CHAPTER-IV
RESULTS

This chapter discusses about the data analysis and its interpretation as per the objectives of the study. The data was coded and a master data sheet was created for systematic analysis of the results. The analysis of the data was carried out by using statistical software SPSS (version 20). Data was assessed for normal distribution by using Kolmogorov-Smirnov test. Data regarding knowledge and practice of staff nurses were normally distributed. Hence, descriptive and inferential statistics were used.

Data regarding clinical outcomes of comatose patients in terms of physiological adverse event, level of consciousness, level of agitation & sedation and level of pain did not follow a normal distribution, hence, non parametric test (Mann–Whitney U test was used.

Data analysis is presented according to the objectives of the study.

Table No. 3: Frequency and percentage distribution of demographic variablesof staff nurses. (N=171)

S.No.	Demographic variables of Staff Nurses	Frequency(f)	Percentage(%)
1.	**Age (Years)** 20-29 30-39 >40	102 58 11	60 34 6
2.	**Total years of experience in nursing practice** <1 Year 1-5 Years 6-10 Years >10 Years	10 92 48 21	6 54 28 12
3	**Gender** Female Male	93 78	54 46
4.	**Qualification** GNM B.Sc. NursingM.Sc. Nursing	79 87 5	46 51 3
5.	**Area of experience**Critical care Noncritical care Critical & Noncritical care	147 5 19	86 3 12
6.	**Nurse-patient ratio in ICU** 1:1 1:2	27 144	16 84

The data in table 3 illustrates that majority 102 (60%) of staff nurses were between 20–29 years of age group, 87 (51%) were graduates, 79 (46%) were GNM. Majority of the staff nurses 93 (54%) were females. Majority staff nurses 92 (54%) had clinical experience between one and five years. The majority 147 (86%) of staff nurses had experience in critical care areas in the past. Majority of staff nurses 144 (84%) maintained 1:2 nurse patient ratio.

Objective 2: To evaluate effectiveness of training on Individualized Communication Protocol on knowledge of staff nurses working in ICU.

H01 There would be no significant improvement in knowledge of nurses after administration of Individualized Communication Protocol.

Table No.: 4 Comparison of pre-test and post-test knowledge scores of staff nurses regarding communication with comatose patients.   (N=171)

S.no	Knowledge Score	Max. Score	Range of Score	Mean ±SD	Mean Difference	t Value	p-Value
1	Pre-test	24	1-19	13.23±2.96	6.86	58.27	0.0001**
2	Post-test		10-24	20.09±3.21			

Note: Paired t -test, Df = 170, p<0.05, **statistically significant.

Data in table 4 revealed that post-test knowledge scores (20.09±3.21) were significantly higher than that of pretest knowledge scores (13.23±2.96). Thus, the null hypothesis was rejected inferring that Individualized Communication Protocol was effective in improving the knowledge of staff nurses.
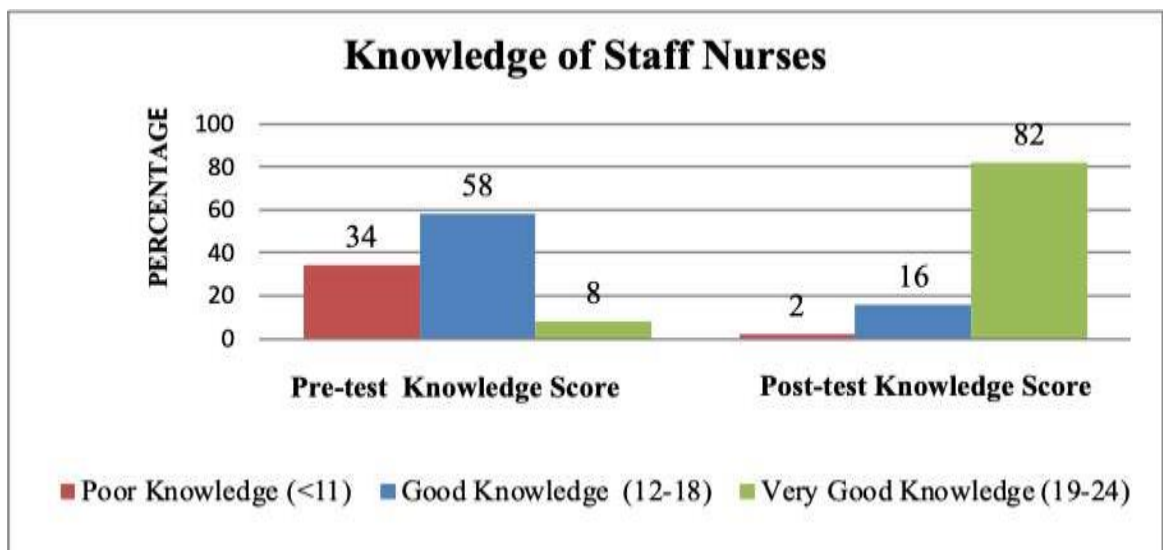
Figure No. 5: Bar diagram representing percentage distribution of staff nurses according to level of knowledge in pre-test and post-test.

The investigator observed that the majority 100 (58%) of the staff nurses were having good knowledge, while 58 (34%) were having poor knowledge, and only 13 (8%) of the staff nurses were having very good knowledge regarding communication in pretest. After administration of Individualized Communication Protocol (ICP) staff nurses, 140 (82%) staff nurses fell into the category of very good knowledge and only 28 (16%) of staff nurses remained in the category of good knowledge.

Objective 3: To evaluate effectiveness of training on Individualized Communication Protocol on practice of the staff nurses working in ICU.

H02 There would be no significant improvement in practice of nurses after receiving training program on Individualized Communication Protocol.

Table No. 5: Comparison of pre-test and post-test practice scores of staff nursesregarding communication with comatose patients.   (N=171)

S.No.	Practice Score	Max Score	Range of Score	Mean ± SD	Mean Difference	t Value	p-Value
1.	Pre-test		4-11	6.75±1.576			
2	Post-test	43	14-40	30.96±4.461	24.21	55.99	0.0001**

Note: **Paired t -test, Df = 170, p < 0.05, **statistically significant**

Data illustrated in table 5 revealed that post-test practice score (30.96±4.461) was significantly higher than that of pretest practice scores (6.75±1.576) inferring that Individualized Communication Protocol was effective in improving the practice of staff nurses. Thus, the null hypothesis was rejected and the research hypothesis (H2) was accepted.
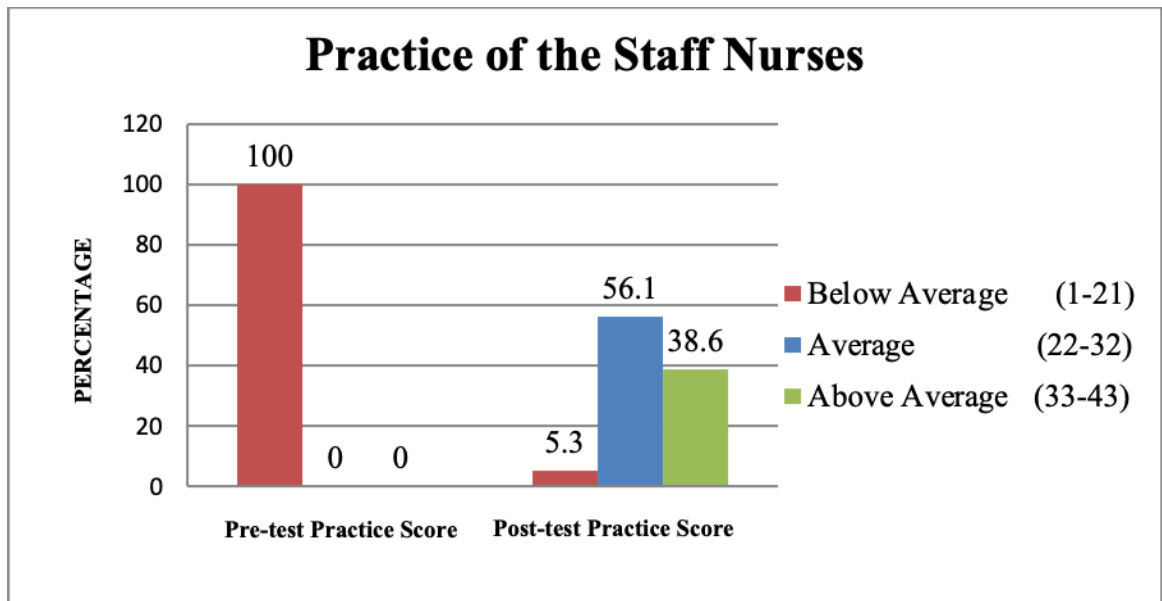
Figure 6: Bar diagram representing percentage distribution of staff nurses according to level of practice in pre-test and post-test.

From Figure 6 the investigator observed almost all 171 (100%) of the staff nurses had below average skills regarding communication, showing less importance to communication with comatose patients. After the conduction of a training program for staff nurses, the majority 97 (56%) had average skills, 66 (39%) had above average skills, showing importance to communication with comatose patients, and only 8 (5%) remained in the category of below average skills.

Objective 5: To find out correlation of pre-test knowledge and pre-test practiceof nurses working in ICU.

Table No. 6: Correlation between pre-test knowledge and practice score of staffnurses on communication with comatose patients.   (N =171)

S.No.	Variable	Pearson's Correlation (r) Value	Significance p value
1.	Knowledge	0.027	0.722
2.	Practice		

Note: $p < 0.05$.

Data in table 6 shows a weak positive correlation between pre-test knowledge andpractice regarding communication.

Objective 6: To find out association between knowledge of nurses working inICU with their selected demographical variables.

Table No. 7: Association between knowledge of staff nurses with their demographic variables.

(N=171)

			Below Median ≤12 f (%)	Above Median ≥12 f (%)	X^2	p-value
Knowledge of the Staff Nurses						
S. No.	**Demographic variables of Staff Nurses**					
1	**Age**	20-29	33	69	0.867	0.648
		30 -39	21	37		
		>40	5	6		
2	**Total years of experiencein nursing practice**	<1 Years	4	6	3.867	0.276
		1-5 Years	26	66		
		6-10 Years	19	29		
		>10 Years	10	11		
3	**Gender**	Male	30	48	0.995	0.425
		Female	29	64		
4	**Qualification**	G.N.M	31	48	1.713	0.327
		B.Sc. Nursing	27	60		
		M.Sc. Nursing	1	4		
5	**Area of Experience**	Critical	50	97	0.128	0.938
		Non Critical	2	3		
		Critical & Non Critical Area	7	12		

Note: Chi –Square Test, $p < 0.05$)

Data in Table 7 illustrates that knowledge scores of the staff nurses were not significantly associated with any of their socio-demographic variables.

Objective 7: To find out association between practice of nurses working in ICUwith their selected demographical variables

Table No 8: Association between practice of the staff nurses with their socio-demographic variables.   **(N=171)**

Data in Table 8 shows that score obtained by all staff nurses were below median level. Hence, association on pretest level of practice scores of the staff nurses and demographic variables were not been computed. **(Annexure-11)**

Objectives 8: To assess the opinion of nurses working in ICU regarding acceptability of Individualized Communication Protocol.

Table No. 9: The opinion of nurses working in ICU regarding acceptability ofIndividualized Communication Protocol.

S.No.	Response	Fully accept		Partiallyaccept		Did not accept	
	Items	f	%	f	%	f	%
1	Adequate information	168	98	3	2	0	0
2	Practical use	158	92	13	8	0	0
3	Areas of communication	156	91	15	9	0	0
4	Content of protocol	168	98	3	2	0	0
5	Language contentof the protocol	167	98	4	2	0	0
6	Usefulness of the protocol	167	98	4	2	0	0
7	Implementation ofthe protocol	158	92	2	2	11	6
8	Time given was sufficient	164	96	3	2	4	2

As shown in Table 9, out of 171 subjects, the majority of respondents (91-98%) opinioned positively regarding acceptability and usability of the Individualized Communication Protocol with regard to the adequate information, practical use of the Individualized Communication Protocol, areas of communication, its content, language content, usefulness, implementation of the protocol, and time given for practice of the Individualized Communication Protocol, was sufficient.

Table No.10 : Frequency and percentage distribution of socio-demographic variables of the comatose patients. (N=113)

Demographic variables	Control group (n=58)		Experimental group (n=55)		Fischer Exact /X²/T Test	p-value
	Frequency	%	Frequency	%		
1. Age						
a. 18-25 years	2	3.4	4	7.2	0.922∞	0.955
b. 26-35 years	6	10.3	5	9		
c. 36-45 years	11	18.9	10	18.1		
d. 46-55 years	14	24.1	13	23.6		
e. 56-65 years	25	43.1	23	41.8		
2. Gender						
a. Male	42	72.73	40	72.41	0.0012α	0.970
b. Female	16	27.59	15	27.27		
3. Marital status						
a. Unmarried	1	1.72	3	5.45	1.151∞	0.283
b. Married	57	98.28	52	94.55		
4. Level of education						
a. No Formal education	2	3.45	3	5.45	4.949∞	0.293
b. till 5th	10	17.24	5	9.09		
c. 10th	25	43.10	17	30.91		
d. 12th	17	29.31	25	45.45		
e. Graduate	4	6.90	5	9.09		
5. Place of living						
a. Rural	28	48.28	26	47.27	0.011 α	0.915
b. Urban	30	51.72	29	52.73		
6. Occupation						
a. House wife	18	31.03	17	30.91	1.450∞	0.919
b. Self employed	12	20.69	7	12.73		
c. Private job	14	24.14	15	27.27		
d. Government	5	8.62	6	10.91		
e. Retired	8	13.79	9	16.36		
f. Students	1	1.72	1	1.82		

Note: ∞Fischer Exact, α Chi –Square Test, p< 0.05

Table 10 reveals that 25 (43%) of the patients in the control group and 23 (42%) of the patients in the experimental group were between 56-65 years of age. The majority (72%) of patients in the control group and 42 (72%) of patients in the experimental group) were males. The majority of patients, 57 (98%) in control and 52 (95%) in the experimental group, were married. About 25 (43%) of the patients in the control group were high school pass and 45% of the subjects in the experimental group had a 12th pass. More than 30 (52%) of the patients in the control group and 29 (52.73%) of the patients in the experimental group belonged to the urban population. Approximately 18 (31.03%) in the control group and 17 (30.91%) in the experimental group were housewives. Comparing the two groups (control and experimental) in relation to socio-demographic variables, these groups were comparable and no significant differences were found.

Table No. 11: Frequency and percentage distribution of clinical variables of the comatose patients. (N=113)

Clinical variables	Control group (n=58)		Experimentalgroup (n=55)		Fischer Exact /X²/T Test	p-value
	Frequency	%	Frequency	%		
1. Diagnosis						
a. Neurologic disorder	36	62.07	20	36.36	11.936∞	0.018
b. Respiratory	6	10.34	13	23.64		
c. Cardiac	4	6.90	4	7.27		
d. Metabolic	6	10.34	15	27.27		
e. Renal	6	10.34	3	5.45		
2. Admitted from						
a. Emergency	47	81.03	43	78.18	0.142 α	0.707
b. Ward	11	18.97	12	21.82		
3. On mechanical ventilation						
a. Yes	58	100.00	55	100.00		
b. No	0	0.00	0	0.00		
4. ICU length of stay						
a. <4days	6	42.9	8	57.2	0.740 α	0.864
b. 4-7days	33	53.2	29	46.8		
c. 8-11days	10	55.6	8	44.4		
d. 12-14 days	9	47.4	10	52.6		
5. APACHE II score(Prognosis)						
a.15-19 (25 % Death rate)	6	10.3	3	5.5	0.158 α	0.694
b. 20-24 (40 % Death rate)	12	20.7	16	29.1		
c. 25-29 (55% Death rate)	27	46.6	29	52.7		
d.30-34 (75%Death rate)	13	22.4	7	12.7		
6.GCS Score at the time of Admission (Mean ±SD)	4.00±1.47		3.65±1.05		1.424δ	0.006

Note: ∞Fischer Exact, α Chi –Square Test, δ T-test, p< 0.05

As illustrated in Table 11 shows that majority of patients 36 (62.07%) in control group and 20 (36.36%) in experimental group had a neurologic disorder as medical diagnosis. Majority of patients, 47 (81.03%) in control group and in experimental group 43 (78.18%) got admitted directly from the emergency ward. All patients in both groups were on mechanical ventilator. Majority 33 (53%) of patients were in control group, and 29 (47%) of patients in experimental group were having a length of ICU stay of four to seven days. Majority of patients 40 (69%) in control group and 36 (65%) in experimental group had a 55% death rate at the time of admission. Mean GCS score was (4.00$\pm$1.473 in control group and 3.65$\pm$1.05) in experimental group

on admission. When the two groups (control and experimental) were compared interms of clinical variables, no significant differences were found.

Table No. 12: Test of homogeneity on clinical outcomes for comatose patients of control and experimental group in terms of physiological adverse events, level ofconsciousness, agitation and sedation level and pain level.

S.No.	Clinical Outcome Parameters	Levine's Statistic	p Value
1	Temperature	0.049	0.825
2	Heart rate	0.312	0.577
3	Respiratory rate	2.655	0.106
4	Oxygen saturation	0.707	0.402
5	Blood pressure	0.180	0.672
6	Blood glucose level	0.065	0.799
7	Level of consciousness	2.511	0.116
8	Level of agitation and sedation	2.688	0.104
9	Level of pain	0.067	0.796

Note: Levine's test, $p < 0.05$, Df-111

Table 12 shows that baseline clinical outcome of comatose patients in both the groups were comparable with the non-significant p value on day one.

Objective 4(a): To evaluate the effectiveness of Individualized Communication Protocol implemented by nurses working in ICU on clinical outcomes of comatose patients in terms of physiological adverse events.

H03 Comatose patients in experimental group would not have significantly lower incidence of physiological adverse event compared to control group.

Table No.13: Comparison of Physiological adverse events (Heart rate) betweencontrol and experimental group of comatose patients. (N=113)

Heart Rate of Comatose patients (Beat/Minute)							
Days	**Timing**	**Incidences**	**Control Group**		**Experimental Group**		**Mann-Whitney U test**	
			f	**Median /IQR**	**f**	**Median /IQR**	**U testvalue**	**p value**
Day-1 (C=58 E=55)	**Morning**	Bradycardia	0	110(20)	0	100(21)	1491.5	0.541
		Normal	23		27			
		Tachycardia	35		28			
	Evening	Bradycardia	0	110(30)	0	96(28)	1554.5	0.788
		Normal	27		27			
		Tachycardia	31		28			
Day-4 (C=52 E=45)	**Morning**	Bradycardia	0	98(24)	0	98(23)	1041.0	0.281
		Normal	22		24			
		Tachycardia	30		21			
	Evening	Bradycardia	0	80(4)	0	90(24)	1123.0	0.565
		Normal	46		38			
		Tachycardia	6		7			
Day-7 (C=32 E=24)	**Morning**	Bradycardia	0	122(22)	0	108(31)	395.5	0.933
		Normal	15		11			
		Tachycardia	17		13			
	Evening	Bradycardia	0	130(28)	0	96(30)	322.5	0.15
		Normal	13		14			
		Tachycardia	19		10			

			Control Group		Experimental Group		Mann-Whitney U test	
Days	Timing	Incidences	f	Median /IQR	f	Median /IQR	U test value	p value
Day-10 (C-10 E=12)	Morning	Bradycardia	0	112(22)	0	108(23)	64.0	0.942
		Normal	4		5			
		Tachycardia	6		7			
	Evening	Bradycardia	0	112(32)	0	100(39)	61.0	0.773
		Normal	4		6			
		Tachycardia	6		6			
Day-14 (C=7 E=9)	Morning	Bradycardia	0	96(0.1)	0	94(7)	31.5	0.403
		Normal	7		8			
		Tachycardia	0		1			
	Evening	Bradycardia	0	100(16)	0	100(17)	33.5	0.793
		Normal	6		8			
		Tachycardia	1		1			

Caption above table: **Heart Rate of Comatose patients (Beats/Minute)**

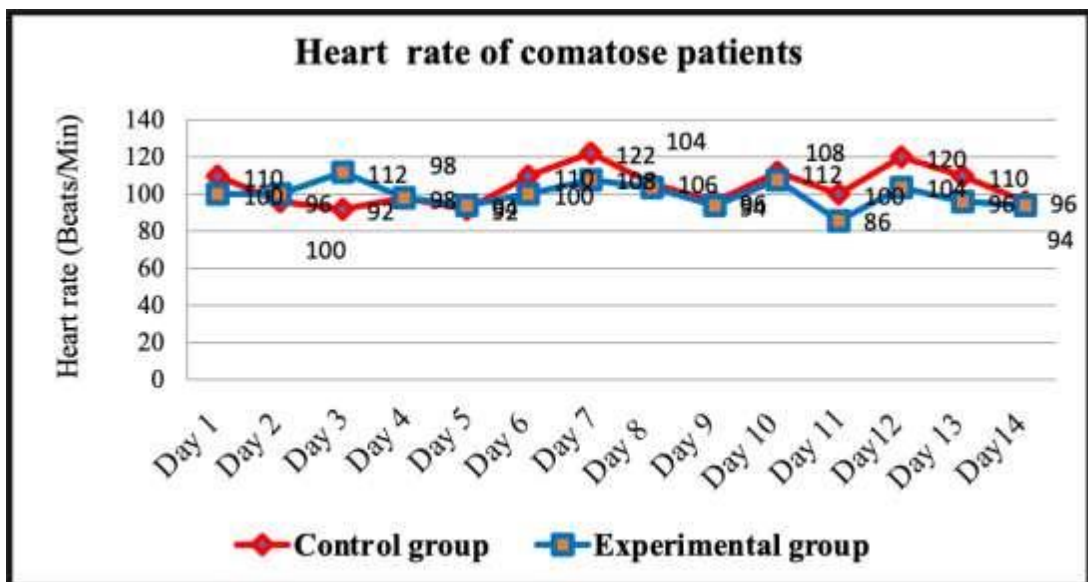**Note: Mann-Whitney U test, p< 0.05, C=Control group, E=Experimental group.**

Figure 7: Comparison of Physiological adverse events (Heart rate) between control and experimental group of comatose patients.

Above Table 13 and Figure 7 shows that both the groups were comparable with the non-significant p value in terms of median scores throughout the study period from the first day till the 14th day. The median score regarding heart rate among the experimental group and control group represents that Individualized Communication Protocol had no effect on heart rate significantly because there was no statistically significant $p < 0.001$ throughout the study period**. (Annexure-11)**

Table No. 14: Comparison of Physiological adverse events (blood pressure) between control and experimental group of comatose patients. (N=113)

Blood Pressure of Comatose patients (mmHg)							
Days	Timing	Incidences	Control Group		Experimental Group		Mann-WhitneyU test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-1 (C=58 E=55)	SBP Morning	Hypotensive	1	110 (10)	1	120 (10)	1536.5	0.45
		Normal	55		50			
		Hypertensive	2		4			
	DBP Morning	Hypotensive	1	80 (10)	4	80 (10)	1481.0	0.92
		Normal	56		51			
		Hypertensive	1		0			
	SBP Evening	Hypotensive	0	130 (20)	2	130 (10)	1513.0	0.186
		Normal	56		52			
		Hypertensive	2		1			
	DBP Evening	Hypotensive	3	80 (20)	2	80(10)	1566.5	0.195
		Normal	53		53			
		Hypertensive	2		0			
Day-4 (C=52 E=45)	SBP Morning	Hypotensive	1	120 (0)	1	120 (10)	1193.0	0.539
		Normal	50		45			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	1	70 (20)	1	70 (15)	1193.0	0.356
		Normal	50		45			
		Hypertensive	1		0			
	SBP Evening	Hypotensive	1	130 (0)	1	130 (0)	1193.0	0.563
		Normal	50		45			
		Hypertensive	1		0			
	DBP Evening	Hypotensive	2	60 (20)	1	70 (25)	1216.0	0.951
		Normal	49		45			
		Hypertensive	1		0			

			Blood Pressure of Comatose patients (mmHg)					
			Control Group		Experimental Group		Mann- Whitney Utest	
Days	Timing	Incidences	f	Median /IQR	f	Median /IQR	U test Value	p value
Day-7 (C=32 E=24)	**SBP Morning**	Hypotensive	1	120 (10)	0	120 (10)	384.0	0.99
		Normal	30		24			
		Hypertensive	1		0			
	DBP Morning	Hypotensive	2	70 (10)	0	70 (20)	360.0	0.21
		Normal	30		24			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	2	130 (0)	0	130 (0)	372.0	0.31
		Normal	29		24			
		Hypertensive	1		0			
	DBP Evening	Hypotensive	2	60 (20)	0	60 (25)	360.0	0.21
		Normal	30		24			
		Hypertensive	0		0			
Day-10 (C-10 E=12)	**SBP Morning**	Hypotensive	0	120 (0)	0	120 (10)	60.0	0.99
		Normal	10		12			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	70 (10)	0	70 (10)	60.0	0.85
		Normal	10		12			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	110 (0)	0	110 (5)	60.0	0.98
		Normal	10		12			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	60 (10)	0	60 (15)	60.0	0.96
		Normal	10		12			
		Hypertensive	0		0			

Blood Pressure of Comatose patients (mmHg)							
Days	Timing	Incidences	Control Group		Experimental Group		Mann-WhitneyU test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-10 (C=7 E=9)	SBP Morning	Hypotensive	0	130 (10)	0	120 (20)	31.5	0.654
		Normal	7		9			
		Hypertensive	0		0			
	DBP Morning	Hypotensive	0	70 (0)	0	70(5)	31.5	0.987
		Normal	7		9			
		Hypertensive	0		0			
	SBP Evening	Hypotensive	0	110 (0)	0	110(15)	31.5	0.966
		Normal	7		9			
		Hypertensive	0		0			
	DBP Evening	Hypotensive	0	60 (0)	0	60(10)	31.50	0.988
		Normal	7		9			
		Hypertensive	0		0			

Note: Mann-Whitney U test, p < 0.05,C=Control group, E=Experimental group,SBP-Systolic Blood Pressure, DBP-Diastolic Blood Pressure
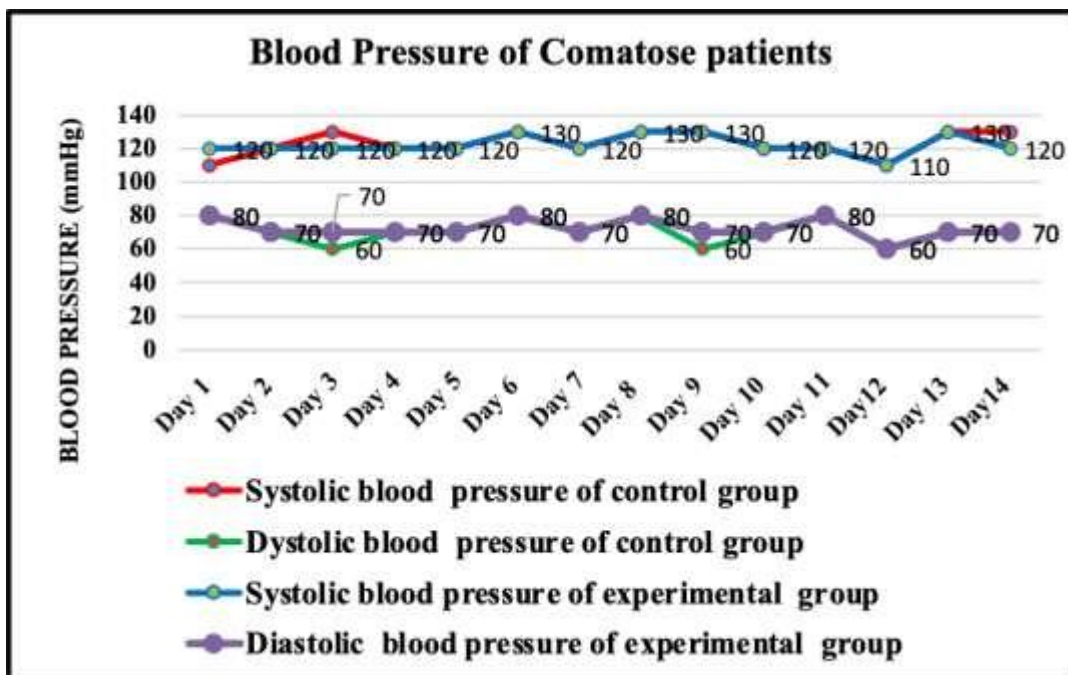

Figure 8: Comparison of Physiological adverse events (blood pressure)

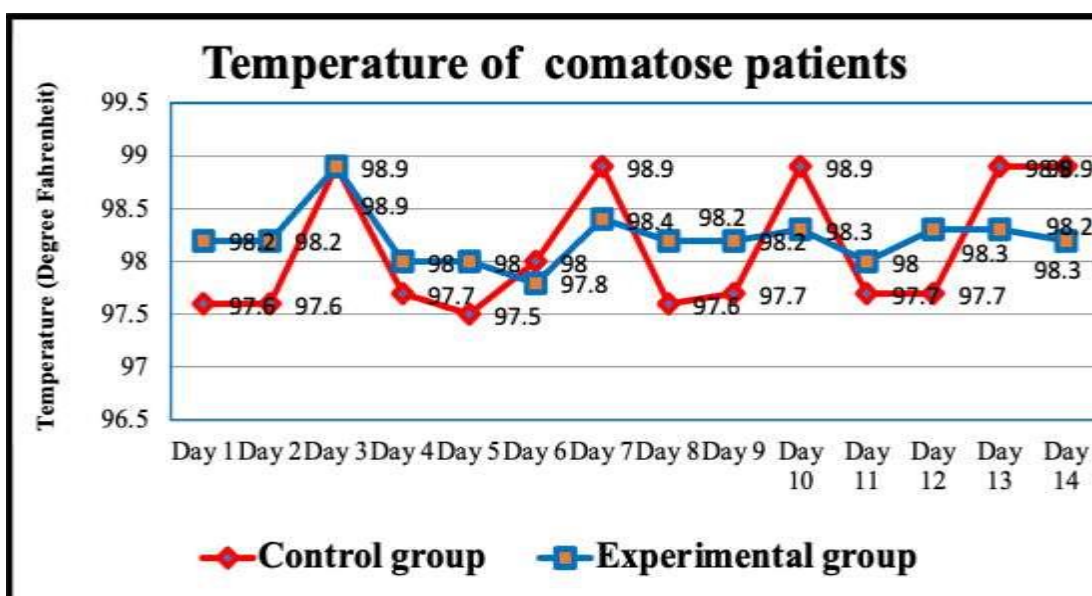**between control and experimental group of comatose patients.**

Data in Table 14 and Figure 8 represents the frequency and percentage distribution of variation in systolic and diastolic blood pressure in terms of normotensive, hypotensive, and hypertension. This table also represents the median score of systolic and diastolic blood pressure with an inter-quartile range throughout the study period. The data shows that both the groups were comparable with the non-significant p value in terms of median scores throughout the study period from the first day till the 14th day. The median score regarding systolic and diastolic blood pressure among the experimental group and control group indicates that Individualized Communication Protocol had no effect on systolic and diastolic blood pressure significantly because there was no statistically significant p<0.001 throughout the study period. **(Annexure-11)**

Table No. 15: Comparison of Physiological adverse events (temperature) between control and experimental group of comatose patients. (N=113)

Temperature of Comatose patients (Degree Fahrenheit)							
Days	Timing	Incidences	Control group		Experimental group		Mann-Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-1 **(C=58** **E=55)**	**Morning**	Hypothermia	3	97.6 (1)	0	98.2 (1)	1595.0	0.969
		Normal	52		55			
		Hyperthermia	3		0			
	Evening	Hypothermia	1	97.6 (1)	0	98.2 (1)	1592.0	0.989
		Normal	53		52			
		Hyperthermia	4		3			
Day-4 **(C=52** **E=45)**	**Morning**	Hypothermia	2	97.7 (0.2)	0	98 (0.3)	1222.0	0.936
		Normal	48		47			
		Hyperthermia	2		0			
	Evening	Hypothermia	2	97.8 (1)	0	98.2 (0.2)	1222.0	0.856
		Normal	48		47			
		Hyperthermia	2		0			
Day-7 **(C=32** **E=24)**	**Morning**	Hypothermia	0	98.9 (0.2)	0	98.4 (1)	387.5	0.377
		Normal	31		25			
		Hyperthermia	1		0			
	Evening	Hypothermia	1	98.7 (1)	1	98.2 (1)	372.5	0.318
		Normal	29		24			
		Hyperthermia	2		0			
Day-10 **(C-10** **E=12)**	**Morning**	Hypothermia	0	98.9 (0.2)	0	98.3 (1)	60.0	0.888
		Normal	10		12			
		Hyperthermia	0		0			
	Evening	Hypothermia	1	98.7 (1)	0	98.2 (1)	54.0	0.233
		Normal	9		12			
		Hyperthermia	0		0			

Temperature of Comatose patients (Degree Fahrenheit)							
Days	Timing	Incidences	Control group		Experimental group		Mann- Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-14 (C=7 E=9)	Morning	Hypothermia	0	98.7 (1)	0	98.2 (1)	31.5	0.997
		Normal	7		9			
		Hyperthermia	0		0			
	Evening	Hypothermia	0	98.7 (1)	0	98.2 (1)	31.5	0.999
		Normal	7		9			
		Hyperthermia	0		0			

Note: Mann-Whitney U test, p <0.05,C=Control group, E=Experimental group

Figure 9: Comparison of Physiological adverse events (temperature) between control and experimental group of comatose patients.
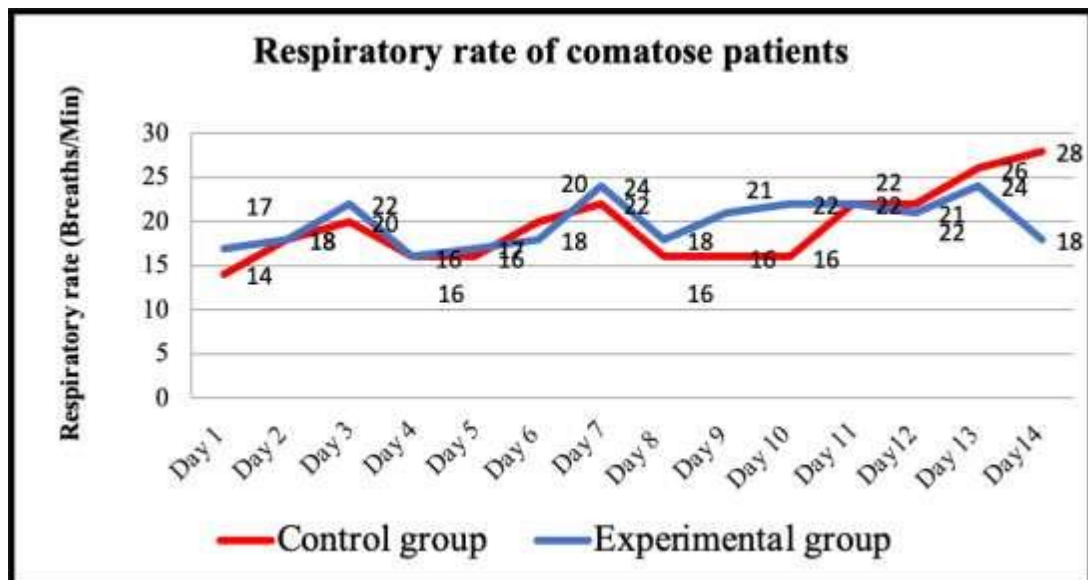
The data in above Table 15 and Figure 9 shows that both groups were comparable with the non-significant p value in terms of median scores throughout the study period from the day 1 till the 14th day. The current study findings indicate that there was no statistically significant difference in the median value of temperature between the experimental and control groups, implying that the Individualized Communication Protocol had no effect on body temperature because there was no statistically significant p<0.001 throughout the study period. **(Annexure-11)**

Table No.16: Comparison of Physiological adverse events (respiratory rate) between control and experimental group of comatose patients.   (N=113)

Days	Timing	Incidences	Control group		Experimental group		Mann- Whitney U test	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-1 (C=58 E=55)	**Morning**	Bradypnea	0	14(6)	0	17 (6)	1595.0	0.984
		Normal	58		55			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	20(5)	0	17 (5.5)	1595.0	0.785
		Normal	58		55			
		Tachypnoea	0		0			
Day-4 (C=52 E=45)	**Morning**	Bradypnea	0	16(6)	0	16 (2)	1192.5	0.9
		Normal	52		45			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	15(10)	0	16 (3)	1192.5	0.9
		Normal	52		45			
		Tachypnoea	0		0			
Day-7 (C=32 E=24)	**Morning**	Bradypnea	0	22(9)	0	24 (8)	384.0	0.555
		Normal	32		24			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	17(40)	0	17 (2.50)	384.0	367
		Normal	32		24			
		Tachypnoea	0		0			

Respiratory rate of Comatose patients (Breaths/Minute)							
Days	**Timing**	**Incidences**	**Control group**		**Experimental group**		**Mann-Whitney Utest**	
			f	**Median /IQR**	**f**	**Median /IQR**	**U test Value**	**p value**
Day-10 (C-10 E=12)	**Morning**	Bradypnea	0	16(8)	0	22(5)	60.000	0.246
		Normal	10		12			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	18(7)	0	22(4)	60.000	0.953
		Normal	10		12			
		Tachypnoea	0		0			
Day-14 (C=7 E=9)	**Morning**	Bradypnea	0	28(12)	0	18(13)	31.500	0.876
		Normal	7		9			
		Tachypnoea	0		0			
	Evening	Bradypnea	0	22(8)	0	22(8)	31.500	0.799
		Normal	7		9			
		Tachypnoea	0		0			

Note: Mann-Whitney U test, p < 0.05,C=Control group, E=Experimental group.

Figure 10: Comparison of Physiological adverse events (respiratory rate) between control and experimental group of comatose patients

The data in above Table 16 and Figure 10 represents that most of the patients included in the study had normal respiratory rates when measured in the morning and evening. This table also represents the median score of respiration with an inter-quartile range throughout the study period. The data shows that both the groups were comparable with the non-significant p value in terms of median scores throughout the study period from the first day till the 14th day. The median score regarding respiration among the experimental group and control group indicates that Individualized Communication Protocol had no effect on respiration significantly because there was no statistically significant $p < 0.001$ throughout the study period. **(Annexure-11)**

Table No.17: Comparison of Physiological adverse events (Oxygen saturation) between control and experimental group of comatose patients.　　(N=113)

Days	Timing	Incidences	Control group		Experimental group		Mann- Whitney Utest	
			f	Median /IQR	f	Median /IQR	U test Value	p value
Day-1 (C=58 E=55)	**Morning**	Desaturation	2	96(4)	0	100 (4)	1481.5	0.18
		Subnormal	1		7			
		Normal	55		48			
	Evening	Desaturation	0	100(1)	0	98 (3)	1419.5	0.02
		Subnormal	1		7			
		Normal	57		48			
Day-4 (C=52 E=45)	**Morning**	Desaturation	0	97(1)	0	97 (2)	1201.5	0.81
		Subnormal	5		5			
		Normal	47		41			
	Evening	Desaturation	0	98(2)	0	98 (2)	1136.0	0.12
		Subnormal	1		4			
		Normal	51		42			
Day-7 (C=32 E=24)	**Morning**	Desaturation	0	98(2)	0	99 (3)	391.0	0.70
		Subnormal	2		1			
		Normal	30		23			
	Evening	Desaturation	0	99(0)	0	99 (2.50)	332.0	0.08
		Subnormal	1		4			
		Normal	31		20			
Day-10 (C-10 E=12)	**Morning**	Desaturation	0	98(0)	0	98 (0)	60.0	0.99
		Subnormal	0		0			
		Normal	10		12			
	Evening	Desaturation	0	97(1)	0	97 (0)	54.0	0.27
		Subnormal	1		0			
		Normal	9		12			
Day-14 (C=7 E=9)	**Morning**	Desaturation	0	97(2)	0	97 (0)	28.0	0.37
		Subnormal	0		1			
		Normal	7		8			
	Evening	Desaturation	0	98(0)	0	98 (0.5)	31.5	0.95
		Subnormal	0		0			
		Normal	7		9			

Note: Mann-Whitney U test, p< 0.05,C=Control group, E=Experimental group
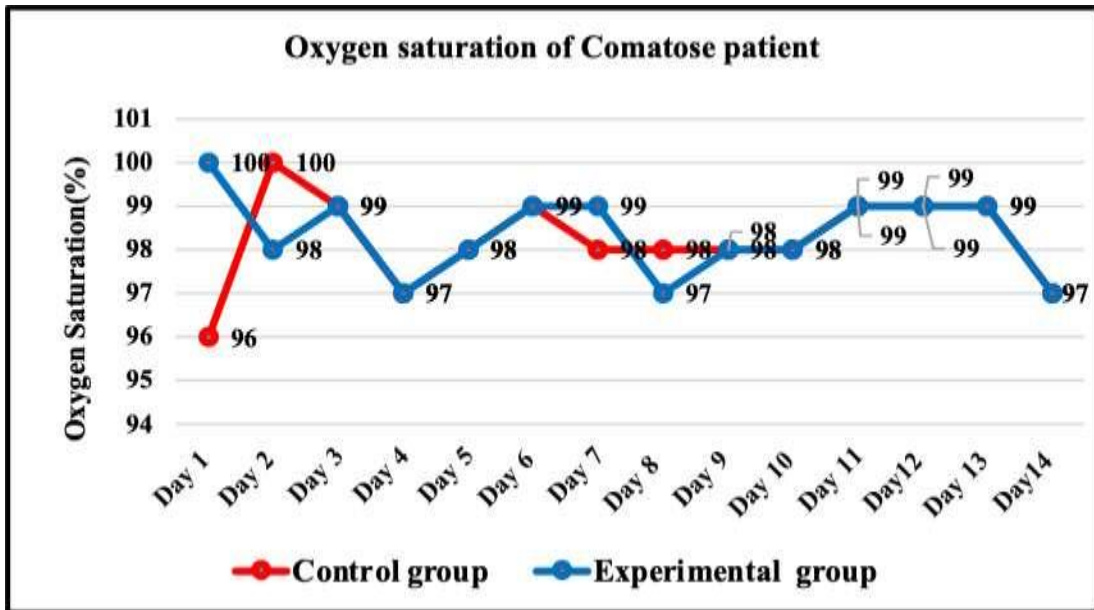
Figure 11: Comparison of Physiological adverse events (Oxygen saturation) between control and experimental group of comatose patients.
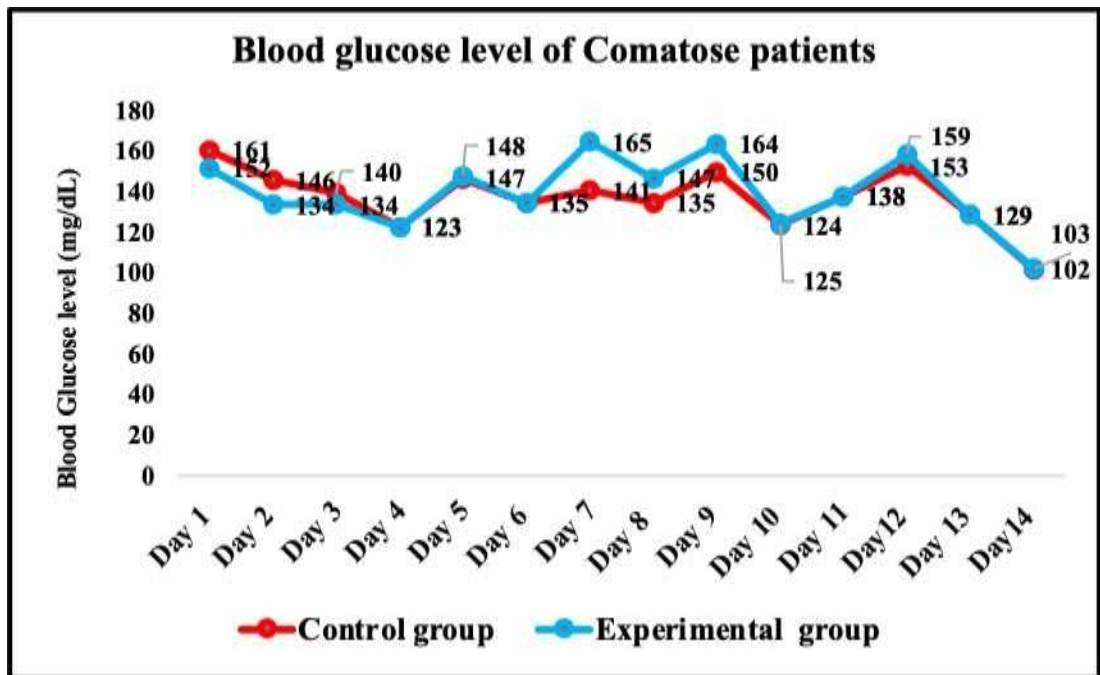
Data in Table 17 and Figure 11 represents the frequency and percentage distribution of variation in oxygen saturation in terms of desaturation, subnormal and normal. The oxygen saturation measured during the evening of the day first shows a significant p value of 0.23 when compared between the experimental and control groups. This table also represents the median score of oxygen saturation with an inter quartile range throughout the study period. The data shows that both groups were comparable with a non-significant p value from day 1 to 14th day of the study period. The median score regarding oxygen saturation among the experimental group and control group remained nearly constant throughout the study periods. (**Annexure-11)**

Table No.18: Comparison of Physiological adverse events (blood glucose level) between control and experimental group of comatose patients.   (N=113)

Blood Glucose level of Comatose patients (mg/dL)								
Days	**Timing**	**Incidences**	**Control group**		**Experimental group**		**Mann-Whitney U test**	
			f	**Median /IQR**	**f**	**Median /IQR**	**U test Value**	**p value**
Day-1 (C=58 E=55)	**Morning**	Hypoglycaemia	0	161(77)	0	152 (55.5)	1079.50	0.432
		Normal	15		32			
		Hyperglycaemia	43		23			
	Evening	Hypoglycaemia	1	131(25)	0	124 (24)	1462.00	0.367
		Normal	37		32			
		Hyperglycaemia	20		23			
Day-4 (C=52 E=45)	**Morning**	Hypoglycaemia	0	123(32)	0	123 (17)	1084.00	0.256
		Normal	30		32			
		Hyperglycaemia	22		14			
	Evening	Hypoglycaemia	0	134(18)	0	136 (28.50)	1218.50	0.996
		Normal	37		33			
		Hyperglycaemia	15		13			
Day-7 (C=32 E=24)	**Morning**	Hypoglycaemia	0	141(44)	0	165 (41.50)	263.00	0.030
		Normal	9		14			
		Hyperglycaemia	22		10			
	Evening	Hypoglycaemia	0	138(19)	0	138 (5.50)	321.00	0.287
		Normal	19		18			
		Hyperglycaemia	12		6			
Day-10 (C-10 E=12)	**Morning**	Hypoglycaemia	0	124(3)	0	125 (9)	47.00	0.288
		Normal	8		7			
		Hyperglycaemia	2		5			
	Evening	Hypoglycaemia	0	186(66)	0	186 (31.50)	47.00	0.200
		Normal	3		1			
		Hyperglycaemia	7		11			
Day-14 (C=7 E=9)	**Morning**	Hypoglycaemia	0	102(20)	0	103 (75)	21.00	0.101
		Normal	7		6			
		Hyperglycaemia	0		3			
	Evening	Hypoglycaemia	0	119(0)	0	119 (13.50)	28.00	0.378
		Normal	7		8			
		Hyperglycaemia	0		1			

Note: Mann-Whitney U test, p < 0.05, C=Control group, E=Experimental group

Figure 12: Comparison of Physiological adverse events (blood glucose level) between control and experimental group of comatose patients.

Data in Table 18 and Figure 12 represents the frequency and percentage distribution of variations in blood glucose levels in terms of normoglycaemia, hypoglycaemia, and hyperglycaemia. This table also represents the median score of glucose level with an inter quartile range throughout the study period. The data shows that both groups were comparable with a non-significant p value from day 1 to 14[th]day of the study period. The median score regarding blood glucose level among the experimental group and control group represents that Individualized Communication Protocol had no effect on blood glucose level because there was no statistically significant p< 0.001 throughout the study period. **(Annexure-11)**

Table No.19: Comparison of incidences of physiological adverse events between control and experimental group throughout the study period. (N=113)

Physiological adverse events	Control Group (n=58)	Experimental Group (n=55)	p-value
Cardiovascular adverse events			
Tachycardia	358	296	0.05*
Hypertension	27	6	0.05*
Hypotension	49	23	0.01*
Respiratory adverse Events			
Desaturation	7	2	0.05*
Sub saturation	41	59	0.01*
Bradypnea	1	0	0.01*
Metabolic adverse events			
Hypothermia	17	1	0.01*
Hyperthermia	35	8	0.05*
Hypoglycaemia	2	0	0.01*
Hyperglycaemia	394	310	0.05*

Note:x^2, Z Test, p< 0.05,*statistically significant

As shown in table 19, the incidence rates of physiological adverse events were significantly higher in control group than experimental group. In terms of cardiovascular adverse events, the current study found a highly significant difference (P<0.001) between two groups in the onset of tachycardia (358 incidences in control group and (296 incidences in experimental group), hypertension (27) incidences in control group and six incidences in experimental group. Regarding the respiratory adverse events, a statistically significant rise in patients who developed

desaturation seven Vs two in both groups. Regarding metabolic adverse events, incidences of hypothermia were (17 vs one), hyperthermia (35 vs eight), hypoglycaemia (two vs zero) and hyperglycaemia (394 vs 310) occurrence rates were significantly elevated in control group as compared to experimental group.

Objective 4(b) To evaluate the effectiveness of Individualized Communication Protocol implemented by nurses working in ICU on clinical outcomes of comatose patients in terms of the consciousness.

H04 Level of consciousness of comatose patients in experimental group and control group would be same before and after implementation of Individualized Communication Protocol.

Table No.20 : Comparison of clinical outcomes (level of consciousness) between control and experimental group of comatose patients.   (N=113)

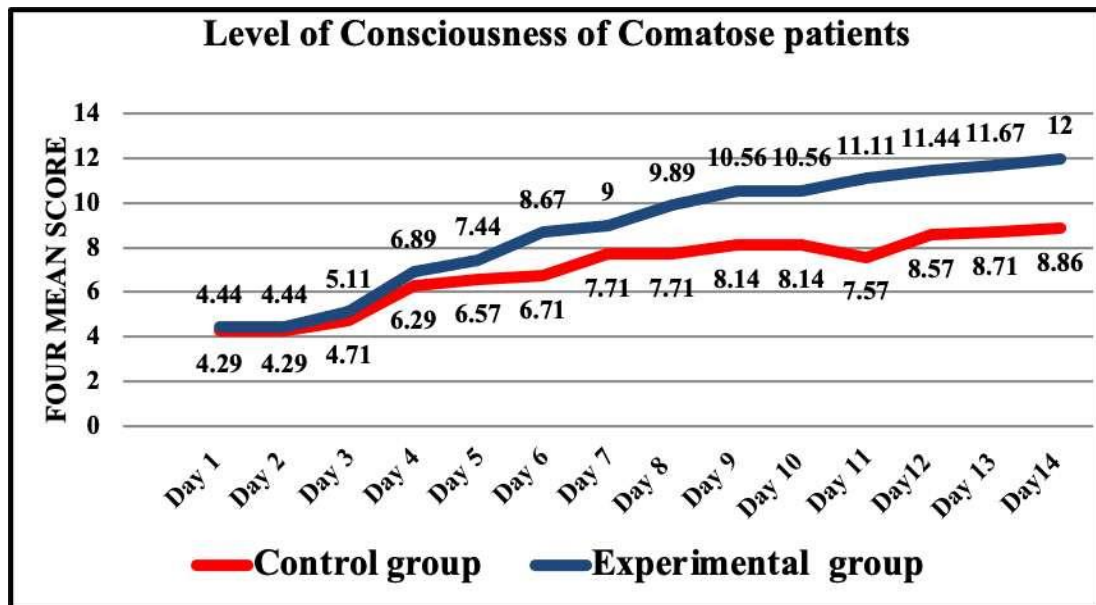| Days	Timing	n	Control group		n	Experimental group		Mann-Whitney U Test	
			Mean	Median (IQR)		Mean	Median (IQR)	U Test	p value
Day-1	**Morning**	58	4.29	5.00(1)	55	4.44	4.00(1)	1558.00	0.821
	Evening		4.29	5.00(1)		4.44	4.00(1)	1558.00	0.821
Day-4	**Morning**	52	6.29	6.00(2)	45	6.89	7.00(3)	690.50	0.001*
	Evening		6.29	6.00(2)		6.89	7.00(3)	647.00	0.001*
Day-7	**Morning**	32	7.71	8.00(5)	24	9.00	9.00(4)	217.00	0.002*
	Evening		7.71	8.00(5)		9.11	9.00(4)	216.50	0.002*
Day-10	**Morning**	10	8.14	9.00(6)	12	10.56	12.00(5)	37.500	0.072
	Evening		8.14	9.00(6)		10.56	12.00(5)	37.500	0.072
Day-14	**Morning**	7	8.86	10.00(7)	9	12.00	13.00(3)	17.500	0.042*
	Evening		8.86	10.00(7)		12.00	13.00(3)	17.500	0.042*

Note: Full Outline of Unresponsiveness (FOUR), Mann-Whitney U test, p < 0.05,

*statistically significant

Table 20 represents that at baseline, means of LOC of control and experimental groups, were 4.29 and 4.44, respectively, with no significant difference between the two groups (p>0.05) inferring both the groups were comparable. On 4th day mean level of consciousness of experimental group increased significantly after commencing the Individualized Communication Protocol compared to the control group. A similar kind of trend of better responsiveness among the patients in

the experimental group was observed throughout study period. On 14th day mean score of responsiveness was clinically better in the experimental group (12) compared to control group (8.86) which indicates that the difference in responsiveness scores was statistically significant ($p<0.05$).

Experimental group patients demonstrated better consciousness as compared to patients in the control group concluding that Individualized Communication Protocol had a positive effect on level of consciousness of comatose patients. (**Annexure-11**)

Figure 13: The change of the level of consciousness between experimental and control group.

As shown in Figure 13, patients in the experimental group displayed higher levels of consciousness on an average than patients in the control group throughout the study period.

Objective 4(c): To evaluate the effectiveness of Individualized Communication Protocol implemented by nurses working in ICUs on clinical outcomes of comatose patients in terms of the sedation level.

H05 Sedation score of comatose patients in experimental group and control group would be same before and after implementation of Individualized Communication Protocol.

Table No. 21 : Comparison of clinical outcomes (sedation level) between control and experimental group of comatose patients .   (N=113)

Level of agitation and sedation in comatose patients									
Days	**Timing**	**n**	**Control group**		**n**	**Experimentalgroup**		**ann-Whitney UTest**	
			Mean	**Median (IQR**		**Mean**	**Median (IQR)**	**U Test**	**p value**
Day-1	**Morning**	58	0.14	1.00(5)	55	-1.44	-3.00(5)	1434.000	0.343
	Evening		-3.00	-4.00(1)		-1.44	-3.00(5)	805.000	0.001*
Day-4	**Morning**	52	-3.71	-4.00(1)	45	-2.56	-3.00(1)	483.500	0.001*
	Evening		-3.71	-4.00(1)		-2.44	-3.009(1)	486.000	0.001*
Day-7	**Morning**	32	-2.71	-3.00(1)	24	-1.67	-2.00(1)	223.000	0.003*
	Evening		-2.71	-3.00(1)		-1.67	-2.00(1)	217.500	0.002*
Day-10	**Morning**	10	-2.00	-2.00(0)	12	-0.78	-1.00(1)	37.000	0.110
	Evening		-1.86	-2.00(1)		-0.44	-1.00(2)	35.000	0.081
Day-14	**Morning**	7	-0.71	-1.00(1)	9	-0.44	0.00(1)	25.500	0.476
	Evening		-0.71	-1.00(1)		-0.44	0.00(1)	25.500	0.476

Note: Richmond agitation sedation scale (RASS), Mann-Whitney U test, p< 0.05 *statistically significant
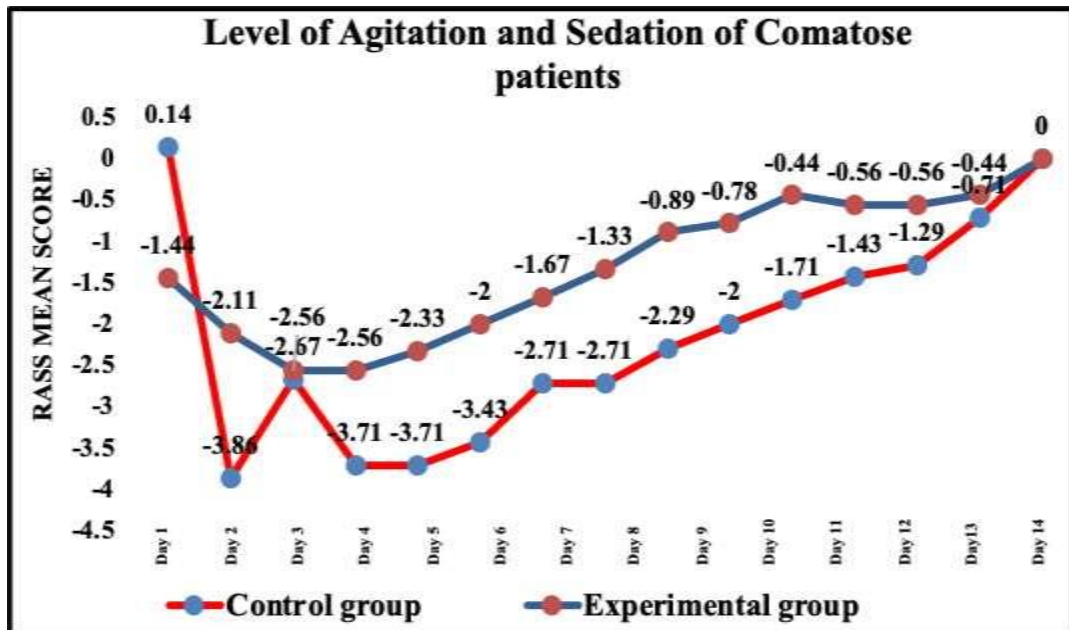
Figure 14: Comparison of level of sedation of comatose patients in experimental and control group.

Data in Table 21 and Figure 14 represents that patient in the experimental group required less sedation (mean score of -1.44) than patients in the control group (mean score of -3.00). The difference between both the groups was statistically significant with a p value of 0.001 on the 4th day till the 9th day. However, it was found that the difference in level of sedation was statistically not significant on the 10th, 11th, 13th, and 14th day indicating that Individualized Communication Protocol had a positive effect on the level of agitation and sedation among comatose patients in the experimental group. **(Annexure-11).** Patients in both groups were receiving sedation i.e., injection Midazolam ranged from l ml to 3 ml and injection Fentanyl at 50 mcg/kg/hour to 100 mcg/kg/hr.

Objective-4(d) To evaluate the effectiveness of Individualized Communication Protocol implemented by nurses working in ICU on clinical outcomes of comatose patients in terms of the behaviour pain scales.

H06 Pain score of comatose patients in experimental group and control group would be same before and after implementation of Individualized Communication Protocol.

Table No.22: Comparison of clinical outcomes (level of pain) between control and experimental group of comatose patients.   (N=113)

Level of pain in comatose patients								
Days	**Timing**	**n**	**Control group**		**n**	**Experimental group**	**Mann-Whitney Utest**	
			Mean	**Median (IQR**		**Mean**	**Median(IQR**	**U Test Value**	**p value**
Day-1	**Morning**	58	8.14	8.00(2)	55	6.67	7.00(3)	1503.00	0.592
	Evening		5.57	5.00(1)		4.89	5.00(2)	1323.50	0.104
Day-4	**Morning**	52	4.00	4.00(2)	45	4.67	5.00(1)	1066.00	0.423
	Evening		4.14	4.00(2)		4.44	4.00(1)	992.50	0.168
Day-7	**Morning**	32	5.29	5.00(1)	24	4.22	4.00(1)	153.50	0.001*
	Evening		5.29	5.00(1)		4.33	4.00(1)	118.00	0.001*
Day-10	**Morning**	10	5.14	5.00(0)	12	3.33	3.00(1)	2.50	0.001*
	Evening		5.29	5.00(1)		3.44	3.00(1)	8.00	0.001*
Day-14	**Morning**	7	5.14	5.00(1)	9	3.22	3.00(1)	0.00	0.001*
	Evening		5.14	5.00(1)		3.22	3.00(1)	0.00	0.001*

Note: Mann-Whitney U test, p< 0.05,*statistically significant, Behavioural painscale (BPS).

Data in Table 22 represents levels of pain in terms of facial expression, upper limb movements, and compliance with mechanical ventilation. At the baseline, means of behavioral pain scale of control and experimental group, were (8.14 vs.6.67, respectively), with no significant difference between the two groups (p>0.05) inferring both the groups were comparable. On 7th day, mean level of pain of experimental group decreased significantly after commencing the Individualized Communication Protocol compared to the control group. A similar kind of trend of reduction in level of pain among the patients in the experimental group was observed throughout the study period. On 14th day, mean pain score was clinically reduce in experimental group (3.22) compared to control group (5.14) which indicates that the difference in level of pain scores was statistically significant (p <0.05).

Patients in the experimental group experienced significantly less pain as compared to control group concluding that Individualized Communication Protocols had a positive effect on the level of pain of comatose patients. **(Annexure-11)**
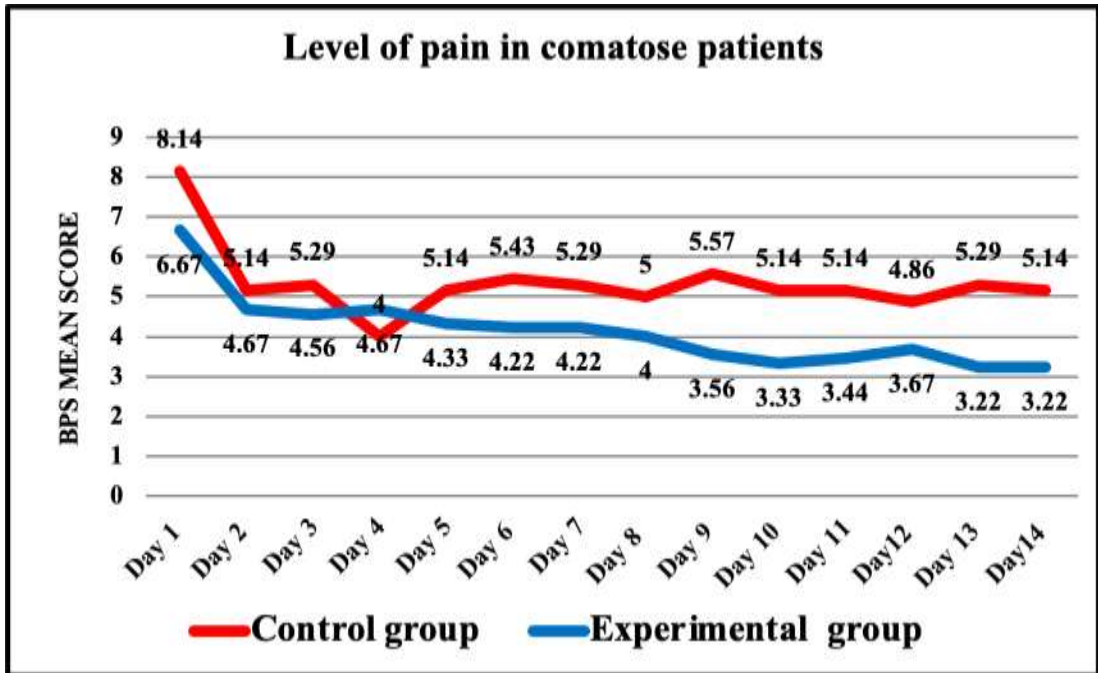
Figure 15: The change of the level of pain between experimental and controlgroup.

As shown in Figure 15, patients in the experimental group experienced less pain allover the study period as compared to control group.

Additional Findings

Table No.23: Comparison between control and experimental group regarding ICU length of stay and duration of mechanical ventilation   (N=113)

Variable	Control Group Mean ± SD	Experimental Group Mean ± SD	Independent student's t test	
			t test	p value
ICU length of stay (Days)	7.16± 3.318	7.22±3.690	0.341	0.924
Duration of Mechanical Ventilation (Days)	6.59±3.234	6.47±3.366	0.183	0.855

Note. t-test, p< 0.05

Table 23 displays that mean number of days for ICU length of stay in experimental group was 7.22±3.690 compared to 7.16±3.318 in control group. The average number of days on mechanical ventilator in experimental group was 6.47±3.366 compared to 6.59±3.234 in control group.

Table No.24: Comparison between control and experimental group regarding infusion of inotropic agent in comatose patients. (N=113)

S.No.	Inotropic Agents	Control Group		Experimental Group	
		f	%	f	%
1	No Inotropic	28	48.3	33	60.1
2	Injection Noradrenalin	23	39.7	19	34.5
3	Combination of Injection Noradrenalin +Injection Dopamine	6	10.3	2	3.6
4	Combination of Injection Noradrenalin +Injection Dobutamine	0	0	0	0
5	Combination of Injection Noradrenalin +Injection Vasopressin	1	1.7	1	1.8

The data illustrated in Table 24 reveal that the majority 28 (48.3%) of the patients in the control group and 33(60%) of the patients in the experimental group did not have any type of inotropic agent for cardiac support. Followed by 23 (39.7%) in the control group and 19 (34.5%) in the experimental group, patients were on Injection Noradrenaline for cardiac support. At least 6 (10.3%) of the patients in the control group and 2 (3.6%) of the patients in the experimental group were on a combination of Injection Noradrenalin + Injection Dopamine and at least 1 (1.7%) of the patients in the control group and 1 (1.8%) of the patients in the experimental group were on an inotropic agent, namely a combination of Injection Noradrenalin + Injection Vasopressin for cardiac support.

Table No.25: Comparison between control and experimental group regarding types of sedation in comatose patients.   **(N=113)**

S.No	Sedation Type	Control Group		Experimental Group	
		f	%	f	%
1	No sedation	10	17.2	22	40
2	Only Injection Fentanyl1 ml-50 mcg 4 ml-200 mcg Dose-50 mcg/kg/hr- 100 mcg/kg/hr	22	37.9	24	43.6
3	Combination of Injection Midazolam +Injection Fentanyl Midazolam Dose-1 ml-0.8 mg/kg Fentanyl Dose- 1 ml-0.20 mcg/kg/hr	26	44.8	9	16.4

The data in Table 25 showed that majority 26 (44.8%) of the patient in control group were on sedative drug i.e., combination of Injection Midazolam + Injection Fentanyl, and 24 (43.6%) of patients in experimental group were on infusion of Injection Fentanyl alone. Only 10 (17.2%) patients in control group and 22 (40%) patients in experimental group were not receiving any type of sedative agent during their duration of ICU stay.

Table No. 26: Comparison between control and experimental group regarding types of ICU stay of comatose patients. (N=113)

S.No.	Types of ICU stay	Control Group(58)		Experimental Group(55)	
		f	%	f	%
1	Expired	34	58.6	15	27.3
2	Shifted to wards	15	25.9	26	47.3
3	Still in ICU	7	12.1	8	14.5
4	LAMA (Leave against medical advice)	2	3.4	6	10.9

The study recruited 113 patients in total as per data illustrated in Table 26. Majority 34 (58.6%) of the patients in the control group and 15 (27.3%) of the patients in the experimental group died during their ICU stay. Following that, 15 (25.9%) in the control group and 26 (47.3%) in the experimental group were shifted out of the ICU. Only 7 (12.1%) of patients in the control and 8 (14.5%) of patients in the experimental group were still in the ICU, and at the very least 2 (3.4%) of the patients in the control group and 6 (10.9%) of patients in the experimental group left the ICU through leave against medical advice.

Summary

The researcher studied the nature of the data and analyzed it according to the objectives of the study. Analyzed data was presented in different forms like tables, graphs, and figures. These presentations were described in an empirical and justified manner.