is largely used in hospitalized contexts. According to Palese and colleagues study [24], we have found the Conley scale as a whole not predictable, but, however, variables taken individually have shown a statistically significance as predictors of falls.

Even though the history of falls is an intrinsic risk factor not always supported by literature [10], in accordance with Clay et al review and Deandrea S. et al (OR=2.85, 95% CI: 1.14 -7.15) [8,25], our results have shown a predictable significance in the three last month's history of falls. In addition to these above-

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Submission received: 28/01/2025
End of Peer Review process: 30/05/2025
Accepted: 04/06/2025

ISSN: 2785-7263 DOI: 10.54103/dn/28125

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mentioned factors, we have also found a correlation between others intrinsic ones, which have an influence on ambulation, as predicable of falls.

It is not uncommon for older people to experience physical impairments, including a decline in balance and gait, which are key factors cited in the literature as contributing to fall risk [8]. Additionally, Usi and colleagues [14] discussed the role of environmental modifications in reducing fall risk, highlighting those simple changes, such as installing grab bars and improving lighting, can significantly enhance safety for at-risk individuals. If we add to this the fact that this part of population often lacks safety awareness, associated in the literature with falls due to poorer balance and slower reaction time [11,12] and is frequently treated with cardiovascular or neurological drugs [8,10,12], which can potentially cause orthostatic hypotension, vertigo or dizziness [12,13], the combined factors provide a comprehensive framework for assessing fall risk. Despite often being able to get in and out of bed without external assistance, these elements collectively underscore the importance of a thorough evaluation of fall risk factors.

Our results have confirmed, what described in literature above-mentioned, with a logistic regression model of predictors, which, associated, could be monitored by nurses and physicians for increasing patient's safety. For the best of our knowledge, in future, this model could be included to electronic medical records, as already shown by Oshiro and colleagues [26], for helping clinicians in assessment decision making process. For this reason, it could be useful adding it to the existing algorithm produced in the Centre for Disease Control and Prevention, in the 2017 Stopping Elderly Accidents Deaths and Injury (STEADI) [27] initiative, which includes modifiable falls' risk factors' assessment and subsequent multifactorial interventions to reduce them [19,28]. Finally, this innovative model could help us to reduce this safety patient issue, which continues to be highly prevalent and incident in hospitalized settings, also with fatal consequences [2,4], in terms of mortality and direct and indirect costs [2].

Limitations

Our study has several limitations. We have only focused on some risk factors instead of all considered in recent literature. In addition, we valued the Conley Scale, even though it was shown to be not predictable, because it is the only screening tool in Italian hospitalized contexts. Despite these limitations, as far as we know, this is likely to be the first multicentric large cohort study to report a model using a large combination of possible risk factors of falls.

CONCLUSION

In conclusion, we could assert that the first step for preventing this significant adverse event is to identify predictors. We found a strictly association with the female sex, difficulty getting out of bed, the history of falls, vertigo or dizziness, the unsteady walk, the inaccurate reach judgement and the use of drugs with an influence on the brain and/or cardiovascular system. These findings could be useful for identifying a combination of covariates capable of assessing the risk of falls. These data could be confirmed by other further studies, focalized on these predictors and on the use of electronic medical records collected data, which could be used to build algorithm. Electronic medical records may be a powerful tool for improving identification of adults at risk for falling. They may be used for nursing decision support at point of care and as a surveillance system.

CONFLICT OF INTEREST

The authors have no relevant financial or non-financial interests to disclose.

FUNDING SOURCES

None

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ETHICS STATEMENT

The study followed the principles of the Declaration of Helsinki and was approved by the Ethical Committee register n° 76/2014/O/Sper of May 13th 2014. All participants gave informed written consent.

DATA AVAILABILITY STATEMENT

All data presented in this study, not yet publicly archived, shall be made available through the corresponding author on request.

AUTHOR CONTRIBUTIONS

Conceptualization, D.M., P.C. and D.G.; formal analysis, L.G. and P.C.; investigation, E.A., D.M. and D.G.; methodology, P.C. and D.G.; resources, P.C. and D.M.; supervision, D.G.; visualization, L.G.; writing—original draft preparation, L.G., and E.A.; writing—review and editing, L.G., L.S., D.R. and R.D. All authors have read and agreed to the published version of the manuscript.

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Submission received: 28/01/2025
End of Peer Review process: 30/05/2025
Accepted: 04/06/2025

Milano University Press

DISSERTATION NURSING V.4, N.2, (31/07/2025)

ISSN: 2785-7263 DOI: 10.54103/dn/28125

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Milano University Press

Submission received: 28/01/2025
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