World Inventia Publishers

Journal of Pharma Research

http://www.jprinfo.com/

Vol. 8, Issue 11, 2019 ISSN: 2319-5622 USA CODEN: JPROK3

Research Article

TOPICAL CADEXOMER IODINE VERSUS SALINE DRESSING IN THE MANAGEMENT OF ACUTE AND CHRONIC EXUDING WOUNDS

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Received on: 24-09-2019; Revised and Accepted on: 21-11-2019

ABSTRACT

Background Information: *Due to low base rate of complete healing in the natural history, exuding wounds have a significant impact on the health and quality of life of patients. Evidence suggests that exuding wounds impose significant and often underappreciated burden to the individual, the healthcare system and the society as a whole. Cadexomer Iodine contains 0.9% w/v iodine within a three-dimensional starch lattice, formed into spherical microbeads and is available as an ointment in India. In this study, topical cadexomer iodine was used to determine its effect in the healing process of acute and chronic exuding wounds.*

Aim of the Study: *To compare the effectiveness of topical cadexomer iodine and saline dressing in the management of exuding wounds.*

Materials and Methods: *It is an observational cohort study which involves 100 patients suffering from various types of exuding wounds and were divided into two cohorts : test cohort - topical cadexomer iodine treated patients and control cohort – normal saline treated patients. Bates-Jensen wound assessment tool was used for the comparision of effectiveness of the test and control treatments on wound healing.*

Results: *After 10 weeks of observation, topical cadexomer iodine demonstrated significant changes in all the parameters involved in wound healing like – wound size, wound size, depth, edges, undermining, necrotic tissue type and amount, exudate type and amount, skin color surrounding wound, peripheral tissue edema and induration, granulation and epithelialization; reduction in pain and odour. The wound status continuum comparision was done with t-test procedure using SAS-9.2. The folded F value of 0.0490 infers that the test is statistically significant.*

Conclusion: *Topical cadexomer iodine is significantly more effective in the management of various types of exuding wounds when compared to normal saline dressing which is the standard dressing being used currently for exuding wounds.*

KEYWORDS: *Topical Cadexomer Iodine, Saline Dressing. Acute and Chronic Exuding Wounds.*

INTRODUCTION

Patients with heavily exuding wounds face many challenges both physically and psychosocially; from increased pain and discomfort, to social isolation and depression. In order to effectively manage these wounds, the clinician must understand the impact on the patient of living day-to-day with such a wound. An equal emphasis must also be placed on the involvement of the patient in the planning of their care, thus assisting in optimising their wellbeing. Excess exudate can have a major impact on a patient's quality of life, affecting both their physical and psychosocial wellbeing. Unresolved excess exudate will increase the risk of wound infection and result in delayed wound healing, thus impacting negatively on the patient's quality of life. Contributory factors resulting in excess exudate are poor wound assessment, wound bed preparation and inappropriate dressing selection/wear time [1-4].

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DOI: https://doi.org/10.5281/zenodo.3706446

Topical antiseptics are antimicrobial agents that kill, inhibit or reduce the number of microorganisms and are thought to be essential for wounds infection control. Iodine is a natural element of the halogen group which is also an essential nutrient in the body. It has been used throughout history in wound care for its antiseptic properties but modern clinicians have concerns regarding its use over fears of its systemic absorption, impact on metabolic function and wound healing. With the emergence of multi-resistant strains of organisms and a better understanding of the dynamics of wound healing, the use of topical iodine in wound care has taken a different profile. Cadexomer iodine represented advancement in iodine preparations because it is the first preparation that is water-soluble and able to provide sustained release of iodine at the wound site [17, 18].

The active ingredient of Cadexomer iodine (figure-1) consists of spherical beads of modified biodegradable starch. These form a three-dimensional lattice that is held together with covalent bonds and is insoluble in water. Iodine is trapped within this lattice at a concentration of 0.9% w/w. The starch has a considerable affinity for water or body fluid and can absorb about five times its own volume of tissue exudate. During this process, as the starch becomes wet iodine is released and an iodine concentration gradient is established between the ulcer surface and the cadexomer iodine. Iodide is normally inactivated in a few minutes by protein. This form, however, allows slow release of this ion, thus conferring a prolonged antiseptic action. The starch gel acts to extract microorganisms and debris from the wound, and the iodine creates an environment on the dressing, which prevents their culture [21, 25, 26].

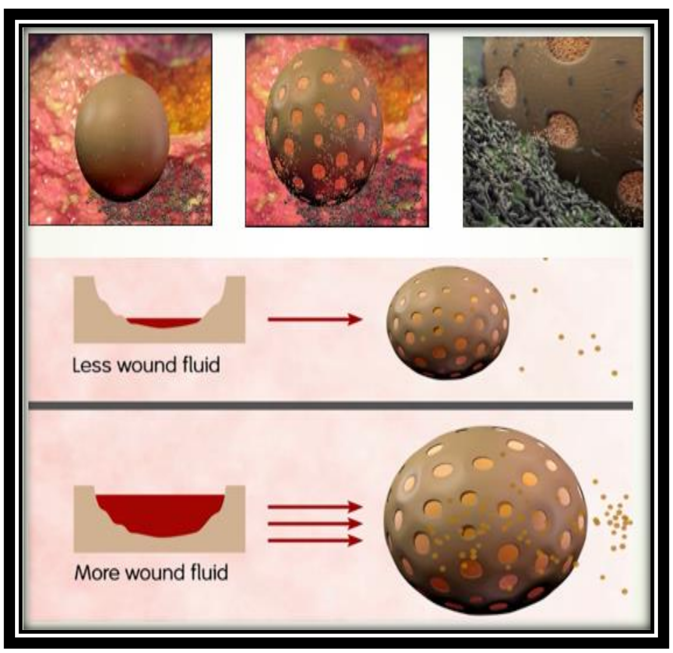


Fig. 1: Mechanism of action of cadexomer iodine beads

Using sterile saline water to irrigate wounds is one of the most common cleansing methods used by health professionals because it's a nontoxic isotonic solution. Since it is gentle enough to not damage healing tissues and neither adds nor takes fluid from the wound bed, saline dressings are good for stimulating the cleaning of heavily draining and discharging infected wounds without leaving the wound dry and itchy [5, 20].

The main objective of this study is to compare the effectiveness of Cadexomer iodine ointment and normal saline dressing in the management of acute and chronic exuding wounds. It also involves evaluation of healing process of various types of exuding wounds.

MATERIALS AND METHODS

The study was performed in the general medicine department in Lalitha super-specialities hospital, Guntur, Andhra Pradesh under the guidance of Dr. B. Praveena (assistant professor, Hindu college of pharmacy, Guntur) and Dr. Uma Shanker (general surgeon, Lalitha super-specialities hospital, Guntur).

This is a prospective cohort study on topical cadexomer iodine ointment which is an innovative anti-microbial agent used to treat acute and chronic exuding wounds. 100 patients were included based on study criteria and were divided into two cohorts. One cohort was given the treatment with topical cadexomer iodine ointment and other group was given with normal saline solution. All the 100 patients were observed during the study period of 6 months from October 2018 to March 2019.

Inclusion criteria:
(a) Patients with age between 21-60 years, (b) Diabetic foot ulcers, (c) I to IV stages of pressure ulcers, (d) Venous ulcers, (e) Post cellulitis wounds, (f) Abscess wounds and (g) Post trauma wounds.

Exclusion criteria:
(a) Patients not willing to participate in the study, (b) Geriatric patients, (c) Malnourished patients, (d) Patients with low haemoglobin, (e) Smoking and underlying cardiopulmonary conditions, (f) Patients with peripheral vascular disease and (g) Patients using steroids and chemotherapy.

Signatures of patients on informed consent form by voluntary patients who meets the inclusion criteria were taken initially. Demographic data (ID number, age, sex and BMI), relevant past medical history and social history were collected. Wound assessment was done using Bates-Jensen wound assessment tool, which includes rating sheet to assess wound status (wound size, depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, skin color surrounding wound, peripheral tissue edema, peripheral tissue induaration, granulation tissue and epithelialization). Wound was also observed for presence or absence of pain and odour.

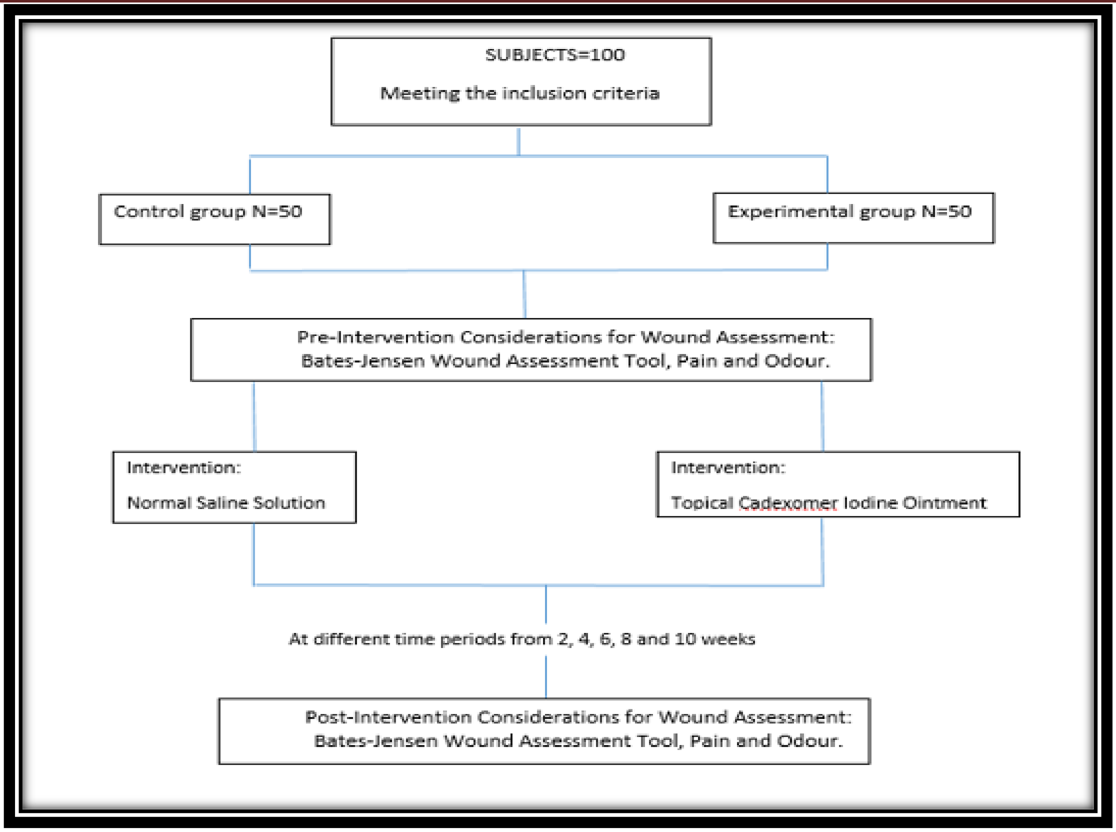


Fig. 2: Study methodology

Usage of topical cadexomer iodine ointment according to protocol- Clean the wound with sterile water or saline. Do not dry the wound surface. With a gloved finger, apply cadexomer iodine ointment to dry sterile gauze, ensuring an adequate amount to cover the entire wound to a depth of 3mm; then position the gauze over the wound. Place a secondary dressing over the gauze and then lightly, smoothen down the dressing and spread the ointment underneath to cover the area of the ulcer and to a minimum depth of 3mm. A single application of cadexomer iodine should not exceed 50g. The total amount of cadexomer iodine used in 1 week should not exceed 150g. The duration of treatment should not exceed 3 months in any single course of treatment.

Usage of saline solution according to protocol- The wound was washed with saline solution by dipping the gauze in solution. Cover the wound with gauze pads soaked in saline solution. Cover the gauze with semi-occlusive dressing.

Treat as above in every 2 days while changing the dressing.

All the relevant and necessary data will be collected from patient demographics (Age, BMI, Sex, Race and Ethnicity), type of wound, wound status before topical cadexomer iodine treatment, wound status before saline dressing, topical cadexomer iodine treatment follow-up, saline dressing treatment follow-up, presence of pain and odour. All the raw data was entered in Excel sheet 2007 in Windows 10 version. The statistical analysis was done using SAS-9.2 software by appropriate statistical methods, namely, shift tables and t-test.

RESULTS

Over 6 months period of our study, we have observed 100 patients who were included based on the study criteria. Data from baseline (week0) to week 10 is collected at intervals of 2 weeks, i.e; week 0, week 2, week 4, week 6, week 8 and week 10. This duration of follow-up had been fixed based on the washout period of topical cadexomer iodine ointment which is 3 months.

The demographic details of the patients we included are Age, Sex and BMI (table-1). Statistics considered are percentile no.of subjects (n(%)), no.of subjects (N), Mean, standard deviation (SD), Median, minimum value (Min) and maximum value (Max).

Table No. 1: Summary of demographics

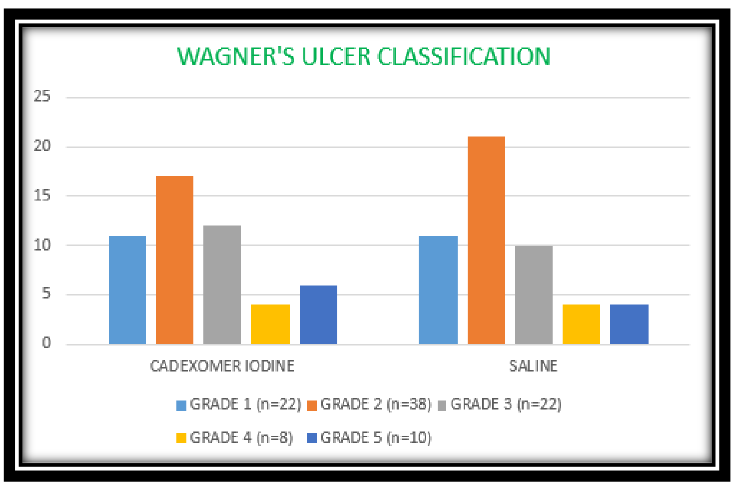
Category	Statistic	Cadexomer Iodine (CI) (N=50)	Normal Saline(NS) (N=50)
		Gender	
Female	n (%)	24 (48.0)	24 (48.0)
Male	n (%)	26 (52.0)	26 (52.0)
		Age Group (years)	
21-30	n (%)	9 (18.0)	15 (30.0)

31-40	n (%)	15 (30.0)	14 (28.0)
41-50	n (%)	11 (22.0)	15 (30.0)
51-60	n (%)	15 (30.0)	6 (12.0)
Marital Status			
Unmarried	n (%)	6 (12.0)	8 (16.0)
Married	n (%)	44 (88.0)	42 (84.0)
Height (cm)	N	50	50
	Mean	1.68	1.69
	SD	0.09	0.10
	Median	1.70	1.71
	Min, Max	1.6, 1.8	1.5, 1.8
Weight (kg)	N	50	50
	Mean	72.70	74.84
	SD	12.04	14.29
	Median	72.50	75.50
	Min, Max	53.0, 97.0	49.0, 104.0
BMI (kg/m²)	N	50	50
	Mean	25.67	26.07
	SD	2.22	2.79
	Median	25.86	26.45
	Min, Max	21.5, 29.8	20.4, 33.6

Wounds of the subjects are observed and classified based on Wagner's ulcer classification (Table-2). Most of the subjects came up with grade-2 type of ulcers (Graph-1) according to this classification.

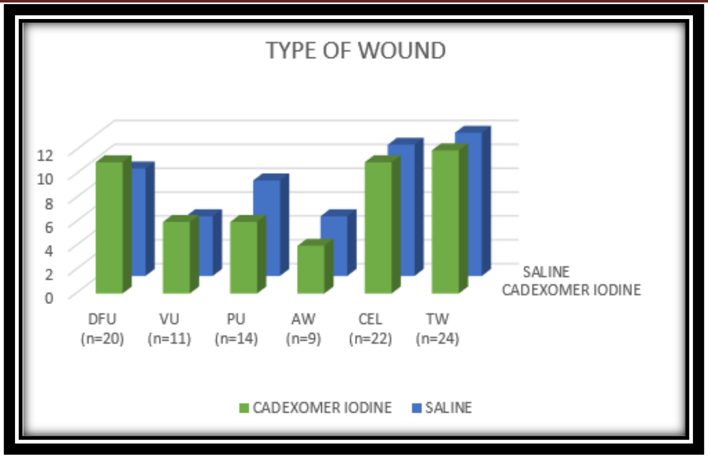
Table No. 2: Wagner's Ulcer Classification

WAGNER SCORE	DESCRIPTION
GRADE 0	No open ulceration, but with possible existence of bone deformation or hyperkeratosis
GRADE 1	Superficial ulceration, but without penetration to deeper tissues
GRADE 2	Deeper extension into tendons, bones, or joint capsule, which may be exposed
GRADE 3	Presence of tendonitis, osteomyelitis, cellulitis, or deeper tissue abscess
GRADE 4	Wet or dry gangrene of toe or dorsum of the foot, often with plantar infection
GRADE 5	Extensive gangrene of the foot, with necrotic lesions and soft tissue infections indicating higher amputation



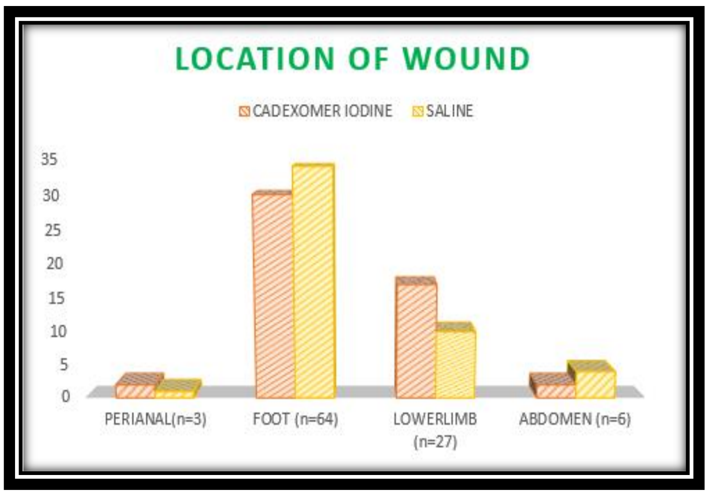
Graph-1: Wagner's Ulcer Classification of study population

Various types of wounds (Graph-2) were observed in the study population- diabetic foot ulcers (DFU), venous ulcers (VU), pressure ulcers (PU), abscess wounds (AW), post cellulitis wounds (CEL) and post trauma wounds (TW). Out of these, post trauma wounds were predominant (n=24), followed by post cellulitis wounds (n=22) and then diabetic foot ulcers (n=20).



Graph-2: Types of wounds observed in study population

Location of wounds was also identified and recorded (graph-3). Most common location was found to be foot (n=64), followed by lower limb (n=27), abdomen (n=6) and perianal (n=3).



Graph-3: Locations of wounds observed in study population

Bates-Jensen Wound Assessment:

Wound size: Ruler was used to measure the longest and widest aspect of the wound surface in centimeters; then length x width were multiplied.

Score was given as following:
1 = Length x width <4 sq cm,
2 = Length x width 4--<16 sq cm,
3 = Length x width 16.1--<36 sq cm,
4 = Length x width 36.1--<80 sq cm and
5 = Length x width >80 sq cm.

Change in wound size was observed from baseline (week0) to week 10 (graph-4). Change in wound size is gradual in both the groups, but Cadexomer iodine group showed 1.5 time faster change in wound size when compared to saline group. By the end of the study, 76% of cadexomer iodine subjects showed wound size <4 sqcm, while it is 56% in case of saline group (table-3).

Wound depth: Depth, thickness, most appropriate to the wound was picked using these additional descriptions:

1 = tissues damaged but no break in skin surface.
2 = superficial, abrasion, blister or shallow crater. Even with, &/or elevated above skin surface (e.g., hyperplasia).
3 = deep crater with or without undermining of adjacent tissue.
4 = visualization of tissue layers not possible due to necrosis.
5 = supporting structures include tendon, joint capsule.

Change in depth of the wound was observed from week-0 to week-10 (graph-5). Change in depth is 2 times faster in case of cadexomer iodine group when compared to saline group. By the end of the study 86% cadexomer iodine subjects showed non-blanchable erythema which is superficial, while it is 38% in case of saline group (table-4).

Wound edges: The following guide was used to determine the status of wound edges- Indistinct, diffuse (unable to clearly distinguish wound outline), Attached (even or flush with wound base, no sides or walls present; flat), Not attached (sides or walls are present; floor or base of wound is deeper than edge), Rolled under, thickened (soft to firm and flexible to touch), Hyperkeratosis (callous-like tissue formation around wound & at edges) and Fibrotic, scarred (hard, rigid to touch).

Score is given as following:
1 = Indistinct, diffuse, none clearly visible

2 = Distinct, outline clearly visible, attached, even with wound base
3 = Well-defined, not attached to wound base
4 = Well-defined, not attached to base, rolled under, thickened
5 = Well-defined, fibrotic, scarred or hyperkeratotic.

Change in wound edges from week0 to week10 was observed (graph-6). By the end of the study, edges of wound were indistinct in 76% of cadexomer iodine subjects, which is three-fold of 26% of saline group subjects (table-5).

Undermining: Undermining of the wound edges was assessed as following: Assess by inserting a cotton tipped applicator under the wound edge; advance it as far as it will go without using undue force; raise the tip of the applicator so it may be seen or felt on the surface of the skin; mark the surface with a pen; measure the distance from the mark on the skin to the edge of the wound. Continue process around the wound. Then use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.

Score was given as following:
1 = None present
2 =Undermining < 2 cm in any area
3 = Undermining 2-4 cm involving < 50% wound margins
4 = Undermining 2-4 cm involving > 50% wound margins
5 = Undermining > 4 cm or Tunneling in any area.

Change in undermining of wound edges was observed from week-0 to week-10 (graph-7). By the end of the study 98% of the cadexomer iodine group subjects showed no undermining, which is 76% in case of saline group (table-6).

Necrotic tissue type: Type of necrotic tissue that is predominant_in the wound was picked according to color, consistency and adherence using this guide: White/gray non-viable tissue (may appear prior to wound opening; skin surface is white or gray); Non-adherent, yellow slough (thin, mucinous substance; scattered throughout wound bed; easily separated from wound tissue); Loosely adherent, yellow slough (thick, stringy, clumps of debris; attached to wound tissue); Adherent, soft, black eschar (soggy tissue; strongly attached to tissue in center or base of wound) and Firmly adherent, hard/black eschar (firm, crusty tissue; strongly attached to wound base and edges (like a hard scab)).

Score was given as following:
1 = None visible
2 = White/grey non-viable tissue &/or non-adherent yellow slough
3 = Loosely adherent yellow slough
4 = Adherent, soft, black eschar
5 = Firmly adherent, hard, black eschar

Change in necrotic tissue type present predominantly in the wound was observed from week-0 to week-10 (graph-8). Necrotic tissue seem to be reduced significantly from week 4 in case of cadexomer iodine group, while it is gradual in case of saline group. 92% of cadexomer iodine subjects showed absence of necrotic tissue, while it is 66% in case of saline group (table-7).

Necrotic tissue amount: A transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants had been used to help determine percent of wound involved.

Score was given as following:
1 = None visible
2 = < 25% of wound bed covered
3 = 25% to 50% of wound covered
4 = > 50% and < 75% of wound covered
5 = 75% to 100% of wound covered.

Change in the amount of necrotic tissue present in the wound was observed from week-0 to week-10 (graph-9). Significant reduction in necrotic tissue amount is seen by week 4 in case of cadexomer iodine group, while it is by week 10 in case of saline group. By the end of the study,90% of cadexomer iodine subjects showed absence of necrotic tissue, while it is 62% in case of saline group (table-8).

Exudate Type: Some dressings interact with wound drainage to produce a gel or trap liquid. Before assessing exudate type, wound was gently cleansed with normal saline or water. Exudate type that is predominant in the wound according to color and consistency had been picked using this guide: Bloody (thin, bright red) ; Serosanguineous (thin, watery pale red to pink) ; Serous (thin, watery, clear) ; Purulent (thin or thick, opaque tan to yellow) and Foul purulent (thick, opaque yellow to green with offensive odor).

Score was given as following:
1 = None
2 = Bloody
3 = Serosanguineous: thin, watery, pale red/pink
4 = Serous: thin, watery, clear
5 = Purulent: thin or thick, opaque, tan/yellow, with or without odor.

Change in the type of exudate present predominantly in the wound was observed from week-0 to week-10 (graph-10). By the end of the study, 70% of cadexomer iodine subjects showed no exudate, which is two times faster when compared to saline group, i.e; 30% (table-9).

Exudate amount: A transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants had been used to determine percent of dressing involved with exudate, with the help of this guide: None (wound tissues dry), Scant (wound tissues moist; no measurable exudate), Small (wound tissues wet; moisture evenly distributed in wound; drainage involves ≤ 25% dressing), Moderate (wound tissues saturated; drainage may or may not be evenly distributed in wound; drainage involves > 25% to < 75% dressing) and Large (wound tissues bathed in fluid; drainage freely expressed; may or may not be evenly distributed in wound; drainage involves > 75% of dressing).

Score was given as following:
1 = None, dry wound
2 = Scant, wound moist but no observable exudate
3 = Small
4 = Moderate
5 = Large.

Change in the amount of exudate present in the wound was observed from week-0 to week-10 (graph-11). There is significant reduction in exudate amount by week 4 in case of cadexomer iodine group, which is gradual in case of saline dressing. By the end of the study, 70% of cadexomer iodine and 30% of saline group subjects showed no exudate. This suggests cadexomer iodine is two-fold times more effective in decreasing the exudate amount when compared to saline dressing (table-10).

Skin color surrounding the wound: Assess tissues within 4cm of wound edge. Dark-skinned persons show the colors bright red and dark red as a deepening of normal ethnic skin color or a purple hue. As healing occurs in dark-skinned persons, the new skin is pink and may never darken.

Score was given as following:
1 = Pink or normal for ethnic group
2 = Bright red &/or blanches to touch
3 = White or grey pallor or hypopigmented
4 = Dark red or purple &/or non-blanchable
5 = Black or hyperpigmented.

Change in the skin color surrounding the wound was observed from week-0 to week-10 (graph-12). By the end of the study, 90% of the cadexomer iodine and 50% of saline group subjects showed normal or pink peri-wound area (table-11).

Peripheral tissue edema: Tissues within 4cm of wound edge were assessed for presence of edema. Non-pitting edema appears as skin that is shiny and taut. Identify pitting edema by firmly pressing a finger down into the tissues and waiting for 5 seconds, on release of pressure, tissues fail to resume previous position and an indentation appears.

Score was given as following:
1 = No swelling or edema
2 = Non-pitting edema extends <4 cm around wound
3 = Non-pitting edema extends ≥4 cm around wound
4 = Pitting edema extends < 4 cm around wound
5 = Crepitus and/or pitting edema extends >4 cm around wound.

Change in the status of peripheral tissue edema was observed from week-0 to week-10 (graph-13). By the end of the study, 100% of cadexomer iodine and 92% of the saline group subjects showed reduction in peripheral tissue edema. This reduction is faster in case of cadexomer iodine group which is significant by week 4 (table-12).

Peripheral tissue induration: Tissues within 4cm of wound edge were assessed. Induration is abnormal firmness of tissues with margins. Assess by gently pinching the tissues. Induration results in an inability to pinch the tissues. A transparent metric measuring guide was used to determine how far edema or induration extends beyond wound.

Score was given as following:
1 = None present
2 = Induration, < 2 cm around wound
3 = Induration 2-4 cm extending < 50% around wound
4 = Induration 2-4 cm extending ≥ 50% around wound
5 = Induration > 4 cm in any area around wound.

Change in the status of peripheral tissue induration was observed from week-0 to week-10 (graph-14). By the end of the study, 100% of cadexomer iodine subjects and 84% of saline dressing subjects showed complete reduction in peripheral tissue induration. Significant reduction started by week 4 in case of cadexomer iodine, but it is gradual and delayed in saline dressing when compared to cadexomer iodine group (table-13).

Granulation tissue: Granulation tissue is the growth of small blood vessels and connective tissue to fill in full thickness wounds. Tissue is healthy when bright, beefy red, shiny and granular with a velvety appearance. Poor vascular supply appears as pale pink or blanched to dull, dusky red color.

Score is given as following:
1 = Skin intact or partial thickness wound
2 = Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth
3 = Bright, beefy red; < 75% & > 25% of wound filled
4 = Pink, &/or dull, dusky red &/or fills ≤25% of wound
5 = No granulation tissue present.

Change in the granulation tissue was observed from week-0 to week-10 (graph-15). By the end of the study, 70% of cadexomer iodine and 26% of saline group subjects' wounds are of partial thickness or superficial (skin intact). The rate of granulation in cadexomer iodine group is more than 2 times that of saline group (table-14).

Epithelialization: Epithelialization is the process of epidermal resurfacing and appears as pink or red skin. In partial thickness wounds it can occur throughout the wound bed as well as from the wound edges. In full thickness wounds it occurs from the edges only. A transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants had been used to help determine percent of wound involved and to measure the distance the epithelial tissue extends into the wound.

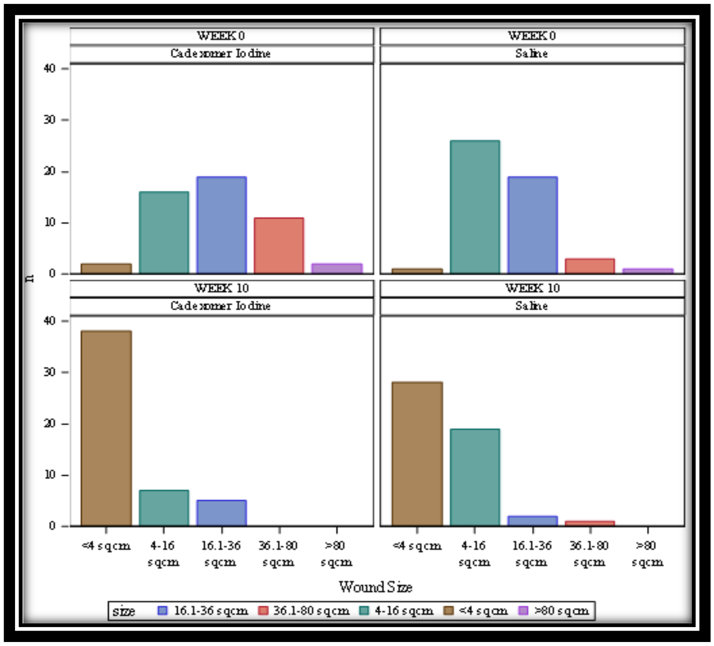
Score was given as following:
1 = 100% wound covered, surface intact
2 = 75% to <100% wound covered &/or epithelial tissue extends >0.5cm into wound bed
3 = 50% to <75% wound covered &/or epithelial tissue extends to <0.5cm into wound bed
4 = 25% to < 50% wound covered
5 = < 25% wound covered.

Change in the epithelialization of wound from week-0 to week-10 was observed (graph-16). By the end of the study, 66% of cadexomer iodine and 20% of the saline group subject have had complete wound closure. So, epithelialization is three-fold times faster in cadexomer iodine group in comparision with the saline group (table-15).

Table No. 3: Wound size comparison

		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Wound size	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	2 (4)	1 (2.0)	3 (6)	1 (2)	9 (18)	3 (6)	15 (30)	10 (20)	31 (62)	24 (48)	38 (76)	28 (56)
2	n (%)	16 (32)	26 (52)	17 (34)	25 (50)	28 (56)	29 (58)	26 (52)	34 (68)	12 (24)	20 (40)	7 (14)	19 (38)
3	n (%)	19 (38)	19 (38)	21 (42)	19 (38)	8 (16)	16 (32)	6 (12)	5 (10)	7 (14)	5 (10)	5 (10)	2 (4)

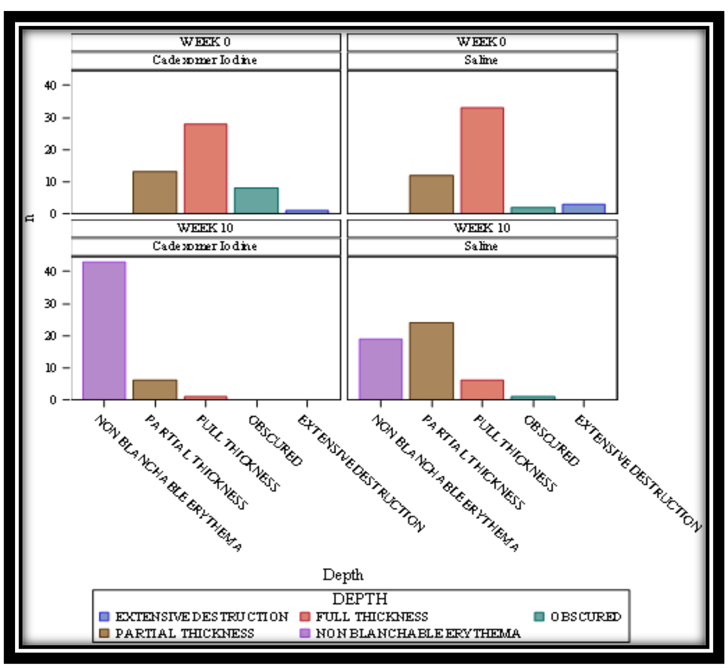
4	n (%)	11 (22)	3 (6.0)	6 (12)	4 (8)	5 (10)	2 (4)	3 (6)	1 (2)	0	1 (2)	0	1 (2)
5	n (%)	2 (4)	1 (2.0)	3 (6)	1 (2)	0	0	0	0	0	0	0	0



Graph-4: Change in wound size from week-0 to week-10

Table No. 4: Wound depth comparison

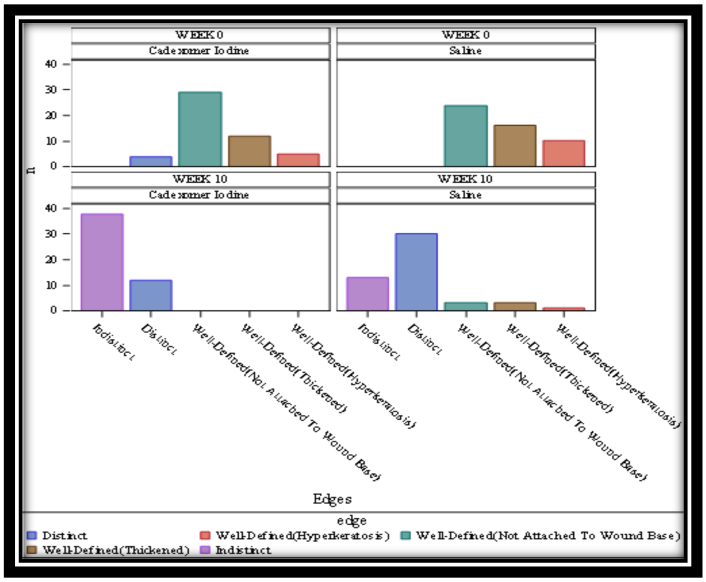
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Depth	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	0	0	2 (4.0)	1 (2.0)	2 (4)	2 (4)	12 (24)	3 (6)	23 (46)	10 (20)	43 (36)	19 (38)
2	n (%)	13 (26)	12 (24)	16 (32.0)	11 (22.0)	14 (28)	14 (28)	36 (72)	24 (48)	25 (50)	31 (62)	6 (12)	24 (48)
3	n (%)	28 (56)	33 (66)	31 (62)	36 (72.0)	23 (46)	32 (64)	2 (4)	22 (44)	2 (4)	8 (16)	1 (2)	6 (12)
4	n (%)	18 (16)	2 (4)	0	1 (2.0)	1 (2)	1 (2)	0	0	0	1 (2)	0	1 (2.0)
5	n (%)	1 (2)	3 (6)	1 (2.0)	1 (2.0)	0	1 (2)	0	1 (2)	0	0	0	0



Graph-5: Change in wound depth from week-0 to week-10

Table No. 5: Wound edges comparison

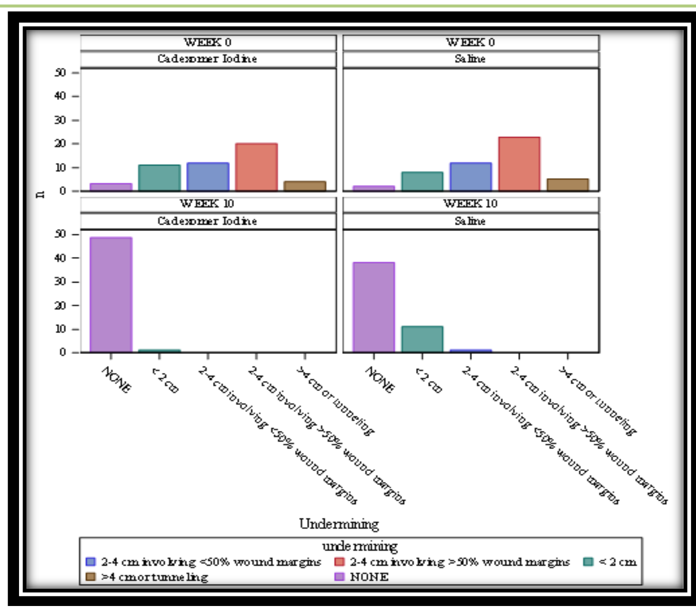
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Edges	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	0	0	1 (2)	0	7 (14)	1 (2)	11 (22)	2 (4)	18 (36)	7 (14)	38 (76)	13 (26)
2	n (%)	0	0	1 (2)	0	7 (14)	1 (2)	11 (22)	2 (4)	18 (36)	7 (14)	38 (76)	13 (26)
3	n (%)	29 (58)	24 (48)	9 (18)	21 (42)	5 (10)	17 (34)	2 (4)	16 (32)	1 (2)	3 (6)	0	3 (6)
4	n (%)	12 (24)	16 (32)	6 (12)	15 (30)	1 (2)	5 (10)	0	2 (4)	0	4 (8)	0	3 (6)
5	n (%)	5 (10)	10 (20)	0	8 (16)	0	4 (8)	0	3 (6)	0	1 (2)	0	1 (2)



Graph-6: Change in wound edges from week-0 to week-10

Table No. 6: Undermining of wound edges comparison

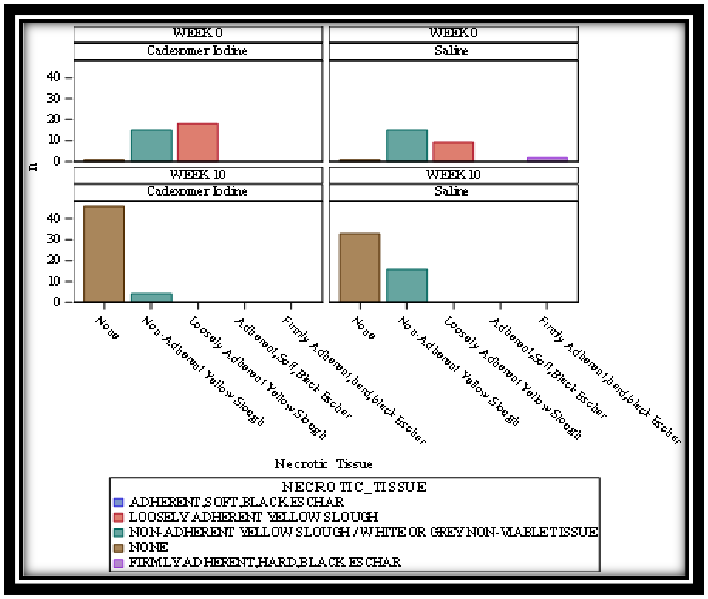
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Undermining	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	3 (6)	2 (4)	17 (34)	5 (10)	40 (80)	10 (20)	40 (80)	10 (20)	40 (80)	10 (20)	49 (98)	38 (76)
2	n (%)	11 (22)	8 (16)	24 (48)	7 (14)	5 (10)	14 (28)	5 (10)	14 (28)	5 (10)	14 (28)	1 (2)	11 (22)
3	n (%)	12 (24)	12 (24)	6 (12)	21 (42)	5 (10)	20 (40)	5 (10)	20 (40)	5 (10)	20 (40)	0	1 (2)
4	n (%)	20 (40)	23 (46)	3 (6)	15 (30)	0	6 (12)	0	6 (12)	0	6 (12)	0	0
5	n (%)	4 (8)	5 (10)	0	2 (4)	0	0	0	0	0	0	0	0



Graph-7: Change in the undermining of wound edges from week-0 to week-10

Table No. 7: Necrotic tissue type comparison

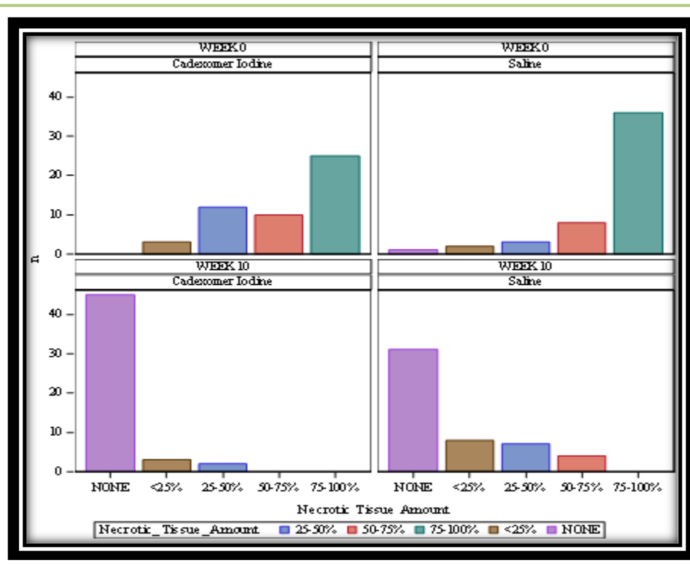
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Necrotic Tissue Type	Stat	CI	NS	CI	NS	CI	NS	CI	NS	CI	NS	CI	NS
1	n (%)	1 (2)	1 (2)	12 (24)	2 (4)	32 (64)	4 (8)	32 (64)	4 (8)	32 (64)	4 (8)	46 (92)	33 (66)
2	n (%)	15 (30)	15 (30)	32 (64)	24 (48)	17 (34)	36 (72)	17 (34)	36 (72)	17 (34)	36 (72)	4 (8)	16 (32)
3	n (%)	18 (36)	9 (18)	6 (12)	18 (36)	1 (2)	8 (16)	1 (2)	8 (16)	1 (2)	8 (16)	0	0
4	n (%)	16 (32)	23 (46)	0	5 (10)	0	1 (2)	0	1 (2)	0	1 (2)	0	1 (2)
5	n (%)	0	2 (4)	0	1 (2)	0	1 (2)	0	1 (2)	0	1 (2)	0	0



Graph-8: Change in necrotic tissue type from week-0 to week-10

Table No. 8: Necrotic tissue amount comparison

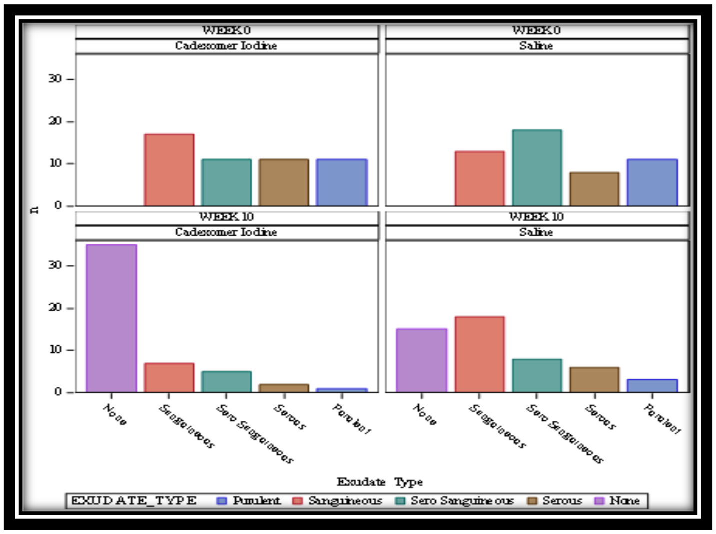
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Necrotic Tissue amount	Stat	CI	NS	CI	NS	CI	NS	CI	NS	CI	NS	CI	NS
1	n (%)	0	1 (2)	12 (4)	2 (4)	32 (64)	6 (12)	32 (64)	6 (12)	32 (64)	6 (12)	45 (90)	31 (62)
2	n (%)	3 (6)	2 (4)	6 (12)	6 (12)	9 (18)	5 (10)	9 (18)	5 (10)	9 (18)	5 (10)	3 (6)	8 (16)
3	n (%)	12 (24)	3 (6)	25 (50)	5 (10)	7 (14)	16 (32)	7 (14)	16 (32)	7 (14)	16 (32)	2 (4)	7 (14)
4	n (%)	10 (20)	8 (16)	5 (10)	21 (42)	2 (4)	18 (36)	2 (4)	18 (36)	2 (4)	18 (36)	0	4 (8)
5	n (%)	25 (50)	36 (72)	2 (4)	16 (32)	0	5 (10)	0	5 (10)	0	5 (10)	0	0



Graph-9: Change in necrotic tissue amount from week-0 to week-10

Table No. 9: Exudate type comparison

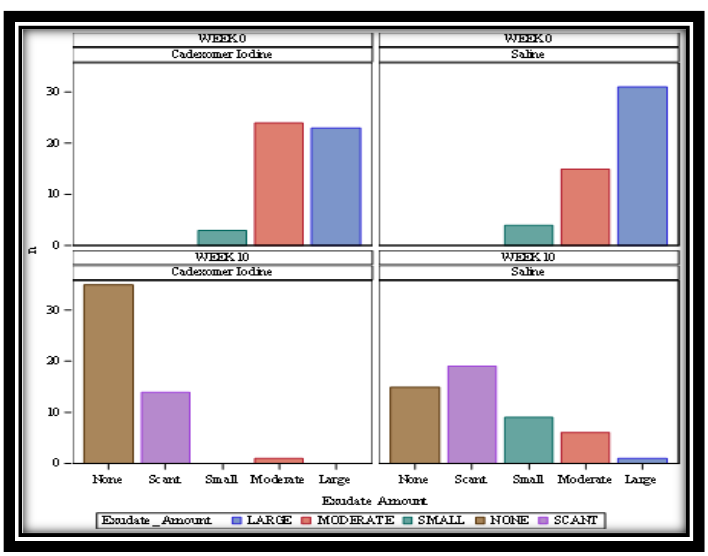
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Exudate Type	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	0	0	1 (2)	0	5 (10)	1 (2)	6 (10)	1 (2)	5 (10)	1 (2)	36 (78)	15 (30)
2	n (%)	17 (34)	13 (26)	20 (40)	16 (32)	28 (56)	16 (32)	28 (56)	16 (32)	28 (56)	16 (32)	7 (14)	18 (36)
3	n (%)	11 (22)	18 (36)	17 (34)	22 (44)	9 (18)	22 (44)	9 (18)	22 (44)	9 (18)	22 (44)	5 (10)	8 (16)
4	n (%)	11 (22)	8 (16)	6 (12)	2 (4)	5 (10)	2 (4)	5 (10)	2 (4)	5 (10)	2 (4)	2 (4)	6 (12)
5	n (%)	11 (22)	11 (22)	6 (12)	9 (18)	3 (6)	9 (18)	3 (6)	9 (18)	3 (6)	9 (18)	1 (2)	3 (6)



Graph-10: Change in the exudate type from week-0 to week-10

Table No. 10: Exudate amount comparison

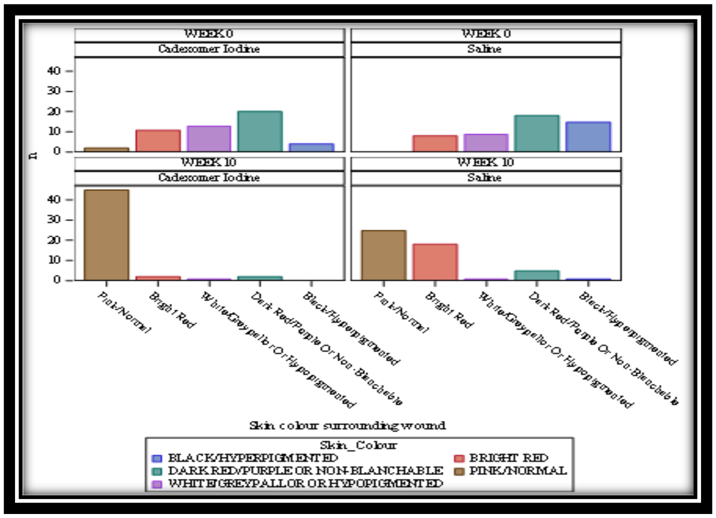
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Exudate amount	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	0	0	1(2)	1(2)	5(10)	1(2)	5(10)	1(2)	5(10)	1(2)	36(70)	15(30)
2	n (%)	0	0	6(12)	3(6)	22(44)	3(6)	22(44)	3(6)	22(44)	3(6)	14(28)	19(38)
3	n (%)	3(6)	4(8)	21(42)	7(14)	18(36)	15(30)	18(36)	15(30)	18(36)	15(30)	0	9(18)
4	n (%)	24(48)	15(30)	21(42)	21(42)	5(10)	24(48)	5(10)	24(48)	5(10)	24(48)	1(2)	6(32)
5	n (%)	23(46)	31(62)	1(2)	18(336)	0	7(14)	0	7(14)	0	7(14)	0	1(2)



Graph-11: Change in the exudate amount from week-0 to week-10

Table No. 11: Comparison of skin colour surrounding the wound

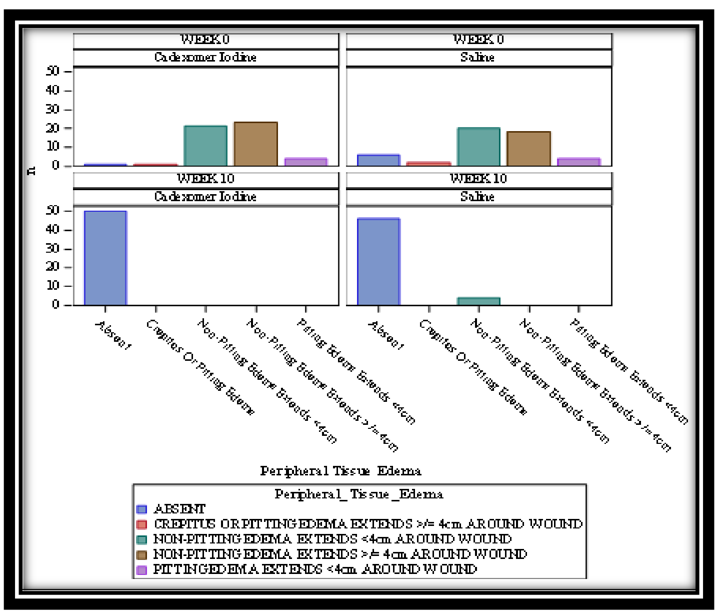
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Skin color	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	2(4)	0	8(16)	0	20(40)	4(8)	20(40)	4(3)	20(48)	4(8)	48(90)	26(50)
2	n (%)	11(22)	8(16)	24(48)	10(20)	25(50)	15(30)	25(50)	15(30)	25(50)	15(30)	2(4)	18(36)
3	n (%)	13(26)	9(18)	5(10)	17(34)	2(4)	16(32)	16(32)	16(32)	2(4)	16(32)	1(2)	1(2)
4	n (%)	20(40)	18(36)	12(24)	10(20)	3(6)	3(26)	3	13(26)	3(6)	13(26)	2(4)	5(10)
5	n (%)	4(8)	15(30)	1(2)	13(26)	0	2(4)	0	2(4)	0	2(4)	0	1(2)



Graph-12: Change in the skin colour surrounding the wound from week-0 to week-10

Table No. 12: Comparison of Peripheral tissue edema

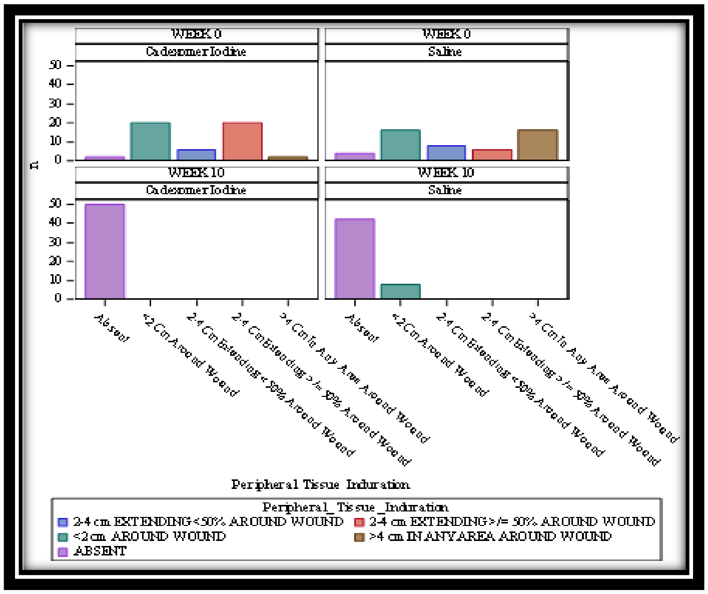
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Edema	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	1(2)	6(12)	15(30)	8(16)	38(76)	14(28)	38(76)	14(28)	38(76)	14(28)	50(100)	46(92)
2	n (%)	21(42)	20(40)	31(62)	21(42)	11(22)	33(66)	11(22)	33(66)	11(22)	33(66)	0	4(8)
3	n (%)	23(46)	18(36)	3(6)	19(38)	1(2)	2(4)	1(2)	2(4)	1(2)	2(4)	0	0
4	n (%)	4(8)	4(8)	1(2)	2(4)	0	1(2)	0	1(2)	0	1(2)	0	0
5	n (%)	1(2)	2(4)	0	0	0	0	0	0	0	0	0	0



Graph-13: Change in peripheral tissue edema from week-0 to week-10

Table No. 13: Comparison of peripheral tissue induration

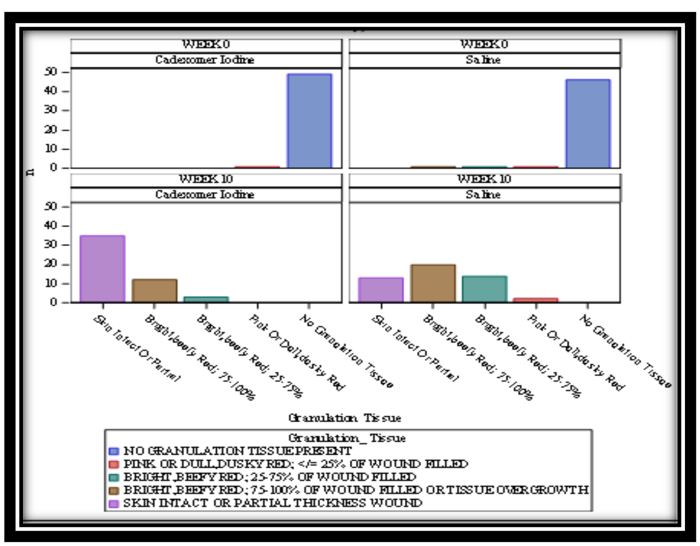
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Induration	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	2(4)	4(8)	4(8)	6(12)	21(42)	9(18)	21(18)	9(18)	9(18)	9(18)	50(100)	42(84)
2	n (%)	20(40)	16(32)	16(32)	20(40)	25(50)	20(40)	25(50)	20(40)	25(40)	20(40)	0	8(16)
3	n (%)	6(12)	8(16)	20(40)	8(16)	4(8)	17(34)	4(8)	17(34)	4(8)	17(34)	0	0
4	n (%)	20(40)	6(12)	2(4)	14(28)	0	4(8)	0	4(8)	0	4(8)	0	0
5	n (%)	2(4)	16(32)	16(32)	2(4)	0	0	0	0	0	0	0	0



Graph-14: Change in the peripheral tissue induration from week-0 to week-10

Table No. 14: Comparison of granulation tissue formation

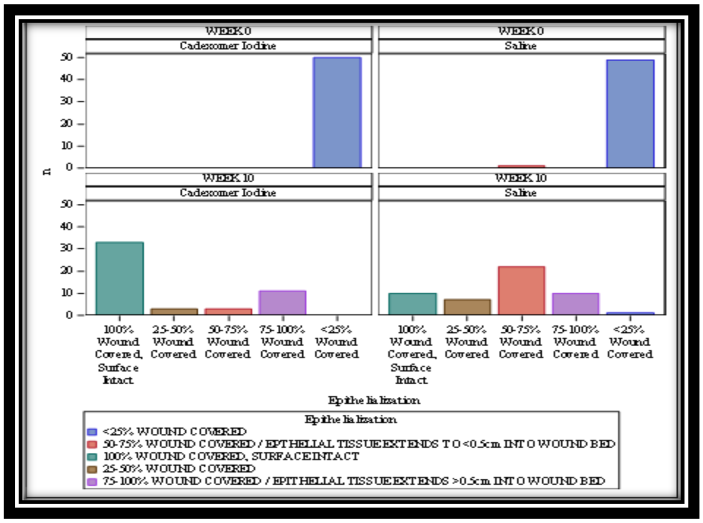
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Granulation Tissue	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
1	n (%)	0	0	0	0	6(12)	1(2)	6(12)	1(2)	6(1)	1(2)	35(70)	13(26)
2	n (%)	0	1(2)	4(8)	1(2)	4(8)	1(2)	4(8)	1(2)	4(8)	1(2)	12(24)	20(40)
3	n (%)	0	1(2)	8(16)	2(4)	33(66)	21(42)	33(66)	21(42)	33(66)	21(42)	3(6)	14(28)
4	n (%)	1(2)	1(2)	35(70)	30(60)	7(14)	23(46)	7(14)	23(46)	7(14)	23(46)	0	2(4)
5	n (%)	49(98)	46(92)	3(6)	17(34)	0	4(8)	0	4(8)	0	4(8)	0	0



Graph-15: Change in the granulation tissue from week-0 to week-10

Table No. 15: Comparison of Epithelialization

		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Epithelialization	Stat	CI	NS	CI	NS	CI	NS	CI	NS	CI	NS	CI	NS
1	n (%)	0	0	0	0	1(2)	0	1(2)	0	1(2)	0	33(66)	10(20)
2	n (%)	0	0	1(2)	0	6(12)	2(4)	6(12)	2(4)	6(12)	2(4)	11(22)	10(20)
3	n (%)	0	1(2)	6(12)	2(4)	8(16)	2(4)	8(16)	2(4)	8(16)	2(4)	3(6)	22(44)
4	n (%)	0	0	8(16)	2(4)	32(64)	19(38)	32(64)	19(38)	32(64)	19(38)	3(6)	7(14)
5	n (%)	50(100)	49(98)	35(70)	46(92)	3(6)	27(54)	3(6)	27(52)	3(6)	27(54)	0	1(2)



Graph-16: Change in the epithelialization from week-0 to week-10

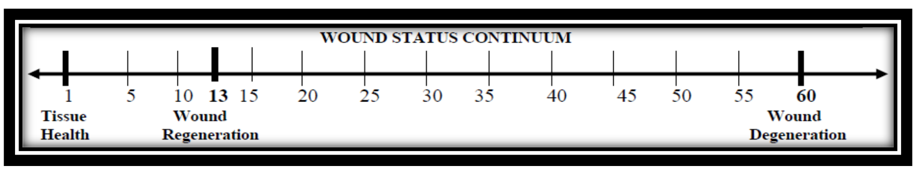


Fig. 3: Wound status continuum based on total score obtained from Bates-Jensen Wound Assessment

T-test for comparison of wound status continuum:

The TTEST Procedure

Variable: Totalscore

cohort	N	Mean	Std Dev	Std Err	Minimum	Maximum
A	50	27.3100	5.4808	0.7751	18.0000	42.1667
B	50	35.1833	7.2849	1.0302	19.1667	53.3333
Diff (1-2)		-7.8733	6.4463	1.2893		

cohort	Method	Mean	95% CL Mean		Std Dev	95% CL Std Dev	
A		27.3100	25.7524	28.8676	5.4808	4.5783	6.8299
B		35.1833	33.1130	37.2537	7.2849	6.0853	9.0779
Diff (1-2)	Pooled	-7.8733	-10.4318	-5.3148	6.4463	5.6564	7.4946
Diff (1-2)	Satterthwaite	-7.8733	-10.4343	-5.3124			

Method	Variances	DF	t Value	Pr > |t|
Pooled	Equal	98	-6.11	<.0001
Satterthwaite	Unequal	91.012	-6.11	<.0001

Equality of Variances				
Method	Num DF	Den DF	F Value	Pr > F
Folded F	49	49	1.77	0.0490

Fig. 4: T-test procedure to compare wound status continuum of both test and control groups

From all the given parameters, it is clear that efficacy Cadexomer Iodine have significant superiority when compared to that of saline dressing. The above table is the comparision of wound status continuum whose data is obtained from the scores given based on all the parameters of Bates-Jensen wound assessment tool. This is supported statistically by comparing the t and f values with the help of T-test. The Folded F value of 0.0490 infers that the test is statistically significant (table-16).

Odour:

Wounds had been assessed for presence or absence of odour from week-0 to week-10 (graph-17). Change in odour started significantly from week 2 itself in case of Cadexomer iodine group, while there is gradual change in case of saline dressing. By the end of the study, 96% of cadexomer iodine had not shown any odour, which is 78% in case of saline dressing (table-18).

Pain:

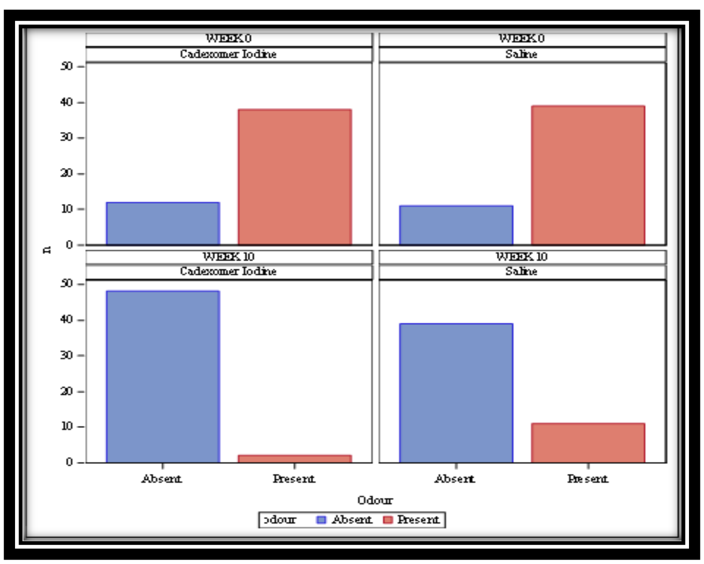
Subjects were assessed for presence or absence of pain from week-0 to week-10 (graph-18). Change in pain started significantly from week 4 in case of cadexomer iodine, while it is delayed in case of saline dressing. By the end of the study 78% of subjects in cadexomer iodine group showed absence of pain, while it is 48% in case of saline dressing (table-19).

Table No. 17: Comparison of average scores based on demographics of both test and control groups along with p-values

	CADEXOMER IODINE			NORMAL SALINE		
PARAMETER	WEEK 0 (avg score)	WEEK 10 (avg score)	p-VALUE	WEEK 0 (avg score)	WEEK 10 (avg score)	p-VALUE
			Age group			
21-30	47.6	14.44	0.0001	14.44	18.80	0.0001
31-40	45.60	13.20	0.0012	13.20	20.14	0.0001
41-50	46.91	16.18	0.0001	16.18	27.13	0.0001
51-60	44.67	19.47	0.0001	19.47	27.83	0.0011
			Gender			
Female	45.92	14.58	0.0021	46.29	21.00	0.0023
Male	46.00	17.23	0.0002	49.58	24.38	0.0002
BMI	45.96	15.96	0.0031	48.00	22.76	0.0033

Table No. 18: Comparison of odour

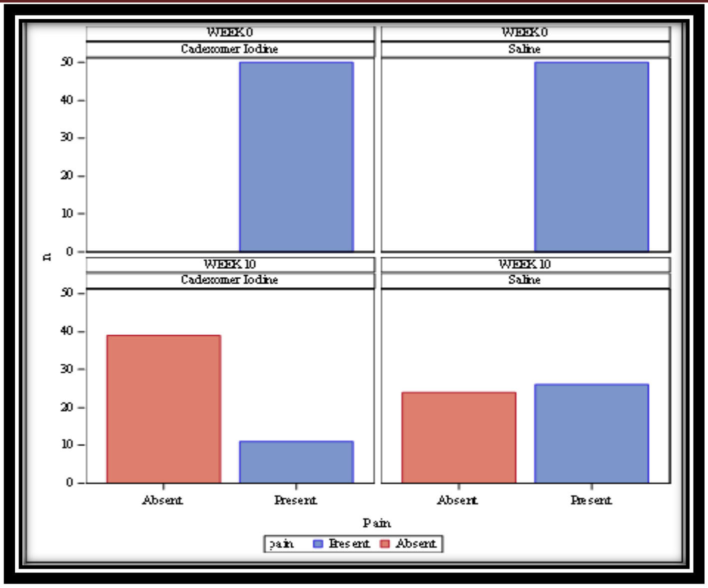
		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Odour	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
Absent	n (%)	12(24)	11(22)	27(54)	11(22)	37(74)	17(34)	41(82)	23(46)	47(94)	36(72)	48(96)	39(78)
Present	n (%)	38(76)	39(78)	23(46)	39(78)	13(26)	33(66)	9(18)	27(6)	3(6)	14(4)	2(4)	11(22)



Graph-17: Change in odour from week-0 to week-10

Table No. 19: Comparison of pain

		WEEK 0		WEEK 2		WEEK 4		WEEK 6		WEEK 8		WEEK 10	
Pain	**Stat**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**	**CI**	**NS**
Absent	n (%)	0	0	6(12)	3(6)	11(22)	4(8)	33(66)	11(22)	37(74)	20(40)	39(78)	24(48)
Present	n (%)	50(100)	50(100)	44(88)	47(94)	39(78)	46(92)	17(34)	39((78)	13(26)	30(60)	11(22)	26(52)



Graph-18: Change in pain from week-0 to week-10

DISCUSSION

In this study, 100 patients were randomly assigned into 2 groups. The treatment group was given with topical cadexomer iodine and the control group was given with saline dressing. The patients were included based on study criteria one after another who ever first come to OPD and those patients who were admitted in the hospital.

Patients who were enrolled in the study, i.e; treatment group and control group were assessed based on several parameters like; Demographic data (Age, Sex and BMI), Location of the wound, Wagner's ulcer classification or grade of the wound (Grade 1, Grade 2, Grade 3, Grade 4 and Grade 5), Bates-Jensen wound assessment (Wound size, Depth, Edges, Undermining, Necrotic tissue type, Necrotic tissue amount, Exudate type, Exudate amount, Skin color surrounding wound, Peripheral tissue edema, Peripheral tissue induration, Granulation tissue and Epithelialization), Pain and Odour. Duration of follow-up is every 2 weeks upto 10 weeks,i.e; week 0, week 2, week 4, week 6, week 8 and week 10. This duration was selected based on the washout period of topical cadexomer iodine, which is nearly 3 months.

In our study, various types of acute and chronic exuding wounds like Diabetic Foot Ulcers, Venous Ulcers, Pressure Ulcers, Abscess Wounds, Cellulitis and Trauma wounds were included. Ellikunnel Vithon Gopi et al. [25],Conducted a study on effectiveness of saline dressing versus povidone iodine dressing in chronic diabetic wounds healing study from a tertiary hospital in south India, Subjects attending diabetic wound clinic and surgery outpatient department/ casualty of Government Medical College and Hospital, Kozhikode, Kerala, India 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.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 6^{th} week in Saline dressing group in comparison to the povidone iodine group at P = 0.03 (<0.05) level of significance. Saline dressing is more effective in achieving healing in chronic diabetic wounds as compared to povidone iodine dressing.

In our study, we assessed various parameters involved in wound healing, among which necrotic tissue amount is one of the parameter. Significant reduction in necrotic tissue amount is seen by week 4 in case of cadexomer iodine group, while it is by week 10 in case of saline group. By the end of the study, 90% of the cadexomer iodine subjects showed absence of necrotic tissue, while it is 62% in case on saline group. There is significant reduction in exudate amount by week 4 in case of cadexomer iodine, which is gradual in case of saline dressing. By the end of the study, 70% of cadexomer iodine and 30% of saline group subjects showed no exudate. This suggest cadexomer iodine is two-fold times more effective in decreasing the exudate amount when compared to saline dressing. Verdú Soriano j et al. Conducted study on ulcer treatment by infected pressure necrosis using iodine based tumble, this study aims to assess, in real clinical conditions and in an exploratory way the utility of iodinated cadexomer in the treatment of wounds with significant necrotic tissue. 70% of the lesions presented clean granulation tissue with 10 dressing changes. In relation to the management of exudate, more than 70% of the injuries were no longer infected in the second change of dressing and over 50% of the injuries had happened to have a slight or no exudate. Erythema and maceration of surrounding skin also showed significant improvement. An added value of the data is that six of the 21 lesions healed during the study and that pain was reduced sharply from a score of 6.5 to 3 on the second change of dressing and from zero to five, resulting in a substantial improvement in quality of life of these people. This study suggests that iodinated cadexomer is useful for wound debridement, while reduces clinical signs of local infection and exudate levels normally associated with these situations.

In our study, by the end, 66% of cadexomer iodine and 20% of saline group subjects have had complete wound closure. So, epithelialization is three-fold times faster in cadexomer iodine group compared to the saline group. E. N. Lamme et al.[32] Conducted a study on Cadoxemer iodine ointment shows stimulation of epidermal regeneration in experimental thickness wounds and concluded that during the first 9 days of treatment, wounds treated with cadexomer-iodine ointment showed significantly more epithelialization than the wounds treated with either cadexomer or saline. In addition, the epidermis of wounds treated with cadexomer-iodine ointment had significantly more epithelial cell layers from day 12 to day 30, and these wounds stained for chondroitin sulphate proteoglycans in the newly formed basement membrane zone, which was not observed with the other treatments. No negative effects of cadexomer- iodine ointment on the formation of granulation tissue, neovascularization or wound contraction were observed. During the treatment systemic iodine absorption was physiologically acceptable. These results showed that treatment with cadexomer-iodine-containing ointment had positive effects on epidermal regeneration during the healing of full-thickness wounds in the pig compared with ointment alone or saline treatment.

In this study, wound healing with the use of topical cadexomer iodine was found to be dominant, when compared to saline dressing in several parameters involved in wound healing which were assessed using Bates-Jenesen wound assessment tool. Most of the patients using topical cadexomer iodine are shown to be having improved wound status by week 4 significantly, while patients using saline have shown gradually improving wound with a slower rate of healing. There is significant decrease in odour in most of the patients using cadexomer iodine by week 2, where 54% of the patients from test group and only 22% of the control group are having no odour from their wound. In case of pain, by week 6, 66% of test group where as only 22% of saline group patients were free of pain associated with the wound.

CONCLUSION

The overall conclusion of this study is, Topical Cadexomer iodine is more effective when compared to Saline Dressing in the management of acute and chronic exuding wounds; improvement of all parameters related to wound healing like wound size, depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, skin color surrounding wound, peripheral tissue edema, peripheral tissue induration, granulation tissue and epithelialization ; reduction in odour and pain, most of the patients experienced mild pain after application of topical cadexomer idoine which resolved on its own in an hour.

ACKNOWLEDGEMENT

We take this opportunity to express our deep sense of gratitude to our esteemed guide Dr. Praveena Bandaru Pharm D, Assistant Professor, Depart ment of Pharmacy Practice, Hindu College of Pharmacy, Guntur for her valuable contributions, suggestions and constructive criticisms in the most appropriate way. We would like to specially thank our supervising doctor at Lalitha Super-specialities Hospital, Dr. S. Uma Shanker, MBBS, DNB, MRCS, HOD, General Surgeon and Laparoscopic Surgeon) for his excellent co-operation and for all the oppurtunities we were given to conduct our research and further our dissertation at Lalitha Super-specialities Hospital. We would like to express our sincere gratitude to Mr.M.Bhargav Ram and Mr.P.Srikanth for their help and guidance in statistical analysis of this study. We extend our sincere thanks to the Principal Dr. R. Govindarajan, M. Pharm, PhD; Dr. A. Suneetha, M. Pharm, PhD and Pharm D Director Sri. P. Seetharamaiah, M. Pharm, PhD; Hindu college of pharmacy, Guntur for providing necessary facilities. We take this chance to express our sincere thanks to Chairman Dr. Mannava Radhakrishna Murthy, MD; Vice-Chairman Dr. S. Madhusudhan Rao, MBBS and Secretary & Correspondent Sri Jupudi Rangaraju, B.Com, LLB; Hindu college of pharmacy, Guntur for providing dexterities to carry out this work.

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How to cite this article:

Sahitya Uppada, et al. TOPICAL CADEXOMER IODINE VERSUS SALINE DRESSING IN THE MANAGEMENT OF ACUTE AND CHRONIC EXUDING WOUNDS. J Pharm Res 2019;8(8):704-721. **DOI: https://doi.org/10.5281/zenodo.3706446**

Conflict of interest: The authors have declared that no conflict of interest exists.

Source of support: Nils