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EFFECTIVENESS OF BETA-GLUCAN COLLAGEN FOR TREATMENT OF PARTIAL THICKNESS BURNS IN PEDIATRIC AGE GROUP PATIENTS: A RANDOMIZED CONTROLLED TRIAL AT TERTIARY CARE CENTRE

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HOW TO CITE THIS ARTICLE:

Sanjay Changole, Adesh Palyekar, Vikrant Nandurkar. "Effectiveness of Beta-Glucan Collagen for Treatment of Partial Thickness Burns in Pediatric age Group Patients: A Randomized Controlled Trial at Tertiary Care Centre". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 71, December 18; Page: 15157-15164, DOI: 10.14260/jemds/2014/4037

ABSTRACT: SUMMARY: BACKGROUND: Burn injuries present a major public health problem for children. In India this constitutes about one-fourth of total burn injuries. This article deals with situations that need to be addressed in the care of partial thickness wounds in children to provide optimal conditions for wound protection and repair while minimizing the morbidity and complications. **AIM:** To compare outcomes for pediatric age group patients who were applied beta-glucan collagen or anti-microbial dressing as primary wound covering in respect to pain, infection rate and healing time. **DESIGN OF STUDY:** Randomized controlled trial. **SETTINGS AND DESIGN:** Tertiary care hospital of central India from 2008-2010. **METHODS:** Patients admitted at tertiary care centre with partial thickness burns at first presentation were recruited to randomized controlled trial. Patients in trial were randomly allocated for beta-glucan collagen or anti-microbial dressings. **RESULTS:** Seventy-two patients were recruited over 28 months. Two were excluded from final analysis due to premature demise. Out of seventy subjects thirty-five were in BGC group while remaining thirty-five were in SSD group. Subjects were in 1-11 age range with majority being in 1-5 age groups. Out of total seventy patients thirty-three were male and thirty-three were females. Flame burns and scald burns were equally distributed in both groups and difference was not significant. Most of the patients presented within 6 hrs of initial injury (54.7%). TBSA% in BGC group was 16.4 while it was 18.2 in control group. Most of the patients in both the groups had burn injury over upper limb followed by anterior trunk. Partial thickness burns in children can be cost effectively treated with BGC with decreased pain, mean healing time and hospital stay with good cosmetic results. **KEYWORDS:** Partial thickness burns; beta-glucan collagen; anti-microbial dressing; randomized controlled trial.

INTRODUCTION: Burn injuries present a major public health problem for children. In India this constitutes to about one-fourth of the total burn accidents.¹ Annually around 250,000 children suffer serious burns that require medical attention.² Approximately 30,000 children are hospitalized for serious burns each year with a large number suffering permanent disfigurement and disability.³ Majority of burns occur in children under five years of age. In younger children scald burns constitutes most of the burn injuries. Scalds are caused when child pulls hot liquid onto himself accidentally. In older children flame burns are more common. We must ensure that children must not only survive initial injury, but also morbidity and complications are decreased. In this hospital annually around 50 pediatric burn patients get admitted, which accounts to 20% of the total burn patients admitted. Burn injuries in pediatric age group require efficient and effective management. Routinely topical antimicrobial dressing, skin grafting, and occlusive dressing are used for management of burn wounds depending on degree of burns.^{4,5} Beta- Glucan, a complex carbohydrate,

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is known to stimulate macrophages. Collagen is natural component of the dermal matrix produced by fibroblasts that functions as protective scaffolding for the migrating epithelial cells in the regenerating skin.⁶

With this background, study was undertaken with objective to compare the effectiveness of Beta-Glucan Collagen dressing with silver sulfadiazine in relation to pain scoring, infection rate, bacteriology, antibiotic usage, healing time, post burn scar, hospital stay and cost effectiveness, to understand the role of Beta-Glucan Collagen sheets versus antibiotic covering dressing in partial thickness burns as a primary wound covering.⁷

METHOD: TRIAL DESIGN: A present randomized controlled trial was carried out at tertiary care hospital of central India from 2008-2010. In this study each group constitute 35 subjects. Out of 284 admitted burn patients 72 fulfilled the eligibility criteria; hence they were enrolled in this study. Out of 72 eligible two were excluded from final analysis due to premature demise. In all 70 subjects were remained for final analysis. Two different treatments were allocated randomly. A simple randomization technique was adopted for the allocation of two different regimens. Patients were allotted to each group on alternate basis. Information pertinent to socio- demographic characteristics, mode of infliction of injuries, etc. was collected from the parents of the study subjects. A detailed history was obtained regarding the mode of injury, intention, place and time of burns. A thorough physical examination was performed with emphasis on the type and extent of burns.

ELIGIBILITY CRITERIA: Patients with both sexes with age <12 years, Partial thickness burns of <50 percent TBSA, with Thermal burns (flame burns and scalds) and Presenting within 24 hours of injury was included. Those with age >12 years, with full thickness burns of >50 percent TBSA, with electrical and chemical burns, presenting after 24 hours of injury, who received local treatment before admission and patients with systemic diseases which are known to affect wound healing like diabetes, tuberculosis, malignancy, and cardiovascular disease were excluded from the study.

INTERVENTION: After initial resuscitations, all the patients fulfilling the inclusion and exclusion criteria were allocated into two groups- Group (BGC) and Group (SSD).

BGC group, - Patients dressed with Beta glucan collagen dressing. SSD group, - Patients dressed with silver sulphadiazine.

Patients and relatives were informed about the treatment given and a written consent was taken before initiation of the treatment.

BETA GLUCAN COLLAGEN: The BGC used in this study is a purified bovine reconstituted collagen. The BGC membranes come in varying dimension of 5*5cm, 10*10cm, 10*25cm and 15*30cm, and its thickness is 0.6cm. It is sterilized by gamma irradiation and is marketed in FFS Aluminum pouch packing containing a mixture of Isopropyl alcohol and water. It has a shelf life of over 5 years at ambient temperature under Indian conditions. Once the patient is stabilized, patient is taken to the operation theatre and dressing is done under general anesthesia. Before dressing the wound swabs were taken from the burn wound and from the surrounding normal skin. Wound was thoroughly cleaned with normal saline. BGC sheets (wet/dry) are then applied and secured with bandage/strips.

The dressing is kept for 3 days unless there are signs of infection (soakage and foul smell). After the 3rd day if the wound is healthy it is kept open. Patient is followed up daily. The collagen

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sheets peels off by itself once the epithelium grows underneath. Pain while management of burn wound was assessed by pain scoring as per.

SSD GROUP: Before dressing the wound, swabs were taken from the burn wound and surrounding normal skin. Wound was thoroughly cleaned with normal saline. Silver sulphadiazine was applied on to the burn surface and then the wound was covered with dry sterile gauze, sterile pads were placed and bandaging was done.

Before dressing the wound, swabs were taken from the burn wound and surrounding normal skin. Wound was thoroughly cleaned with normal saline. Human placental extract was applied on to the burn surface and then the wound was covered with dry sterile gauze, sterile pads were placed and bandaging was done.

Dressing was done after every 24 hours till the soakage is minimal (single layer pad). Thereafter dressings were done daily. In case of increased soakage, dressings were repeated. In case of foul smelling discharge, wound was exposed, swab taken, debrided and dressing was done. Follow up.

RESULTS: Most common age group involved in both groups was 1-5 yrs. Males and females were roughly equally distributed in both Beta Glucan Collagen group and in SSD group. Flame burns were equally distributed with scald burns in both the groups. Mean TBSA% Beta Glucan Collagen group was 16.4% whereas it was 18.2% in silver sulphadiazine group. Most of the patients in both the groups presented within 6 hours after initial burn injury. Most common site involved in both groups was upper limb followed by anterior trunk. Both the groups were comparable as far as Hb% and serum total protein levels were concerned. Pain due to burn injury on the day of admission was similar in both groups. But subsequently the pain was highly decreased in BGC group as compared to ssd group. The difference was highly significant with P value of <0.001.

The mean healing time in BGC group was 18.2 days whereas it was 25.5 days in SSD group. The mean duration of hospital stay was 7.6 days in BGC group and 13.35 days in SSD group. The difference was highly significant ($p < 0.001$) Majority of the patients in BGC group had good scar. Infection rate was significantly low in BGC collagen group.

CLINICAL PHOTOGRAPHS:

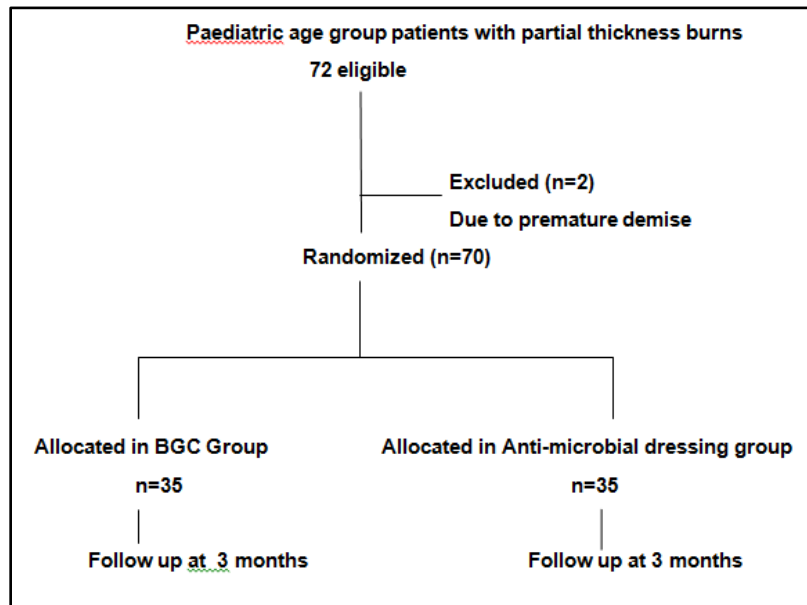


5 yrs old male child treated with collagen sheets

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1 year old male child treated with beta glucan collagen



DISCUSSION: It is observed in the present study that the youngest age was 1 year and oldest was 11 years in both the study groups. The mean age was 4.58 years in study group and 4.65 years in control group. The frequent occurrence of burn injuries in children reflects a combination of factors including a no awareness of potential dangers and a limited ability of the child to respond in a prompt, appropriate manner

	Group	N	Mean Age	Std. Deviation	T value	P value	Result
Age	Study	35	4.58	3.4	0.0916	0.5357	NS
	Control	35	4.65	3.1			
TBSA (Extent of burns)	Study	35	16.4%	3.98	1.875	0.0651	NS
	Control	35	18.28%	4.41			

Table 1: Age and total body surface area (TBSA) of burns in two groups.

Females outnumbered males in the study group and males outnumbered females in control group. But in overall study, males outnumbered females.

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Majority of the patients in both the study group presented within 6 hours. The patients presented early to the hospital were from the nearby place of the study conducted and the patients who presented late were far away, from the rural place that took primary treatment in the form of intravenous fluids and referred to our hospital for further management. The mode of burn injury in majority of the patients was found to be scald (55.71%) followed by flame (44.28%). It is found that most of the pediatric burns occur due to accidental kitchen associated injury and hence commonest injury being scald. The minimum TBSA% of burns was found to be 5% and maximum being 31% with mean of 16.4% in study group and minimum of 10% and maximum of 30% with mean of 18.28% in control group. The patients with high percentage of burns have high chances of wound infection, increased hospital stay and bad post burn scar.

		Group Study Control	Total	Chi Sq Value	P value	Result
Sex Distribution	Females	19	14	1.43	0.231	NS
	Males	16	21			
Mode Of Burns	Flame	15	16	0.06	0.81	NS
	Scald	20	19			
Time of Presentation	<6 hrs	19	21	0.35	0.881	NS
	6-12 hrs	14	12			
	12-24 hrs	02	02			

Table 2: Sex Distribution, Mode of Burns And Time of Presentation of Burns in Two Groups

NS- Non-Significant

	Group	N	Total Pain Score	Mean	Std. Deviation	T value	P value	Result
Pain scoring	Study Control	35	562	3.21	6.048	8.255	<0.001	S
		35	1020	5.82	7.166			
Healing Time	Study Control	35		18.2	0.7050	5.608	<0.001	S
		35		25.54	0.8641			
Mean duration of stay (days)	Study Control	35		7.65	2.838	7.7	<0.001	S
		35		13.37	3.361			

Table 3: Pain Scoring, Healing Time And Mean Duration Of Hospital Stay (Days) In Two Groups Of Burn Patients

S-Significant

The present study showed that the pain suffering was minimal with average score of 3.21 in study group as compared to the average score of 5.82 in control group. This difference was highly

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significant with P value <0.001, which seems to be due to the covering of the exposed nerve endings of burn wound with the collagen sheet and avoidance of daily painful dressings in study group. The present study showed that the healing time was reduced in study group as compared to the control group. The average healing time was 18.2 study group and 25.54 days in control group. The difference was highly significant with P value <0.001. The reasons for early healing of burn wound in study group was prevention of evaporative water and heat loss, BGC acts as a protective layer against the migration of bacteria and hence less infection. It is observed in the present study the hospital stay was reduced in study group as compared to the control group, with average stay of 7.65 days and 13.37 days in study and control group respectively. This difference was highly significant with P value <0.001. The following are reasons for increased hospital stay in control group:

- High infection rate.
- Increased daily requirement of dressings.
- Increased healing time.
- Decreased general immunity in control group because of infection.

INFECTION RATE AND BACTERIOLOGY: The present study showed positive cultures in 9 out of 35 patients (25.71%) in study group and 26 out of 35 patients (74.28%) in control group which showed the significant difference (P value <0.001) between the two study group. But the organism isolated in both groups did not differ with most common organism being staphylococcus aureus, and pseudomonas aeruginosa followed by klebsiella pneumonia and mixed culture.

INFECTION RATE:

Group	N	Infection		Chi sq value	P Value	Result
		Yes	No			
Study	35	9 (25.71%)	26 (74.28%)	16.51	<0.001	significant
control	35	26 (74.28%)	9 (25.71%)			

WOUND BACTERIOLOGY:

	Day 0		Day 3		1st		2nd		3rd		4th		5th	
	Study	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study	Control
Pseudomonas			4	10	2	7		1						
Klebsiella			1	2		2								
Staph. aureus	1	2	4	11	2	11								
Streptococci				1		1								
E. Coli														
Mixed culture				2		1								
Total no. of Positive report	1	2	9	26	4	22		1						

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SCAR APPEARANCE (COSMESIS): Post burn scar may appear Good or Bad depending upon the following features:

- Texture and colour of new epithelium as compared to the surrounding normal skin.
- Whether the scar is normal or hypertrophic.
- Whether the scar is at the same level (even) or elevated compared to the surrounding skin.
- General appearance of the scar – good or ugly.

In the present study, the post burn scar in 27 out of 35 patients (77.14%) in study group showed normo-pigmentation with better appearance, having texture as that of the normal surrounding skin without leaving any prominent scar, as compared to 13 out of 35 patients (37.14%) in control group. But 22 out of 35 patients (62.85%) in control group showed a bad scar, majority having hypopigmentation and some hyperpigmentation with prominent scar as compared to only 8 out of 35 patients (22.85%) in study group. The difference was significant with P value 0.001.

SCAR APPEARANCE:

Group		Scar		Chi sq value	P	
		Good	Bad			
Study	35	27 (77.14%)	8 (22.85%)	11.43	0.001	Significant
Control	35	13 (37.14%)	22 (62.85%)			

COST EFFECTIVENESS: Cost effectiveness is a very important comparative feature, which signifies the overall efficacy of Beta-Glucan Collagen dressing over Silver sulfadiazine dressing in the treatment of partial thickness burns. The cost of treatment was significantly decreased with use of collagen sheet as compared with silver sulfadiazine, thus proving its cost effectiveness.

CONCLUSION: Treatment of partial thickness burns in pediatric age group with BGC results in significantly decreased pain level, duration of hospital stay and healing time as compared to SSD. Treatment with BGC also results in good cosmetic scar and cost effective treatment of partial thickness burns.

ACKNOWLEDGEMENT: Special thanks to Dr. S. P. Matkari, Dr. B. B. Gupta and Dr. Raj Gajbhiye.

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Date of Submission: 01/12/2014.
Date of Peer Review: 02/12/2014.
Date of Acceptance: 12/12/2014.
Date of Publishing: 17/12/2014.