Original Article

Comparison of Efficacy of Gabapentin Versus Cetirizine in Patients with Post-Burn Pruritus

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Abstract

Objective: To compare the efficacy of gabapentin and cetirizine in the management of post-burn pruritus.

Methodology: This was designed as a comparative study carried out in Hayatabad Medical Complex, Peshawar, from September 2020 to February 2021. A total of 100 patients with post-burn pruritus were included in the study. The subjects were randomly assigned by lottery method into one of two groups: Group A: gabapentin group or Group B: cetirizine group. The 50 patients allotted to Group A received gabapentin for their post-burn pruritus, whereas the 50 patients assigned to Group B received cetirizine. The efficacy of both drugs in post-burn pruritus management was noted.

Results: The results showed that 90%(n=45) patients in Group A showed a VAS score of zero, i.e. efficacy of gabapentin was 90%. In contrast, only 50%(n=25) patients in Group B showed VAS=0, i.e. the efficacy of cetirizine was 50%. The result was statistically significant.

Conclusion: In conclusion, this study noted that management of post-burn pruritus with gabapentin monotherapy was significantly more effective than cetirizine.

Keywords: Burns, Gabapentin, Histamine antagonists, Pruritus

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Introduction

The itching or pruritus that ensues during the wound healing stage after the burn is termed Post-burn pruritus.[1] It normally sets in few days after receiving the burn. A prevalence of 80-100% has been reported for it in the literature.[2] Factors like female gender, more significant burns, extensive surgery, and limb or facial burns increase the risk in the patients.[1,3] This, in turn, not only affects the patient's quality of life (QoL) but also significantly affects their psychosocial well-being.[4] Hence, mitigating the symptoms of post-burn pruritus is a significant rehabilitation challenge for burn patients.

Physicians are currently using visual analogue scales (VAS) and numerical rating scales (NRS) clinically to assess the severity of itching in post-burn patients. However, no tool has been established yet to measure the severity of pruritus[5] specifically.

Post-burn wound healing evolves through three phases; an inflammatory phase, followed by a proliferative phase, and finally a remodeling phase.[6] In addition to mast cells, histamine usually dominates the acute phase of healing of the wound. However, in contrast to the acute phase, in chronic phase it is converted into a neuropathic pruritus, which is characterized by antihistamine-resistant wounds with sensitized central nervous system.[1]

Various treatments options are available for the management of post-burn pruritus which range from topical emollients, antihistamines, and massages, to psychological and dermatological treatments.[2,7,8] Despite the availability, there is no agreed upon management strategy which has shown significant experimental evidence.[7] Therefore, well-designed, randomized, placebo-controlled trials are still needed to develop regimens suitable to patients' values, risks, and resources.

The emollients used by patients in post-burn pruritus management are usually items available at hand, like simple moisturizers, liquid paraffin, aloe vera, lanolin, and coconut oil or some other type of oil.[9] Additionally, antihistamines like diphenhydramine, hydroxyzine, and cetirizine are another current mainstay for pruritus management.[10] They are being used as a first-line treatment for both children and adults.[1,10] However, recently, gabapentin and pregabalin, which is an anti-epileptic drug also used for neuropathic pains, have garnered much attention due to their role in the management of post-burn pruritus.[11] Many investigators are showing interest in its efficacy as an anti-pruritic agent. However, in Pakistan, limited evidence is present for its use, and cetirizine is still being used as the first-line treatment.

The aim of this study was to compare the efficacy of gabapentin and cetirizine in the treatment of pruritus.

Methodology

This comparative study was carried out in Burns and Plastic Surgery Center, Hayatabad, Peshawar, during the year 2020-2021, after obtaining ethical approval from the Ethical Committee of Hayatabad Medical Complex (Ref. No. 243/HEC/B&PSC/19). The participants were selected through non-probability convenience sampling. The sample size was calculated using the WHO sample size calculator. The Confidence Level was 95%; alpha 5% (two-sided) with power 80%. Additionally, the expected proportion (efficacy) in population 1 was taken as p1=95%; the expected proportion (efficacy) in population 2 was taken as p2= 52% (12). The estimated sample size was 16; however, in this study, 100 participants were selected after obtaining their informed consent. Fifty participants were allotted to Group A (gabapentin group), whereas 50 participants were allotted to Group B (cetirizine group).

Patients with burns, thermal, electrical, or scalding, covering >5% of total body surface area (TBSA), with post-burn pruritis ensuing for more than 1 week, were selected for this study. However, patients who had received split skin grafting on >1% of TBSA previously were excluded from the study. Additionally, wounds with pruritis that were treated with topical treatments other than the ones used in the study and patients with co-morbidities like diabetes, renal disease etc., and patients lost to follow-up were also excluded from this study.

This study was conducted in accordance with Helsinki Declaration after approval from the ethical committee and research committee of Hayatabad Medical Complex, Peshawar. One hundred patients with a history of post-burn pruritis for more than one week and fulfilling the inclusion criteria of the study were selected by non-probability convenience sampling from the outpatient department of Burns and Plastic Surgery Center, Peshawar. All the participants were informed about the study and their consent was obtained. The base line demographic information of the patients including age, gender, weight, type of burn, duration of complaint, VAS score, and TBSA burned, were recorded on the day of the recruitment (day 0). The participants were divided into 2 groups; gabapentin group was designated as Group A, whereas, the cetirizine group was designated as Group B. Participants were randomly assigned by lottery method to either groups. The participants in Group A were prescribed gabapentin; patients with VAS scores ranging between 2-5 were given 300mg of gabapentin once daily, patients with scores between 6-8 were given 300mg gabapentin twice a day, and patients with VAS scores between 9-10 were given 300mg gabapentin three times daily. The drug was prescribed for 28 days.[12] For participants in Group B, cetirizine was prescribed. The duration of prescription was kept same as that of gabapentin i.e., 28 days.12 For patients with VAS score between 2-5, 10mg cet-

irizine per day was prescribed, whereas, for patients with VAS score ≥6, 10mg cetirizine was given twice a day. Patients were requested to visit for a follow-up after 28 days. Efficacy of the drug was defined as no itching on the visual analogue scale (VAS=0), and noted on specially designed proformas by the researcher.

Data Analysis:

Using statistical analysis program (IBM-SPSS V22), the data was analyzed. Frequency and percentage were computed for qualitative variables like gender, type of burn and efficacy. Mean ±SD was presented for quantitative variables like age, duration of complain, baseline VAS score, TBSA burn, post treatment VAS score and weight. Chi-square test was applied to compare efficacy of both groups, taken p ≤0.05 as significant.

Age, gender, duration of complain, type of burn, TBSA burn, baseline VAS score and weight were used for stratification, to see the effect of these variables on efficacy. Post stratification chi-square test for both groups was applied, p≤0.05 was considered statistically significant.

Results

In this study 100 participants were divided into two groups; Group A representing the gabapentin group, whereas, Group B presenting cetirizine group. The demographic data of the participants summarized in Table 1 shows that the age range of participants in both the groups is between 18-70 years, with the mean age being 38.260±12.84 years for group A and 32.540±8.94 years for group B. Additionally, the comparison of duration of complaint, baseline VAS scores, TBSA%, weight, and post-treatment VAS scores between the two groups are also given in Table 1. Similarly, the data regarding the gender distribution of the participants in both groups shows that 62%(n=31) participants were male while 38%(n=19) were female in Group A, whereas, 76%(n=38) participants were male and 24%(n=12) were female in Group B as shown in Figure 1.

This study included patients with complaints of either thermal, electrical, or scalding burns. The recorded data showed that majority of the patients in both groups had thermal type of burns as evident in Figure 2.

In the study the participants were grouped as Group A, which was prescribed gabapentin, and Group B, which was prescribed cetirizine. The results of the follow-up carried out after 28 days of administration of the drugs showed that 90%(n=45) of patients in Group A showed a VAS score of zero, i.e., efficacy of gabapentin was 90%. In contrast, only 50%(n=25) patients in Group B showed VAS=0, i.e. the efficacy of cetirizine was 50%. This result was statistically significant, given that the p-value was 0.000. Table 2. To see the effects of demographic variables on the efficacy of both drugs, strati-

Table 1. Showing the demographic data of the two groups

	Group A (n=50)	Group B (n=50)
Age (in years)	38.260± 12.84	32.540± 8.94
Duration of complaint(in weeks)	2.740± 0.94	2.840± 0.88
Baseline VAS score	5.060±1.05	5.200±1.04
TBSA (%)	15.960±6.58	14.720±4.96
Post treatment VAS score	0.260±0.80	1.200±1.27
Weight (Kg)	74.040±11.87	67.940±12.31

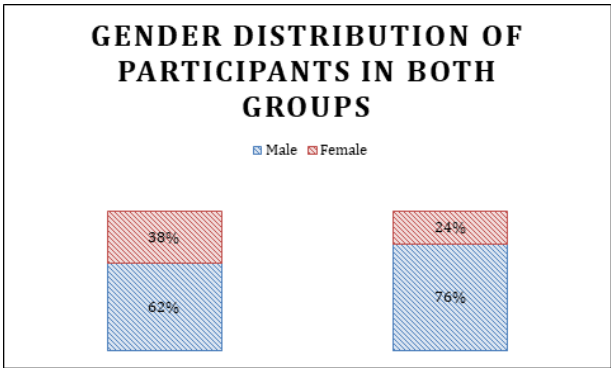

Figure 1: Showing the gender distribution data of the two groups

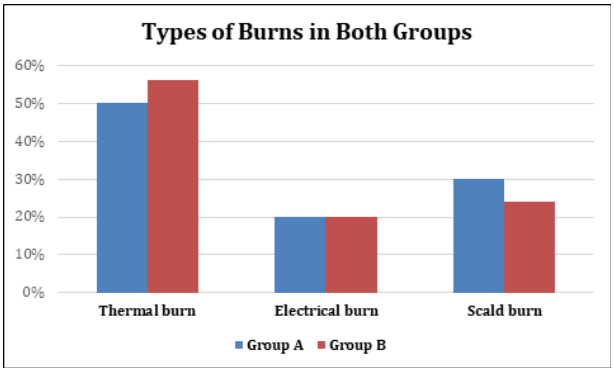

Figure 2: Showing the prevalence of different types of burns in both the groups

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fication was done in regards to age, gender, duration of complaint, type of burn, TBSA%, baseline VAS, and weight. The post-stratification Chi-square test results showed a statistically significant difference between the efficacy of both drugs in regards to age, gender, duration of complaint, type of burn, and baseline VAS. However, the results were insignificant for patients having burns on >20% TBSA, as well as patients with weights more than 60kgs. The results have been summarized in Table 3.

Discussion

The itching or pruritus that ensues during the wound healing stage after the burn is termed Post-burn pruritus.[1] It normally sets in a few days after receiving the burn. A prevalence of 80-100% has been reported for it in the literature.[2] High TBSA% burns and protracted healing have been documented by Vitale et al. as a major risk factor for severe post-burn pruritus.[13] Currently, the first line of treatment prescribed for post-burn pruritus is antihistamines and emollients.[14] Cetirizine, which is a selective antihistamine (H1 blocker), is usually the drug of choice. However, recently, much work has been carried out on gabapentin to be used for post-burn pruritus. Gabapentin is an antiepileptic drug which is also used for neuropathic pain. A complex interaction between pain and itch pathways has been documented, which was validated by Mendham, Yesudian & Wilson., and Winhoven et al., reporting itch relief with gabapentin.[15–17] Itch pathway with epidermal C fiber receptors relaying to dedicated C neurons in dorsal horn cells has been reported; the impulse is then projected to parts of the parietal motor cortex and anterior cingulate cortex.[14,18] This shows the interaction between pain and itch pathways. Mendham, in

Table 2. Showing the efficacy of gabapentin in Group A and cetirizine in Group B

Efficacy	Group A (n=50)	Group B (n=50)	p Value
Yes	45 (90%)	25 (50%)	0.000
No	5 (10%)	25 (50%)	
Total	50 (100%)	50 (100%)	

Table 3. Showing the post-stratification efficacy of gabapentin and cetirizine

Characteristic	Group	Efficacy		p Value
		Yes	No	
Age	18-40 years			
	A	26 (89.7%)	3 (10.3%)	0.000
	B	21 (51.2%)	20 (48.8%)	
	41-70 years			
	A	19 (90.5%)	2 (9.5%)	0.006
	B	4 (44.4%)	5 (55.6%)	
Gender	Male Gender			
	A	28 (90.3%)	3 (9.7%)	0.000
	B	18 (47.4%)	20 (52.6%)	
	Female Gender			
	A	17(89.5%)	2(10.5%)	0.043
	B	7(58.3%)	5(41.7%)	

Duration of Complaint	1-2 Weeks			
	A	23(85.2%)	4(14.8%)	0.003
	B	10(45.5%)	12(54.5%)	
	>2 Weeks			
	A	22(95.7%)	1(4.3%)	0.000
	B	15(53.6%)	13(46.4%)	
Type of Burn	Thermal Burn			
	A	23(92%)	2(8%)	0.016
	B	18(64.3%)	10(35.7%)	
	Electrical Burn			
	A	9(90%)	1(10%)	0.006
	B	3(30%)	7(70%)	
	Scalding Burn			
	A	13(86.7%)	2(13.3%)	0.004
	B	4(33.3%)	8(66.7%)	
TBSA%	5-20%			
	A	33(97.1%)	1(2.9%)	0.000
	B	21(48.8%)	22(51.2%)	
	>20%			
	A	12(75%)	4(25%)	0.391
	B	4(57.1%)	3(42.9%)	
Baseline VAS	VAS ≤5			
	A	32(88.9%)	4(11.1%)	0.000
	B	16(50%)	16(50%)	
	VAS >5			
	A	13(92.9%)	1(7.1%)	0.009
	B	9(50%)	9(50%)	
Weight	≤60 kg			
	A	9(100%)	0(0%)	0.306
	B	13(61.9%)	8(38.1%)	
	>60 kg			
	A	36(87.8%)	5(12.2%)	0.000
	B	12(41.4%)	17(58.6%)	

2004, used gabapentin in controlling post-burn pruritus in children with much success. Ahuja RB et al. and Zachariah JR et al. showed the efficacy of gabapentin to be 95% and 87% in the management of pruritus.[3,19] Goutos et al., in 2010, in the UK, also reported the efficacy of gabapentin in combination protocols. However, he suggested that the use of gabapentin in monotherapy tends to be more effective as compared to its use in combination therapy.[10]

In Pakistan, the first line treatment employed for post-burn pruritus is usually antihistamines or emollients. Cetirizine, a selective H1 blocker, is the drug of choice. However, the relief provided by cetirizine to the patient in post-burn pruritus has been reported by the patients to be unsatisfactory. Presently, globally, many

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investigators and clinicians are showing interest in the role and efficacy of gabapentin for post-burn pruritus. However, limited evidence is available for its use in Pakistan. Therefore, this study was carried out to provide quality evidence for the efficacy of the drug in the management of pruritus in comparison to cetirizine. The results of our comparative study showed that gabapentin was significantly more effective than the commonly used cetirizine when given in monotherapy, regardless of the initial VAS scores. This is in accord with the studies carried out by Ahuja et al., Zachariah et al., and Goutas et al., cited previously.[3,10,19]

In conclusion, gabapentin is significantly more effective than cetirizine in relieving post-burn pruritus, when given in monotherapy. Hence it is suggested that the protocol for management of post-burn pruritus used in hospitals of Pakistan should be revised to bring it in line with the current advances.

Additionally, the use of gabapentin to control post-burn pruritis further needs a dose optimizing trial in the future. Another limitation of this study was that dose-dependent side effects were not studied in detail; this further needs to be studied in the future.

Conclusion

Pacemaker's lead dislodgment is not very uncommon complication. There is no one risk factor responsible for lead displacement. However if all the factors are kept in mind at time of implantation, the rate of this complication can significantly be reduced, if not completely avoided.

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Authors' Contribution Statement

HF contributed to the conception, design, acquisition, analysis, interpretation of data, drafting of the manuscript, critical review, and final approval of the version to be published. LF contributed to the design, acquisition, interpretation of data, drafting of the manuscript, and final approval of the version to be published. All authors are accountable for their work and ensure the accuracy and integrity of the study.

Confilct of Interest

Authors declared no conflict on interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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