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Construction and initial validation of a new tool for the hetero-evaluation of sleep disturbance risk in hospitalized older adults: The Biazzi scale

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ABSTRACT

Background: Hospitalization increases older adults' vulnerability to sleep disorders, yet their assessment in hospital settings remains challenging due to the limitations of self-report tools. This study describes the development and validation of the Biazzi Scale, a clinician-administered instrument designed to identify sleep disturbance risk in hospitalized older adults.
Methods: The study was conducted in two phases. In the first phase, scale items were developed through a literature review and expert consultation, and content validity was assessed using the Item-Level Content Validity Index (I-CVI) and the Scale-Level Content Validity Index (S-CVI). In the second phase, the Biazzi Scale was administered to 150 patients aged ≥65 years hospitalized in four wards of the Piacenza Local Health Authority. Inter-rater reliability was evaluated using Cohen's Kappa. Functional convergent validity at the level of clinical classification was examined through Receiver Operating Characteristic (ROC) analysis using the Pittsburgh Sleep Quality Index (PSQI) as an external reference.
Results: Content validity was satisfactory (I-CVI ≥0.78; S-CVI = 0.90), and inter-rater reliability was good (κ = 0.77). ROC analysis demonstrated adequate classification performance, with an optimal cut-off score of 6. Sleep disturbance risk differed significantly across hospital wards and between genders, with higher risk observed among female patients.
Conclusion: The Biazzi Scale is a reliable and clinically applicable tool for identifying sleep disturbance risk in hospitalized older adults.
Implications for practice: The scale supports early risk screening and may prompt further individualized clinical assessment to inform clinical decision-making during hospitalization.

Introduction

Hospital environments inherently induce stress, impacting patients' well-being.[1] Moreover, an inadequate rest during hospitalisation, influenced by hospital-related factors, causes many health risks. Quality sleep is vital for overall health, influencing cognitive, emotional, and physiological functions,[2] but current healthcare practices often overlook sleep quality as a crucial aspect of patient care.[3]

In literature there are only self-report tools dedicated to assess sleep disturbance risk,[4,5] including some questionnaires based on patient-provided information, as well as some instrumental tests such as polysomnography and wrist actigraphy, which however are

Abbreviations: I-CVI, Item-Level Content Validity Index; S-CVI, Scale-Level Content Validity Index; PSQI, Pittsburgh Sleep Quality Index; ROC, Receiver Operating Characteristic; AUC, Area Under the Curve; AUSL, Azienda Unità Sanitaria Locale (Local Health Authority); AVEN, Area Vasta Emilia Nord

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not always accessible.[6,7] Currently, there are no professionally administered tools available, which would be considered more reliable than self-assessment questionnaires.

To address this problem, it was decided to develop a hetero-evaluation scale aimed at precisely and specifically assessing and monitoring patients' sleep disturbance risk.

The Biazzi scale, built on established risk factors in the scientific literature, would help identify individuals at risk of poor sleep and provide a warning to healthcare professionals, who could then assess and plan appropriate treatment for each patient's needs.

This study focuses on validating the Biazzi scale, a new tool that can evaluate the sleep disturbance risk in hospitalized older adults.

Background

Sleep is a fundamental biological necessity for individual well-being, and poor sleep quality can have adverse effects on a person's health.[8] Quality sleep not only enhances cognitive and emotional functions but is also crucial for the proper functioning of the immune, metabolic, and endocrine systems. Additionally, it contributes to a faster recovery of well-being after illness or surgery.[9]

Sleep health influences every aspect of human function and it is essential to optimise cardiometabolic, immune, brain, and mental health.[10]

Recent studies have shown that sleep disturbance risk plays a critical role in overall health, with poor sleep being linked to various health risks including cardiovascular diseases and metabolic disorders.[11] Symptoms related to sleep disturbance are also common in the working-age population of both sexes (e.g., waking up during sleep in approximately 70% of cases, non-restorative sleep in about one-third) .[12] When they occur every night or almost every night, these symptoms may be associated with an increased risk of mortality (OR 1.70), especially among those with somatic illnesses (OR 1.40) .[12]

Furthermore, sleep disorders is a health problem that increases with age: several studies reported an association between sleep quality and frailty.[13]

Recent studies have highlighted that even mild levels of sleep deprivation can have non-negligible negative effects both at the physical and cognitive levels.[14] Poor sleep quality is a common issue in the modern world[5] and it has been observed to compromise decision-making, speed, accuracy in performance and activities, as well as post-exercise recovery.[15] It has also been linked to cardio-metabolic risks (obesity, diabetes, hypertension, and stroke), cognitive impairment, and health-risk behaviours (substance abuse, eating disorders, and suicidal ideation) .[5]

Sleep disorders are classified in the International Classification of Sleep Disorders.[16] Specifically, in the third edition, seven categories of disorders have been identified, including: insomnia disorders, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders, sleep-related movement disorders, parasomnias, and other sleep disorders.[16] The term "disturbed sleep" can encompass various conditions, but it is often associated with insomnia, which is clinically defined as a persistent difficulty in initiating or maintaining sleep, or as non-restorative sleep. Insomnia can cause significant discomfort during the day and compromise the social or occupational functioning of the individual.[17]

Insomnia is a very common disorder across various populations and at different stages of the life cycle, but especially among the elderly. In fact, 50% of them suffer from sleep problems, a significantly higher percentage compared to the 15.9−22.3% found in the general population.[18] Insomnia remains one of the most common sleep disorders encountered in the elderly population (insomnia symptoms prevalence from 30% to 48%, insomnia disorder prevalence from 12% to 20%.9). It is often characterised by subjective complaints of difficulty in falling or staying asleep, which produce negative symptoms during the day, including difficulties in concentration and mood disturbances.[19]

The high rate of insomnia related issued among the elderly may be explained by several reasons. As people age, significant changes occur in sleep disturbance risk, including alterations in sleep patterns and circadian rhythms.[20] Various clinical conditions, such as blindness, substance dependence, dementia, and psychiatric disorders, can impact sleep quality.[21,22] Obesity, prolonged use of benzodiazepines, and intake of stimulating substances like caffeine can also disrupt sleep.[19,23,24] Moreover, chronic pain is closely linked to sleep disturbances, with a complex interplay between pain severity, emotional evaluation, and sleep quality.[25,26] Nocturia, bed rest during waking hours, and low physical activity levels also contribute to sleep disturbances.[17,27] Some studies have highlighted that poor sleep efficiency, increased sleep onset latency, and overall reduced total sleep time are associated with a significantly higher risk of mortality.[12,28] This risk persists even after accounting for related variables, underscoring the importance of addressing sleep disorders promptly and appropriately, especially among the elderly and residents in healthcare facilities.[28]

As a consequence, insomnia continues to be a prevalent issue among the elderly population, with studies indicating that 40%−60% of the older population has poor sleep quality and sleep difficulties, reporting sleep disturbances affecting their daily functioning.[29] Despite the strength of evidence showing that sleep has a critical influence on all aspects of human health, the importance of sleep health remains under-recognised globally.[10]

Sleep is influenced by various factors including biology, environment, lifestyle, and mental health. Understanding these factors is crucial for enhancing sleep quality and overall well-being.[21] Additional challenges arise when the sleep setting is that of a medical hospital, where people are dealing with health issues and live day and night in an environment that follows the rhythms dictated not only by their own medical treatments but also by those of other patients in the room, ward, and facility.

Importantly, scientific research highlighted a significant connection between nighttime noise and sleep disturbances, particularly in hospital settings.[30] Noise, along with excessive light pollution, can negatively affect sleep disturbance risk.[21]

Among the factors influencing the quality of sleep, there are organization-related factors which are independent of the patient (e.g., noise, light, room changes), non-modifiable factors related to the patient condition (e.g., age, hormonal imbalances, comorbidities), and modifiable factors related to the patient condition (e.g., medication intake, presence of pain).

Summarizing, recent scientific literature has emphasized the impact of environmental factors on sleep disorders, such as noise and light pollution, thus highlighting the need for improved sleep environments in healthcare settings.

Some difficulties and challenges are also specific to the procedure of assessing sleep difficulties. It is crucial to note that patients often do not report issues of sleep disorders to healthcare professionals, risking an inaccurate overall assessment and lowering the effectiveness of the overall treatment to improve psychophysical health.[8]

The use of questionnaires to assess perceived sleep disturbance risk also has certain limitations, including the patient's difficulty in completing them independently. This difficulty may result from factors such as functional illiteracy, poor language skills, concentration difficulties or the presence of cognitive disorders. Such obstacles may compromise the quality of the data collected and make it necessary for a health professional to complete it, thus increasing the expenditure of time and resources.

Although sleep disturbance risk assessments are generally consistent among individuals, findings indicate that the relationship between education and self-reported sleep varies significantly when accounting for reporting heterogeneity.[11] In detail, people with more years of education are more likely to report mild sleep issues, while they report severe sleep issues at a lower threshold. For this reason, hetero-reported tools, in which a healthcare professional observes and evaluates the symptoms reported by the patient, are preferable to self-reports. Self-reports are affected by well-known biases and limitations, including the respondent's subjectivity and potential recall bias. Moreover, they may lack sensitivity to short-term changes in symptoms, particularly when patients are asked to reflect on their sleep patterns over a 30-day period, which can hinder the tool's accuracy in detecting acute variations in sleep quality.

To date, there are no valid and reliable tools available to assess sleep disorder symptoms in hospitalized patients over 65 years of age that are administered by a health-professional.

The Sleep Disorder Inventory (SDI) tool[31] is available in the literature such as a screening tool utilised by healthcare professionals for sleep disorder. However, there is no single official version of the SDI, as it may refer to various checklist models or inventories that differ depending on the clinical context and specific sleep disorders intended to be identified.

Therefore, it is crucial to address the notable gap in the availability of practical, reliable, and easily accessible hetero-assessment tools specifically designed to support healthcare professionals in collecting accurate data and optimizing assessment processes, while ensuring the efficient use of time and resources.

Considering the foregoing reasons, this study aims to develop and ascertain the validity of the new Biazzi scale – a hetero-reported tool specifically designed to assess the quality of sleep among elderlies in hospital settings – thereby rendering it accessible to a wider array of healthcare professionals and facilitating its application across a broader spectrum of patients. The decision to focus specifically on the elderly population stems from the higher risk, reported in the literature, of developing sleep disorders.[18]

Methods

Research procedure

This study aims to develop and validate a new hetero-administered tool for measuring sleep disturbance risk in hospital settings in individuals with age above 65 years old: the Biazzi scale. The study was conducted in two main phases.

The first initial phase was dedicated to the construction and content validation of the Biazzi scale. It was created based on a literature review and expert input. Following this, content validity was assessed using the Item-Level Content Validity Index (I-CVI) and Scale-Level Content Validity Index (S-CVI).[32]

The second phase focused on its application and statistical validation. The Biazzi scale was administered to patients across four different hospital wards at the AUSL of Piacenza: General Surgery, Internal Medicine, Oncology, and Orthopaedics.

First phase, construction of the items

In the initial phase, a multidisciplinary team (consisting of nurses, physicians and physiotherapists) from the "E. Biazzi" Institute developed the scale items based on the literature data.[21,33] Based on studies, key external factors, such as noise and light disturbances, were identified, along with internal factors including specific physiological and pathological conditions (e.g., cardiovascular, neurological, and psychiatric disorders). A preliminary version of the scale was drafted, consisting of 15 items categorized into three main areas: Organization-related items, independent of the patient (e.g., noise, light, room changes); non-modifiable patient-related items (e.g., age, hormonal imbalances, comorbidities); Modifiable patient-related items (e.g., medication intake, presence of pain). Each item was dichotomously scored by the administering health professional, who were selected for the study, as 1 (= symptom/condition present) or 0 (= symptom/condition absent). Table 2 lists the items of the Biazzi Scale in English.

Content validity was initially explored through face validity, involving 10 experts (5 nurses, 2 neurologists, 2 geriatricians, and 1 psychologist), who participated in semi-structured interviews. Experts provided feedback on items' clarity, comprehensibility, and relevance. Following this, content validity was assessed by experts rating the relevance of each item on a Likert-type scale with 4-points (1 = "not relevant", 2 = "not very relevant", 3 = "relevant", 4 = "very relevant"). The I-CVI was calculated for each item by dividing the number of experts rating it as "relevant" (scores 3 or 4) by the total number of experts. An I-CVI of $\geq$0.78 was considered acceptable.[34] The S-CVI was computed as the average of the I-CVI scores for all items, with a value $\geq$0.90 considered satisfactory.[35]

Second phase-validation and reliability

In the second phase, two independent healthcare operators, specifically the ward nurse participating in the study and a nursing student, administered the Biazzi Scale to hospitalized patients aged above 65 years. Inter-rater reliability was measured using Cohen's Kappa (κ), where κ values were interpreted as follows: $<$0.40 "poor," 0.41–0.59 "fair," 0.60–0.74 "good," and $\geq$0.75 "excellent" reliability.[36]

In addition, comparative analyses were conducted among the variables considered. Independent *t*-tests were performed to explore differences in sleep disturbance risk scores across various patient characteristics gender, presence of cardiac pathology, respiratory disorders and presence of diabetes. A one-way ANOVA was conducted to compare sleep disturbance risk across the four hospital wards and post-hoc comparisons using Tukey's HSD to observe where there is a difference. Additionally, the scale's accuracy in predicting sleep disturbance risk in hospitalized older adults was assessed through the analysis of the Receiver Operating Characteristic (ROC) curve.[37]

The comparison with the PSQI was conducted to examine functional convergent validity at the level of clinical classification. Although the two instruments differ in item structure and measurement approach, they are intended to identify the same clinically relevant phenomenon: impaired sleep during hospitalization.

The categorised PSQI score served as the reference standard, and the Biazzi Scale's total score was categorised based on an empirically determined cut-off.

Sample

The sample size was calculated based on the rule of thumb of 10 patients per item, leading to a total sample size of 140 patients. Recruitment took place between January and October 2023. Following guidelines from the literature,[38] the Biazzi scale was administered to patients hospitalised in four different wards of the AUSL Piacenza: General Surgery, Internal Medicine, Oncology and Orthopaedics. To ensure that patients could independently complete the PSQI, those with cognitive impairments, language barriers, or who did not consent to participate were excluded.

Measures

The Biazzi scale. The Biazzi scale is a hetero-evaluation instrument designed to assess the risk of poor sleep in elderly patients in

Table 1
Descriptive statistics.

Item	Mean	SD	Skewness	Kurtosis	Shapiro-Wilk (p-value)
Oper1	5.993	1.891	0.118	−0.711	< 0.001
Oper2	5.893	1.803	0.043	−0.648	< 0.001

healthcare settings. It consists of 14 dichotomous items across the three thematic areas identified in the construction phase:

- Area 1: items related to organization, independent of the person.
- Area 2: items related to the person, non-modifiable.
- Area 3: items related to the person, but potentially modifiable.

Each symptom/condition is scored as 1 if present and as 0 if absent, leading to a total score ranging from 0 (= no risk of poor sleep) to 14 (= maximum risk of poor sleep).

Pittsburgh sleep quality index (PSQI). The PSQI is a widely used self-assessment tool to evaluate poor sleep experience over the previous month.[39,40] It includes 19 items across 7 components that assess various aspects of sleep: quality, latency, duration, efficiency, disturbances, sleep medications, and daily dysfunctions. The PSQI was selected for comparison with the Biazzi scale due to its similar structure. The potential association between the value (0/1) of each item on the Biazzi scale and the categorized PSQI value was then assessed using Pearson's χ^2 test, with a p-value < 0.05 considered statistically significant. According to the cut-offs, a global PSQI score of >5 indicates poor sleep quality, while ≤ 5 indicates good sleep quality.

Statistical analysis

Statistical analyses were conducted using STATA 16.1 software (StataCorp LLC, College Station, Texas, USA). As reported in Table 1, descriptive statistics of the items were calculated, including means (M), standard deviations (SD), minimum and maximum scores, skewness, and kurtosis.

Cohen's Kappa coefficient was used to evaluate inter-rater reliability. To validate the scale, a comparison with the PSQI reference standard was made using ROC curve analysis. The accuracy of the Biazzi scale in predicting poor sleep was quantified by the area under the ROC curve (AUC), with higher AUC values indicating better predictive accuracy.

For further analyses, participants were categorised into "good" and "poor" sleepers according to the scores obtained at the Biazzi scale and PSQI.

Ethical considerations

The study was conducted in accordance with Good Clinical Practice and the principles set in the Declaration of Helsinki. The study began following approval from the Ethical Committee of the "Area Vasta Emilia Nord" (AVEN) on April 27, 2022, with protocol number 2022/0149885. After approval for this study, an amendment was requested due to the extension of the enrolment period to reach the sample size. Amendment number 1 with protocol number 2023/0009367 was approved on January 24, 2023. A comprehensive information regarding the study was provided to all participants before the enrolment, and the study proceeded only after obtaining the informed consent signed by each patient.

Results

The first version of the Biazzi scale, consisting of 15 items divided into three thematic areas, was developed by integrating data from the literature with the contribution of a panel of experts. Face validity highlighted issues of clarity and wording in some items, which were subsequently revised.

The items were modified based on the experts' suggestions, and the final version of the scale, consisting of 14 items organised into the same three thematic areas, was resubmitted to the experts, who confirmed its clarity and adequate content validity. I-CVI and S-CVI were then evaluated, with satisfactory results, as shown in Table 3.

Consequently, it was possible to proceed with the analysis of inter-rater reliability and accuracy. Then, during the second phase of the validation process, a total of 150 patients were enrolled (75 males [50%] and 75 females [50%]), whose characteristics are described in Table 4: the median age was 78 (interquartile range 73 - 82). Patients were hospitalised in four wards: 36 (24%) in Orthopaedics and Traumatology, 41 (28%) in Internal Medicine, 38 (25%) in General Surgery, and 35 (23%) in Oncology.

Table 2
Items of the Biazzi scale in english.

Area 1: items related to organization, independent of the person	
Presence of noise in the room or surrounding environment **(Doors, trolleys, and/or noisy equipment; Night-time care activities; Talkative roommate or snoring; Television/devices at high volume)**	☐ 0 ☐ 1
Presence of excessive light stimulation **(Absence of dim night lights in the room and/or hallways; Television on; Windows without shutters)**	☐ 0 ☐ 1
Room occupant changes **(New admission; Room change; Change of roommate)**	☐ 0 ☐ 1
Area 2: items related to the person, non-modifiable	
Age **(≥ 65 years)**	☐ 0 ☐ 1
Visual impairments **(Blindness; Glaucoma; Cataract)**	☐ 0 ☐ 1
Clinically diagnosed dependency **(Alcoholism; Smoking; Substance abuse)**	☐ 0 ☐ 1
Clinically diagnosed dementia	☐ 0 ☐ 1
Conditions affecting sleep **(Cardiovascular; Respiratory; Gastrointestinal; Neurological; Psychiatric; Orthopedic; CKD-Dialysis; Parkinson's disease; Obesity)**	☐ 0 ☐ 1
Area 3: items related to the person, but potentially modifiable	
Use of sleep-inducing substances for at least 3 months **(Benzodiazepines; Natural and/or homeopathic substances)**	☐ 0 ☐ 1
Presence of pain	☐ 0 ☐ 1
Nocturia **(>2 episodes of urination per night)**	☐ 0 ☐ 1
Bed confinement during waking hours **(Confined to bed for >50% of waking hours without being able to get up regularly)**	☐ 0 ☐ 1
Consumption of stimulating substances **(Drinks containing caffeine/tea/taurine; Sugary drinks)**	☐ 0 ☐ 1
Change in habits **(Need to sleep with multiple pillows/special mattress; Need for someone in the room to fall asleep)**	☐ 0 ☐ 1

Table 3
Results of I-CVI and S-CVI.

ITEM	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9	Expert 10	I-CVI
Noise	1	1	1	1	1	1	1	1	1	1	1
Excessive light stimulation	0	1	1	1	1	1	1	1	1	1	0,9
Variations occupying the room	1	1	0	1	1	1	1	1	1	1	0,9
Age	1	1	0	1	1	1	1	0	1	1	0,8
Visual deficits	1	1	0	1	1	1	0	1	1	1	0,8
Diagnosed addiction	1	1	1	1	1	1	1	1	1	1	1
Dementia diagnosed	1	1	1	1	1	1	1	1	1	1	1
Pathologies affecting sleep	0	1	1	1	1	1	1	1	1	1	0,9
Sleep-inducing substances	1	1	1	1	1	1	1	1	1	1	1
Pain	1	1	1	1	1	1	1	1	1	1	1
Nocturia	1	1	0		1	1	1	1	1	1	0,8
Bedtime during waking hours	1	1	1	1	1	1	1	0	1	1	0,9
Stimulants	0	1	0	1	1	1	1	1	1	1	0,8
Changing habits	1	1	0	1	1	1	0	1	1	1	0,8
										S-CVI	0,9

Table 4
Characteristics of the participants.

Cut-off	Sensitivity	Specificity	Correctly classified
≥ 2	100.00%	0.00%	79.33%
≥ 3	99.16%	4.84%	79.67%
≥ 4	92.02%	12.90%	75.67%
≥ 5	78.99%	40.32%	71.00%
≥ 6	64.29%	64.52%	64.33%
≥ 7	44.54%	80.65%	52.00%
≥ 8	26.05%	93.55%	40.00%
≥ 9	11.34%	100.00%	29.67%
≥ 10	2.94%	100.00%	23.00%
>10	0.00%	100.00%	20.67%

The inter-rater reliability, calculated using Cohen's κ coefficient for the total Biazzi Scale score, was 0.77 (95% CI: 0.69−0.84). This indicates good agreement among raters, low measurement error, and that the scale reliably measures the intended construct.

Independent *t*-tests were performed to explore differences in sleep disturbance risk scores across various patient characteristics:

- Gender: A significant difference with large effect size was observed between males and females($t(148) = -4.203$, $p < 0.001$, Cohen's $d = -0.686$), with males reporting lower sleep disturbance risk scores.
- Cardiac Pathology: No significant difference was found with small effect size ($t(148) = 1.386$, $p = 0.168$, Cohen's $d = 0.254$).
- Respiratory Disorders: Differences were not statistically significant but there was a medium effect size ($t(148) = -1.520$, $p = 0.131$, Cohen's $d = -0.306$), with those with respiratory disorders obtaining scores indicative of lower sleep disturbance risk.
- Diabetes: No significant difference was observed and the effect size was small ($t(148) = 0.957$, $p = 0.340$, Cohen's $d = 0.180$).

A one-way ANOVA (Table 5) was conducted to compare sleep disturbance risk across the four hospital wards ($F(3, 146) = 5.340$, $p = 0.002$) and a statistically significant difference across wards emerged. Post-hoc comparisons using Tukey's HSD revealed that patients in Orthopaedics had significantly lower risk of sleep disorders compared to Internal Medicine patients ($p < 0.001$).

Table 5
One way ANOVA.

Ward	N	Mean	SD	Coefficient of Variation
General Surgery	41	6.134	2.034	0.332
Internal Medicine	38	5.079	1.343	0.264
Oncology	35	5.900	2.064	0.350
Orthopaedics	36	6.681	1.455	0.218

Then, the analysis of the ROC curve allowed for the evaluation of the performance of the Biazzi classification model compared to the categorised PSQI reference standard (Table 6, Fig. 1). A score of 6 on the Biazzi Scale was identified as the optimal threshold for discriminating between good and poor sleepers, maximising sensitivity and specificity.

The total score of the Biazzi scale was thus categorised using this cut-off for subsequent analyses. Using this cut-off, subsequent analyses categorised patients as "good sleepers" (score <6) or "poor sleepers" (score ≥6). The percentage of patients reporting increased risk of sleep disorders across wards was as follows: 34% in the Orthopaedics and Traumatology ward, 27% in the Internal Medicine ward, 24% in the Oncology ward, and 15% in the General Surgery ward. These results show that patients in Orthopaedics reported the highest risk of sleep disorders ($p = 0.001$), whereas those in General Surgery had the best, aligning with PSQI findings.

Also, in line with the PSQI, significant differences in sleep disturbance risk between males and females were confirmed using the Biazzi Scale, as indicated by the chi-square test that was statistically significant ($\chi 2 = 0.09$, $df = 1$, $p = 0.008$). Among females, a higher percentage of patients reported increased risk of sleep disorders (59%) compared to lower sleep disturbance risk (38%). Conversely, among males, a higher percentage reported lower sleep disturbance risk (62%) compared to increased risk of sleep disorders (41%).

Table 6
Comparison between PSQI and Biazzi scale.

		N (%)
Ward	Internal Medicine	41 (28%)
	General Surgery	38 (25%)
	Onchology	35 (23%)
	Orthopaedics and Traumathology	36 (24%)
Gender	Males	75 (50%)
	Females	75 (50%)
Cardiopathy	No	41 (27%)
	Yes	109 (73%)
Respiratory disease	No	119 (79%)
	Yes	31 (21%)
Diabetes	No	112 (75%)
	Yes	38 (25%)
PSQI	≤5, good sleeper	31 (21%)
	>5, poor sleeper	119 (79%)

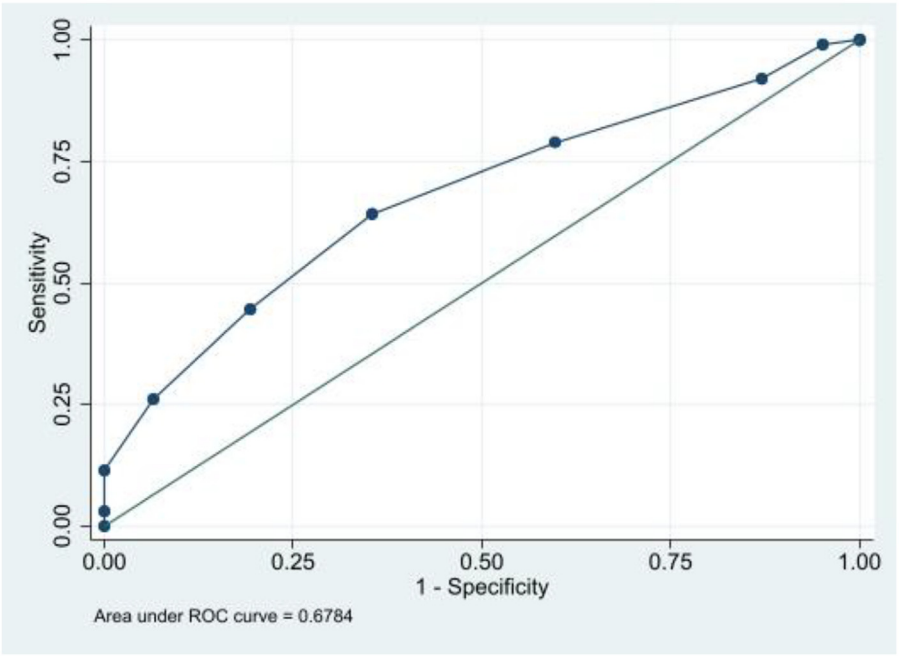

Fig. 1. Graphic of the ROC curve.

The Biazzi Scale findings were consistent with PSQI results regarding gender differences, indicating strong concordance between the two scales in identifying patterns of sleep disturbance risk.

Discussion

The development of the Biazzi scale aimed to address the intricate analysis of risk of sleep disorders, filling a gap in readily available hetero-evaluation tools for healthcare professionals. The last phase of the study showed high I-CVI and solid S-CVI, with excellent inter-rater reliability. Although the PSQI is a validated questionnaire, its use is hindered by limitations, including patient inability to complete it independently due to various factors, such as: functional illiteracy, poor language comprehension, reduced ability to concentrate or the presence of cognitive disorders. Such obstacles may limit the quality of the data collected and require the intervention of a health professional to compile it, resulting in increased time and resources needed. For all the further analyses, a cut-off value of 6 has been established, justified by its high sensitivity and specificity. However, future revisions of this threshold might be necessary based on desired sensitivity levels. Also, some differences in sleep patterns among wards emerged, with significant associations found between PSQI categories and specific Biazzi scale items. However, certain factors like pain, urination, substance abuse, and bed rest did not show significant associations, possibly due to their isolated impact on sleep disturbance risk.[25]

Although the PSQI showed some inconsistencies in its results, both assessment tools have proven to be valuable and relevant in identifying and analysing differences in sleep disturbance risk between genders, thereby contributing to a deeper understanding of the variables associated with such disparities. Indeed, the results revealed that women sleep worse than men, as also highlighted in the literature.[41]

Although the Biazzi Scale and the PSQI do not assess sleep using the same measurement model, they converge at the level of clinical decision-making. Both instruments consistently identify overlapping groups of patients experiencing clinically relevant sleep impairment. We therefore interpret their association as evidence of functional convergent validity, reflecting convergence on the same clinical phenomenon rather than structural convergence of latent constructs.

Consistent with its risk-based framework, the Biazzi Scale assesses environmental factors through hetero-evaluation, as noise, light exposure, and room changes are well-established risk factors for sleep disturbance during hospitalization, even though their subjective impact may vary across patients.

Healthcare professionals praise the Biazzi scale's utility, but concerns exist about its systematic use, particularly in high-turnover settings like emergency departments. As for this, integration of the Biazzi scale into hospital care protocols, especially in long-stay wards, is recommended based on its clinical applicability and potential to replace self-assessment questionnaires.

While the absence of similar tools in literature precludes direct comparisons, the Biazzi scale shows promise in addressing sleep disturbance risk issues effectively.

Study limitations

One of the main limitations of this study concerns the composition of the sample, as only patients over the age of 65 were recruited. This choice aimed to specifically focus on the elderly population, as they are at higher risk of sleep disorders according to the literature.[18] However, this may affect the generalisability of the results to younger age groups. Therefore, the findings of this study are directly applicable only to older individuals, and further research will be needed to extend these conclusions to other age groups. The item "change in habits" was considered locally and conditionally modifiable, reflecting real-world ward practices where limited adaptations (e.g., additional pillows or caregiver presence) may occasionally be feasible; however, we acknowledge that such adaptations are context-dependent and not universally applicable.

Implications for practice

The Biazzi Scale provides healthcare professionals with a reliable and practical tool for assessing risk of sleep disorders in hospitalized older adults. Its use enables early detection of patients at risk of sleep

disturbances, even when self-report tools are unsuitable, and supports the development of personalized care plans, when indicated after further individualized clinical assessment, through targeted interventions on environmental factors, pain management, and medication use. By fostering better rest and recovery, the scale may help prevent complications such as delirium, falls, and delayed healing, while also standardizing sleep assessment across wards and improving continuity of care. Beyond the immediate clinical benefits, its integration into hospital protocols could enhance organizational efficiency and serve as a potential quality indicator for geriatric nursing, with future applications in both hospital and community settings.

Conclusion

The study's analysis of the Biazzi scale scores demonstrates its excellent reliability, validating its potential for future applications. The scale effectively distinguishes between individuals at risk of sleep disorders.

It is crucial to promote awareness of the risks associated with sleep disorders in hospitals, especially among the elderly, and practical solutions like adapting equipment alarms and providing noise-reducing measures are suggested. Improving sleep quality could reduce healthcare workers' workload and costs. Based on the findings of this study, the Biazzi scale has the potential to lead to substantial improvements in the assessment and management of patients' health, contributing to optimising medical care and enhancing the overall quality of healthcare services. In general, healthcare professionals should consider sleep quality as a fundamental aspect of care. In fact, a more accurate assessment of sleep disturbance risk would allow a better treatment planning to manage the health and well-being of individuals. At present, the Biazzi Scale provides an initial cut-off value to support early risk identification; future studies will be required to refine risk stratification and optimize threshold values according to different clinical contexts.

In conclusion, the results of this study underscore the necessity for additional research aimed at refining the use of the Biazzi scale in clinical practice and seamlessly integrating it into hospital care protocols.

Ethics approval and consent to participate declarations

The study was conducted in accordance with Good Clinical Practice and the principles set in the Declaration of Helsinki. The study began following approval from the Ethical Committee of the "Area Vasta Emilia Nord" (AVEN) on April 27, 2022, with protocol number 2022/0149885. After approval for this study, an amendment was requested due to the extension of the enrolment period to reach the sample size. Amendment number 1 with protocol number 2023/0009367 was approved on January 24, 2023. A comprehensive information regarding the study was provided to all participants before the enrolment, and the study proceeded only after obtaining the informed consent signed by each patient.

Consent for publication

Not applicable.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Massimo Guasconi: Writing – original draft, Conceptualization. **Nunzia Montesanto:** Writing – original draft, Conceptualization. **Nicola Pisaroni:** Conceptualization. **Camilla Faverzani:** Writing – original draft, Investigation. **Marina Bolzoni:** Formal analysis, Data curation. **Anna Genovese:** Writing – original draft, Investigation. **Alessia Scaramuccia:** Investigation. **Anna Panzeri:** Writing – review & editing. **Evelina Cattadori:** Writing – review & editing, Supervision. **Antonio Bonacaro:** Writing – review & editing. **Andrea Contini:** Writing – review & editing, Supervision.

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Supplementary materials

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