Research Article

Design, Develop, and Validate Limb Restrainer Device on Physical and Physiological Parameters among Patients Admitted in Intensive Care Units

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Abstract

Introduction: Physical restraint is a common way of restricting the movement of the patients in majority of the hospitals in India. However, it is not yet proved that the use of physical restraints can reduce the complications such as extubations.

Aim: Majority of the hospitals uses restraints made with gauze and bandages as physical restraints. Hence, the researcher finds a need to design and develop a limb restrainer device which is reusable. A quantitative approach with Delphi technique was adopted to design limb restrainer device.

Objectives: The objectives of the study were to assess the various types of restrainer used in intensive care unit (ICU), to design limb restrainer device using Delphi technique, and to assess the physical and physiological parameters before and after implementation of the limb restrainer device.

Materials and Methods: The opinions to develop the limb restrainer device were obtained from 12 Delphi experts in three rounds. The researcher developed the limb restrainer device and validated the device using it on patients agreement of the experts increased in round 3. Time series design was adopted to find the effect of limb restrainer admitted in ICUs.

Results: The results revealed that majority (75%) of the hospital does not have an effective physical restraint.

Conclusions: The limb restrainer device developed by the researcher does not have any effect on physical and physiological parameters of the patients and it is safe to use among patients admitted in ICUs. It can reduce the complications associated with the use of improper restraints made within the hospital and health-care providers.

Keywords: Delphi technique, design, develop, intensive care unit, limb restrainer device, physical and physiological parameters, staff nurse, validate

Introduction

Intensive care units (ICUs) are the specialized areas which provide critical treatments to various patients who are seriously ill and needs continuous observation and management. It consists of a well-organized team of specialized doctors, experienced and skilled nurses, intensivist, technician's, etc. The patients who are admitted in these units are those who require special care which cannot be provided in the general wards including cardiac patients, neurologically impaired patients, and pre-operative and post-operative patients. Majority of the patients admitted in the ICUs will be confused or disoriented and need assistance in moving and doing the self-care activities. It is the responsibility of the health professionals, especially the nurse who is taking care of them to make sure the safety of the patient.[1]

A cross-sectional investigation done among critical care nurses in Japan revealed that the use of physical restraints is also

Access this article online
Website: http://innovationalpublishers.com/Journal/ijnmi
ISSN No: 2656-4656
DOI: 10.31690/ijnmi.2021.v06i03.002

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associated with mechanically ventilated patients. The reasons for using this are to avoid self-extubation by the patient.[2]

A descriptive study conducted to investigate various guidelines of using bodily restraints in ICUs of Korea. The results revealed that 90% of the decision to restraint the patients were made by the staff nurses. The main reason for applying restraint was to prevent the patient from removing therapeutic lines and tubes including nasogastric tube.[3]

A study was done to pick up the number of patients who are agitated, risk factors, and reasons of agitation in a medical and surgical ICUs. They observed 182 participants of which 52% of them were shown agitation.[4] The researchers found that agitation is usually seen among patients admitted in ICUs which are commonly associated with increased stay, hospital-acquired infections, and extubations which are not planned. The study also suggested the need of ways to decrease complications associated with agitated behavior among clients.[1]

Materials and Methods

The present study aimed at design, develop and validate a limb restrainer device. The research approach used is mixed method. Delphi technique was adopted to assess the effect of restrainer device on physical and physiological factors of patients admitted in ICUs.

Criteria for selection of Delphi experts

- Registered nurses and nurse practitioners who have minimum 2 years of experience in critical care units and have completed either masters in nursing or Ph.D. in nursing.
- Those who are willing to participate in three rounds.

Independent variables

In the present study, independent variable is limb restrainer device for patients admitted in ICU.

Dependent variables

In the present study, physical and physiological parameters among patients admitted in ICU.

Setting of the study

The setting for the study was various Intensive Care Units of a selected teaching hospital in Navi Mumbai.

Population

In this study, population is all patients admitted in ICUs.

Target population

In this study, target population is patients admitted in ICUs in various of hospitals.

Accessible population

In the present study, accessible population is all patients who are admitted in ICUs of selected teaching hospital.

Sampling criteria

Inclusion criteria

The following criteria were included in the study:

- Patients who are on physical restraints.
- Present at the time of data collection.
- Patients who are admitted in ICU.
- Patients above 18 years of age.

Exclusion criteria

Those who are not cooperative were excluded from the study.

Data collection technique

A modified Delphi study consisting of three rounds was performed in the first step; an extensive review of the literature was conducted.

Expert selection was conducted through a convenient sampling. Twelve experts were selected for the study.

In the first round, the open-ended questionnaire was distributed to the 12 experts and it is collected back.

After collecting the questionnaire, ranking of the opinions from the experts was done and a draft of the restrainer device is made according to the opinions in the first round.

In the second round, a rating scale (5-point Likert scale) was given to the experts along with the draft of the device and it is collected back and the second round of open-ended questionnaire was distributed.

After collecting the second round of open-ended questionnaire, ranking of the opinions from the experts was done.

According to the opinions in the second round, required modifications were made in the device.

In the third round, the researcher approached the 12 Delphi experts with the Likert scale and the device for the purpose of validating the device.

After validating the design by the Delphi experts, the researcher developed the limb restrainer device.

The effect of the limb restrainer device was checked by applying the device on the upper limbs of the patients admitted in ICUs of selected hospital and those who fulfill the criteria.

A checklist was used to assess the effect of limb restrainer device on the physical and physiological parameters of the restrained limb before and after implementation. The effect of the device was checked by the researcher every 2 hourly up to 24 h.

Five-point Likert scale was used to obtain feedback from staff nurses regarding various aspects of the limb restrainer device.

Development of instrument

The tools were prepared on the basis of the objectives of the study. The following steps were adopted in the development of the instruments.

- Review of literature provided adequate content for the tool preparation
- Personnel experience, consultation with nursing experts, nurse practitioners, doctors, and discussion with the peer group

- Development of a blueprint
- Construction of demographic pro forma, open-ended questionnaire to obtain the opinion of Delphi experts, Likert scale to obtain level of agreement, observation checklist to assess various types of restraints used in various hospitals, checklist to assess the effect of the limb restrainer device on physical and physiological factors, and Likert scale for obtaining feedback from the staff nurses
- The questionnaire was sent to 11 experts from medicine, nursing, etc., for content validity of tool and suggestions were taken and necessary corrections were made
- Pre-testing the instrument.

Reliability of the tool was done by rater inter rater method and the toll was found to be reliable.

Description of the instrument

Tool 1 – To find out the various types of physical restraints used in ICUs of various hospitals

An observation checklist was used to find out the various types of restraints used in the ICUs of various hospitals. The tool was prepared with six items included in it that is availability of restraint device in the hospitals, documented policy for restraining the patient, obtaining informed consent from the concerned person, restraint device used for the patients which are dispensed in the hospital pharmacy, checklist to assess the patients on physical restraints, and the type of restraint used in the hospital.

Tool 2: To obtain opinions of Delphi experts in two rounds

The tool was divided into two sections.

- Section A: The demographic details of the Delphi experts. The four items included in the section were name, designation, qualification, and years of experience of the expert
- Section B: The open-ended questionnaire for the Delphi experts. The items included in the section were design, material, cost, and size advantages and disadvantages.

Tool 3: To find out the level of agreement of the Delphi experts in two rounds

The level of agreement given in the tool was (1) strongly agree, (2) agree, (3) neutral, (4) disagree, and (5) strongly disagree. There were a total of eight items in the tool.

Tool 4: To assess the effect of limb restrainer device on physical and physiological parameters before and after implementation of the device on the restrained limb

The tool consists of two sections.

- Section A: The demographic characteristics of the sample. There were a total of eight items which were gender, age in years, diagnosis, type of ICU, ICU day, hospital day, reason for restraint, and the site of restraint
- Section B: The parameters included in the checklist were temperature, skin peeling, blister, pressure sore, discolouration,SPO_2, capillary refill, and swelling, the parameters were assessed before and every 2 hourly up to 24 h after applying the restrainer device.

Tool 5: To obtain feedback from the staff nurses regarding various aspects of the limb restrainer device

The options included in the tool were (1) strongly agree, (2) agree, (3) neutral, (4) disagree, and (5) strongly disagree. There were a total of 10 items in the tool.

Scoring and interpretation of the instrument

- Tool 1

The scoring for observation checklist was done by calculating the frequency and percentage for presence and absence of observed practices. Presence of practice carried 1 mark and absence of practice carried 0 marks.

- Tool 2

The scoring of the demographic profile of the Delphi experts was done by calculating the frequency and percentage.

Frequency and percentage response were used to compare the level of agreement and mean and standard deviation for importance ranking of each limb restrainer device item in round 1 and round 2.

- Tool 3

The scoring of the 5-point Likert scale was done by calculating the frequency and percentage of consensus of top rated opinions given by the Delphi experts to finalize the design of limb restrainer device.

- Tool 4

The scoring of the demographic profile of the sample was done by calculating the frequency and percentage.

Wilcoxon signed-rank correlation was used to analyze the effect of limb restrainer device on physical and physiological parameters before and after implementation of the device on the restrained limb

- Tool 5

The scoring of the 5-point Likert scale was done by calculating the frequency and percentage to obtain feedback from the staff nurses on various aspects of the limb restrainer device.

Content validity of the tool

The content validity of the tool was done from 12 experts.

Reliability of the tool

The reliability of the observation checklist was done by rater-inter-rater method and the reliability was 0.9 which was above 0.75 and the tool was found reliable.

Pretesting of the tool

The pretesting of the tool was done to make sure whether the tool is feasible and clear.

Ethical consideration

- Ethical approval was granted from the Institutional Ethical Review Committee of MGM Institute of Health Sciences, Kamothe
- Permission was granted from the medical superintendent and nursing superintendent
- Explanation of the process to the sample
- The matter was read before the subject and their signature was taken on the consent form and confidentiality and anonymity were assured before the initiation of the study.

Pilot study

Pilot study was done in MGM Hospital, Kamothe, on five samples. The samples were selected according to the inclusion criteria and using purposive convenient sampling technique. The samples were observed for 24 h after implementation of the device.

Data collection process

The data collection process involves the precise, systematic gathering of information relevant to the research purpose, questions, or hypothesis of a study.

The various types of restraints used in the hospitals were assessed using an observation checklist.

- Twelve Delphi experts were selected and each expert was met in person and explained regarding the study and obtained a consent from them.
- Distribution and collection of open-ended questionnaire and 5-point Likert scale to the 12 experts.
- Ranking of the opinion obtained from the experts in two rounds.
- Finalizing the design of the limb restrainer.
- Developing the limb restrainer device considering the opinions from the experts using reusable material.
- Implementing the device among patients admitted in various ICUs of selected hospital and observing the physical and physiological parameters every 2 hourly.

Analysis

Analysis of the data was done by using descriptive and inferential statistics.

- Section 1: Distribution of demographic variables of Samples [Tables 1-3]
- Section 2: Distribution of Demographic variables of samples [Tables 4-6]

Wilcoxon signed rank co-relation was used to identify the change in physical and physiologocal factors of patients before and after applying restraint. There was no change in the physical and physiological parameters before and after applying the restraint.

Table 1: Distribution of designation of Delphi experts *n*=12

Designation of Delphi experts	Percentage
Nursing superintendent	17
Assistant nursing superintendent	8
Nurse educator	8
Senior staff nurses	8
Infection control nurse	17
Nurse practitioner	42

Table 2: Qualification of Delphi experts, *n*=12

Qualification of Delphi experts	Percentage
BSC nursing	8
MSC nursing	84
Ph.D. nursing	8

Table 3: Experience of Delphi experts, *n*=12

Experience of Delphi experts	Percentage
1–5 years	33
5–10 years	42
10–15 years	25

Table 4: Distribution of gender of the sample, *n*=12

Gender	Percentage
Male	93
Female	7

Table 5: Distribution of age of sample, *n*=50

Age	Percentage
21–30 years	10
31–40 years	14
41–50 years	16
51–60 years	32
Above 61	28

Table 6: Distribution of diagnosis of sample, *n*=50

Diagnosis	Percentage
Medical	78
Surgical	12

Discussion

The findings of the study revealed that out of four hospitals examined by the researcher for the present study, majority of the hospitals does not have a proper physical restraint available to restrict the movement of the patients. They make use of gauze bandages and other materials such as gamgee pads and cloths to prepare a physical restraint whenever needed. The disadvantage of these materials is it gets wet easily causing irritation to the skin and as the surface is hard; it causes various complications to the patients. The reason for non-availability of a proper physical restraint is because all the commercially available restraint devices are disposable after single use and it is costly. Hence, all the patients may not be able to afford the same. None of the hospitals has the policy of dispensing the restraints from the hospital pharmacy. One among the four hospitals had a physical restrainer device available which was a private hospital. There are various studies done regarding the same topic. The reason for restraining the patients in the ICUs is to avoid removal of

therapeutic tubes and lines, prevent harm to self and others, etc. However, it is not yet proved that applying restraints can prevent the removal of tubes and other complications. There are studies which suggest that self-extubations happened when the patient was already on restraints. Proper monitoring is necessary for the patients who are already on restraints to prevent complications such as skin peeling and obstruction of blood flow. Informed consent was taken before application of restraints in all the four hospitals observed by the researcher. Only one hospital had a checklist for monitoring the physical and physiological parameters of the restrained limb.

A similar study done in Punjab in 2015 also reveals that the majority of the health-care facilities use physical restraint made with gauze to restraint the patients admitted in ICUs due to non-availability of an affordable physical restraint in the hospital. The study also reveals that the relatives refuse to buy costly commercially available physical restraints.[5]

The researcher also found that all four the hospitals obtain an informed consent form the concerned person before restraining the patient. A study done by Ankara University also found that the nurses obtain consent from the relatives before restraining the patient in ICUs. They make sure that the relatives are well aware about the reason and aftereffects of restraints.[6]

The present study also revealed that out of four hospitals, all the hospitals have a documented policy for restraining the patient. Alike study in South Africa also found out that majority of the hospitals has a documented policy for restraining the patient.[7]

Conclusions

Limb restrainer device developed by the researcher is found to be safe to use among patients admitted in ICUs as it does not have any effect on the selected physical and physiological parameters.

Acknowledgment

I would like to express my gratitude to MGM Institute of Health Sciences, Ethical Committee for permitting me to conduct this study. I would like to express my deep sense of gratitude to Dr. Prabha. K. Dasila (Director cum Professor), Mrs. Susan Jacob, Professor (Research Guide), and all other teachers, library in charge for their continuous support, guidance, inspiration, motivation, and cooperation for the completion of this study. I would like to express my thanks to my parents Mr. Chandrahasan. B and Mrs. Anila Chandrahasan, my sister Ms. Athira Chandran, and my friend Mr. Nithin. N for their support and encouragement.

Funding

No funding.

Conflicts of Interest

Authors declare no conflicts of interest in the study.

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How to cite this article: Chandran A, Jacob S. Design, Develop, and Validate Limb Restrainer Device on Physical and Physiological Parameters among Patients Admitted in Intensive Care Units. Int J Nurs Med Invest. 2021;6(3):37-41