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Original Article

A randomized open-label study comparing the safety and efficacy of a natural antimicrobial dressing with silver sulfadiazine in the management of second-degree burn wounds

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Abstract: Objective: This study evaluates the efficacy of VELVERT, a novel antimicrobial dressing, compared to the standard Silver Sulfadiazine dressing in treating second-degree burns. Method: Conducted at a tertiary burn care center, 63 patients were enrolled and randomized into two groups: VELVERT (n = 31) and Silver Sulfadiazine (n = 30). The primary outcomes measured were wound closure percentage and time to complete healing within 24 days, while secondary outcomes included infection control, pain relief, and adverse events. The study was registered with CTRI with the registration number CTRI/2020/12/029698 (https://ctri.nic.in/Clinicaltrials/pmaindet2.php?EncHid=NDY5MDc=&Enc=&userName=). Result: Among 61 patients who completed the study, 87% (27/31) in the VELVERT group achieved complete wound healing compared to 63% (19/30) in the Silver Sulfadiazine group. The BWAT score, assessing wound healing, showed a decline from 31.66 ± 3.15 to 15.55 ± 4.42 in the VELVERT group and from 31.55 ± 3.35 to 16.18 ± 5.37 in the Silver Sulfadiazine group (P = 0.176). Both treatments were well tolerated, but VELVERT exhibited superior wound healing outcomes. Conclusion: These findings suggest that VELVERT may serve as a more effective alternative for second-degree burn treatment, offering improved healing rates. Further research with larger sample sizes is recommended to validate its clinical benefits over standard treatments.

Keywords: Second degree burn, wound healing, BWAT score, infection, VELVERT

Introduction

According to WHO, approximately 11 million people suffer burn wounds annually [1], with 6-7 million annual incidences in India [2]. The transfer of energy from a source of heat to human body triggers a sequence of physiological event, that in the most severe cases culminates in irreversible tissue damage. Burn patients are prone to morbidities like infections and scarring, along with physical, mental and social disabilities [3, 4]. The first half of the 20th century witnessed a higher rate of mortality due to limited treatment options. However, the last two decades have seen drastic improvements in the overall care of burn survivors, leading to an increase in survival rate [1].

Burn injuries are classified based on the depth of the wound as superficial, partial thickness and full-thickness. Second degree wounds are partial thickness wherein the epidermis and dermis are damaged. These partial thickness wounds are red and painful with presence of blisters [1, 5] and are more vulnerable to hypertrophic scarring and pigmentation [6]. The critical factors triggering scar formation are the area of the body exposed to the burn injury and the healing time of these wounds [6, 7]. Wound healing is a complex and dynamic process that initiates with inflammation and ends with the formation of extracellular matrix [1, 6]. Superficial partial thickness wounds heal faster with rapid epithelization of the wound site taking approximately 2-3 weeks. On the other hand,

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the deep partial thickness wounds exhibit delayed healing due to slower epithelization of the wound site and take around 3-5 weeks.

One of the factors delaying the wound healing process is the vulnerability of the moist burnt skin surface to bacterial infection [8]. The primary contributor to infection-induced delay in the wound healing process is the presence of biofilms. A variety of available literature on in-vivo models have demonstrated that the presence of biofilms impairs inflammation, granulation and epithelialization processes [9, 10]. Therefore, an ideal burn prophylactic dressing should accelerate the wound healing process with minimal intervention, along with combatting infection [4]. The need of the hour is the development of a new antimicrobial wound dressing which would be effective against these treatment resistant biofilms.

Silver, a centuries-old antimicrobial and medicinal agent has marked its place in wound healing. At present there are plethora of silver-based topical agents like silver nitrate, silver sulfadiazine, as well as silver based-dressings, like Acticoat, Actisorb, Aquacel to name a few. Silver sulfadiazine is the conventional and the gold standard therapeutic for treating second degree burn wounds. Despite the widespread use of silver sulfadiazine, the advent of silver-based dressings has been encouraged due to extended release of silver from these dressings in the wound environment [10-12]. Though Silver has potent antimicrobial efficacy, the cytotoxicity along with delayed wound healing and epithelization are limiting the use of these silver-based therapeutics.

Present study was conducted with the rationale to assess the safety and efficacy of a novel burn dressing VELVERT, with the most established burn dressing silver sulfadiazine. VELVERT is a non-adherent topical dressing consisting of gelatin, chitosan and a formulation of natural components like curcumin, amla extract and green tea extract all of which are well-known for its antimicrobial efficacy [13, 14]. Additionally, gelatin and chitosan are also professed for its optimal wound healing activity [14]. VELVERT is a highly porous biocompatible and biodegradable dressing that has shown to be safe and effective in healing venous leg ulcers and infected wounds [15, 16]. Further, VELVERT helps in cellular migration, angiogenesis and accelerates the wound healing by acting as an antimicrobial barrier that not only reduces the infection present over the wounds, but also prevents any kind of infections from the outer atmosphere.

Methods

Study design

This was a randomized, open label, two arm, single center, post market clinical study conducted at Department of Plastic Surgery of a burn care center. First patient was enrolled on 23-Feb-2021 and last patients was enrolled on 03-Jan-2023. It was conducted in accordance with ICH-GCP, and complied with all requirements regarding the obligations of investigators, other pertinent requirements of ICH E6(R2), Guideline for Good Clinical Practice. The study protocol was approved by the institutional ethical committee of Institute of Post Graduate Medical Education & Research, Kolkata, West Bengal, India (Regi no.: ECR/35/Inst/WB/2013/RR-19). Further in obtain-ing and documenting informed consent, the Investigator complied with applicable regulatory requirements, and the Declaration of Helsinki. Subject confidentiality was maintained throughout the study-by patient specific codes. Participants were enrolled and the random allocation generated at the burn care center. The study was registered with CTRI with the registration number CTRI/2020/12/029698. This article is adhered to the STROBE guidelines (http://www.strobe-statement.org/) (Supplementary Table 1).

Sample size determination

The sample size for current study was based on hypothesis testing for two means with equal variances, using wound healing status at the last follow-up visit (end of the treatment or the study last visit) as the primary endpoint. The standard deviations for the two treatment groups for burn patients were S1 = 0.16 and S2 = 0.22, with an average difference of 0.1568 and an effect size of 0.825. By keeping an alpha error of 5% ($Z\alpha = 1.96$) and 90% power ($Z\beta = 1.238$), a sample size of 64 patients inclusive of 32 participants per group was determined using the formula for pooled standard deviation, where $S = (S1 + S2)/2$. There was an anticipated 10% withdrawal rate con-

Table 1. Inclusion exclusion criteria for screening subjects

Inclusion Criteria
1. Adult non-diabetic male and female subjects of age group between 18 to 70 years.
2. Subjects with second degree burn wounds.
3. Total Body Surface Area of burns 5% to 20%.
4. Subjects/LAR must be able to read and understand informed consent, and sign the informed consent to provide data for the study.
5. Subjects who allow their data to be collected for the study at predefined follow-up periods.
6. All sexually active female subjects of childbearing potential without any clinical evidence of pregnancy.
Exclusion Criteria
1. Subjects unwilling or unable to comply with the postoperative visits necessary for data collection.
2. Subjects found positive for HIV and HCV.
3. Concurrent participation in another clinical trial that involves an investigational drug or dressing that would interfere with this study.
4. Pregnant females.
5. Comorbidities which could interfere with clinical evaluations or interpretation of results.
6. Subjects with known allergy to the constituents of investigational products/device.
7. Subjects with immunosuppression, corticosteroids or chemotherapy.
8. Subjects with a severe comorbid disorder, not expected to survive more than 12 months.
9. Subjects requiring concomitant use of negative pressure wound therapy (NPWT) on the reference wound.
10. Poor adaptivity or seriously ill subjects who cannot finish the observation period.
11. Any other condition which, according to the judgment of the investigator, could interfere in the study.
12. Subjects with Diabetic foot ulcer and Infected wound.

sidered for the study, so the total sample size was kept at 70 burn patients (35 in each group), with 1:1 allocation ratio. The sample size for this study was referenced from the study done by Manzoor et al. in which author examined the clinical efficacy of heparin treatment for treating second-degree burns [17].

Participants and selection criteria

All potential subjects of both genders between 18-70 years of age, patients of all socio-economic status who met the study-related inclusion and exclusion criteria (**Table 1**) and provided written informed consent in their local language were considered for participation in the study. Eligible subjects were non-diabetic adults with second-degree burn wounds involving 5-20% total body surface area and were willing to comply with predefined follow-up visits. Subjects were excluded if they had conditions or circumstances that could interfere with study participation or outcome assessment, including pregnancy, significant comorbidities, immunosuppression, active infections such as HIV/HCV, diabetic foot ulcers, infected wounds, or concurrent participation in another clinical trial. The standard dressing group had 3 female and 28 males, whereas the VELVERT group had 8 female and 23 males (**Table 2**). 75 second degree burn subjects were screened to evaluate the wound closure within a 24-day time frame. Of the 75 subjects screened, 63 were enrolled as they met the inclusion criteria and were randomized into two groups as per randomization by Interactive Web Responsive system. 31 subjects received Silver Sulfadiazine and 32 subjects received VELVERT. The study was completed on 61 subjects, as one subject withdrew consent and one was lost to follow up. 30 out of 61 subjects were treated using the standard dressing *i.e* silver sulfadiazine and the remaining 31 were treated using VELVERT. This is depicted in the CONSORT flow diagram of the study (**Figure 1**).

Burn dressings

In this two-arm study VELVERT was compared with the standard dressing i.e. Silver Sulfadiazine. The product VELVERT is an antimicrobial dressing intended to treat second degree burn wounds. VELVERT is claimed to be a non-adherent topical wound dressing which is loaded with an antimicrobial formulation on a biopolymeric sponge matrix. Preclinical studies have affirmed VELVERT to be non-toxic. VELVERT was compared to the current gold standard in treating second degree wounds *i.e* Silver Sulfadiazine. This sulfonamide containing topical formulation is known for its efficient broad spectrum antimicrobial properties.

Table 2. Summary of the demographic characteristics

Summary Statistics	Standard Dressing (N = 31)	VELVERT Dressing (N = 32)	Overall (N = 63)
Age (Years)			
N	31	32	63
Mean ± SD	35.29 ± 9.85	36.78 ± 12.03	36.05 ± 10.95
Median	37	36.5	37
Min, Max	21.00, 54.00	19.00, 66.00	19.00, 66.00
BMI (kg/m^2)			
N	31	32	63
Mean ± SD	21.75 ± 3.68	22.53 ± 4.83	22.14 ± 4.28
Median	21.22	21.91	21.55
Min, Max	17.31, 35.94	16.98, 36.79	16.98, 36.79
Height (cm)			
N	31	32	63
Mean ± SD	169.24 ± 6.00	165.01 ± 9.47	167.09 ± 8.17
Median	168	165	167.64
Min, Max	156.00, 179.00	132.56, 180.00	132.56, 180.00
Weight (kg)			
N	31	32	63
Mean ± SD	62.06 ± 9.26	60.88 ± 11.15	61.46 ± 10.20
Median	61	57.5	60
Min, Max	51.00, 92.00	42.00, 88.00	42.00, 92.00
Gender n (%)			
Female	3 (9.7)	8 (25.0)	11 (17.5)
Male	28 (90.3)	24 (75.0)	52 (82.5)
Smoker n (%)			
No	21 (67.7)	16 (50.0)	37 (58.7)
Yes	10 (32.3)	16 (50.0)	26 (41.3)

Clinical application

Second degree burn patients received either VELVERT or the Silver Sulfadiazine dressing on the wound site as per the randomization list. The maximum duration of each participant in the study was 24 days after first application of VELVERT/Silver sulfadiazine dressing, including follow ups, while total duration of the study was twelve months. A window period of ± 1 day was applicable for all the visits. Silver sulfadiazine dressing was changed every alternate day (day 0, 2, 4...24) whereas VELVERT dressing was changed every fourth day *i.e.* on every evaluation visit (day 0, 4, 8, 12...24). Clinician evaluated each wound before and after the use of VELVERT/Silver Sulfadiazine.

Endpoints

Primary endpoint: The primary endpoint of the study was complete wound closure within 24 days. This was assessed by evaluation of the total wound area, defined as the sum of the areas of all wounds present on both limbs, compared with baseline at inclusion, and by the time taken to achieve complete wound closure. Wound condition was assessed using the Bates-Jensen Wound Assessment Tool (BWAT), which took into consideration evaluation of wound or injury type and site, wound size and depth, wound edges and undermining, surrounding skin color, peripheral tissue edema and induration, granulation tissue, and epithelialization [18]. Standardized wound photographs were taken at each visit prior to dressing application, along with monitoring of vital parameters.

Secondary endpoints: The secondary endpoints included the proportion of wounds achieving complete closure by Day 24 ± 1, pain relief, presence of infection at wound site, subject comfort, and the incidence of adverse

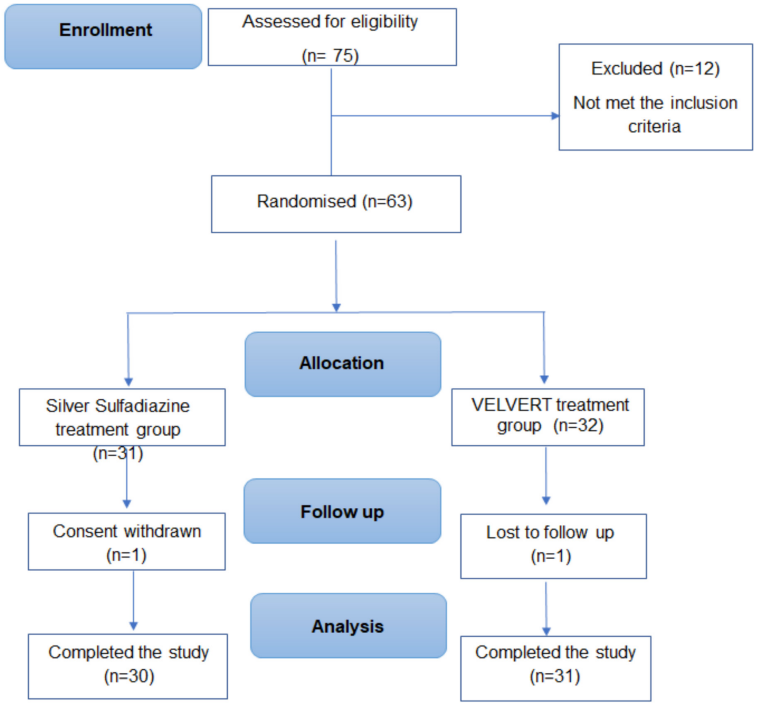

Figure 1. CONSORT flow diagram of the study.

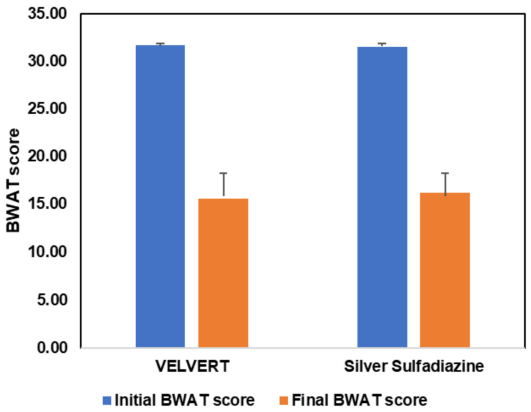

Figure 2. Graph depicting Initial and Final BWAT score of the Standard and VELVERT arms of the study; BWAT stands for Bates-Jensen Wound Assessment Tool.

events, serious adverse events, and device deficiencies. Pain relief was evaluated by the number of subjects reporting reduction in pain using a 0-10 Numeric Pain Rating Scale recorded on the day of dressing application and at final dressing removal, where 0 indicated no pain and 10 indicated worst imaginable pain. Subjects were also instructed to report the name, dosage, and number of analgesic medications consumed, if any. Subject safety was monitored throughout the study period from the first application of the investigational product or device through Day 24.

Data collection

Prior to the application of wound dressing, all the subjects were assessed for wound sites (through Bates-Jensen Wound Assessment Tool) and vital parameters on all visits. Assessment of any AE/SAE and device (dressing) deficiency was observed and recorded. Data related to subject's safety will be recorded on follow-up visits till day 24, starting from the first day of application of investigational product/device.

Statistical intervention

All patients enrolled in the study were analyzed on an intention-to-treat basis. Statistical analyses were performed using R Software Version 4.3.0, with between-group comparisons for quantitative data conducted using the two-sample t-test. For safety analysis, all subjects who received the study product were included. Results are presented as frequencies (percentages) for categorical data and Mean ± SD (Standard Deviation) for quantitative data.

Results

Primary outcomes

This study was conducted on 63 subjects with second degree burns at a Burn ward of a Tertiary burn care center. The summary of subject demographics is described in **Table 2**. Of the 63 subjects randomised, 31 were treated using Silver Sulfadiazine and 32 using VELVERT. 61 patients completed the study, as 1 patient withdrew consent and one was lost to follow up. Complete wound closure was achieved by 27 subjects in VELVERT group and 19 subjects in the standard dressing group.

The wound closure was evaluated through Bates-Jensen Wound Assessment (BWAT) Tool. The score generated using this tool takes into account wound size, depth, edges, undermin-

Table 3. Timeline for wound closure assessed through wound size reduction; Score 1 = 100% wound covered, surface intact, Score 2 = 75% to <100% wound covered &/or epithelial tissue extends >0.5 cm into wound bed

Days	Value of Standard Dressing		Value of VELVERT Dressing	
	(Score 1)	(Score 2)	(Score 1)	(Score 2)
Day -15	0	0	0	0
Day 0-8	0	0	0	0
Day 8-12	2	-	5	-
Day 13-16	3	1	4	-
Day 17-20	7	-	12	-
Day 21-25	7	10	6	4
Total	19	11	27	4

"–" indicates that there were no patients in that score range during that time period.

ing, skin color surrounding wound, exudate level and color, peripheral tissue edema, peripheral tissue induration, granulation tissue and epithelialization. Higher score is directly proportional to the wound severity, whereas a score of 13 is defined as complete wound regeneration. On Day 0, BWAT score for standard dressing and VELVERT was 31.55 ± 3.35 and 31.66 ± 3.15 respectively (*p* value-0.8346). Standard pulled the mean score down to 16.18 ± 5.37 and VELVERT to 15.55 ± 4.42 (*p*-value 0.1760). The BWAT score of both dressing group, on first and last visit, is shown in **Figure 2**.

Secondary outcomes

By Day 12, 2 subjects in Standard arm and 5 subjects in VELVERT arm achieved complete wound closure. This increased to 5 subjects in Standard and 9 subjects in VELVERT dressing group by Day 17. On day 20 visit, around 21 out of 31 subjects (67.75%) achieved complete wound closure in VELVERT dressing group when compared to 12 of the 30 subjects (40.0%) in the Standard dressing. While, on the last visit day *i.e* Day 24 ± 1, around 27 (87.1%) subjects achieved complete wound closure in the VELVERT dressing group when compared to 19 (63.33%) subjects in the Standard dressing (**Table 3**). **Tables 4** and **5** depicts the endpoints *i.e* the individual subject area healed, time to healing and the BWAT scores for Standard and VELVERT dressing group respectively.

Relief from subjective pain was scored using Numeric Pain Chart of 0-10, on the day of dressing and its final removal, with 0 indicating no pain and 10 indicating worst pain imaginable. Mean pain imaginable recorded on the last day in standard dressing group was 2.08 ± 1.84 and in VELVERT group was 2.0 ± 2.52 (*p*-value 0.3671) (**Figure 3**). Though the pain level scores were very similar, it was observed that on the last day of the study, only 5 of the 31 subjects complained of pain in VELVERT group compared to 12 out of 30 subjects in the comparative dressing group.

Infection at the wound site, another critical endpoint, was assessed through the Swab test procedure. In the case of the standard dressing, which involved the use of silver sulfadiazine, two subjects exhibited infections during their screening visit but subsequently were free from infections, by their last visit. However, five new subjects of this group developed infections by their last visit, these cases were positive for *E. coli* and normal commensal flora. While in the VELVERT dressing group, although all subjects had non-infected wounds during their screening visit, four subjects tested positive for *Staphylococcus* and other common microbial flora by their last visit, (**Tables 6**-**8**). No adverse events and wound complications were reported in the study due to dressing material or other causes in either of the study group. **Figure 4** shows the representative pictures of second degree burn subjects, treated with Silver Sulfadiazine dressing and VELVERT dressing.

Discussion

Management of partial thickness burn wounds depends on the depth of burn wound, whether superficial or deep. Although, most of the partial thickness wounds heal in 1-2 weeks and do not require surgery, the ones with longer healing time are primarily managed by surgery. Topical antibiotics, biological dressing and/or non-biological dressing are the commonly available non-surgical wound management options [6]. Silver-based therapeutics are commonly used for managing partial thickness wounds,

Table 4. Primary endpoint of individual subjects that received Standard Dressing

Subject Initial	Screening Number	Area (cm^2) of the wound visit 01 (-15 to 0)	Area (cm^2) last day	Area Reduction %	Days	BWAT score
MS	01-001	379	8	97.89	16	13
MDA	01-002	489.5	10	97.96	25	21
SM	01-008	600	0	100.00	28	13
NS	01-009	1000	200	80.00	28	27
CJ	01-010	900	60	93.33	24	26
TG	01-011	800	0	100.00	15	13
FJ	01-014	600	0	100.00	24	13
RK	01-018	1530	0	100.00	17	13
KN	01-022	1210	0	100.00	14	13
SNR	01-023	800	0	100.00	19	13
KJ	01-025	1500	0	100.00	24	13
KD	01-027	800	0	100.00	21	13
RHM	01-030	1350	33	97.56	23	23
RSS	01-032	5940	3	99.95	25	19
RH	01-033	1000	3.75	99.63	22	18
GM	01-037	1000	36	96.40	26	24
SA	01-039	950	0	100.00	21	13
SY	01-040	1050	32	96.95	25	22
AK	01-042	1500	0	100.00	21	13
MK	01-044	1925	0	100.00	21	13
SS	01-047	950	0	100.00	11	13
SM	01-050	1500	112	92.53	23	25
cm	01-053	1200	0	100.00	20	13
JB	01-056	700	0	100.00	18	13
SHB	01-059	1047	0	100.00	15	13
SM	01-062	1400	0	100.00	19	13
MD	01-064	900	0	100.00	18	13
JM	01-065	900	0	100.00	25	13
KR	01-068	1575	0	100.00	19	13
FA	01-072	668	0	100.00	11	13

Table 5. Primary endpoint of individual subjects that received VELVERT dressing

Subject Initial	Screening Number	Area (cm^2) of the wound visit 01 (-15 to 0)	Area (cm^2) last day	Area Reduction %	Days	BWAT score
PR	01-004	900	0	100.00	17	13
AB	01-005	990	0	100.00	11	13
SB	01-006	600	149	75.17	25	26
SM	01-012	1400	0	100.00	24	13
GRM	01-013	1300	16	98.77	24	21
DM	01-016	1600	0	100.00	19	13
PA	01-017	675	0	100.00	17	13
SY	01-020	2700	0	100.00	12	14
TM	01-021	900	0	100.00	19	13
MK	01-024	1400	0	100.00	16	14
SD	01-028	1400	0	100.00	25	13
PS	01-029	2000	0	100.00	22	13

PS	01-031	1200	0	100.00	21	13
AB	01-035	900	0	100.00	19	13
PH	01-036	1440	0	100.00	19	13
SM	01-038	768	0	100.00	19	13
SG	01-041	843	0	100.00	12	13
AB	01-045	1200	16	98.67	24	23
SM	01-046	450	0	100.00	19	13
SS	01-048	1500	0	100.00	17	13
DM	01-049	1125	0	100.00	17	13
JK	01-052	782	0	100.00	21	13
SR	01-055	1975	0	100.00	19	13
MK	01-060	1200	16	98.67	24	17
RS	01-061	2400	0	100.00	16	14
BD	01-063	1200	0	100.00	20	13
AA	01-066	1350	0	100.00	16	15
KC	01-069	792	0	100.00	16	13
AH	01-071	1650	0	100.00	12	13
MN	01-074	600	0	100.00	11	13
AM	01-075	810	0	100.00	21	13

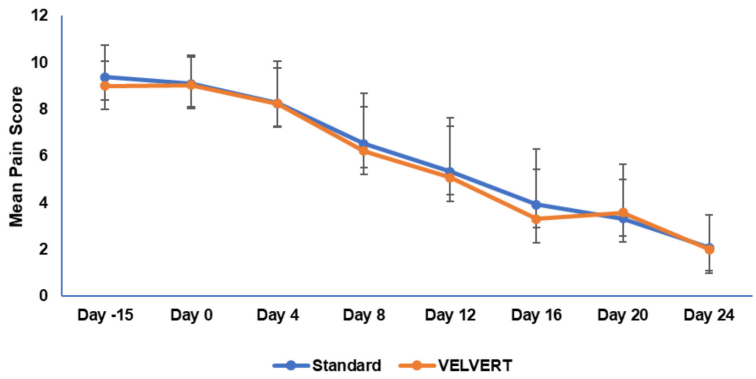

Figure 3. Mean pain score in standard and VELVERT arm throughout the study period.

Table 6. Number of dressings used in both arms of the study

Dressing Type	VELVERT	Standard
Number of evaluable patients	31	30
Total Number of dressings used	134	300
Average per patients dressing used	4.32 ± 1.08	10 ± 2.32

primarily owing to its efficient and widely acclaimed bactericidal properties. Currently, Silver Sulfadiazine, an FDA approved drug, is the most extensively used topical therapeutic for treating second and third degree burn wounds. This sulphonamide-containing formulation is preferred over other silver based sulpha drugs due to its efficient broad spectrum antibacterial efficacy [4, 10, 12]. However, the frequent dressing induced risk in infection have led to the advent of prolonged release nanocrystalline silver-based dressings. Primarily, silver-based dressings work by controlling infection at wound site and the healing takes place naturally.

While using any dressing the major criteria the surgeons have is to achieve higher wound healing rates along with epithelization of the wound region. Delayed re-epithelialization of the partial deep thickness wounds lead to hypertrophic scarring. Scarring is a major challenge in second degree burn patients, which affects their quality of life and causes psychosocial impairment [4, 6]. This signifies that early optimization of wound care and dressing selection plays a decisive role in minimizing delayed healing and subsequent scarring.

Silver sulfadiazine due to its extensive use in treating second degree wound is a common comparator for the new and emerging wound

Table 7. Assessment of micro-organisms at the wound site, first and last visit

Characteristics	Days	Standard Dressing (N = 31), n (%)	VELVERT Dressing (N = 32), n (%)
Was the sample taken from infection site for culture			
Done	Day (-15)	31 (100.0)	32 (100.0)
Done	last Visit	30 (100.0)	31 (93.75)
Microorganism Identified			
No	Day (-15)	29 (93.5)	32 (100.0)
Yes	Day (-15)	2 (6.5)	0
No	Last visit	25 (83.33)	27 (87.1)
Yes	Last Visit	5 (16.66)	4 (12.90)

Table 8. Micro-organisms found in the wound culture in the Standard and VELVERT group

Subject Number	Standard Dressing		VELVERT Dressing	
	First Visit (Screening)	Last Visit (Wound Closure)	First Visit (Screening)	Last Visit (Wound closure)
01-006	-	-	-	*Staphylococcus* (Day-24)
01-008	-	Normal commensal flora (Day-24)	-	-
01-009	-	Normal commensal flora (Day-24)	-	-
01-010	-	Normal commensal flora (Day-24)	-	-
01-012	-	-	-	Normal commensal flora (Day-24)
01-013	-	-	-	Normal commensal flora (Day-24)
01-014	*Escherichia coli*	-	-	-
01-016	-	-	-	Normal commensal flora (Day-19)
01-018	*Escherichia coli*	-	-	-

"–" indicates that no microorganism was found during that visit.

Figure 4. Representative images of the subject burn area on First and last visit of (A) Standard dressing treatment and (B) VELVERT dressing treatment.

healing therapeutics [4, 6, 12]. The present 24 ± 1 days study, reported a wound healed percentage of 66.33% for the standard dressing group and 87.1% for the VELVERT dressing group. Baghel *et al.* reported 37% and 81% wound healing by Silver Sulfadiazine and honey respectively in their 14-day study [19]. This high wound healing percentage observed with VELVERT in the present study suggests that this device - led combination product may offer a more favorable wound environment, potentially through sustained antimicrobial action and reduced wound disturbance. Although silver sulfadiazine is considered as a standard prophylactic for treating burn wounds, there are numerous studies that have reported its delayed wound healing potential along with inducing systemic toxicity [20]. Wound epithelialization was also evaluated through the BWAT score. At the end of the study the average BWAT score

for VELVERT was better compared to the standard dressing. The improved BWAT scores observed with VELVERT may be attributed to its non-adherent nature, which minimizes trauma during dressing changes and preserves newly formed epithelium. Studies have demonstrated that this standard sulfonamide is not appropriate for the treatment of partial thickness burns as it is not efficient in removing the dead tissues from the wound skin, thereby delaying the epithelization of the region [4, 6]. Despite this limitation, the antimicrobial efficacy of silver sulfadiazine justifies its widespread use, as infection remains one of the most serious morbidities associated with burn wounds and leading cause of mortality among burn patients [20]. Second-degree burns damage the dermis, resulting in prolonged healing times and increased vulnerability of necrotic tissue to microbial colonization [10]. Castellano et al. evaluated the antimicrobial efficacy of eight silver-based wound care agents and reported that while silver dressings effectively prevented infection and supported healing, topical agents such as silver sulfadiazine demonstrated superior bactericidal activity [12].

In the present study, silver sulfadiazine was compared with VELVERT a device-led combination product composed of a solid wound dressing (device) and antimicrobial agent (drug). VELVERT has shown moderately better antimicrobial activity compared to silver sulfadiazine. Swab analysis revealed the presence of pathogens in both groups; five subjects in the standard dressing group showed *Escherichia coli* and normal microbial flora, whereas four subjects in the VELVERT group showed *Staphylococcus* species along with normal flora. Previous studies indicates that burn wounds are initially colonized by Gram-positive bacteria, with Gram-negative organisms appearing later [10]. Furthermore, it is reported that though silver sulfadiazine is active against *Staphylococcus*, but prolonged use of this topical cream leads to the emergence of *Escherichia* coli, a resistant strain [21]. This suggests that VELVERT has microbiological advantage by reducing the emergence of pathogens during prolonged wound care [15].

Pain management is another critical concern in burn patients. Blister formation resulting from epidermal damage is characteristic of second-degree burns, and rupture of these blisters exposes nerve endings, leading to significant pain [5]. On the final day of the study, 40% of subjects in the standard dressing group and 16.1% in the VELVERT group reported pain, with mean pain scores being comparable between groups. Although overall pain scores were similar, the lower proportion of patients reporting pain in the VELVERT group suggests improved patient comfort. Recent studies on VELVERT have demonstrated its safety and efficacy in promoting wound healing, reducing pain, lowering microbial load, and achieving significant ulcer size reduction in patients with venous leg ulcers [15]. In infected wounds, VELVERT has also shown comparable efficacy to standard care, with significant wound size reduction, improved BWAT scores, reduced microbial load, and favorable clinician and patient acceptance [16].

The characteristics of a dressing play a crucial role in alleviating pain and promoting wound healing. Silver sulfadiazine is known to adhere to the wound bed, often making dressing changes painful and difficult. In contrast, the non-adherent nature of VELVERT minimizes trauma during removal, thereby reducing discomfort and improving patient compliance. Additionally, fewer dressing changes and the ability to maintain a moist wound environment facilitate faster healing, representing a meaningful clinical advantage. The current study was conducted on a small sample size, extending the study on a larger and more diverse population can give us more meaningful insight on the use of VELVERT in treating burn wounds.

Conclusion

Conclusively, both the burn dressings were well accepted by all the subjects. However, on comparing the primary and the secondary endpoints, it was observed that VELVERT displayed better wound healing efficacy, improved BWAT score, comparatively lesser pain and infection, along with all the characteristics of an ideal burn dressing. Therefore, VELVERT can be considered as a safe and effective dressing for treating second degree burn wounds.

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Written informed consent was obtained from the patient and his family.

Disclosure of conflict of interest

None.

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Supplementary Table 1. STROBE statement-checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	A Randomized Open-Label Study Comparing the Safety and Efficacy of a Natural Antimicrobial Dressing with Silver Sulfadiazine in the Management of Second-Degree Burn Wounds.
		Objective: This study evaluates the efficacy of VELVERT, a novel antimicrobial dressing, compared to the standard Silver Sulfadiazine dressing in treating second-degree burns. Method: Conducted at a tertiary burn care center, 63 patients were enrolled and randomized into two groups: VELVERT (n = 31) and Silver Sulfadiazine (n = 30). The primary outcomes measured were wound closure percentage and time to complete healing within 24 days, while secondary outcomes included infection control, pain relief, and adverse events. The study was registered with CTRI with the registration number CTRI/2020/12/029698 (https://ctri.nic.in/Clinicaltrials/pmaindet2.php?EncHid=NDY5MDc=&Enc=&userName=). Result: Among 61 patients who completed the study, 87% (27/31) in the VELVERT group achieved complete wound healing compared to 63% (19/30) in the Silver Sulfadiazine group. The BWAT score, assessing wound healing, showed a decline from 31.66 ± 3.15 to 15.55 ± 4.42 in the VELVERT group and from 31.55 ± 3.35 to 16.18 ± 5.37 in the Silver Sulfadiazine group (P = 0.176). Both treatments were well tolerated, but VELVERT exhibited superior wound healing outcomes. Conclusion: These findings suggest that VELVERT may serve as a more effective alternative for second-degree burn treatment, offering improved healing rates. Further research with larger sample sizes is recommended to validate its clinical benefits over standard treatments.
Introduction		
Background/rationale	2	Second-degree burns damage both the epidermis and dermis, making wound healing a complex process prone to infection and scarring. Silver Sulfadiazine is widely used as a standard treatment for burn wounds.
Objectives	3	This study compares the effectiveness of Silver Sulfadiazine dressing with VELVERT, a novel antimicrobial dressing, in promoting wound healing.
Methods		
Study design	4	Randomized, open-label, two-arm, single-center, post-market clinical study conducted at a burn care center from 23-Feb-2021 to 03-Jan-2023. Approved by IEC, registered with CTRI (CTRI/2020/12/029698), conducted under ICH-GCP guidelines.
Setting	5	Conducted at the Department of Plastic Surgery of a burn care center. Recruitment started on 23-Feb-2021 and ended on 03-Jan-2023. Follow-up continued till 24 days post-treatment initiation.
Participants	6	(*a*) Included burn patients aged 18-70 years, 5-20% TBSA burns, both genders, informed consent provided. 75 screened, 63 enrolled, 61 completed the study. Randomization via Interactive Web Responsive system.
		(*b*) Not a matched study; randomized allocation in 1:1 ratio.
Variables	7	Primary outcome: complete wound closure in 24 days. Secondary: pain relief, infection, subject comfort, adverse events. Assessment via BWAT and wound photographs.
Data sources/measurement	8	BWAT used at all visits, vital signs and AE/SAE monitoring done. Photographs taken at each visit. Same tools used across both study arms.
Bias	9	Randomization employed; informed consent taken; subject confidentiality maintained; standard protocols followed for dressing applications.
Study size	10	Calculated based on hypothesis testing for two means with equal variance. Effect size 0.825, power 90%, α = 5%, resulting in 64 subjects. With 10% attrition, final sample size = 70 (35/group). Derived from Manzoor et al. study.
Quantitative variables	11	Mean ± SD used; comparison through two-sample t-test. BWAT scores and wound area measured and analyzed.
Statistical methods	12	Analysis based on intent-to-treat. *P*-values from two-sample t-tests.
		No specific mention of subgroup/interactions.
		One subject withdrew consent and one lost to follow-up; 61 subjects included in analysis.
		Accounted as mentioned above; not included in final analysis.
		Not explicitly reported.
Results		
Participants	13	75 subjects screened, 63 met inclusion criteria and were enrolled. 31 received Silver Sulfadiazine and 32 received VELVERT. 61 completed the study; 1 withdrew consent and 1 was lost to follow-up.
		1 subject withdrew consent; 1 subject lost to follow-up.
		Participant flow depicted in CONSORT diagram (**Figure 1**).

Descriptive data	14	(Demographic summary provided in **Table 2**. Subjects aged 18-70 years, both genders. 3 females and 28 males in standard dressing group; 8 females and 23 males in VELVERT group.
		No missing data reported for primary variables.
		Each subject was followed up for a maximum of 24 days post-treatment. Follow-ups conducted at defined intervals with ± 1 day window.
Outcome data	15	Primary outcome: Complete wound closure achieved in 27/31 subjects (87.1%) in VELVERT vs. 19/30 (63.33%) in standard group by Day 24 ± 1. Assessed using BWAT score: Day 0 scores ~31.6 in both groups; final scores reduced to 15.55 ± 4.42 (VELVERT) and 16.18 ± 5.37 (Standard). Pain scores on last day: 2.0 ± 2.52 (VELVERT) vs. 2.08 ± 1.84 (Standard). Infection reported in 5 subjects (Standard) and 4 subjects (VELVERT). No adverse events reported.
Main results	16	Unadjusted comparisons reported with *p*-values. BWAT score change P = 0.1760; baseline P = 0.8346. Pain score P = 0.3671. No adjustments reported.
		BWAT score: Score of 13 = complete wound healing. Pain scale: 0-10.
		Not applicable; relative risks not reported.
Other analyses	17	Time-point-wise comparison of complete wound closure on Day 12, 17, 20, and 24 ± 1. Microbial analysis performed for infection assessment (**Tables 6**, **7**). No sensitivity or interaction analysis reported.
Discussion		
Key results	18	The study aimed to evaluate the wound healing efficacy of VELVERT versus Silver Sulfadiazine in second-degree burns. By Day 24 ± 1, complete wound closure was achieved in 87.09% of VELVERT-treated subjects versus 66.33% in the standard group. BWAT scores showed greater reduction in the VELVERT group. Pain scores were similar, but fewer subjects in the VELVERT group reported pain on the final day. VELVERT showed moderate antimicrobial activity and a favorable safety profile.
Limitations	19	Limitations include the relatively small sample size (63 subjects), short follow-up period (24 ± 1 days), and lack of blinding, which could introduce performance and detection bias. No stratification based on burn depth within second-degree classification may have influenced variability. The study used a semi-quantitative infection assessment via swab test rather than a quantitative culture, limiting precision. BWAT score is subjective and operator-dependent, potentially introducing measurement bias.
Interpretation	20	VELVERT demonstrated superior wound healing outcomes and lower reported pain incidence compared to Silver Sulfadiazine. The findings align with literature highlighting the delayed healing potential of silver sulfadiazine and its tendency to adhere to the wound. Prior studies, including Baghel et al., have shown better healing outcomes with alternatives to silver-based dressings. However, the antimicrobial efficacy of silver remains significant. VELVERT's combination of non-adhesive dressing with antimicrobial action may offer a promising solution but requires larger, multicentric trials for confirmation.
Generalisability	21	The results are potentially generalisable to other tertiary care burn centers treating second-degree burns, particularly in settings where infection control and patient comfort are critical. However, broader applicability may be limited by sample size, regional microbial flora, and healthcare resource availability. Further studies in diverse populations and extended follow-up are needed to validate these findings in routine clinical practice.
Other information		
Funding	22	This study was funded by Datt Mediproducts Pvt. Ltd.