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ORIGINAL ARTICLE

Efficacy of topical steroid in treatment of hyper granulation tissue in burn patients: A randomized control trial.

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ABSTRACT… Objective: To determine the efficacy of topical steroid in treatment of hyper granulation tissue in burn patients in term of healing time. **Study Design:** Randomized Control Trial (RCT). **Setting:** Jinnah Burn & Reconstructive Surgery Center, Allama Iqbal Medical College, Lahore. **Period:** May 2017 to November 2017. **Material & Methods:** A total of 32 patients fulfilling the inclusion criteria were enrolled in the study. Patients were randomly divided into 2 groups with 16 patients in each group by lottery method. Written informed consent was obtained from all patients. In group A, topical 1% hydrocortisone (Fusidin H) cream was applied and Group B received Medicated Paraffin gauze (bactigrass) dressing. Wound assessment was done weekly by 2 consultant plastic surgeons and final assessment was done at 3weeks after the treatment. **Results:** The mean age of patients was 28.6 + 8.81 years, among them 22(68.8%) were male and 10(31.3%) were females. Mean healing time in Group A and Group B was 12.8 +2.08 days and 15.4+1.6 days respectively. Efficacy was calculated as P value of 0.12 which is significant ($p < 0.05$). **Conclusion:** Topical steroid (hydrocortisone 1%) is more effective in treatment of hyper granulation in post burn wounds with early healing than medicated paraffin gauze dressing.

Key words: Burn, Bactigrass, Debridement, Hyper Granulation, Split Thickness Graft, Topical Steroid.

INTRODUCTION

Burn is still one of the injuries that affect both genders and all age groups in developed and developing countries. It is usually associated with a long term disability, including multiple operations; prolong hospitalization, rehabilitation and higher health care costs.[1,2] The optimum final outcome in the management of burn is wound healing and epithelialization, in order to prevent secondary burn deformities.[3]

Hyper granulation tissue which develops during the healing process of deep partial and full thickness wounds can impede epithelisation.[4] Excess granulation tissue found in wound bed that extended beyond the surface of the wound usually results from persistent inflammation, infection and fibrosis.[4,5,6] Clinically, it appears as a soft, red friable, shiny tissue above the level of the nearby skin.[7] However, the underlying cause for the generation of hyper granulation tissue is not well established.[8] Suspected causative factors predisposing hyper granulation are delayed wound healing[9], moist environment, infection due to prolonged inflammatory response[10], excessive use of occlusive dressings and surface friction.[5] Furthermore, hyper granulation tissue formation is stimulated by prolonged activation of fibroblasts and angiogenic cells. This hampers the process of wound healing.[4]

Various treatment strategies for hyper granulation have been reported, including non- occlusive dressings[5], wound debridement, silver-nitrate cauterization[11], hypertonic saline[4] and laser ablation.[9] However, these treatment modalities did not produce consistent results.[4] According to various studies, topical corticosteroids contribute to the suppression of inflammatory response, which is one of common factor that leads to

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the formation of hyper granulation.[4,6,12] Other mechanisms are angiogenesis inhibition[4,6] and decrease in the amount of oedema resulting in stabilization of the cell membranes.[4]

In contrast, medicated paraffin gauze is universally accepted mode of dressing for skin graft donor sites. It helps in prevention of infection in skin loss areas, burns and ulcers.[13]

Regarding burn wound there is little clinical evidence for treatment of hyper granulation tissue. Application of topical steroid is in common practice for the management of hyper granulation tissue at our Burn Centre. This study was designed to establish clinical evidence by comparing topical steroids (hydrocortisone 1%) with medicated paraffin gauze dressings in burn wounds for the healing time.

MATERIAL & METHODS

A, single blind, parallel-group, randomized control trail was carried out at Jinnah Burn and Reconstructive Surgery Centre, Lahore. (JBRS&C) from 10th May 2017 to 9th November 2017. After the approval from Institutional Ethical Review Board (No.4279/JB&RSC, Dated 1st May, 2017), a total of 32 patients were recruited. Patient with either gender, age range between 13-50 years and post burn wound 63 after initial debridement and skin grafting with graft loss of $<5cm^2$ area were included in the study. Patients with post burn wound after debridement and skin grafting with graft loss of $>5cm^2$ area, culture positive patients, pregnant females and patients on oral and intravenous steroid medications (immunocompromised) were excluded from study.

Written informed consent was obtained from all patients. They were randomly divided into two groups by the lottery method. A computer-generated table of random numbers was used for allocation (ratio 1:1). Sample size of 32 cases were calculated with 95% confidence level, 4% margin of error and taking expected efficacy as 85.0%. In Group-A (n=16), topical 1% Hydrocortisone (Fusidin-H cream) and in Group-B (n=16) Medicated Paraffin gauze (bactigrass) dressing were applied. Thinly layer of steroids was applied daily onto the wound bed by using the 4x4 gauze piece. Digital photographs were taken during the change of dressing. Wound was observed and assessed weekly with the visual analog scoring system and photographic evaluation was done by two consultant plastic surgeons with 10 year post fellowship experience. Final assessment was done at 3 weeks after initiation of treatment.

Healing time was noted in terms of the number of days till complete epithelialization is achieved. The variables like TBSA %, gender, age and type of burn were also noted. Data was entered and analysed by SPSS version 20. For continuous numerical variables like age, TBSA% and the modified Baux score, the mean and standard deviation was calculated. For categorical variables like efficacy, gender and type of burns, frequency and percentages were calculated. The Chi square test was applied to see the efficacy, the p value ≤ 0.05 was considered as significant.

RESULTS

After randomization, 32 patients were divided into two groups. The age ranges from 13-50 years in both groups. Mean age was 28.6 + 8.81, (range 15-46 years). Total 22 (68.8%) were male and 10 (31.3%) were females.

In Group-A, (n=16) the mean age and standard deviation was calculated as 27.1 + 8.67 years. Eleven (68.8%) were male and 5 (31.3%) were females. The mean Total body surface area (TBSA) was 24.3 + 4.79%. Modified baux score mean was 51.5 + 12.32. Thirteen patients (81.3%) were flame burns while 2 (12.5%) were scald burns and only 1 (6.3%) patient sustained chemical injury. Mean healing time was 12.8 + 2.08 days. Efficacy showed excellent (100%) response in 11 (68.8%) patients.

In Group-B, Mean age was 30.1 + 8.97. Eleven (68.8%) were male and 5 (31.3%) were females. TBSA mean was 23.81+ 5.60 %, the Modified Baux score was 53.93 + 9.5. Flame burns were 9 (56.3%), scald 3(18.8%), chemical burn 3 (18.8%), and High voltage electrical current injury was only 1(6. 3%). Mean healing days were calculated as

15.4+1.6. Efficacy, (100%) excellent response was shown in only 4 (25%) patients. Stratification for the outcome was done for age (p=0.71), gender (p=1.00), TBSA% (p=1.00), the Modified Baux score (p=0.47), healed days (p=0.34), burn type (p=0.403) and efficacy was p=0.012 which was significant (< 0.05).

Variable		Group		Total	Chi-square P-Value
		Group A	Group B		
Age	< 35 years	10	9	19	X^2=.130 P=.719
		62.5%	56.3%	59.4%	
	> 35 years	6	7	13	
		37.5%	43.8%	40.6%	
Gender	Male	11	11	22	X^2=.000 P=1.000
		68.8%	68.8%	68.8%	
	Female	5	5	10	
		31.3%	31.3%	31.3%	
TBSA%	< 25%	11	11	22	X^2=.000 P=1.000
		68.8%	68.8%	68.8%	
	> 25%	5	5	10	
		31.3%	31.3%	31.3%	
Baux score	< 55	10	8	18	X^2=.508 P=.476
		62.5%	50.0%	56.3%	
	> 55	6	8	14	
		37.5%	50.0%	43.8%	
Heal days	< 14 days	11	5	16	X^2=4.500 P=.034
		68.8%	31.3%	50.0%	
	> 14 days	5	11	16	
		31.3%	68.8%	50.0%	
Burn Type	flame burn	13	9	22	X^2=.2.927 P=.403
		81.3%	56.3%	68.8%	
	scald burn	2	3	5	
		12.5%	18.8%	15.6%	
	chemical burn	1	3	4	
		6.3%	18.8%	12.5%	
	HVECI	0	1	1	
		0.0%	6.3%	3.1%	
Efficacy	no response	0	2	2	X^2=11.036 P=.012
		0.0%	12.5%	6.3%	
	good response <50% healed	2	0	2	
		12.5%	0.0%	6.3%	
	fair response >50% healed	3	10	13	
		18.8%	62.5%	40.6%	
	excellent response 100% healed	11	4	15	
		68.8%	25.0%	46.9%	

Table-I. Demographic data and results.

Case Summaries					
Group		Age	TBSA	Baux Score	Heal Days
Group A (TH)	N	16	16	16	16
	Mean	27.1875	24.3125	51.5000	12.8125
	Std. Deviation	8.66579	4.78496	12.31260	2.07264
	Minimum	15.00	18.00	33.00	11.00
	Maximum	42.00	35.00	77.00	17.00
Group B (MG)	N	16	16	16	16
	Mean	30.1250	23.8125	53.9375	15.3750
	Std. Deviation	8.96568	5.69466	9.50417	1.50000
	Minimum	16.00	16.00	38.00	13.00
	Maximum	46.00	34.00	68.00	19.00
Total	N	32	32	32	32
	Mean	28.6563	24.0625	52.7188	14.0938
	Std. Deviation	8.80106	5.18022	10.89017	2.20497
	Minimum	15.00	16.00	33.00	11.00
	Maximum	46.00	35.00	77.00	19.00

Table-II. Case summaries.

Groups	50% Epithelization	70% Epithelization	100% Healed
Group A	7.6 + 2.1	10.2 + 1.98	12.8 + 2.07
Group B	11.3 + 1.4	13.3 + 1.9	15.3 +1.5
p value	0.002	0.001	0.001

Table-III. Healing time (days) of wounds in both group.

DISCUSSION

The application of topical steroids in treatment of non-burn wounds has been documented in multiple literatures.[6,12,14] The role of steroids in arresting the inflammatory response contributing to hypergranulating tissue is already proven.[5,12] But, its role in treating the wounds showing hypergranulation and the chronic inflammatory response is not well reported.[14] Moreover, in burn wounds, we succeeded in finding only two studies emphasising upon treatment of hypergranulation tissue with topical steroids, but both the studies have limited number of patients.[4,15]

Topical steroids suppress the immune pathway in keratinocytes, and this effects inflammatory cells maturation, viability and immune functions.[16,17] Additional evidence shows that topical steroid decreases the number of fibroblasts; thus helps in producing the anti- inflammatory effect.[18,19] Topical use of fusidic acid is effective for treatment of primary or secondary wound infections.[20,21] Although its resistance against staphylococcus has been reported, in vitro evidence suggests that resistance is lower with the use of high concentrations of fusidic acid, which reflects the situation after topical application.[22]

Many of the clinicians are still reluctant to use topical corticosteroids on wounds concerning about immunosuppression, impairment of wound healing and infection.[4] The results of this study suggest that fears concerning the use of topical corticosteroids on wounds may be unfounded. Healing was achieved in 68.8% of patients. Exudate was reduced and over granulation suppressed in all patients. However, sensitisation and resistance to antibiotics following prolonged use of Fusidin H cream is still a concern. All the patients had been regularly followed up and no major complications of skin hypertrophy, unstable scaring and skin ulceration was noted except 4 (12.5%) had itching, and was managed conservatively with emollient massage.

In this study, the results showed a convenient and non-invasive method of treatment for hypergranulation, which was well accepted by our subjects. However, there are some limitations in study in terms of its design and sample size(

sample size is smaller in number, post burn wound size chosen were smaller in size, single centre study and long term results not available yet). Nonetheless, the purpose of this study was to establish clinical evidence to our usual practice of treating hypergranulating tissue at our Burn Centre. We believe that the application of topical hydrocortisone 1% is a plausible method to bring the desirable results in achieving hypergranulation regression and wound healing in both the burn wound and wounds within the grafted areas. It reduces the healing time and also reduces the number of secondary procedures. However, further researches are required to affirm our results and to quantify its effects. This study, does not provide a basis for recommendations on the frequency or type of steroid to use. However, we feel that the topic is worthy of further investigation and to compare the current methods of management in terms of efficacy, adverse effects, and cost-effectiveness in treating the hypergranulation in burn wounds.

In the meantime, we advocate the cautious use of topical corticosteroids by experienced practitioners in the management of such wounds.

CONCLUSION

Topical steroid (hydrocortisone 1%) is more effective in treatment of hyper granulation in post burn wounds with early healing than medicated paraffin gauze dressing.It helps in reducing the inflammation and thought to reverse the hypergranulation to proceed normal wound healing in burn patients. Topical steroid can be used as one of modality of dressing for burn patients with caution to improve the wound healing.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

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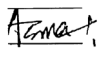
1	Abdul Malik Mujahid	Principal contributor, conceptualization and design of research work, data collection.	
2	Zain Ul Abidin	Data collection, statistical analysis, Interpretation of data.	
3	Asma Ilyas	Writing of manuscript, results analysis.	
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