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Effectiveness of conventional therapy along with humidified oxygen therapy versus conventional therapy only on decubitus ulcers healing among patients admitted in selected units of GGSMC&H, faridkot: A randomized control trail

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Abstract
Context: Decubitus ulcers also called bed sores or pressure sores are injuries to skin and underlying tissue due to prolonged pressure exerted on the skin over the bony prominences. Pressure decreases the blood supply leading to starvation of oxygen. Humidified Oxygen therapy can be a most effective therapy for the treatment in the healing of Decubitus ulcer. The study was undertaken to assess the effectiveness of conventional therapy along with humidified oxygen therapy versus conventional therapy only on decubitus ulcers healing.
Aims and Objectives: The study aims to assess the effectiveness of conventional therapy along with humidified oxygen therapy versus conventional therapy only on decubitus ulcers healing among patients admitted in selected units of GGSMC&H, Faridkot, Punjab. The objective was to assess the grades of decubitus ulcer in patients after and before implementation of conventional therapy along with humidified oxygen therapy versus conventional therapy only and to compare the grades of decubitus ulcers healing in patients among interventional and conventional group.
Methodology: A randomized controlled trail research design was used to conduct the study. By random allocation, 60 patients with decubitus ulcer of grade II, III & IV, admitted in GGS medical hospital were selected and randomly divided into two groups [interventional(n=30) and conventional group (n=30)]. The interventional group received a humidified oxygen therapy for 8 days and wound was assessed on 1st day before intervention and 8th day after intervention. The socio-demographic profile and clinical profile sheet and standardized tool PUSH 3.0 was used to evaluate the effectiveness of conventional therapy along with humidified oxygen therapy versus conventional therapy only on decubitus ulcers healing.
Results: The findings revealed that significant reduction in mean total PUSH score in both interventional and conventional group. The data was analyzed by using Paired t-test and Independent t-test. The pre-assessment mean total PUSH score in interventional group was 11.13 on 1st day which reduced to 6.40 on 8th day and in conventional group was 11.07 on 1st day which reduced to 9.30 on 8th day, calculated t value 0.095, df 58 and p value 0.924 on 1st day which was non-significant and t value was 3.453, df 58 and p value 0.001 on 8th day which was statistically significant at the level of significant at $p \leq 0.05$.
Conclusion: The study statistically proved that conventional therapy along with humidified oxygen therapy was found to be more effective than conventional therapy only on decubitus ulcer healing.

Keywords: Decubitus ulcer, humidified oxygen therapy, decubitus ulcer healing

1. Introduction
Decubitus ulcers usually affect the patients with mobility problems, sensory impairment, bowel and bladder incontinence, malnutrition, obesity and patients with mental illness such as Alzheimer's diseases [1]. Pressure decreases the blood supply leading to starvation of oxygen and nutrients to tissue which finally lead to breakdown and ulcer formation occur [2]. The internal and external factors also form the decubitus ulcer. The internal factors involved immobilization, fever, anemia, chronic illness (diabetic mellitus), use of corticosteroids, malnutrition and four external factors which involved pressure, friction, humidity and shear [3].

Decubitus ulcers mainly occur over bony prominences such as sacrum, shoulders, occiput, ear lobes, elbow, heel and trochanter and can develop when a prolonged pressure is applied to an area of skin over the bony prominences. The soft tissues are compressed or sheared when the patient is sitting or lying. The occurrence of decubitus ulcers involves one or more factors like paralyzed patient with a spinal injury loses sensation and the ability to move the affected area [3].

The study revealed that 33% of I.C.U. patients rated and features of decubitus ulcer and most common sites of pressure ulcers were different site of vertebra (28.6%), heel (15.5%), shoulder (7.7%) and ischium (7.7%) [4].

The oxygen therapy generate new tissue growth, because decubitus ulcers are formed by a lack of blood supply to a specific part due to pressure, encouraging blood flow in the area by taking the pressure off the affected area is one of the primary intervention. When the blood vessels are damaged in the surrounding area by the pressure then by increasing oxygen levels encourages the formation of new blood vessels [5].

2. Methodology

2.1 Research Approach: In this study, Quantitative research approach was used.

2.2 Research Design: In this study, Randomised control trail was used.

2.3 Study area: The study was conducted in selected units (Surgical ICU, Medical ICU, Neuro-surgery ICU, Burn ICU, Surgery department, Orthopedic ward) at GGSMC&H, Faridkot, Punjab.

2.4 Sample: The study was conducted among the patients with decubitus ulcer grade II, III and IV admitted at the selected units of GGSMC&H, Faridkot, Punjab.

2.5 Sample Size: In this study total sample size was 60 (30 each in interventional and conventional group)

2.6 Sampling Technique: The subjects was selected by random allocation on the basis of inclusion/exclusion criteria and randomly allocated in each interventional and conventional group.

2.7 Tool: The socio demographic variables, Clinical Profile sheet, PUSH (Pressure ulcer scale for healing) tool 3.0 and assessment sheet was used to collect data on 1st day and 8th day.

2.8 Ethical Consideration: The ethical approval was taken from the ethical committee of Baba Farid University of Health Sciences, Faridkot. The permission to conduct study in the hospital was taken from the Medical Superintendent, GGSMCH&H, Faridkot. The subjects or the subject's attendants were explained regarding the intervention and informed consent was taken. The confidentiality of the patients was maintained.

2.9 Data collection: The data for the final study was collected from 60 subjects (30 subjects from each interventional and conventional group) with decubitus ulcers of grade II, III & IV from the selected units of GGS Medical Hospital, Faridkot fulfilling the inclusion and exclusion criteria. All the information about the study was provided to the patient and the patient's relatives before taking informed consent. The socio-demographic data was collected by interview method and data for clinical profile sheet was collected by patient file and assessment. Before intervention, pre-assessment of length and width, exudate amount and tissue type were done by using PUSH TOOL 3.0 in both interventional and conventional group at the day 1st. After pre-assessment, Interventional group receive standard wound care with 10 liter/min topical humidified oxygen therapy for 30 minute/ thrice a day on decubitus ulcer by disposable catheter tube. After intervention, ulcer cover with soaked gauze with 0.9% Normal saline and conventional group receive only standard wound care for thrice a day on decubitus ulcer. Post-intervention assessment of grading of decubitus ulcers was done on 8th day by using PUSH tool 3.0 on Assessment sheet.

3. Results

Table 1: Frequency and percentage distribution of study subjects as per socio-demographic characteristics among interventional and conventional group. N=60

S. No	Variables	Interventional Group (n=30)		Conventional group (n=30)		Total Freq (%)	χ^2 df	p-value
		Freq. (n)	%	Freq. (n)	%			
1.	**Age (in years)**							
	20-35	8	26.7	10	33.3	18 (30.0)	0.752 3	0.861^{NS}
	36-50	6	20.0	7	23.3	13 (21.7)		
	51-65	10	33.3	9	30.0	19 (31.7)		
	66-85	6	20.0	4	13.3	10 (16.7)		
2.	**Gender**							
	Male	22	73.3	20	66.7	42 (70.0)	0.317 1	0.573^{NS}
	Female	8	26.7	10	33.3	18 (30.0)		
3.	**Weight**							
	Underweight	2	6.7	1	3.3	3 (5.0)	0.777 2	0.678^{NS}
	Normal	17	56.7	20	66.7	37 (61.7)		
	Overweight	11	36.7	9	30.0	20 (33.3)		
4.	**Education**							
	Illiterate	10	33.3	12	40.0	22 (36.7)	1.143 3	0.767^{NS}
	Primary	10	33.3	10	33.3	20 (33.3)		
	High school	3	10.0	4	13.3	7 (11.7)		
	Secondary	7	23.3	4	13.3	11 (18.3)		

5.	**Occupation** Private Unemployed Laborer	 8 17 5	 26.7 56.7 16.7	 5 21 4	 16.7 70.0 13.3	 13 (21.7) 38 (63.3) 9 (15.0)	1.224 2	0.542^{NS}
6.	**Smoking** Smoker Non-smoker	 3 27	 10.0 90.0	 7 23	 23.3 76.7	 10 (16.7) 50 (83.3)	1.920 1	0.166^{NS}
7.	**Dietary habits** Vegetarian Non-vegetarian	 9 21	 30.0 70.0	 6 24	 20.0 80.0	 15 (25.0) 45 (75.0)	0.800 1	0.371^{NS}
8.	**Location of ulcer** Buttocks Sacrum Heels Others…….	 13 15 1 1	 43.3 50.0 3.3 3.3	 13 16 0 1	 43.3 53.3 0.0 3.3	 26 (43.3) 31 (51.7) 1 (1.7) 2 (3.3)	1.032 3	0.793^{NS}
9.	**Skin texture** Dry Moist	 4 26	 13.3 86.7	 8 22	 26.7 73.3	 12 (20.0) 48 (80.0)	1.667 1	0.197^{NS}

p>0.05: NS

Table 2: Frequency and Percentage distribution of study subjects as per the Clinical profile among interventional and conventional group. N=60

S. No	Sample characteristics	Interventional Group		Conventional group		Total N (%)	χ^2 df	p-value
		Freq. (n)	%	Freq. (n)	%			
1.	**Diagnosis** Medical Surgical Orthopedics Neuro-surgery	 9 6 5 10	 30.0 20.0 16.7 33.3	 12 5 5 8	 40.0 16.7 16.7 26.7	 21 (35.0) 11 (18.3) 10 (16.7) 18 (30.0)	0.742 3	0.863^{NS}
2.	**Duration of ulcer** < 1 week 1-3 week 4-6 week 7-9 week	 21 5 3 1	 70.0 16.7 10.0 3.3	 22 7 1 0	 73.3 23.3 3.3 0.0	 43 (71.7) 12 (20.0) 4 (6.7) 1 (1.7)	2.357 3	0.502^{NS}
3.	**Body temperature** <97.6˚F 97.7˚-99.5˚F >99.6˚F	 0 14 16	 0.0 46.7 53.3	 1 16 13	 3.3 53.3 43.3	 1 (1.7) 30 (50.0) 29 (48.3)	1.444 2	0.486^{NS}
4.	**Edema** No edema Mild edema Moderate severe edema	 24 5 1	 80.0 16.7 3.3	 27 3 0	 90.0 10.0 0.0	 51 (85.0) 8 (13.3) 1 (1.7)	1.676 2	0.432^{NS}
5.	**BMI** <18.5 18.5-24.9 >25	 1 18 11	 3.3 60.0 36.7	 1 18 11	 3.3 60.0 36.7	 2 (3.3) 36 (60.0) 22 (36.7)	0.000 2	1.000^{NS}
6.	**Stages of ulcer** Stage II Stage III Stage IV	 22 6 2	 73.3 20.0 6.7	 24 6 0	 80.0 20.0 0.0	 46 (76.7) 12 (20.0) 2 (3.3)	2.087 2	0.352^{NS}
7.	**Mobility** Fully Restlessness Restricted/Chair bound Unconscious/Traction	 1 1 16 12	 3.3 3.3 53.3 40.0	 1 0 20 9	 3.3 0.0 66.7 30.0	 2 (3.3) 1 (1.7) 36 (60.0) 21 (35.0)	1.873 3	0.599^{NS}
8.	**Bowel/Bladder function** Catheterized Incontinence of Urine Void with assistance	 28 0 2	 93.3 0.0 6.7	 25 2 3	 83.3 6.7 10.0	 53 (88.3) 2 (3.3) 5 (8.3)	2.370 2	0.306^{NS}
9.	**Haemoglobin** <13 gm/dl 13-16 gm/dl	 27 3	 90.0 10.0	 25 5	 83.3 16.7	 52 (86.7) 8 (13.3)	0.577 1	0.448^{NS}
10.	**White blood cell** < 4.5 X 10^9 /L 4.5-11 X 10^9 /L >11 X 10^9 /L	 0 13 17	 0.0 43.3 56.7	 1 15 14	 3.3 50.0 46.7	 1 (1.7) 28 (46.7) 31 (51.7)	1.433 2	0.488^{NS}
11.	**Serum Iron** <60 mg/dl 60-170 mg/dl	 6 24	 20.0 80.0	 6 24	 20.0 80.0	 12 (20.0) 48 (80.0)	0.000 1	1.000^{NS}

12.	**Serum Protein** <6 gm/dl 6-8 gm/dl	 13 17	 43.3 56.7	 11 19	 36.7 63.3	 24 (40.0) 36 (60.0)	0.278 1	0.598^{NS}
13.	**Serum Albumin** <3.4 gm/dl 3.4-5.4 gm/dl >5.4 gm/dl	 16 14 0	 53.3 46.7 0.0	 14 15 1	 46.7 50.0 3.3	 30 (50.0) 29 (48.3) 1 (1.7)	1.168 2	0.558^{NS}
14.	**ESR** 0-20 mm/hr >20 mm/hr	 22 8	 73.3 26.7	 18 12	 60.0 40.0	 40 (66.7) 20 (33.3)	1.200 1	0.273^{NS}
15.	**Serum Creatinine** <0.6 mg/dl 0.6-1.2 mg/dl >1.2 mg/dl	 7 18 5	 23.3 60.0 16.7	 7 15 8	 23.3 50.0 26.7	 14 (23.3) 33 (55.0) 13 (21.7)	0.965 2	0.617^{NS}
16.	**BUN** <7 mg/dl 7-20 mg/dl >20 mg/dl	 1 21 8	 3.3 70.0 26.7	 0 19 11	 0.0 63.3 36.7	 1 (1.7) 40 (66.7) 19 (31.7)	1.574 2	0.455^{NS}

p>0.05: NS

Table 3 (a): Mean and standard deviation of study subject according to total PUSH tool 3.0 of pre- interventional assessment grading of decubitus ulcer. N=60

Pre interventional assessment (Day 1)				
Ulcer Characteristics	**Interventional group**		**Conventional group**	
	Mean	**SD**	**Mean**	**SD**
Total PUSH score	11.13	2.636	11.07	2.778

Table 3 (a) depicts that pre interventional assessment of decubitus ulcer grading on 1st day. In interventional group, the pre interventional mean of total PUSH score was 11.13 and standard deviation was 2.636 and in conventional group. The pre interventional mean of total PUSH score was 11.07 and standard deviation was 2.778.

Table 3 (b): Mean and standard deviation of study subject according to total PUSH tool 3.0 of post- interventional assessment grading of decubitus ulcer. N=60

Post interventional assessment (Day 8)				
Ulcer Characteristics	**Interventional group**		**Conventional group**	
	Mean	**SD**	**Mean**	**SD**
Total PUSH score	6.40	3.865	9.30	2.493

Table 3 (b) depict the post interventional assessment of decubitus ulcer grading on 8th day. In interventional group, the post interventional mean of total PUSH score was 6.40 and standard deviation was 3.865 and in conventional group, the post interventional mean of total PUSH score was 9.30 and standard deviation was 2.493.

Table 3 (c): Comparison of mean and standard deviation (PUSH scores) of study participants on decubitus ulcer characteristics in interventional and conventional group. N=60

Ulcer Characteristics	**Assessment Of Decubitus ulcer**	**Interventional group (n=30)**	**Conventional Group (n=30)**	**t value (DF=58)**	**p value**
		Mean±SD	**Mean±SD**		
Total PUSH Score	Pre-assessment (D_1)	11.13±2.636	11.07±2.778	0.095	0.924
	Post-assessment (D_8)	6.40±3.865	9.30±2.493	3.453	0.001*
		t value-15.245 p value-0.000*	t value-12.504 p value-0.000*		

*p≤0.05 level of significance

Table no 3 (c) illustrates the comparison between pre and post- interventional assessment of total PUSH score among decubitus ulcer patients in interventional and conventional group. The difference between the mean scores was computed by using independent t-test and paired t-test.

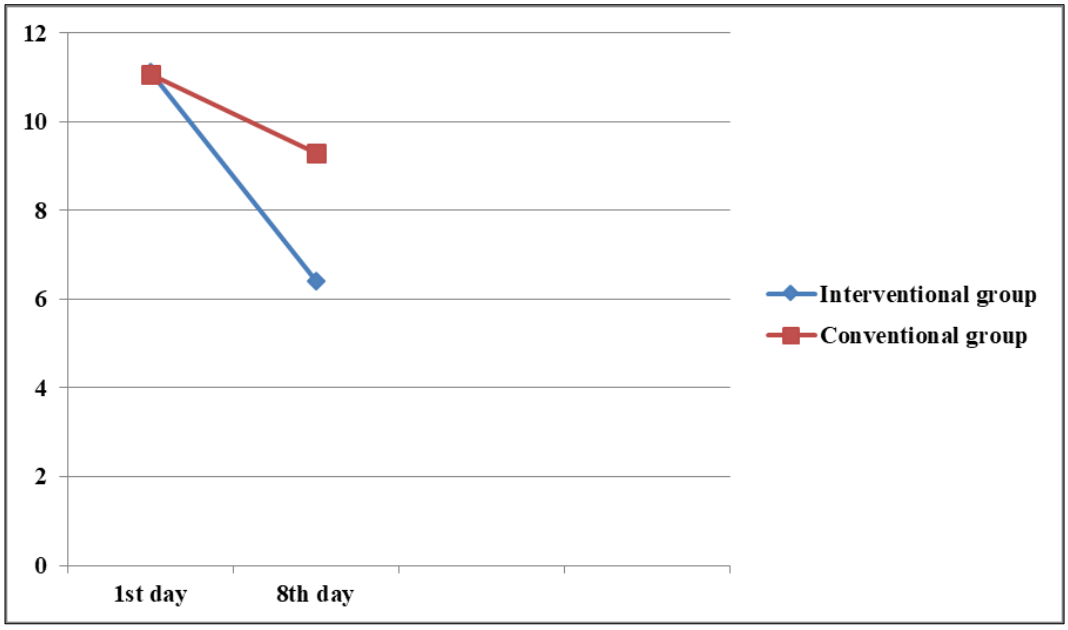

Fig 3 (c): Comparison of mean of "Total PUSH score" of decubitus ulcer between interventional and conventional group on 1st day and 8th day

The pre-interventional mean and standard deviation of "Total PUSH scores" was 11.13±2.636 on 1st day which reduced to 6.40±3.865 on 8th day in interventional group whereas in conventional group, the pre-interventional mean and standard deviation of "Total PUSH scores" was 11.07±2.778 on 1st day which reduced to 9.30±2.493 on 8th day. The t-value was 0.095 and p value was 0.924 on 1st day which was statistically non-significant at the level of p≤0.05 whereas t-value was 3.453 and p value was 0.001 on 8th day which was found to be statistically significant at the level of p≤0.05.

4. Discussion

The results of the study shows that on pre-assessment total mean score of PUSH tool in interventional group was 11.13 on 1st day which reduced to 6.40 on 8th day among patients with decubitus ulcer grade II, III & IV which is supported by similar study conducted by Borgohain U *et al* (2017) [6] where mean before and after were 11 and 7 respectively and value of t was 27.75 highly significant at 0.05% level which shows that transdermal oxygen therapy helps in healing pressure ulcer.

Similar findings were reported by Azimian J *et al* (2015) [7] where total mean of wound area in interventional group was significantly lower than conventional group. The present study revealed that total mean surface area score of decubitus ulcer reduced from 7.70 to 5.17, exudate amount reduced from 1.33 to 0.27 and mean score of tissue type from 2.10 to 0.97 in interventional group.

Ahmadinejad M (2020) [8] also given the supportive finding that PUSH score were 5.59± 3.6 in the intervention group and 8.90± 3.2 in the control group and the findings suggest that transdermal oxygen therapy reduced exudation and surface area of the wounds and increase granulation tissue formation in patients with decubitus ulcers. Similar findings were reported by Sano H *et al* (2015) [12] that topical wound oxygen therapy reduced the size of wound and formation of granulation tissue. The reviewed of study by Kimmel MH (2016) [5] also given the supported finding that oxygen administration showed wound healing to produce granulation tissue.

The present study shows that on pre-assessment total mean score of PUSH tool in conventional group was 11.07 on 1st day which reduced to 9.30 on 8th day among patients with decubitus ulcer grade II, III & IV. Bigliadi PL (2017) [9] also conducted the study which results showed that povidone-iodine is rapid, potent, broad-spectrum anti-microbial properties and it is highly effective for acute and chronic wounds treatment. Flynn J (2003) [10] reviewed a study evaluated that povidone- iodine should be expand by health care professionals to preventing and treating infection in acute and chronic wounds.

Another similar study conducted by Lee BY (1979) [11] topical application of povidone-iodine in the management of decubitus and statis ulcer. The study sample was 18 male patients (age 33-68 years) and dressing was change twice a day for 42 days. The results showed that 67% of ulcers were cured and 33% showed improvement and appear no adverse effect and can reduce the infection and enhance healing process.

5. Recommendations

- A similar study can be replicated with large sample for better generalization.
- A comparative study can be done between humidified oxygen therapy and any other measures to evaluate the best.
- A study can be conducted to assess the knowledge, attitude and practice of nursing staff regarding the decubitus ulcer care.
- A study can be conducted to assess the effectiveness of humidified oxygen therapy on diabetic foot ulcer healing.

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