Effectiveness of Betadine Versus Normal Saline on Pressure Ulcers among Bedridden Patients

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ABSTRACT

Background of the study: Pressure ulcers also known as bed sores, are localized damaged to the skin or underlying tissues that usually occurs over a bony prominence as a result of usually long term pressure or pressure in combination with shear or friction. The most common sites are the skin overlying the sacrum, coccyx, heels and hips, other sites can also be affected such as elbows, knees, ankles, back of shoulder or back of the cranium. Pressure ulcers occur due to pressure applied to soft tissues resulting in completely or partially obstructed blood flow to the soft tissues.

Objective: To assess the effectiveness of Betadine versus normal saline on pressure ulcers among bedridden patients.

Methods: A pretest posttest control group design (two groups) was used to assess the effectiveness of Betadine versus Normal saline on pressure ulcers among bedridden patients admitted in critical care areas of a tertiary care hospital, Ludhiana of DMCH. Total 30 bedridden patients were drawn from the target population by using total enumerative sampling technique and then allocation of subjects was done into experimental group1 ($n1=15$) and experimental group2 ($n2=15$) by lottery method. In experimental group1, betadine dressing twice a day for 6 consecutive days was done. In experimental group2, normal saline dressing twice a day for 6 consecutive days was done. Data was collected by using patients profile (which include socio- demographic profile and clinical profile) and PUSH tool for healing of pressure ulcers which include 3 components- Surface area, Exudate amount and Tissue type with the help of interview, observation, bio-physiological parameters and records and reports. Data was analyzed by using inferential and descriptive statistics.

Results: The findings revealed that for healing process of pressure ulcer which includes surface area, exudates amount and tissue type: Non- significant result were found between experimental group$_1$ and experiential group$_2$ ($p>0.05$) in surface area, exudates amount and tissue type in all the observations from Day I to Day IV. It was concluded that there was no statistical significant results in mean of surface area within experimental group1 ($p=.993$) and experimental group2 ($p=.996$) and there was no statistical difference between the experimental group1 and experimental group2 from day I ($p=.183$) to day II ($p=.176$) to day III ($p=.190$) to day IV ($p=.251$) to day V ($p=.224$) to day VI ($p=.127$).It was concluded that there was no statistical difference between the total score of healing process of experimental group$_1$ and experimental group$_2$ on day I ($p=.460$) and day VI ($p=.392$). There was significant difference between the total score of healing process within the experimental group$_1$ ($p=.001$) and experimental group$_2$ ($p=.001$). Thus, null hypothesis was accepted.

Conclusion: Both Betadine 10% and normal saline 0.9% can be recommended for pressure ulcer dressing in clinical practice**.**

Keywords: Betadine, Normal saline, Pressure ulcers, bedridden patients

INTRODUCTION

Critically ill patient's admitted in intensive care units have severe respiratory, cardiovascular or neurological derangements. Due to number of such physiological problems patients become bedridden.[i] A Bedridden patient becomes vulnerable to various health complications and one of the most unfortunate and preventable complications that can occur in these patients are bedsores.[ii] The National Pressure Ulcer Advisory Panel (NPUAP) defines pressure ulcers as localized damage to the skin and underlying tissue. Pressure ulcers most commonly develop in individuals who are on chronic bed rest or who is bedridden or immobile from a long period.[iii] Pressure lead on the skin and tissues that covers the bony areas of the body are at biggest risk. It can cause warmth, redness and swelling of the affected area. People with pressure ulcers can experience great pain, discomfort, depression and reduced quality of life and must be prevented and treated.[iv]

The most common sites for bed sores are the skin overlying the sacrum, coccyx, heels, hips, elbows, knees, ankles, back of shoulder or back of the cranium. Due to pressure applied to soft tissues over these pony prominences there is complete or partial obstruction of blood flow to the soft tissues.[v] Shear is also a cause as it can pull on blood vessels that feed the skin. The rate of pressure ulcers in hospital setting is high. The incidence rates of pressure ulcers vary greatly with the health care settings. The National Pressure Ulcer Advisory Panel (NPUAP) says the incidence ranges from 0.4 percent to 38 percent in hospitals, from 2.2 percent to 23.9 percent in skilled nursing facilities, and from 0 percent to 17 percent for home health agencies.[vi]

Bedsores are divided into 4 stages, from least severe to most severe in symptoms. Various strategies are used to cure and prevent the pressure ulcers like perform skin assessments every 8 hours using the Braden Scale. Reposition the patient from left, right, and back every 2 hours to offload pressure using a pillow or wedge. Ensure adequate nutritional status to improve wound healing. Maintain adequate hydration. Eliminate friction or shear by limiting linen layers. Manage moisture or incontinence.[vii]

In ancient Greek and Roman medicine, sea sponges were used to absorb fluid from wounds. These were also soaked in wine and used as an antibacterial wound dressing. In 1880s the dressing was made from gauze, cotton and coconut fiber, and had a center capsule containing an antiseptic. Later these gauze, small pieces of which were impregnated with extracts of opium and lettuce seeds and inserted into wound cavity of patients as a device to induce wound healing.[viii] The first 'modern' dressings to be used in wound management and became widely available in the mid-1970s. The dressings are able to absorb exudates into the air spaces within the structure in a similar manner. Dressing absorbs the exudates by capillary action and it is held within the structure thereby removing the exudates and edema fluid and enhancing epithelialization.[ix]

Wound healing is a complex and dynamic process of restoring cellular structures and tissue layers. The human adult wound healing process can be divided into 3 distinct phases: the inflammatory phase, the proliferative phase, and the remodeling phase. Within these 3 broad phases is a complex and coordinated series of events that includes chemo taxis, phagocytosis, neocollagenesis, collagen degradation, and collagen remodeling.[x] In addition, angiogenesis, epithelization, and the production of new glycosaminoglycan's (GAGs) and proteoglycans are vital to the wound healing milieu. The culmination of these biological processes results in the replacement of normal skin structures with fibroblastic mediated scar tissue.[xi]

Various types of dressings are used to cure the pressure ulcers. Current treatment approaches for pressure ulcers include hydrocolloid, transparent film, hydro gel, alginate, normal saline, foam, polymeric membrane, silver-impregnated gauze, insulin, gauze, silicone dressings, collagen matrix, and composite dressings. In the management of pressure ulcer, the wound care is inevitable one.[xii] There are many antibiotic ointments/dressings used in the treatment of healing of pressure sores. These include: tap water, normal saline, procaine spirit,

distilled water, acetic acid (25%), povidone-iodine, hydrogen peroxide (3%) and others. The Normal saline dressing and Betadine dressing is also effective in the healing process of pressure ulcers.[xiii]

Basava AH, et al. (2017) conducted a prospective study to compare the effectiveness of saline dressing versus povidone iodine dressing in chronic diabetic wound healing in Government Medical College and Hospital, Kozhikode, Kerala. Subjects were divided into two groups by consecutive sampling i.e., Povidone iodine and Saline dressing group. Regular occlusive dressing was done for 6 weeks of follow-up period. Results indicated that 3 out of 20 subjects in Saline treated group achieved complete healing by 6 weeks as compared to 1 out of 20 subjects in Povidone iodine treated group. There was a significant decrease in the wound surface area at 6th week in Saline dressing group in comparison to the povidone-iodine group at $p=0.03(<0.05)$ level of significance. Therefore, Saline dressing was more effective in achieving healing in chronic diabetic wounds as compared to Povidone iodine dressing.[xiv]

Prabusankar P, et al. (2011) conducted a comparative study on efficacy of normal saline wound dressings versus povidone iodine wound dressings in chronic non healing nonmalignant foot ulcers in Surat Municipal Institute of Medical Education and Research (SMIMER), Surat. 60 patients were randomly divided into two groups The results showed that there was similar improvement in ulcer size in both the groups (p value = 0.001*).[xv]

Various similar studies conducted in different clinical settings showed that there is a greater impact of Normal saline and Betadine on the healing process of wound among bedridden patients. Hence researcher felt that there is the need to replicate this program in our clinical setting, so that it advocates studies with empirical evidence about the effectiveness of Betadine versus Normal saline on the healing process of pressure ulcers among bedridden patients

MATERIAL AND METHODS

An experimental- pretest posttest control group design (two experimental groups) was used to assess the effectiveness of Betadine versus Normal saline on pressure ulcers among bedridden patients admitted in Critical Care Units of DMCH, Ludhiana, Punjab. A written permission was taken from Institutional Ethics Committee of DMCH, Ludhiana. Consented patients who were having: age of 18years & above and pressure ulcers of stage 2-4 were enrolled in the study. The patients who were excluded from the study were those who were: hemodynamically unstable (airway, breathing, circulation affected), un-cooperative and not willing to participate in the study. As per inclusion and exclusion criteria, total 30 bedridden patients were drawn from the target population by using total enumerative sampling technique and then allocation of subjects was done into experimental group1 ($n1= 15$) and experimental group2 ($n2= 15$) by lottery method. In experimental group1, betadine dressing twice a day for 6 consecutive days was done. In experimental group2, normal saline dressing twice a day for 6 consecutive days was done. **{Fig 1(a) & Fig 1(b)}**

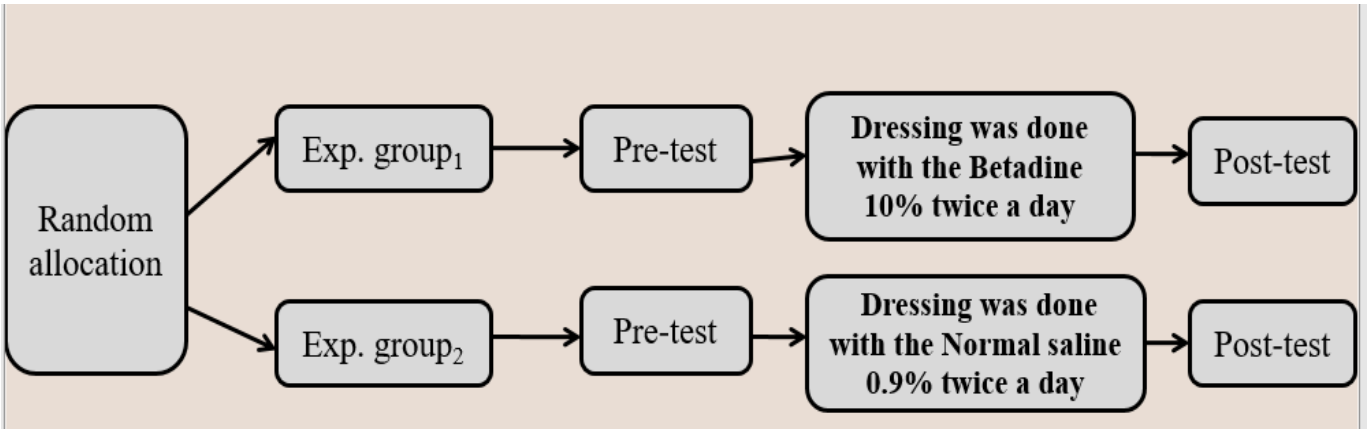


Fig 1(a): Pretest posttest control group design (Two experimental groups)

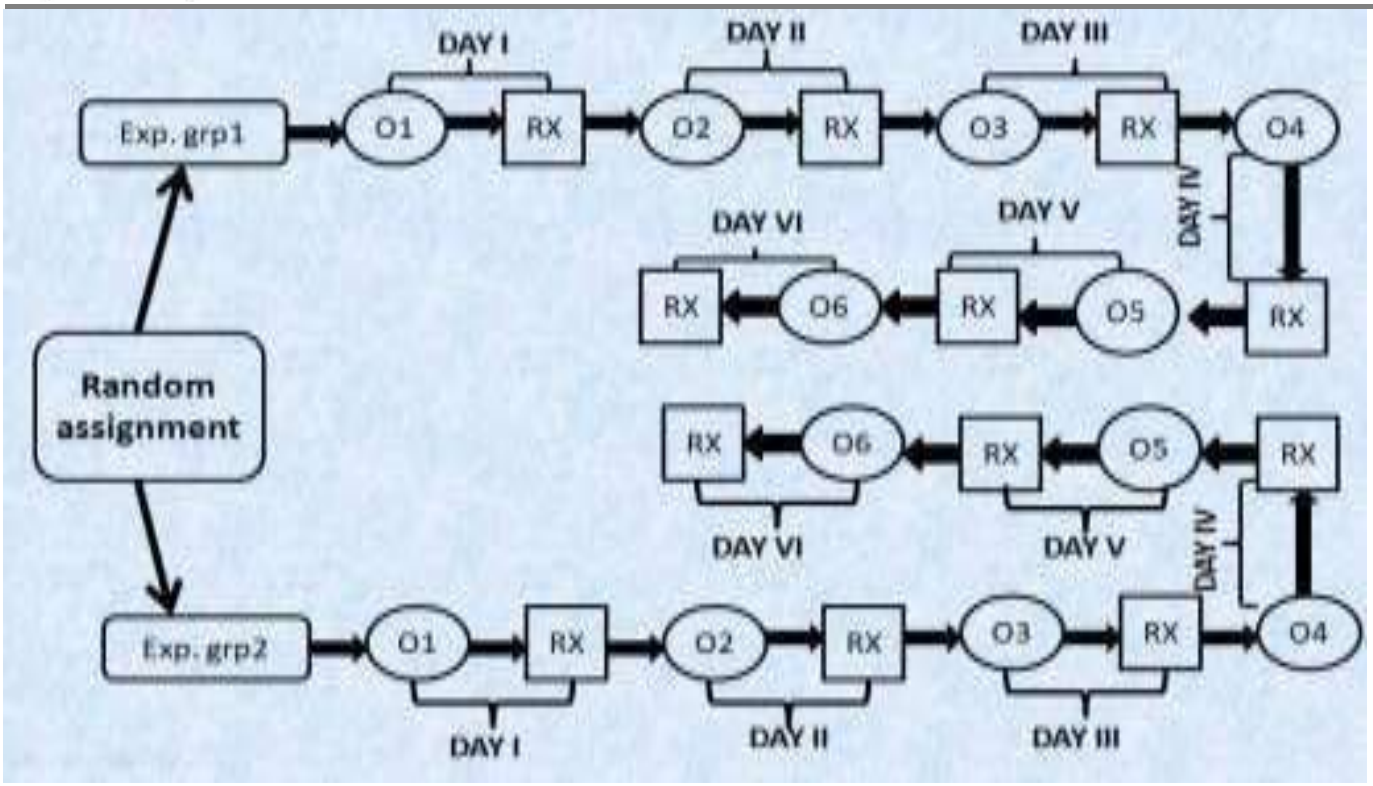


Fig 1(b): Research design for this study

Pretest posttest control group design (two experimental groups)

Betadine dressing in experimental group1: It refers to cleaning the pressure ulcer with normal saline solution and application of povidone iodine (Betadine) dressing over the pressure ulcer site twice a day for 6 consecutive days.

Normal saline dressing in experimental group2: It refers to cleaning the pressure ulcer with normal saline solution and application of normal saline dressing over the pressure ulcer site twice a day for 6 consecutive days.

Following guidelines were taken into consideration for dressing of pressure ulcers in bedridden patients in both the experimental groups:

- Wash hands with soap and water
- Ensure privacy and provide proper position
- Remove the soiled dressing
- Assess the wound according to PUSH tool
- Remove gloves and wash hands
- Wear new gloves
- After cleaning the wound with NS and apply the dressing with Betadine/ Normal saline
- Cover the wound with sterile dressing and remove gloves
- Wash hands and document the finding

Research Tool which was used to collect data in the study was divided into two parts:

PART A: **Patient's profile** which is further divided two sections:

Section I -Socio Demographic Profile: It includes 9 items to obtain information about age in years, gender, habitat, educational status, religion, marital status, dietary habits, occupation, and socio-economic status.

Section II- Clinical Profile: It includes 16 items to obtain information about patient diagnosis, duration of hospitalization, duration in critical care area, BMI, diabetes status, co morbidities, site of pressure ulcer, duration of pressure ulcers, degree of pressure ulcer, using pressure relieving devices, known case of sepsis, incontinence, duration of immobilization, on ventilator support, on medications and any addiction.

PART B: PUSH Tool: It is standardized tool adopted from National Pressure Ulcer Advisory Panel version 3.0, 1998. Its reliability is pre-established (kappa = 0.97 to 1.00). It is used to measure the healing process of pressure ulcers which include 3 components- Surface area, Exudate amount and Tissue type over time. The total score ranges from 0 to 17 in which 0 means healed and 17 means serious pressure ulcer of considerable size, heavy Exudate and non-viable tissue. A comparison of total scores measured over time provides an indication of the improvement or deterioration in pressure ulcer healing.

Before intervention bedridden patients were interviewed for socio demographic & clinical profile and baseline observation for healing process i.e. O1 was done in both the experimental group. In experimental group1, betadine dressing twice a day for 6 consecutive days was done. In experimental group2, normal saline dressing twice a day for 6 consecutive days was done. After intervention every day post interventional observation for healing process i.e. O2, O3,04, O5 & O6 was done in both the experimental groups till sixth day. Comparison of baseline and post interventional healing process of pressure ulcers in both the experimental groups was done. Methods used for data collection were interview, observation, records & reports and bio-physiological parameters. Data was analyzed with the use of descriptive and inferential statistics.

RESULTS

Table1 depicts the frequency and percentage distribution of bedridden patients among experimental group1 and experimental group2 as per their selected socio demographic profile and it was found that the two groups i.e. experimental group$_1$ and experimental group$_2$ were statistically identical ($p>0.05$) as per their socio demographic profile which includes age, gender, habitat, educational status, religion, marital status, dietary habits, occupation and socio economic status of the bedridden patients **(Table 1)**

Table 1: Frequency and Percentage distribution of bedridden patients among experimental group$_1$ and experimental group$_2$ as per their selected Socio Demographic profile

N=30

Socio-demographic profile	**Experimental group$_1$ n_1=15 f(%)**	**Experimental group$_2$ n_2=15 f(%)**	**X^2 Statistics**
Age (in years)*			
18-35	3(20.0)	1(6.7)	3.175
36-50	1(6.7)	4(26.7)	df=3
51-65	3(20.0)	2(13.3)	p=.365^{NS}
More than 66	8(53.3)	8(53.3)	
Gender*			1.292
Male	11(73.3)	8(53.3)	df=1
Female	4(26.7)	7(46.7)	p=.256^{NS}
Habitat			1.222

Rural	5(33.3)	8(53.3)	df=1
Urban	10(66.7)	7(46.7)	p=.269^{NS}
Educational status*			2.612
Elementary	2(13.3)	4(26.7)	df=2
Secondary education	6(40.0)	8(53.3)	p=.271^{NS}
Graduate and above	7(46.7)	3(20.0)	
Religion *			
Hindu	10(66.7)	8(53.3)	1.700
Sikh	5(33.3)	6(40.0)	df=2
Jainism	0(0.0)	1(6.7)	p=.427^{NS}
Marital status*			
Married	11(73.3)	14(93.3)	7.292
Unmarried/single	2(13.3)	0(0.0)	df=3
Divorced/separated	0(0.0)	1(6.7)	p=.063NS
Widow/widower	2(13.3)	0(0.0)	
Dietary habits*			1.292
Vegetarian	11(73.3)	8(53.3)	df=1
Non-vegetarian	4(26.7)	7(46.7)	p=.256NS
Occupation*			1.449
Working	3(20.0)	6(40.0)	df=1
Non-working	12(80.0)	9(60.0)	p=.426NS
Socio-economic status*			.136
Upper middle (II)	7(46.7)	6(40.0)	df=1
Lower middle (III)	8(53.3)	9(60.0)	p=.713NS

Mean age (in years) ±SD in Experimental gp1= 62.13±18.45

*significant

Mean age (in years) ±SD in Experimental gp2= 6 1.33±15.79

NS=Non-Significant

*wherever expected count was less than 5, likelihood ratio used for homogeneity

Table 2 depicts frequency and percentage distribution of bedridden patients among experimental group$_1$ and experimental group$_2$ as per their selected clinical profile and it was found that the two groups i.e. experimental group$_1$ and experimental group$_2$ were statistically identical ($p>0.05$) as per their clinical profile which includes duration of hospitalization, duration in critical care areas, duration of pressure ulcers, duration of immobilization, BMI, and diabetic status of the bedridden patients.

Table 2- Frequency and percentage distribution of bedridden patients among experimental group[1] and experimental group[2] as per their selected clinical profile.

N=30

Clinical profile	**Experimental group$_1$ n_1=15 f(%)**	**Experimental group$_2$ n_2=15 f(%)**	**X2 Statistics**
Duration of			
hospitalization*			
1-10 days	10(66.66)	06(40)	3.606
11-20 days	03(20)	08(53.33)	df=2
21-31 days	02(13.3)	01(6.66)	p=.164^{NS}
Duration in critical			
care area*			
1-10 days	12(80.0)	10(66.6)	2.315
11-20 days	01(06.6)	04(26.6)	df=2
21-31 days	02(13.3)	01(06.6)	p=.314^{NS}
Duration of			
pressure ulcers*			
1-10 days	10(62.5)	7(43.8)	2.462
11-20 days	3(18.8)	7(43.8)	df=2
21-31 days	2(12.5)	1(6.2)	p=.291^{NS}
Duration of			
immobilization*			
1-10 days	7(43.8)	5(31.2)	2.333
11-20 days	4(25.0)	8(50.0)	df=1
21-31 days	4(25.0)	2(12.5)	p=.361^{NS}
BMI*			
Underweight (<18.5)	01(06.7)	00(00.0)	5.662
Normal (18.5-24.9)	06(40.0)	05(33.3)	df=4
Overweight (25-29.9)	02(13.3)	07(46.6)	p=.226NS
Obese (>30)	06(40.0)	03(20.0)	
Diabetic status			1.2
Non-diabetic	9(60.0)	6(40.0)	df=4
Diabetic	6(40.0)	9(60.0)	p=.273^{NS}

Mean BMI±SD in Experimental gp1=26.09±4.744

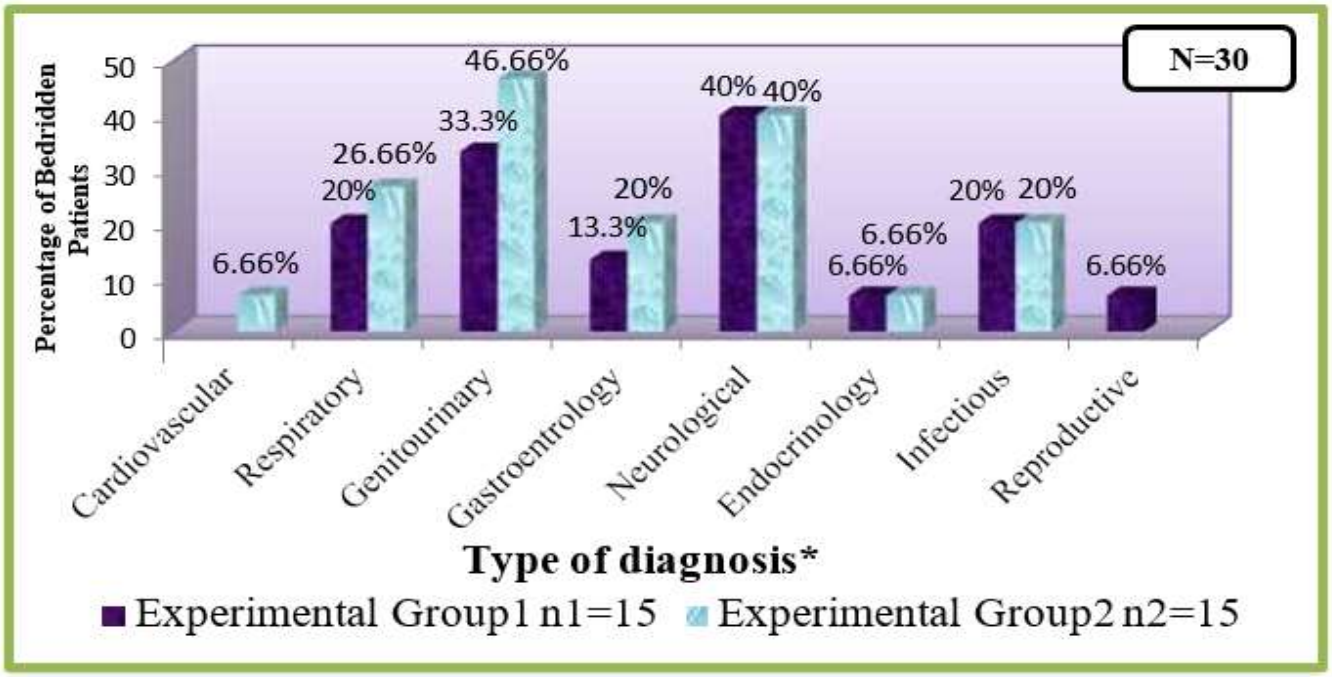
*significant

Mean BMI±SD in Experimental gp2= 26 .43±3.256

NS=Non-Significant

*wherever expected count was less than 5, likelihood ratio used for homogeneity

Fig 2 depicts distribution of bedridden patients according to their diagnosis and it shows that in experimental group$_1$, maximum patients (40%) were having neurological disorders and in experimental group$_2$, maximum patients (46.66%) were having genitourinary disorders.



*Multiple responses

Fig 2- Distribution of bedridden patients according to their diagnosis

Fig 3 depicts distribution of bedridden patients according to their site of pressure ulcers and it shows that in both the groups i.e. in experimental group$_1$ and in experimental group$_2$, maximum patients (66.7%) were having pressure ulcers on buttocks.

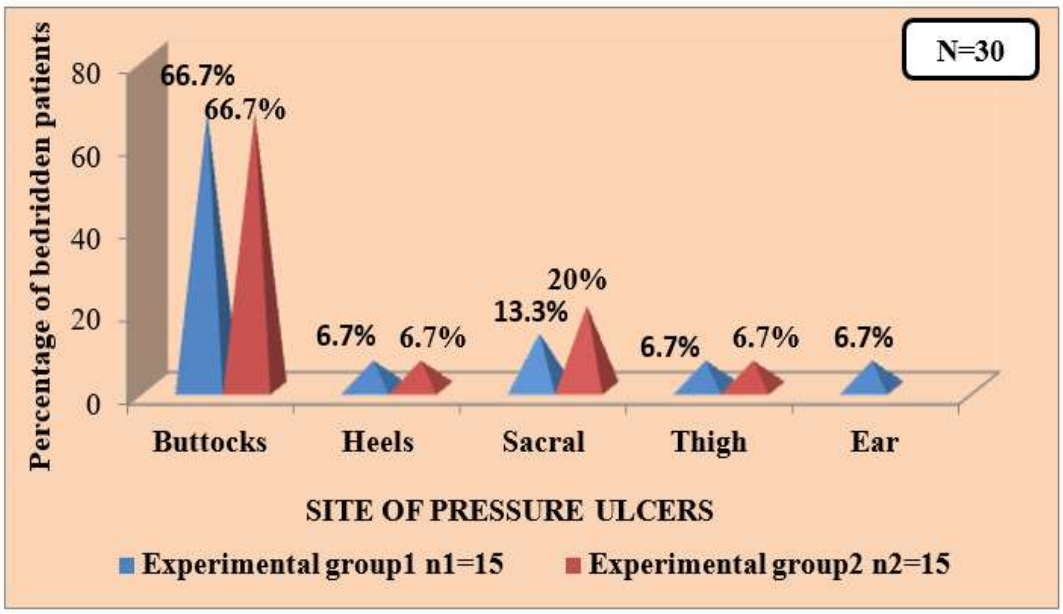


Fig 3- Distribution of bedridden patients according to their site of pressure ulcers

Fig 4 depicts distribution of bedridden patients according to their degree of pressure ulcers. In both the groups i.e. experimental group$_1$ and in experimental group$_2$, all of 100% patients were having second degree of pressure ulcers.

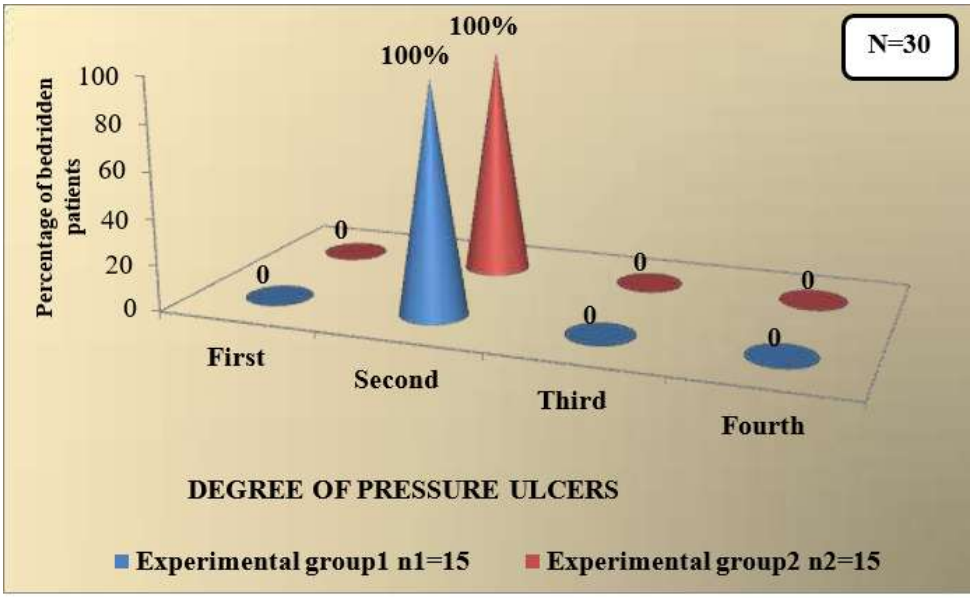


Fig 4- Distribution of bedridden patients according to their degree of pressure ulcers

Table 3- Comparison of bedridden patients in experimental group[1] and experimental group[2] according to their mean total score of pressure ulcer healing on day I and day VI

N=30

DAYS	Experimental group1 n1=15	Experimental group2 n2=15	Mean difference	Unpaired t/p value
	Mean ± SD	Mean ± SD		
Day I	9.67±3.395	10.67±3.904	1	t= .749 p=.460^{NS}
Day VI	7.13±5.181	8.73±4.906	1.6	t= .869 p=.392^{NS}
Paired t/p value	t= 4.219 p=.001*	t= 4.005 p=.001*		

*Significant

NS=Non-significant

Table 3 and Fig 5 depicts comparison of bedridden patients in experimental group[1] and experimental group[2] according to their mean total score of pressure ulcer healing on day I and day VI. It shows that there was no statistical difference between the total score of healing process of experimental group$_1$ and experimental group$_2$ on day I (p=.460) and day VI (p=.392). and there was significant difference between the total score of healing process within the experimental group$_1$ (p=.001) and experimental group$_2$ (p=.001).

As per three 3 components- Surface area, Exudate amount and Tissue type of PUSH Tool there is no statistical significant difference between experimental group1 and experimental group2 (p>0.05) in surface area (length × width) in cm2, in exudates amount and in tissue type of pressure ulcers in all the observations from Day I to Day VI but statistically significant difference was found within the experimental group1 and experimental

group2 ($p<0.05$) in surface area (length × width) in cm2, in exudates amount and in tissue type of pressure ulcers in all the observations from Day I to Day VI.

Hence it is concluded that null hypothesis was accepted i.e. ***H0: There will be no significant difference in the healing process of pressure ulcers among both the experimental groups.*** So, both Betadine 10% and normal saline 0.9% can be recommended for pressure ulcer dressing in clinical practice.

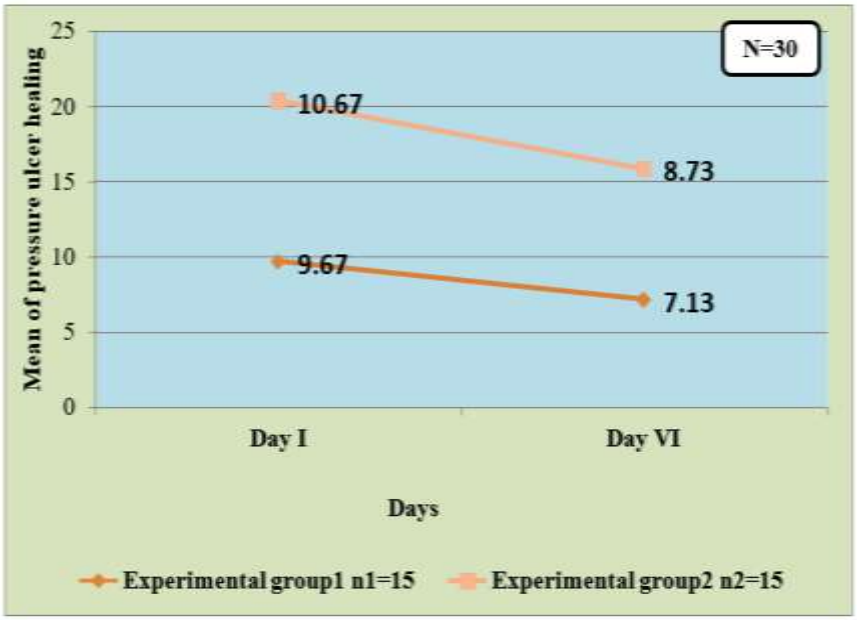


Figure 5- Line diagram showing comparison of bedridden patients in experimental group[1] and experimental group[2] according to their mean total score of pressure healing on day I and day VI

DISCUSSIONS

Prolonged bedridden patient becomes vulnerable to various health complications. One of the most unfortunate and preventable complications that can occur in these patients are bedsores. The most common sites for bedsores are over the sacrum, coccyx, heels, hips, elbows, knees, ankles, back of shoulder and back of the cranium. The incidence rate of pressure ulcers is increasing day by day. Various types of dressings are used to cure the pressure ulcers. There are many antibiotic ointments and dressings used in the treatment of healing of pressure sores. The Normal saline dressing and Betadine dressing is also effective in the healing process of pressure ulcers.

Present study was conducted to assess the effectiveness of Betadine versus Normal saline on pressure ulcers among bedridden patients admitted in critical care areas of a tertiary care hospital, Ludhiana, Punjab and gives the evidence that there was no statistical difference between the total score of healing process of experimental $group_1$ and experimental $group_2$ on day I ($p=.460$) and day VI ($p=.392$) and there was significant difference between the total score of healing process within the experimental $group_1$ ($p=.001$) and experimental $group_2$ ($p=.001$). As per three 3 components- Surface area, Exudate amount and Tissue type of PUSH Tool there is no statistical significant difference between experimental group1 and experimental group2 ($p>0.05$) in surface area (length × width) in cm2, in exudates amount and in tissue type of pressure ulcers in all the observations from Day I to Day VI but statistically significant difference was found within the experimental group1 and experimental group2 ($p<0.05$) in surface area (length × width) in cm2, in exudates amount and in tissue type of pressure ulcers in all the observations from Day I to Day VI. ***So, it was concluded that null hypothesis was accepted.*** Hence, both Betadine 10% and normal saline 0.9% can be recommended for pressure ulcer dressing in clinical practice.

Similar study was conducted by Basava AH, et al. (2017) on the effect of saline dressing versus povidone iodine dressing in chronic diabetic wound healing. Subjects were divided into two groups by consecutive

sampling i.e. povidone iodine and saline dressing group. The findings revealed that 3 out of 20 subjects in saline treated group achieved complete healing by 6 weeks as compared to 1 out of 20 subjects in povidone iodine treated group. There was a significant decrease in the wound surface area at 6th week in saline dressing group in comparison to the povidone iodine group ($p = 0.03$).[xiv]

Similar study was conducted by Prabusankar P, et al. (2011) on efficacy of normal saline wound dressings versus povidone iodine wound dressings in chronic non healing nonmalignant foot ulcers in Surat, Municipal Institute of Medical Education and Research (SMIMER), Surat. 60 patients were randomly divided into two groups The results showed that there was similar improvement in ulcer size in both the groups (p value = 0.001*), no complications were seen in either of the group and reduction in size of ulcer in both the test group was similar.[xv]

Another study was conducted by Belwin Prem, (2017) on the effectiveness of povidone iodine dressing versus normal saline dressing on wound healing among patients with diabetic foot ulcers. 60 patients were selected purposively and then randomly assigned into both the groups i.e. experimental group1 (povidone iodine dressing: n=30) and experimental group2 (normal saline dressing: n=30). PEDIS tool was used in this study. The findings of the study revealed that a pre-test mean ± SD of healing score of pressure ulcer in povidone iodine group was 5.80 ±0.48 and in normal saline group was 5.97 ±0.18. Whereas the posttest mean ± SD of healing score of pressure ulcers in povidone iodine group was 2.53 ±1.38 and in normal saline group was 4.30 ±1.42. The mean difference in pretest was 0.17 and posttest was 1.77. The above result showed that there was statistical improvement in posttest level of wound healing score of pressure ulcer within and between the groups (p value = 0.02*). Study concludes that, povidone iodine dressing was more effective in healing bedsores as compared to normal saline dressing.[xvi]

CONCLUSION

The findings revealed that there was no statistical difference between the total score of healing process of experimental $group_1$ and experimental $group_2$ on day I ($p=.460$) and day VI ($p=.392$) and there was significant difference between the total score of healing process within the experimental $group_1$ ($p=.001$) and experimental $group_2$ ($p=.001$). As per three 3 components- Surface area, Exudate amount and Tissue type of PUSH Tool there is no statistical significant difference between experimental group1 and experimental group2 ($p>0.05$) in surface area (length × width) in cm2, in exudates amount and in tissue type of pressure ulcers in all the observations from Day I to Day VI but statistically significant difference was found within the experimental group1 and experimental group2 ($p<0.05$) in surface area (length × width) in cm2, in exudates amount and in tissue type of pressure ulcers in all the observations from Day I to Day VI. So, it is concluded that null hypothesis was accepted i.e. ***H0: There will be no significant difference in the healing process of pressure ulcers among both the experimental groups.*** Hence, both Betadine 10% and normal saline 0.9% can be recommended for pressure ulcer dressing in clinical practice.

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Conflict of Interest: None

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Ethical Approval: Approved

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