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A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF PTP ON KNOWLEDGE REGARDING PHARMACOVIGILANCE OF STEROID THERAPY AMONG GNM AND BSC NURSING STUDENTS IN SELECTED NURSING COLLEGES AT BIJAPUR.

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Abstract: **BACKGROUND OF THE STUDY:** Pharmacovigilance has been defined by the WHO as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems'. The objectives of pharmacovigilance includes, preventing harm from adverse reaction in humans arising from the use of authorized medicinal products within or outside the terms of marketing authorization or from occupational exposure; and promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public. Pharmacovigilance is therefore an activity contributing to the protection of patients and public health. **AIM:** The aims of Pharmacovigilance are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines. **METHODOLOGY:** Evaluative research approach was used to assess and compare the knowledge regarding pharmacovigilance of steroid therapy. Non probability purposive sampling technique was adopted to select the sample, which is 60 students at BLDEA's Shri B M Patil institute of nursing Sciences, Bijapur. The tool used is structured knowledge questionnaire to collect the data. **RESULT:** The overall knowledge of GNM students depicts that majority of the respondents 19 (63.33%) had good level of knowledge regarding pharmacovigilance of steroid therapy whereas 11 (36.66%) of respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy. The overall knowledge of BSC students depicts that majority of the respondents 19 (63.33%) had good level of knowledge regarding pharmacovigilance of steroid therapy whereas 11 (36.66%) of respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy. The unpaired t test value showing the level of knowledge of pharmacovigilance of steroid therapy for GNM and BSC nursing students. Observing the level of knowledge of pharmacovigilance of steroid therapy for GNM and BSC nursing students, it was found that 't' value is 1.16 and indicating that there is no significant difference between in the level of knowledge between GNM and BSC students. The association of post test level of knowledge with age, sex and religion and indicates that there is no significant difference association between demographic variables and post test level of knowledge of GNM students. The association of post test level of knowledge with age, sex and religion and indicates that there is no significant difference association between demographic variables and post test level of knowledge of BSC students. **CONCLUSION:** After analyzing the gathered information, the researcher got to know the facts about knowledge of pharmacovigilance of steroid therapy among GNM and BSC students. Based on the outcome of the study, following suggestions are made to the various fields of nursing such as nursing practice, nursing education, nursing administration and nursing research.

Keywords: Pharmacovigilance, Nursing College



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INTRODUCTION

Pharmacovigilance has been defined by the WHO as ‘the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems’.¹ The aims of Pharmacovigilance are to enhance patient care and patient safety in relation to the use of medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.²

The objectives of pharmacovigilance includes, preventing harm from adverse reaction in humans arising from the use of authorized medicinal products within or outside the terms of marketing authorization or from occupational exposure; and promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public. Pharmacovigilance is therefore an activity contributing to the protection of patients and public health.³

Pharmacovigilance a process involving detection, assessment, understanding, and prevention of adverse events ensures that medicines are used in the full knowledge of risks; patients, health professionals, pharmaceutical companies and medicines regulators all contribute to pharmacovigilance activity. The purpose of pharmacovigilance is to minimize, in practice, the potential for harm that is associated with all active medicines.⁴

The activities of pharmacovigilance includes; collecting and managing data on the safety of medicines, looking at the data to detect signals, evaluating the data and making decisions with regard to safety issues, acting to protect public health, communicating with and informing stakeholders and the public and Audit, both of the outcomes of action taken and of the key processes involved. The members directly involved in pharmacovigilance include, Patients who are the users of medicines, Doctors, pharmacists, nurses and all other health care professionals working with medicines, Regulatory authorities, including the European Medicines Agency(EMA) and those in the Member States responsible for monitoring the safety of medicines.⁵

METHODOLOGY AND MATERIAL:

This chapter deals with the description of the methods and different steps used for collecting and organizing data. It includes research design, research approach, setting, and sample, sampling technique, development and description of tool, pilot study, data collection and plan for data analysis.

OBJECTIVES

1. To assess the pretest knowledge scores of GNM and BSC nursing students on pharmacovigilence of steroid therapy.
2. To assess the post test knowledge scores of GNM and BSC nursing students on pharmacovigilence of steroid therapy.
3. To compare the pre-test knowledge scores on pharmacovigilence of steroid therapy between GNM and BSC nursing students.
4. To determine the association between knowledge score of selected demographic variables of GNM and BSC nursing students.

RESEARCH APPROACH

In the present study evaluative research approach was used to assess and compare the knowledge regarding pharmacovigilence of steroid therapy among GNM and BSc nursing students.

RESEARCH DESIGN

The research design selected for the study was a Pre-test Post test design was best suited to assess the knowledge of students regarding pharmacovigilence of steroid therapy.

SETTING OF THE STUDY:

The present study was conducted in selected nursing college at Bijapur.

VARIABLES:

Study variable refers: Knowledge

Extraneous variable refers to: Demographic variables viz, age, gender, religion and educational status.

POPULATION:

The populations of the present study consist of students between age group of 17 to 24.

SAMPLE

The sample of the present study includes the students studying in GNM and BSc nursing in selected nursing college at Bijapur.

SAMPLE SIZE

The sample size of the present study comprises of 60 students.

SAMPLING TECHNIQUE

In the present study non probability purposive sampling technique was adopted to select the sample.

SAMPLING CRITERIA

Inclusion criteria

1. Students studying in 3rd year GNM nursing.
2. Students studying in 3rd year BSc nursing.
3. Both male and female nursing students are included in this.
4. Students between the age group of 17-24 years.

Exclusion criteria

1. The nursing students who are not willing to participate in the study.
2. Few nursing students are absent during the time of the study.

DESCRIPTION OF THE TOOL USED IN THE STUDY

The tool exclusively constructed by the investigator to assess the knowledge regarding pharmacovigilance of steroid therapy.

Section A: Socio demographic data of the students

Section B: Structured knowledge questionnaire to assess the levels of knowledge among GNM and BSC students.

SECTION -A: CONSISTS OF SOCIO- DEMOGRAPHIC DATA OF THE STUDENTS

In socio-demographic data out of 06 items all items (1, 2, 3, 4, 5, 6) were relevant and retained and none of the items were deleted. The final draft had 04 items related to demographic variables such as age, gender, religion, education status, and 02 questions were related to previous knowledge and source of knowledge. Scoring key was prepared by coding the demographic variables.

SECTION-B: STRUCTURED QUESTIONNAIRE TO ASSESS THE LEVELS OF KNOWLEDGE AMONG STUDENTS

The structured knowledge questionnaire includes 30 MCQS (Multiple-choice questions). Each MCQS carries 4 options out of them one correct answers and others are distracters & it has organized under following headings.

This tool has been constructed based on the following headings.

1. Knowledge about general pharmacology (1,2,3,4,5,6,7,8)
2. Knowledge about Steroid therapy (9,10,11,12,13,14,15,16,17,18,19,20,30)
3. Importance of pharmacovigilance (21,22,23)
4. ADR monitoring (24,25,26,27,28,29)

SCORING PATTERN

- Each correct answer score – 1 mark
- Each wrong answer score - 0 mark
- Total maximum scores - 30 marks
- Minimum scores – 0 mark

INFERENCES WILL BE DRAWN AS BELOW:

1. Poor: 0-7 marks
2. Average: 8-15 marks
3. Good: 15-21 marks
4. Excellent: 22-30 marks

CONTENT VALIDITY: The prepared tool along with the objectives of the study, and blue print were submitted to all experts for content validity. Four experts were from the field of Medical-Surgical Nursing, two is from Pediatric nursing, and two is from Community health nursing in order to obtain content validity.

RELIABILITY: The reliability of the tools was computed by using **split half technique** employing **Spearman Brown's Prophecy formula**. The reliability value of structured knowledge questionnaire is 0.91 and the tool is found to be reliable.

PILOT STUDY:

The investigator after obtaining formal permission from Principal of BLDEA's Shri B M Patil institute of nursing sciences, Bijapur and conducted pilot study among 6 subjects selected by Non-probability purposive sampling technique. The investigator given self-introduction explained the purpose of the study and the written consent was obtained from the subjects. The data is collected from the sample by using structured tools descriptive and inferential statistics was used for analysis of data.

DATA COLLECTION PROCEDURE:

The investigator after obtaining formal permission from Principal of BLDEA's Shri B M Patil institute of Nursing sciences, Bijapur to conduct the data collection of the main study from 20-3-2014 to 26-04-2014 among 60 subjects who were selected by non-probability sampling technique.

The investigator given self-introduction and explained the purpose of the study and the written consent was obtained from the subjects. Tools are administered to the subjects with adequate information and collected the data. The data was collected within the stipulated time.

PLAN FOR DATA ANALYSIS:

Both descriptive and inferential statistics were used for analysis of data. Descriptive statistics was used to analyze the demographic variables of the students in terms of frequency and percentage. Frequency percentage, mean and standard deviation was used to assess the knowledge. Chi-square was used to associate the knowledge score with demographic variables. Unpaired t test was used to assess the significance difference between GNM and BSC students.

DATA ANALYSIS AND INTERPRETATION OF RESULT

"There is nothing more exhilarating than to be shot at without result"

- Winston Churchill

This chapter deals with the analysis and interpretation of data obtained from 60 subjects in order to assess the knowledge regarding pharmacovigilance of steroid therapy among GNM and BSC students. Descriptive and inferential statistics were used to analyze the collected data. The data findings have been organized and finalized according to plan for data analysis and presented under the following

Section A: Frequency and percentage distribution of demographic variables of GNM and BSc students.

Section B: Frequency and percentage distribution of pretest knowledge scores regarding pharmacovigilance of steroid therapy among GNM students.

Section C: Frequency and percentage distribution of pretest knowledge scores regarding pharmacovigilance of steroid therapy among BSC students.

Section D: Frequency and percentage distribution of post test knowledge scores regarding pharmacovigilance of steroid therapy among GNM students.

Section E: Frequency and percentage distribution of post test knowledge scores regarding pharmacovigilance of steroid therapy among BSC students.

Section F: To compare the pre-test knowledge scores on pharmacovigilance of steroid therapy between GNM and BSC nursing students.

Section G: Association of post test level of knowledge scores of GNM students with demographic variables.

Section H: Association of post test level of knowledge scores of BSC students with demographic variables.

Table: 1: Frequency and percentage distribution of demographic variables of GNM and BSc students

N: 60

SI NO	Sample characteristics	GNM Nursing		BSC Nursing	
		Frequency	Percentage	Frequency	Percentage
1	Age				
	14-20 years	05	16.66	13	43.33
	21-22	17	56.66	17	56.66
	23-24	07	23.33	---	--
	24 & above	01	3.33	---	--
2	Sex				
	Male	16	53.33	4	13.33
	Female	14	46.66	26	86.66
3	Religion				
	Hindu	18	60	16	53.33
	Muslim	01	3.33	--	--
	Christian	11	36.66	14	46.66
	Others	--	--	--	--

4	Previous knowledge regarding pharmacovigilance				
	Adequate	02	6.66	--	6.66
	Inadequate	01	3.33	02	93.33
	No knowledge	27	90	28	

Table 1. Represents the frequency distribution of study subjects by age group of the students. Among 30 samples from GNM students, 5(16.66%) were from 14-20 years of age group, 17(56.66%) were from 21-22 years of age group, 7(23.33%) were from 23-24 years of age group and 1(3.33%) was from 24 and above age group. Among 30 samples from BSc, 13(43.33%) were from 14-20 years of age group and 17(56.66%) were from 21-22 years of age group.

Among 30 samples from GNM, 16(53.33%) were males and 14(46.66%) were females. Among 30 samples from BSc, 4(13.33%) were males and 26(86.66%) were females students.

Among 30 samples from GNM, majority were Hindu that is 18(60%), 1(3.33%) was Muslim and 11(36.66%) were Christian. Among 30 samples from BSc, 16(53.33%) were Hindu and 14(46.66%) were Christian.

Among 30 samples from GNM, 2(6.66%) were having adequate knowledge regarding pharmacovigilance previously, 1(3.33%) was having inadequate knowledge and 27(90%) were having no knowledge regarding pharmacovigilance. Among 30 samples from BSc, 2(6.66%) were having inadequate knowledge regarding pharmacovigilance and 28(93.33%) were having no knowledge regarding pharmacovigilance.

Table: 2: Frequency and percentage distribution of pretest knowledge scores regarding pharmacovigilance of steroid therapy among GNM students.

N: 30

Grades	Scores	Frequency	Percentage
Poor	0-7	00	00
Average	8-15	17	56.66%
Good	15-21	12	40%
Excellent	22-30	01	3.33%

The table 2 depicts that majority of the respondents 17 (56.66%) had average knowledge regarding pharmacovigilance of steroid therapy whereas 12 (40%) of respondents had good level of knowledge and 01 (3.33%) of the respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy.

Graph 1: Distribution of pretest knowledge scores regarding Pharmacovigilance of steroid therapy among GNM students.

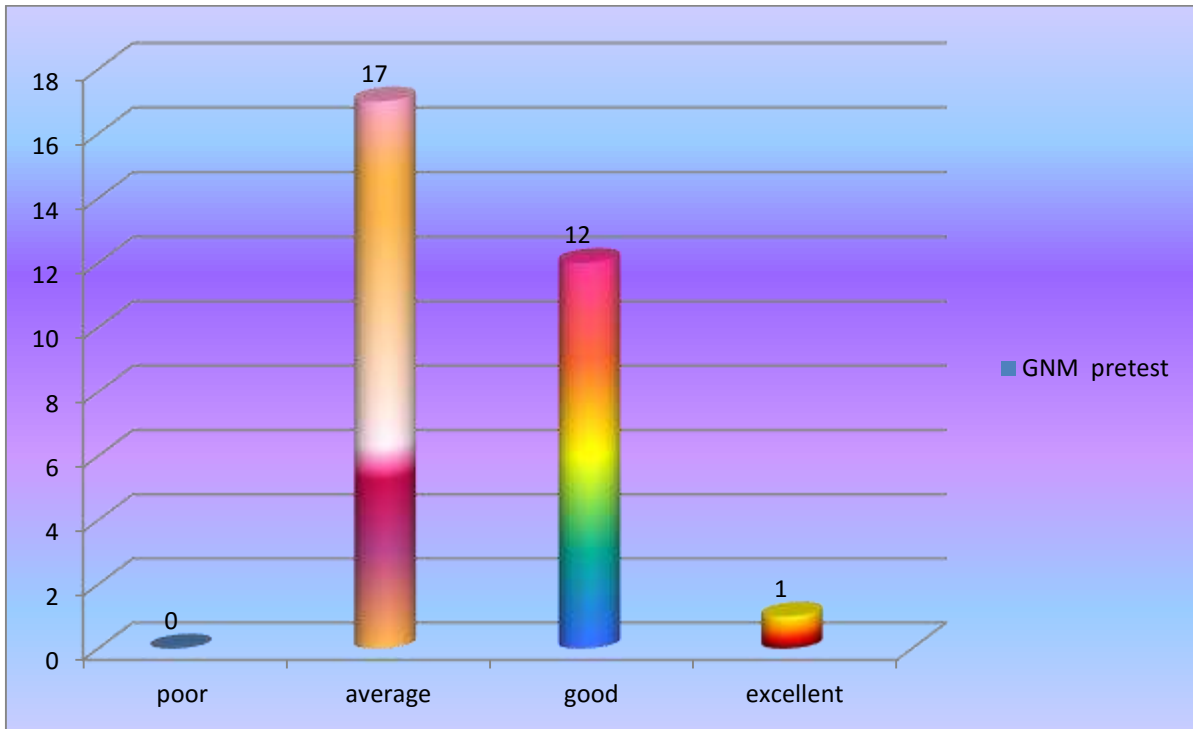


Table: 3: Frequency and percentage distribution of pretest knowledge scores regarding pharmacovigilance of steroid therapy among BSC students.

N: 30

Grades	Scores	Frequency	Percentage
Poor	0-7	01	3.33%
Average	8-14	16	53.33%
Good	15-21	13	43.33%
Excellent	22-30	00	00%

The table-3 depicts that majority of the respondents 16 (53.33%) had average knowledge regarding pharmacovigilence of steroid therapy whereas 13 (43.33%) of respondents had good level of knowledge and 01 (3.33%) of the respondents had poor level of knowledge regarding pharmacovigilence of steroid therapy.

Graph 2: distribution of pretest knowledge scores regarding pharmacovigilence of steroid therapy among BSc students.

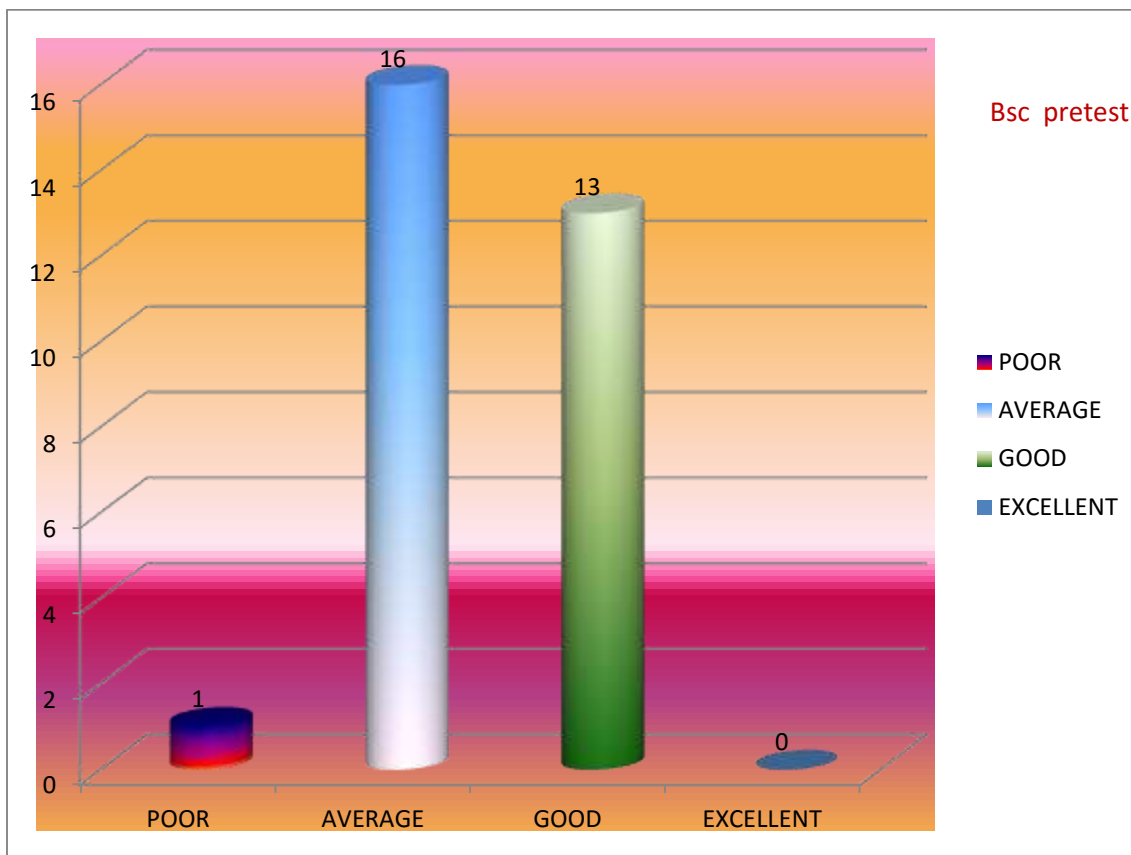


Table: 4: Frequency and percentage distribution of post test knowledge scores regarding pharmacovigilence of steroid therapy among GNM students.

Grades	Scores	Frequency	Percentage
Poor	0-7	00	00
Average	8-14	00	00
Good	15-21	19	63.33%
Excellent	22-30	11	36.66%

The table-4 depicts that majority of the respondents 19 (63.33%) had good level of knowledge regarding pharmacovigilance of steroid therapy whereas 11 (36.66%) of respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy.

Graph 3: Distribution of post test knowledge scores regarding pharmacovigilance of steroid therapy among GNM students.

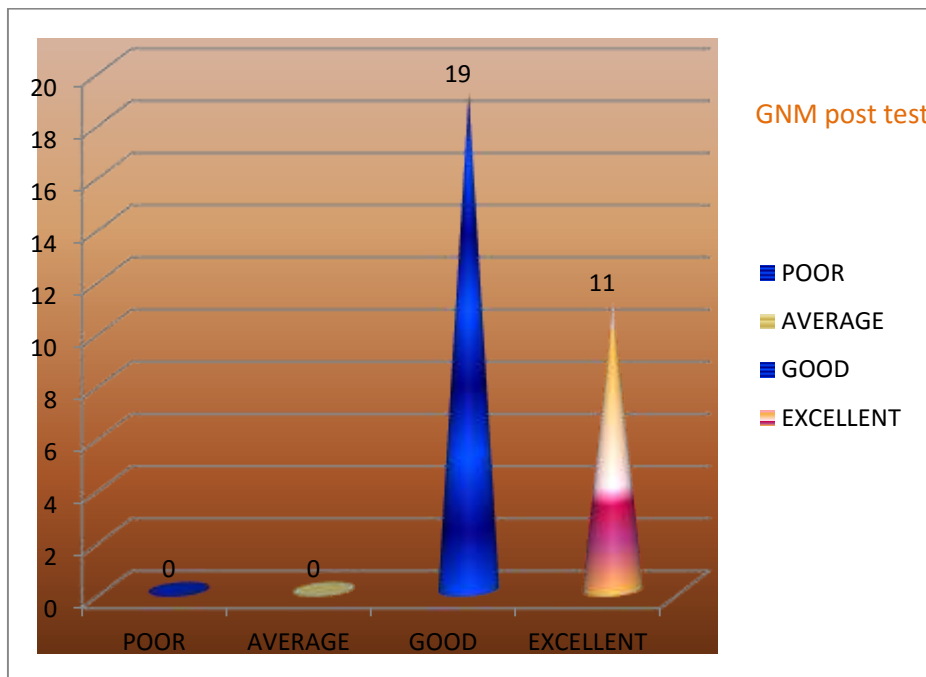


Table: 5: Frequency and percentage distribution of post test knowledge scores regarding pharmacovigilance of steroid therapy among BSC students.

Grades	Scores	Frequency	Percentage
Poor	0-7	00	00
Average	8-14	00	00
Good	15-21	19	63.33%
Excellent	22-30	11	36.66%

The table-5 depicts that majority of the respondents 19 (63.33%) had good level of knowledge regarding pharmacovigilance of steroid therapy whereas 11 (36.66%) of respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy.

Graph 4: distribution of post test knowledge scores regarding pharmacovigilance of steroid therapy among BSc students.

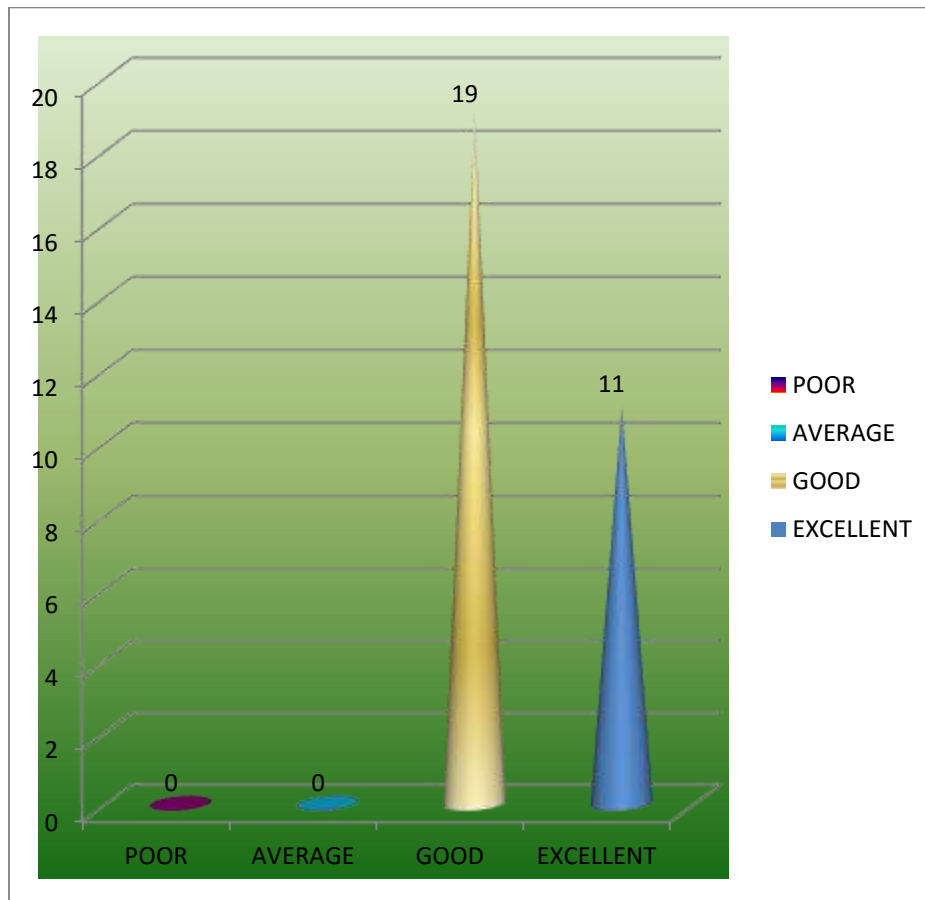


Table: 6: To compare the pre-test knowledge scores on pharmacovigilance of steroid therapy between GNM and BSC nursing students.

Variables	BSC nursing		GNM nursing		Unpaired t test	Significance
	Mean	SD	Mean	SD		
Pretest	13.63	3.3	14.53	3.18	1.16	NS
Post test	20.66	2.04	21.13	1.82		

Table 6 reveals the unpaired t test value showing the level of knowledge of pharmacovigilance of steroid therapy for GNM and BSC nursing students. Observing the level of knowledge of pharmacovigilance of steroid therapy for GNM and BSC nursing students, it was found that ‘t’

value is 1.16 and indicating that there is no significant difference between in the level of knowledge between GNM and BSC students.

Table: 7: Association of post test level of knowledge of GNM students with demographic variables

Si No	Demographic variables	df	Chi-square value	Significance
01	Age	01	1.18	NS
02	Sex	01	0.13	NS
03	Religion	01	0.2	Ns

Table 7 shows that the association of post test level of knowledge with age, sex and religion and indicates that there is no significant difference association between demographic variables and post test level of knowledge of GNM students

Table: 8: Association of post test level of knowledge scores of BSC students with demographic variables.

SI No	Demographic variables	df	Chi-square value	Significance
01	Age	01	2.24	NS
02	Sex	01	1.002	NS
03	Religion	01	2.02	Ns

Table 8 shows that the association of post test level of knowledge with age, sex and religion and indicates that there is no significant difference association between demographic variables and post test level of knowledge of BSC students.

RESULT AND DISCUSSION:

This chapter attempts to discuss the significant findings on the knowledge of pharmacovigilance of steroid therapy among GNM and BSC students. The research outcome is discussed based on the results of the present work and also quoting of the similar findings of the studies conducted in India and other countries. This chapter discusses with the findings of data analysis in accordance with the objectives and stated hypotheses of the present study. The statement of the problem was “A comparative study to assess the effectiveness of PTP on knowledge regarding pharmacovigilance of steroid therapy among GNM and BSC nursing students in selected Nursing colleges at Bijapur”.

To assess the pretest knowledge scores of GNM and BSC nursing students on pharmacovigilance of steroid therapy.

The overall knowledge of GNM students depicts that majority of the respondents 17 (56.66%) had average knowledge regarding pharmacovigilance of steroid therapy whereas 12 (40%) of respondents had good level of knowledge and 01 (3.33%) of the respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy.

The overall knowledge of BSC students depicts that majority of the respondents 16 (53.33%) had average knowledge regarding pharmacovigilance of steroid therapy whereas 13 (43.33%) of respondents had good level of knowledge and 01 (3.33%) of the respondents had poor level of knowledge regarding pharmacovigilance of steroid therapy.

To assess the post test knowledge scores of GNM and BSC nursing students on pharmacovigilance of steroid therapy.

The overall knowledge of GNM students depicts that majority of the respondents 19 (63.33%) had good level of knowledge regarding pharmacovigilance of steroid therapy whereas 11 (36.66%) of respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy.

The overall knowledge of BSC students depicts that majority of the respondents 19 (63.33%) had good level of knowledge regarding pharmacovigilance of steroid therapy whereas 11 (36.66%) of respondents had excellent level of knowledge regarding pharmacovigilance of steroid therapy.

To compare the pre-test knowledge scores on pharmacovigilance of steroid therapy between GNM and BSC nursing students.

To compare the pretest knowledge scores on pharmacovigilance of steroid therapy shows the unpaired t test value showing the level of knowledge of pharmacovigilance of steroid therapy for GNM and BSC nursing students. Observing the level of knowledge of pharmacovigilance of steroid therapy for GNM and BSC nursing students, it was found that 't' value is 1.16 and indicating that there is no significant difference between in the level of knowledge between GNM and BSC students.

To determine the association between knowledge score of selected demographic variables of GNM and BSC nursing students.

The association of post test level of knowledge with age, sex and religion and indicates that there is no significant difference association between demographic variables and post test level of knowledge of GNM students.

The association of post test level of knowledge with age, sex and religion and indicates that there is no significant difference association between demographic variables and post test level of knowledge of BSC students.

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