ADDIS ABABA UNIVERSITY

COLLEGE OF MEDICINE

DEPARTMENT OF EMERGENCY AND CRITICAL CARE MEDICINE

Prevalence of physical restraint and associated factors among Intensive Care Unit patients in Addis Ababa hospitals, Ethiopia: A dual-center Cross-Sectional Study

By: Dr.Rediet Alemayehu(emergency and critical care resident)

A Thesis Submitted to the Department of Emergency and Critical Care Medicine, College of Medicine, Addis Ababa University in Partial Fulfillment of the Requirements for the specialty certification in Emergency and Critical care medicine.

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Declaration

I declare that I carried out the work in this thesis, titled ‘’Prevalence of physical restraint and associated factors among ICU patients in Addis Ababa hospitals, Ethiopia: A dual-center Cross-Sectional Study," in the Department of Emergency and Critical Care Medicine. The information derived from the literature has been duly acknowledged in the text, and a list of references has been provided. No part of this thesis was previously presented for another degree or diploma at this or any other institution.

A Thesis Submitted to the Department of Emergency and Critical Care Medicine, College of Medicine, Addis Ababa University in Partial Fulfillment of the Requirements for the specialty certification in Emergency and Critical care medicine. It complies with the university's regulations and meets the accepted standards concerning originality and quality.

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Acknowledgment

I thank God for the time he gives and for the wisdom we share.

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I appreciate that the university provides the resources and opportunity to practice evidence-based medicine.

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Abbreviations and Acronym

CAM-ICU- confusion assessment method in intensive care unit

CI- confidence interval

CMS- The Centers for Medicare & Medicaid Services (CMS)

CVC-Central venous catheter

DHHS- The Department of Health and Human Services

GCS- Glasgow coma scale

ICU- intensive care unit

IMV- invasive mechanical ventilation

JCAHO- Joint Commission on Accreditation of Healthcare Organizations

KAP- knowledge, attitude, and practice

NICE- The National Institute for Health and Care Excellence

OR- odds ratio

PI- principal investigator

PR- physical restraint

RAAS- Richmond agitation and sedation scale

TASH- Tikur Ambessa Specialized Hospital

Contents

Abstract

Introduction: Research done in most parts of the world demonstrates the high prevalence of physical restraint use in the intensive care unit. Though clinical use of physical restraint in Ethiopia is widely practiced evidence lacks to show its magnitude. Knowing the prevalence of physical restraint added a reference to the associated factors that might be used in the future formulation of policy and guidelines regarding the use of physical restraint in the intensive care unit.

Objective: To assess the prevalence of physical restraint and associated factors among intensive care unit patients in two selected hospitals in Addis Ababa, Ethiopia from August- September 2024

Method: Institution-based cross-sectional study design was implemented in the two selected hospitals in Addis Ababa. A total of 120 patients were enrolled in the study. Data was collected using an interviewer-administered structured questionnaire and Physical Restraint Evaluation Survey observational survey tool for 2 consecutive months. One nurse from each hospital was collecting the data. Questioners were coded and data was cleaned then exported to SPSS version 27 for analysis. Descriptive analysis was used to characterize selected variables. A bivariate logistic regression was conducted and a variable with a P value of <0.25 was analyzed by multivariable logistic regression. After multivariable logistic regression, a P value of <0.05 was used to declare statistical significance.

Result: The prevalence of physical restraint use was found to be 40.9%. Factors associated with the use of physical restraint were mechanical ventilator, age, and lower Richmond agitation and sedation score. Mechanically ventilated patients are 7 times more likely to be restrained AOR (95%CI) 7.97(2.37, 26.80). Patients aged 38-61 were shown to be at increased risk of physical restraint with AOR (95%CI) 3.88(1.04, 14.59). This study has found that patients who were sedated have 0.13 times lower risk of being physically restrained 0.13(0.03,0.52).

Conclusion: This study found that the prevalence of physical restraint use is common practice in the intensive care unit. It has also shown that there are risk factors for this practice. The use of mechanical ventilators and age were associated with the use of physical restraint. A lower Richmond agitation and sedation scale is protective against physical restraint.

List of Tables

List of Figures

Introduction

1.1 Background of The Study

Restraints are defined as the act of withdrawing a person's rights of movement, and this takes different forms(1). Two types of restraints have been described in the literature: chemical and physical(2,3). Chemical restraints are medications in the course of treatment used only aiming at limiting patients' movement(4). As defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), restraint is "any physical method of restricting a person's freedom of movement, physical activity, or normal access to his or her body"(5). According to the Centers for Medicare and Medicaid Services(CMS), restraint is “any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient’s body that he or she cannot easily remove that restricts freedom of movement or normal access to one’s body”(6).

The only exception where using restraint and seclusion is supported by the law is when a patient is believed to be a risk to the safety of one’s self or others. Otherwise, the use of restraints violated patients' rights which has been stated in the standard prepared by the Department of Health and Human Services(DHHS) and CMS of the United States(6). But history tells us that it hasn’t always been like this for patients all over the world.

Documentation in English around 1740 states the people of power had the right to subjugate people who seemed to be acting out of order. This inhumane law was challenged by activists like Philipe Pinel who was unchaining female patients who were in a psychiatric hold. It wasn’t until the 1960s consumer movement in mental health, that the problem was been reached out by stakeholders. (7).

Application of PR in the medical settings is a common encounter especially in the units like the psychiatry and further in acute and critical care units. A patient in the ICU needs continuous use of invasive and active medical devices to treat and approach a medical condition with high morbidity and mortality outcomes. The nature of the unit makes it difficult to follow a structured rule on the decision of restraining patients. The decision of whether to apply PR lies in the justification of health professionals. (2)

1.2 Statement of The Problem

The health professional attending to the care of patients has a responsibility to do no harm and do good(8). The incidence of PR that is shown in different studies from different areas is high even though no study evidenced a positive impact. In the US it is estimated that 27000 people are physically restrained every day in the hospital setting(9). So the use of physical restraint in medical facilities tends to be pretexted to the type of care and type of medical condition a patient has. There are some variabilities in the reports of the incidence but the overall burden of the problem is shown in different studies from around the world.

There is uneven distribution among units seen in studies. Providing a reason for this result mandates further investigation. However, it has been pointed out that the nature of the care that is provided in a critical care setting and the lack of capacity to consent due to underlying critical and life-threatening conditions justifies the action. This might be part of the reason that some wards and units have more prevalence than others. It was reported that the use of PR in the ICUs is 3-20 times more than in other units(9). In Brazil, there is a 93.3% prevalence of physical restraint use in the ICU, where the numbers for medical and surgical units are 50.9% and 3.8% respectively(10). This was also revealed in findings from the United States, Canada, and Korea. (9–11). The clinical application of PR should be supported with evidence. However numerous observations found unwanted effects that have been directly linked to the use of PR. In the medical world, the principle of treatment approach is based on the weighted course of complications and benefits. With the complications triumphing over benefits, the use of PR in the ICU area will increase patient dissatisfaction, mistrust, sense of abuse, and trauma(12).

Showing how and what is related to the high PR prevalence in the ICU is important. This will help in the depth of understanding of the problem and further identify predictors to target. The treatment characteristics like medical devices used on patients and medications prescribed are mentioned to be associated with the PR practice in the ICU(10,13–17). Age and gender of patients, diagnosis, presence of delirium, and level of consciousness are another group of lists(10,14,16–19). Hospital units like the surgical ICU have a higher prevalence(13,18). The knowledge, educational experiences, and demographic character of the nursing team greatly affect the practice of PR(20).

Through the years medical community has developed regulations, statements, and guidelines in order to minimize improper use of physical restraint. A patient with agitation, restlessness, anxiety, or defensiveness should not be approached with PR primarily. Other ways to control and limit movement must be first tried. If this fails and the decision has been made to apply PR, withdrawing it sooner is warranted (3).

The rule to not harm should always be thought of when there is a need for the application of physical restraint. With the growing interest in, humanitarianism one should be aware of actions toward patients' human rights. Though there is a lack of standards in our countries major countries have actively pursued the reduction and regulation of physical restraint use. This fact shows the data in our country is still not enough to have a better understanding to further propose a solution. Research in this area is warranted.

1.3 Significant of The Study

The prevalence of physical restraint use in the ICU is high as evidenced by research done in most parts of the world. With no data to support the use of physical restraint for a favorable outcome for patients, it is a practice that should be reduced and then abandoned. Counties that started this journey had their fair share of research done in the setups where change was needed. Following this were regulations, standards, educational forums, inspection, and evaluation of the health care system that are being implemented in the light of better solutions. Though clinical use of physical restraint in Ethiopia is widely practiced evidence lacks to show the magnitude. And this research was the first to produce numbers that will report the practice of physical restrain in the ICU. The output was a resource for the growth in improving patient care and service delivery.

Knowing the associated factors to the practice of physical restraint is one way to approach the burden of the problem. Studies in Ethiopia regarding PR were only done on the KAP of nurses. So this study added a reference to the associated factors that might be used in the future formulation of policy and guidelines regarding the use of PR in ICU.

Literature Review

2.1 Prevalence of The Use of Physical Restraint

The three multicenter studies from China show a high prevalence of physical restraint use these are 48.8%(13),59.07%(21), and 61.2%(14). When compared to the 32.9% prevalence in Japan the incidence in China is higher(16). But this result is roughly similar to the numbers demonstrated in Korea and Jordan, which are 34.3% and 35.8% respectively(11,22). Among the patients in 3 north Iran ICUs, 74.5% of them were physically restrained(15).

The PRICE study done on 669 patients from nine European countries showed that 39 % of patients were physically restrained(23). In the Netherlands, there is a 23% prevalence(24) while in Germany it is investigated to be 11.8%(25). A much lower measurement of PR was shown in Switzerland and Austria, that is 8.7%.(26). In general, the incidence in Europe is lower than what has been seen in Asia.

A descriptive study done in the US indicated that physical restrain prevalence was 50 per 1,000 patient days (based on 155,412 patient days)(9). A higher prevalence of 77.4% was seen in Brazil(17). Though this is a larger number the prevalence in 51 Canadian ICUs was also high, demonstrating a 53% practice(27). There are some similarities in the incidence of PR use in Asian and South American ICUs

There are two comparable researches done in Africa, one in Egypt and the other in South Africa that show the prevalence of PR in their respective country. Analysis of the use of PR in 11 Egypt ICUs found that PR was used in 6.2% to 46.2% of the total 275 patients(28) and 48.4% of the patients were restrained according to a mixed method study done in 3 ICUs in South Africa(29). This result is within the balance of the numbers demonstrated in other studies from different areas as well. Overall data around the world suggests a lower prevalence in Europe.

2.2 Factors Associated with The Use of Physical Restraint in ICU

2.2.1 Patient/Behavioral Character

Most research done in different parts of the world shows an increasing age is significantly associated with the use of PR. A study from China found age to be an independent risk factor with a p-value of 0.001(14). Studies done in Jordan and Japan data demonstrated that for every increase in patients' age, there is a one-fold increased chance of being restrained (16,22). Similar results were seen in Egypt as well as Germany(25,28).

Female patients were found to be 10 times more likely to be restrained than their male counterparts in Chinese and Brazilian studies. (13,17).

The application of physical restraint is more pronounced in patients with delirium(14). A study from Japan and the Netherlands stated that delirious patients are almost 4 times more likely to be restrained(16,24). A cross-sectional Study in North Iran found the presence of delirium (OR, 15.13; 95% CI: 4.61–49.65) is related to the practice of physical restraint(15).

ICU patients in Brazil and Japan with the behavioral character of agitation are 5 and 8 times more probably to encounter PR respectively(16,17). In China, the less sedated patients are more likely to be restrained(21).

A more depressed level of consciousness measured by GCS was protective against the use of PR(21). A study in Iran also showed low GCS (OR, 0.69; 95% CI: 0.53–0.9) to be protective (15). This report was further supported by data from Jordan where conscious patients were 2.2 times more likely to be restrained(22). Opposing the observations above is a study done in the Netherlands demonstrating comatose mental status [2.14(1.04–1.69); p = 0.001] and inability to communicate verbally [2.84(1.56–5.2); p = 0.001] to be negatively associated factors(24).

2.2.2 Treatment Character

A medical condition that requires mechanical ventilation increases the risk of PR use(14,23). Invasive mode of ventilation has been associated with the application of PR (OR, 9.013; 95% CI, 7.417–10.953) and (2.15(1.16–4.01); p = 0.016) in China and Japan respectively (13,16). Similarly, findings of a Brazilian study related invasive airways to the use of physical restraint showing a 6 times increased risk(17).

The presence of indwelling catheters like central venous catheters, urinary catheters, nasogastric tubes, or abdominal drainage is associated with 2.6 times, 6.7 times, 2.7 times, and 1.8 times increased risk of physical restraint application respectively(13,16,25). Many other forms of treatments have been associated with PR(21).

Some researchers identify sedation as a protective factor. The findings in China revealed patients not sedated have 0.5 times more increased probability for PR(13). This is supported by another study from China(14). While others find it to be negatively associated. According to the observation in Japan and Iran sedative medication had a 2.8 times risk for patients to be restrained(15,16). A mirrored result of association with psychoactive or sedative medication [1.45(1.06–1.96); p = 0.001]was seen in Switzerland(26). Additionally, the PRICE and a Brazilian study have shown the same relationship(17,23).

2.2.3 Nurse Character

Because many researches lack documented order of the application of physical restraint it is assumed that the decision is up to the nurse who is attending the patient.

This practice has been an area of interest and the associations have been demonstrated in studies. A descriptive study from Syria concluded that older nurses and those with higher qualifications and years of experience have better restraint-related performance than others(19). Factors affecting nurse practice of physical restraint are work unit, knowledge, and educational experience on physical restraints(20). There are two research done in Ethiopia around the topic of the interest(30,31). A statistically significant association with the practices of nurses was found to be age(31).

2.2.4 Hospital/Unit Character

Results from research on the associated factors have shown have some identities to help classify in categories. And hospital/unit characteristics have been described in many.

Specific ICUs like the surgical ICU have higher figures of association. As shown in China(2 fold) and Jordan(10 fold) risk for PR(13,18). Another character that is related is the resource. The greater the number of ventilators in the ICU the greater the incidence of PR(27). This is consistent with the bed capacity of the unit. Patients kept in ICU units with large numbers of beds are more likely to be restrained (18,23), as opposed to sharing a semi-private room(25).

A low number of nurse to patient ratio has been associated with complications and well as the application of PR(23,28).

The night shift is 3.6 times a risk for the practice of PR and each day in the ICU is related to a fold increase in the incidence of PR(18). Length of stay was also described to be associated with physical restraint use in both studies done in Egypt and China(13,28).

Conceptual framework

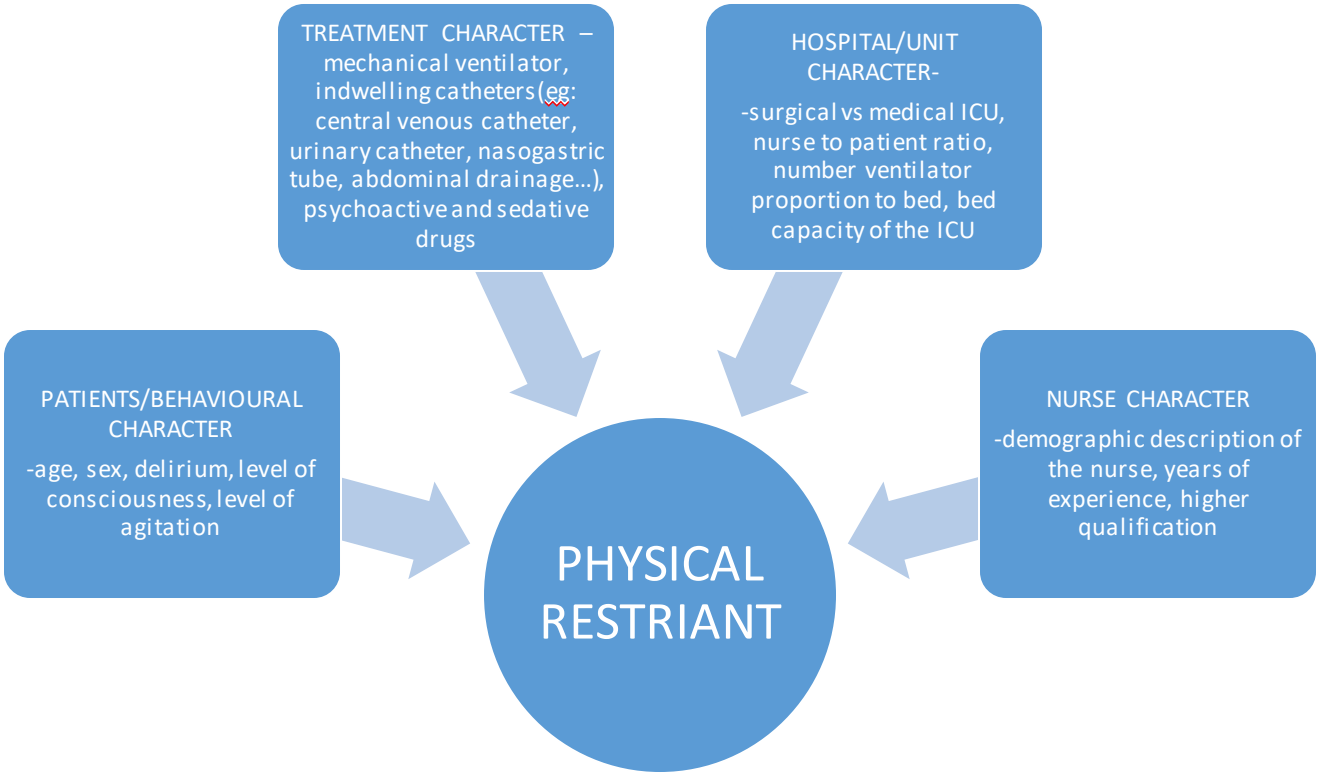

Figure 1: conceptual framework

Objective

4.1 General Objective

- To assess the prevalence of physical restraint and associated factors among ICU patients in two hospitals in Addis Ababa, Ethiopia from August - September 2024

4.2 Specific Objective

- To assess the prevalence of physical restraint among ICU patients in two hospitals in Addis Ababa Ethiopia from August – September 2024
- To assess associated factors of physical restraint among ICU in two hospitals in Addis Ababa Ethiopia from August - September 2024

Methodology

5.1 Study Area and Study Period

The study was conducted in two hospitals in Addis Ababa. Tikur Ambessa Specialized Hospital and Zewditu Memorial Hospital. Tikur Ambessa Specialized Hospital was established in 1964, it offers service by receiving referred and emergency patients from almost all of the nation's regional and federal hospitals. Of the many units that run in the hospital, the intensive care units are one of them. It gives service to both adult and pediatric age groups with diverse specialties as well as sub-specialty consultation. The adult ICU has a medical and surgical wing, and one special type of ICU that is cardiac. The pediatric ICU is a mixed type, where surgical as well as medical patients are treated. Zewditu Memorial Hospital was built, owned, and operated by the Seventh-day Adventist Church, but was nationalized during the Derg regime in about 1976. It is currently providing outpatient and inpatient services in its catchment area. One of the inpatient services is provided at the ICU unit. This unit is the mixed type where medical, surgical, adult, or pediatric patients are admitted.

Data was collected from August 2024- September 2024

5.2 Study Design

- The institution-based cross-sectional study design was implemented in the two hospitals in Addis Ababa.

5.3 Source Population

- All ICU patients in Addis Ababa hospitals

5.4 Study population

- All ICU patients in the two hospitals in Addis Ababa during the study period from August 2024- September 2024

5.5 Sample population

- ICU patients in the two hospitals in Addis Ababa that were included in the study

5.6 Eligibility Criteria

5.6.1 Inclusion Criteria

- ICU patients in the two hospitals in Addis Ababa within the study period who were newly admitted stayed for more than or equal to 24 hours.
- Newly admitted patient to the ICU that has consented or consented via legal proxy.

5.6.2 Exclusion Criteria

- Newly admitted patients whose length of stay in the ICU is less than 24 hours
- Pediatric and neonatal ICU patients
- Eligible candidates that haven't consented

5.7 Sampling Procedure

Convenient sampling is used to select the hospitals. Each tertiary hospitals in Addis Ababa were listed and 2 hospitals were chosen. These are Tikur Ambessa specialized hospital and Zewditu Memorial hospital.

The sample size is calculated by taking the confidence interval of 95% and marginal error of 5% and a P value of 47% was used from a previous study in Egypt(27). The sampling frame was calculated by taking the average of new ICU admissions within the last 6 months and multiplying by two as the data collection period is 2 months. TASH has an average admission of 44 patients both in the medical and surgical ICU. And ZMH had an average of 37 new admissions to the ICU in the last 6 months. So the sample size is calculated to be 120 after the population correction formula was implemented and by taking a 5% non-respondent rate.

Unlimited population: $n = \frac{z^2 \times \hat{p}(1-\hat{P})}{\varepsilon^2}$

Finite population: $n' = \frac{n}{1+\frac{z^2 \times \hat{p}(1-\hat{P})}{\varepsilon^2 N}}$

Where z is z score- that is 1.96

ε is the margin of error- that is 0.05

N is the population size- in this study the population size was determined from the 6-month average new ICU admissions of the two hospitals and multiplying by two since the data collection period was 2 months. This was found to be 162.

$\hat{p}$ is the population proportion- in this study, 47% was used from the study done in Egypt.

With this, the unlimited population size was calculated to be 383. But since the study population is less than 10000 the population correction formula was used and the sample size for the finite population was 114. And by adding the 5% non-response rate the final sample size was computed to be 120.

The sample size was distributed among the hospitals proportionally based on the bed capacity of the ICU in each hospital. There are a total of 10 and 12 beds in Zewditu Memorial Hospital and TASH respectively. Data was collected until the allocated sample size was reached in each of the hospitals.

5.8 Study Variable

5.8.1 Dependent Variable

- Physical restraint

5.8.2 Independent Variable

- Sociodemographic characteristics
- Patients characteristics
- Treatment characteristics
- Hospital/unit characteristics
- Nurses' characteristics

5.8.3 Operational Definition

Adult- age >13

Physical restraint- any form of instrument applied to limit patients' movement and access to one's body after 24hrs of patients' admission to the ICU

Patients and behavioral characteristics- it is a character of the individual that was studied after 24hrs of patients' admission to the ICU: delirium, RAAS score, GCS, and admission diagnosis (medical vs surgical)

Treatment characteristics- it is the character of the treatment that is applied to the patients during the ICU stay that was assessed after 24 hours of the patient's admission to the ICU: mechanical ventilator, noninvasive positive pressure ventilation, noninvasive oxygen therapy, nasogastric tube, urinary catheter, central venous line, peripheral venous line, arterial line, drainage tube, use of sedative and psychoactive drugs.

Hospital/unit characteristics- the character of the unit at which the patient is admitted and treated: ICU (medical vs surgical), nurse-patient ratio, bed capacity of the unit, the proportion of ventilator-capable beds

Nurses' characteristics- it is the character of the nurse that is attending to the care of the patient at the time of data collection: demographic description of the personnel, years of experience, and educational background.

5.9 Data Collection and Measurement

Data was collected using an interviewer-administered structured questionnaire and the Physical Restraint Evaluation Survey observational survey tool. This tool is adapted from the literature that has been found regarding the topic of interest. This observational survey tool was used to assess patients' course of stay in the ICU. The prevalence of physical restraint use was defined as the patient being ever restrained throughout the duration of the observation. One nurse from each hospital was collecting the data. A two-day training was held for the nurses to be involved before the data collection.

5.10 Data Processing and Analysis

The collected data was checked for its completeness and coded then exported to SPSS ver.27 for summarization and analyses of data. Frequencies, mean/median, and proportions were used for the descriptive analysis of data. A binary logistic regression model was used to the association between the outcome variable and explanatory variable. After bivariate logistic regression, variables having $P < 0.25$ were entered into a multivariate logistic regression model to identify the independent contribution of each explanatory variable. Adjusted odds ratios and their corresponding 95% CI were reported to assess the association between individual variables and the outcome variable, and $p< 0.05$ was considered statistically significant.

5.11 Ethical Consideration

Ethical clearance was obtained from the Ethical Review Committee of the Department of Emergency and Critical Care Medicine, AAU, and Addis Ababa Regional Health Bureau ethical review committee. Each respondent was informed about the aim of the study. They were also informed that all data obtained from them was kept confidential by using codes instead of any personal identifiers and was meant only for the study. Informed written consent was obtained from each participant or caregiver. Each participant was informed that they could withdraw from the study at any time without affecting their service utilization.

Results

6.1 Socio-demographic characteristics of ICU patients in two selected hospitals in Addis Ababa

One hundred and twenty ICU patients were involved in the study making the response rate 100%. Table 1 shows the socio-demographic characteristics of the ICU patients in the two selected hospitals during the study period. The mean ± SD age was 41.56 ± 20.08. Male patients accounted for 57.50% of the patients and 51 (42.50%) were female. The majority of the patients were urban 97(80.83%) while the remaining 23 (19.17%) were rural. The data shows that 52, (43.33%) of patients were single, 46(38.33%) were married and 22(18.33%) were divorced or widowed.

Table 1. Socio-demographic characteristics of ICU patients in two selected hospitals in Addis Ababa Ethiopia.

Variable	Categories	Frequency (percentage)
Age of the patient	14-37	61(50.83)
	38-61	32 (26.67)
	62-85	27(22.50)
Sex	Male	69 (57.50)
	Female	51(42.50)
Residence	Urban	97 (80.83)
	Rural	23(19.17)
Marital status	Single	52(43.33)
	Married	46 (38.33)
	Divorced/widowed	22(18.33)
	Unable to read and write	16 (13.33)
	Primary school	29 (24.17)

Educational status	Secondary school	52(43.33)
	Tertiary and above	23 (19.17)
Occupation	Farmer	12 (10.00)
	Government employee	22 (18.33)
	Self-employed	48 (40.00)
	Other	38 (31.67)

6.2 Patients and behavioral characteristics

Among the admissions 55% of patients were medical and 54(45%) were surgical. Patients who had delirium accounted for 27%. Regarding RAAS score 39(32.5%) of patients were agitated, 40(33.33%) were alert and normal and the remaining 41(34.17%) were sedated.

6.3 Treatment characteristics

Some of the treatment characteristics of patients have been demonstrated in Figure 1. Patients who were receiving non-invasive oxygen therapy were 52 (43.33%). Mechanical ventilators were used for sixty-seven (55.83%) patients. Patients who had nasogastric tubes, urinary catheters, and central venous lines were 76 (63.33%), 110 (91.67%), and 10(8.33%) respectively. Drainage tubes of different types were reported in 25(20.8%) patients (Table 2). Most patients had chest tubes and subgaleal drains.

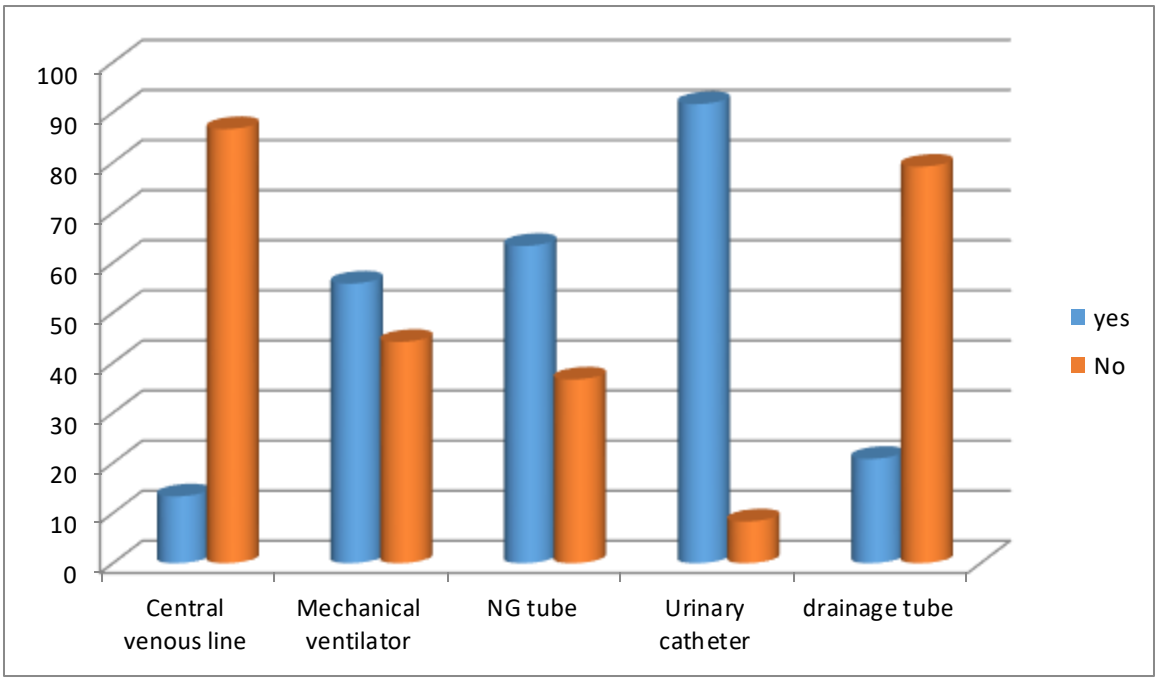

Figure 2: treatment characteristics of patients at two selected hospitals in Addis Ababa Ethiopia.

Table 2- frequency distribution of physically restrained patients with drainage tubes

Type of drainage tubes	Physically restrained	Physically not restrained	Total
Chest tube	1(7.1%)	6(54.5%)	7(28%)
Cortical drain	1(7.1%)	0	1(4%)
CSF drain	2(14.3%)	0	2(8%)
Duodenal drain	1(7.1%)	0	1(4%)
Epidural drain	0	2(18.2%)	2(8%)
Jejunostomy tube	0	1(9.1%)	1(4%)
Peritoneal drain	1(7.1%)	0	1(4%)
Subdural drain	2(14.3%)	1(9.1%)	3(12%)
Subgaleal drain	6(42.9%)	1(9.1%)	7(28%)
Total	14(100%)	11(100%)	25(100%)

6.4 Hospital/ unit character

TASH had six beds in the medical and surgical ICU each. There are five and six functional mechanical ventilators in the surgical ICU and medical ICU respectively. ZMH had a mixed type of ICU with a bed capacity of 10 and 8 functional mechanical ventilators.

Table 3 Frequency distribution of physically restrained and unrestrained patients across the hospital/unit character

		Physically restrained	Physically not restrained	Total
Place of admission and number of ventilators in the unit	Medical, 6 ventilators	11(22.4%)	22(31%)	33(27.5%)
	Surgical, 5 ventilators	10(20.4%)	15(21.1%)	25(20.8%)
	Mixed type ICU, 8 ventilators	28(57.1%)	34(47.9%)	62(51.7%)
	Total	49(100%)	71(100%)	120(100%)

6.5 Characteristics of health professionals

Table 4 shows the socio-demographic characteristics of health professionals. The mean ± SD age of health professionals is 30.86 ± 5.65. More than half of the health professionals were male (58.33%) while the remaining 50(41.67%) were female. The majority of nurses had BSc 84 (70.00%), and the remaining 36 (30.00) had MSC. Single nurses were reported to be 58(48.33%) and 62(51.67%) were reported to be married.

Table 4: socio-demographic characteristics of health professionals

Variables	Categories	Frequency (percentage)
Age	24-30	82(68.33)
	31-54	38 (31.67)
Sex	Male	70 (58.33)
	Female	50(41.67)
Marital status	Single	58(48.33)
	Married	62 (51.67)
Educational background	BSC	84 (70.00)
	MSC	36 (30.00)
Years of experience	Junior	51(42.5)
	Senior	38(31.67)
	Chief	14(11.67)
	Expert, senior expert	6(5)
	Chief expert, consultant	11(9.17)

6.6 Physical restraint and associated factors

The prevalence of physical restraint was 40.83%, (95%CI 32.33-49.99). A-bivariable logistic regression analysis was performed to select variables for multivariable logistic regression analysis. Variables with p-value <0.25 were used for multivariable logistic regression analysis these variables included age, sex, admission type, delirium, RAAS score, drainage tube, mechanical ventilator, use of sedatives or psychoactive, and central venous line.

Multivariable analysis was used to find the association factors for PR use, the model had a good fit according to the Hosmer and Lemeshow goodness of fit test (R^2= 0.429, X^2=6.43 and p=0.599). Table 5 shows data from the multivariable analysis and statistically significant associated factors.

On multivariable logistic regression analysis patients on mechanical ventilators were 7 times more likely to be physically restrained AOR (95%CI) 7.97(2.37, 26.80). Patients aged 38-61 have 3

times higher risk of physically restrained AOR (95%CI) 3.88(1.04, 14.59), and patients who were sedated have 0.13 times lower risk of being physically restrained 0.13(0.03,0.52).

Table 5. physical restraint and associated factors among ICU patients at two selected hospitals in Addis Ababa Ethiopia.

Variables	Categories	PR yes	PR no	COR (95%CI)	AOR(95%CI)	P-value
Age of the patient	14-37	29	32	1	1	
	38-61	8	24	2.71(1.05,6.99)	3.88(1.04,14.59)	**0.04**
	62-85	12	15	1.13(0.45,2.81)	0.80(0.23,2.82)	0.73
Sex of the patient	Male	32	37	1	1	
	Female	17	34	1.72(0.81,3.66)	0.92(0.32,2.67)	0.88
Admission Type	Medical	21	45	1	1	
	Surgical	28	26	0.43(0.20,0.91)	0.31(0.09,1.04)	0.05
RAAS score	Agitated	17	22	1	1	
	Alert	6	34	4.37(1.49,12.81)	1.45(0.34,6.21)	0.61
	Sedated	26	15	0.44(0.18,1.09)	0.13(0.03,0.52)	**0.004**
Drainage tube	Yes	14	11	1	1	
	No	35	60	2.18(0.89,5.32)	1.60(0.42,6.03)	0.51
Sedative /psychoactive	Yes	26	11	1	1	
	No	23	60	6.16(2.62,14.47)	2.28(0.70,7.33)	0.16
Mechanical ventilator	No	35	18	1	1	
	Yes	14	53	7.36(3.24, 16.68)	7.97(2.37,26.80)	**0.001**
Central line	Yes	10	6	1	1	
	No	39	65	2.77(0.93,8.23)	3.34(0.75,14.78)	0.11
Sex of the health professional	Male	30	40	1	1	
	Female	19	31	1.22(0.58,2.56)	1.19(0.44,3.24)	0.72

Note: AOR: Adjusted odds ratio, COR: crude odds ratio, PR physical restraint

Discussion

This cross-sectional study aimed to determine the prevalence of physical restraint use in two selected ICUs in Addis Ababa. The prevalence of physical restraint use was 40.9%. The study showed some variables to be associated with the use of physical restraint during multivariate logistic regression. The results found that the use of a mechanical ventilator, age, and lower RAAS were related to physical restraint use.

The prevalence that was determined in this study (40.9) aligned with multiple research done around the world. In ICUs in Egypt and South Africa, the incidence of physical restraint was 46% and 48.4% respectively(28,29). In addition to these African studies, a prospective point prevalence study conducted in nine European countries found 39% of patients to be restrained(23). The result from one Chinese study showed a 48.8% prevalence(13). Another study in Japan, Korea, and Jordan reported a prevalence that is in line with this study(11,16,22). There is a difference in the study designs, areas as well as the method of calculations used to determine the prevalence among these studies. But still, the aforementioned studies including the current one can reflect the practice of physical restraint in the ICUs. In contrast to these findings, some studies demonstrated a lower prevalence than this study. This was shown in the Netherlands with a 23% prevalence(24). Another study in Germany found the prevalence of physical restraint to be 11.8%(25). An even lower prevalence was seen in Switzerland and Austria, 8%(26). Some studies found the prevalence of physical restraints to be higher than the findings of this study. In 3 Iranian ICUs, 74.5% of 272 patients were restrained(15). Another study was done in Brazil that showed a 77.4% prevalence(17). In Canada it was found to be 53%(27).

According to the findings of our study, the age category of patients (38-61) had three times increased risk of being physically restrained. Based on the research reviewed in the literature review every study shows that there is an increased risk of being physically restrained with an increasing age. In Egypt, they found a positive correlation between patients' age and restraint use(28). A multicenter cross-sectional study done in Germany found patients in the age group of 80-99 to be 4 times more at risk of restraint(25). A one-fold increased risk was seen for every one-year increment in patients' age in Jordan and Japan(16,22). Another observation in China related to the elderly (>75) with 13 times more likely to be restrained(14).

This study found mechanical ventilators and physical restraint to be strongly associated. The incidence of physical restraint for the patients studied here was 7 times more if they were mechanically ventilated similarly studies from Brazil and China demonstrated a 6 times greater risk of physical restraint during the invasive mode of ventilation(14,17). Additionally, another study from China found 9 times increased risk with the use of invasive ventilation(13). A multicenter prospective observational study from Japan found mechanical ventilators to be a risk factor for physical restraint use, which is also shown in our study. Among the 787 patients that were observed during the study period patients on mechanical ventilators are 2 times more likely to be restrained(16).

One behavioral characteristic of the patient is strongly associated with the use of physical restraint. Our study found lower RASS is protective against the use of physical restraint. This is contrasted by the cross-sectional study from China that showed a one-fold increased risk for a total of 386 ICU patients if they had a higher RASS(21). Brazilian and Japanese studies found agitation to increase the use of physical restraint by 5 and 8 fold respectively(16,17). Though this research didn't find an association between agitation and physical restraint, it showed that sedated patients based on the RAAS score are protected.

7.1 Limitations of the study

The limitations that have been seen in this study are: it is a cross-sectional study. A prospective study would have been a better method to follow patients and assess the practice as well as the factors that will change through the course of the study. It has a smaller sample size and limited study area. The study used a nonrandom sampling technique which will be difficult for generalization and representativeness. The budget that was allocated is small.

Conclusion and recommendation

This study found that the prevalence of physical restraint use is common practice in the ICU. It has also shown that there are risk factors for this practice. The use of a mechanical ventilator and age were associated with the use of physical restraint where having a lower RAAS is protective against it.

Based on this research we recommend that physical restraint should be reported as part of the continuous follow-up of patients admitted in the ICU. The evaluation of every ICU patient care should also involve the assessment of the prevalence of physical restraint practice in that particular ICU. This will improve the care and follow-up of patients that are mechanically ventilated, who are at increased risk of restraint. Patients with increased age are subject to many malpractice and this might be part of the problem. Addressing this age group is indicated based on the study. In general, research on this area is lacking in our country so we recommend a more extensive study to bring change and improvement for better outcomes for patients.

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ANNEX

10.1 Annex I. Information sheet (English version)

My name is _____ I am currently doing my residency in Emergency and Critical Care Medicine at Tikur Ambessa Specialized Hospital. I am researching the prevalence of physical restraint and associated factors in the ICU setup of three hospitals, in Addis Ababa, Ethiopia 2024. This study aims to assess the prevalence of physical restraint use in the ICU. It would be the first study to be done regarding the prevalence and associated factors of physical restraint in Ethiopia. Dear participant, your participation in this study is voluntary and no compensation was given for the participation. There was a face-to-face interview for no more than 10 minutes to answer some of the questions in the questionnaire. The rest of the study is completed by a trained nurse. There was a daily assessment based on an observational survey tool for the duration of stay in the ICU. The data obtained from this questionnaire is strictly confidential. During the interview period, if you feel uncomfortable, you can interrupt to ask for explanations. If you still aren't comfortable continuing you can withdraw participation at any time without affecting your service utilization.

10.2 Annex II. Consent form (English version)

I have obtained adequate information about the process and the objective of the study and I have been told how the data collection is proceeding. I am assured that my response was confidential. It has also been explained to me that I have the right to stop participation at any time during the course without my service utilization being compromised. I agree to participate in the study and I hereby approve my agreement with my signature.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

Thank you for your participation and the information provided. For further information or questions, you can contact me.

Investigator : Dr. Rediet Alemayehu

Phone -+251925314740

Email: redualem11@gmail.com

10.3 Annex III. questionnaire (English version)

Part one: Socio-demographic characteristics of the patients

	questions	Response
1	Age	In years
2	Sex	Female Male
3	Residency	Urban Rural
4	Educational background	Unable to read and write able to read and write Primary school secondary school A higher form of education
5	Marital status	Married single widowed divorced
6	Occupation	Government employee Self-employee Farmer NGO merchant other

The next 5 sections are completed by the data collector.

Part two: Patients and Behavioral characteristics

	Question	Response
7	CAM ICU score of the patient (0-7) fill only one number	
8	RAAS score of the patient(-5 - +4)fill only one number	
9	GCS level of patients(3-15)fill only one number	
10	Admission diagnosis	Medical surgical

Part three: Treatment characteristics (it is the character of the treatment that is applied to the patients)

	Question	Response
11	Mechanical ventilation	1. Yes 2. No
12	Noninvasive positive pressure ventilation	1. Yes 2. No
13	Noninvasive oxygen therapy	1. Yes 2. No
14	Nasogastric tube insitu	1. Yes 2. No
15	Urinary catheter in situ	1. Yes 2. No
16	Central venous line in situ	1. Yes

		2. No
17	Peripheral venous line in situ	1. Yes 2. No
18	Arterial line in situ	1. Yes 2. No
19	Drainage tube in situ	1. Yes 2. No
20	If yes to Question number 13: please specify	1. Yes 2. No
21	Use of sedatives and psychoactive drugs	1. Yes 2. No

Part four: hospital and unit character (the character of the unit at which the patient is admitted and treated)

	Questions	Response
22	Where is the patient admitted?	1. Surgical ICU 2. Medical ICU
23	The nurse-patient ratio	
24	How many beds are in the ICU?	
25	How many ventilators are there in the ICU?	

Part Five: The character of the nurse that is attending to the care of the patient

	Questions	Response
26	Age	In years
27	Sex	1. Female 2. Male
28	Marital status	Married single widowed divorced
29	Years of experience working in the ICU	
30	Educational background	Diploma BSC MSC other specify

Part six: physical restraint use

	Questions	Response
31	Is the patient physically restrained?	1. Yes 2. No

10.4 Annex IV. information sheet (Amharic version)

ስሜ ዶክተር ፈድኤት አለማየሁ ይባላል።የአዲስ አበባ ዩኒቨርሲቲ የጤና ሳይንስ ኮሌጅ ጥቁር አንበሳ ሆስፒታል የድንገተኛ እና ፅኑ ህሙማን ዲፓርትመንት የስፔሻላይዜሽን ተማሪ ነኝ። በአሁኑ ሰአት በፅኑ ህሙማን ክፍል ውስጥ ህሙማን ተኝተው በሚታከሙበት ጊዜ የአካላዊ እገዳ አጠቃቀም መስፋፋት እና ተያያዥ ምክንያቶች ላይ ምርምር እያደረኩ ነው። በኢትዮጵያ ውስጥ የሚታየውን የአካላዊ እገዳ አጠቃቀም መስፋፋት እና ተያያዥ ምክንያቶች ላይ በተመለከተ የተደረገ የመጀመሪያው ጥናት ነው። ውድ ተሳታፊ፣ በዚህ ጥናት ውስጥ ያለዎት ተሳትፎ በፈቃደኝነት ነው ።ስተሳትፎ ምንም ካሳ አልተሰጠም። በመጠይቁ ውስጥ ያሉትን አንዳንድ ጥያቄዎች ለመፈፀም ከ10 ደቂቃ ያልበለጠ የፊት ለፊት ቃለ መጠይቅ ይደረጋል። የተቀረው ጥናት በሰለጠነ ነርስ ይጠናቀቃል። በፅኑ ህሙማን ክፍል ውስጥ በሚደረግ ቆይታ በተመልካች የዳሰሳ ጥናት መሳሪያ ላይ የተመሰረተ ግምገማ ይደረጋል። ከዚህ መጠይቅ የተገኘው መረጃ በጥብቅ ሚስጥራዊ ነው። በቃለ መጠይቁ ወቅት ምቾት የማይሰማዎት ከሆነ ማብራሪያ ለመጠየቅ ማቋረጥ ይችላሉ። ለሁንም ለመቀጠል ካልተመቸዎት የአገልግሎት አጠቃቀምዎን ሳይነኩ ተሳትፎዎን በማንኛውም ጊዜ ማቆም ይችላሉ።

10.5 Annex V. consent form (Amharic version)

ስለ ሂደቱ እና የጥናት ስላማ በቂ መረጃ ስግኝቻለሁ እና የመረጃ ስሰባሰብ ሂደት እንዲት እንደሚካሄድ ተነግሮኛል። ምሳሼ ሚስጥራዊ እንደሆነ እርግጠኛ ነኝ። የስገልግሎት ስጠቃቀሜ ሳይጎዳ በማንኛውም ጊዜ ተሳትፌን የማቆም መብት እንዳለኝም ተብራርቶልኛል። በጥናቱ ስመሳተፍ ተስማምቼያለሁ እናም በዚህ ፈርማ ያለኝን ስምምነት አጽድቄያለሁ።

የተሳታፊው ፈርማ _____ ቀን _____

የመርማሪው ፈርማ _____ ቀን _____

ስተሳትፎ እና መረጃ ስለሰጡን እናመሰግናለን። ስበለጠ መረጃ ወይም ጥያቄ ከዚህ በታች ባለው አድራሻ ልታገኙኝ ትችላላችሁ።

ዋና መርማሪ ዶክተር ረድኤት ስለማየሁ
ስልክ ቁጥር 0925314740
ኢሜይል redualem11@gmail.com

10.6 Annex VI. questioner (Amharic version)

ክፍል ሰንድ: የታካሚዎች ማህበራዊ እና ስነ-ሕዝብ ባህሪያት

	ጥያቄዎች	ምላሽ
1	ፅድሜ	በዓመት
2	ጸታ	ሴት ወንድ
3	የመኖሪያ ቦታ	ከተማ ገጠር
4	ትምህርታዊ ጸራ	ማንበብና መጻፍ አለመቻል ማንበብና መጻፍ ያችላል የመጀመሪያ ደረጃ ትምህርት ሁለተኛ ደረጃ ትምህርት ከፍተኛ የትምህርት ዓይነት
5	የጋብቻ ሁኔታ	ያገባ/ች ያላገባ/ች ባል/ሚስት የሞተበት/ባት የተፋታ
6	የስራ መደቡ	የመንግስት ሰራተኛ የግል ሰራተኛ ገበሬ መንግሥታዊ ያልሆነ ነጋዴ ሌላ

የሚቀጥሉት 5 ክፍሎች የተጠናቀቁት በመረጃ ሰብሳቢው ነው::