

Efficacy of Oral Pregabalin versus Narrowband Ultraviolet B Therapy in Patients with Uraemic Pruritus: A Randomised Clinical Trial

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ABSTRACT

Introduction: Uraemic pruritus is a common and distressing symptom experienced by patients with Chronic Kidney Disease (CKD). It affects 15-49% of patients with predialysis CKD and 50-90% of those undergoing dialysis. Uraemic pruritus significantly impairs the quality of life of these patients; however, well-designed clinical trials evaluating effective treatment options remain limited. Although studies have demonstrated the benefits of pregabalin and Narrowband Ultraviolet B (NB-UVB) phototherapy, limitations such as small sample sizes, methodological variability, and lack of long-term follow-up highlight the need for further research, particularly studies comparing systemic therapies with phototherapy.

Aim: To compare the efficacy and assess the adverse effects of oral pregabalin and NB-UVB phototherapy in the treatment of uraemic pruritus.

Materials and Methods: This randomised clinical trial was conducted in the dermatology outpatient department of Madras Medical College, Chennai, Tamil Nadu, India from September 2020 to August 2021. The study included 30 patients in each treatment group. Patients aged over 18 years, diagnosed with CKD, presenting with symptoms of uraemic pruritus, and willing to give informed consent were included. Patients younger than 18 years, those with acute illness, liver cirrhosis, or decompensated heart failure were excluded. Additionally, patients allergic to pregabalin, those with a history of photosensitivity, pruritus due to secondary causes, and pregnant or lactating women were excluded. The intensity of pruritus was assessed using the Visual

Analogue Scale (VAS). Group A received oral pregabalin 75 mg on alternate nights for 12 weeks, while group B underwent NB-UVB phototherapy with the dose titrated upward over the same duration. Patients in both groups were followed-up fortnightly during the 12-week treatment period and subsequently on a monthly basis until the 24th week. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 23.0. The Chi-square test was used to compare qualitative variables between the two groups, and the independent sample t-test was used to compare mean values. A p-value of <0.05 was considered as statistically significant.

Results: The mean age of the participants was 48.01±12.66 years. Male predominance was observed in both groups, accounting for 63.3% in group A and 53.3% in group B. Both groups showed a similar distribution in terms of age, gender, mean duration and intensity of pruritus, and mean estimated Glomerular Filtration Rate (eGFR) (p-value>0.05). The mean baseline VAS score was 8.89±0.69 in the pregabalin group and 8.73±1.07 in the NB-UVB group. At the end of the follow-up period, the mean VAS score in the pregabalin group was significantly lower than that in the NB-UVB group (p-value=0.001). Pruritus relapse was observed eight weeks after the final dose of oral pregabalin in group A. Both treatment modalities were associated with minimal adverse effects.

Conclusion: A faster and more pronounced reduction in mean VAS scores was observed in patients treated with pregabalin compared to those receiving NB-UVB phototherapy. The adverse drug reactions observed in this study were minimal.

Keywords: Chronic kidney disease, Dialysis, eGFR adverse effects, Phototherapy, Visual analog scale

INTRODUCTION

Uraemic pruritus is a common and frustrating symptom experienced by patients with CKD. The term “uraemic pruritus” is considered a misnomer, as it incorrectly implies that pruritus is directly related to elevated blood urea levels. It is defined as localised or generalised pruritus occurring in a non dermatomal pattern over bilaterally symmetrical areas of the body without primary skin lesions. Symptoms are typically reported at least once daily or with near-daily frequency [1-3]. Uraemic pruritus affects 15-49% of patients with predialysis CKD and 50-90% of those undergoing dialysis [4]. The aetiology of uraemic pruritus is multifactorial, making its management complex and challenging [5]. Both uraemic and non uraemic factors contribute to its pathogenesis [6]. Recent theories include the immune hypothesis and the opioid hypothesis [7]. Currently, first-line treatment options for CKD-associated pruritus include agents such as pregabalin and gabapentin, while narrowband or broadband ultraviolet therapy is considered second-line treatment [8].

A randomised trial demonstrated the efficacy of pregabalin at a dose of 25 mg/day in reducing pruritus among dialysis patients [9]; however, the study lacked long-term follow-up to assess sustained benefits after treatment cessation. Similarly, studies reporting favourable outcomes with NB-UVB phototherapy are limited by small sample sizes and the absence of extended follow-up periods [5]. Overall, existing literature is characterised by methodological heterogeneity, limited study populations, and inconsistent outcome measures. Notably, the comparative efficacy of systemic therapies such as pregabalin versus NB-UVB phototherapy remains inadequately explored, underscoring the need for further research in this area. Despite its high prevalence and significant impact on quality of life, there is a paucity of well-designed clinical trials evaluating effective treatments. This study aimed to compare the efficacy of a first-line systemic agent, oral pregabalin, with a second-line therapeutic modality, NB-UVB phototherapy, in the management of uraemic pruritus.

MATERIALS AND METHODS

This non blinded randomised clinical trial was conducted in the outpatient department of Dermatology at Rajiv Gandhi Government General Hospital, Chennai, Tamil Nadu, India between September 2020 and August 2021. The trial was initiated after obtaining ethical clearance from the Institutional Ethics Committee (Approval No.: 24092020).

Sample size calculation: A total of 60 patients were included and allocated into two groups, as calculated using OpenEpi software. The expected mean VAS score after treatment was taken as 3.2 ± 2.35 in the pregabalin group [10] and 1.9 ± 0.4 in the NB-UVB group [11], with an alpha error of 0.05, 80% power, and a 95% confidence interval.

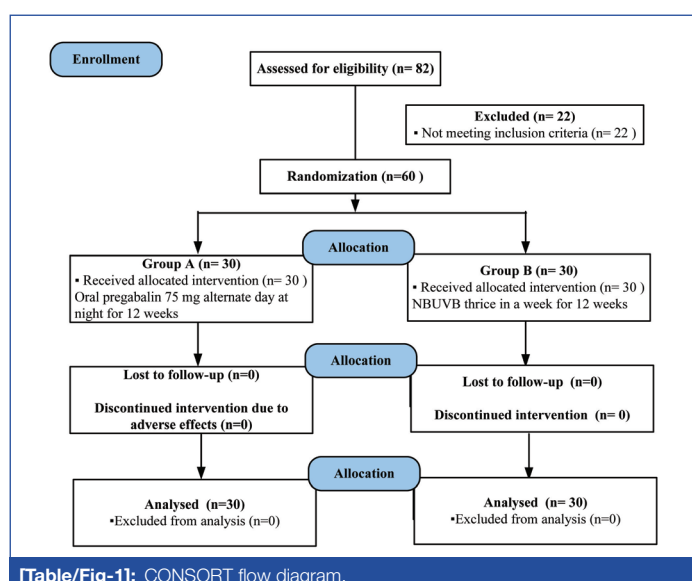
Inclusion criteria: Patients aged above 18 years, diagnosed with CKD, presenting with symptoms of uraemic pruritus, and willing to give informed consent were included in the study.

Exclusion criteria: Patients aged <18 years, those diagnosed with acute illness, liver cirrhosis, or decompensated heart failure were excluded. Additionally, patients allergic to pregabalin, those with a history of photosensitivity, pruritus due to secondary causes, and pregnant or lactating women were excluded from the study.

Study Procedure

Patients fulfilling the inclusion criteria were enrolled after obtaining written informed consent, and an information sheet was provided. A detailed history was recorded, followed by dermatological, general, and systemic examinations. The severity of pruritus was assessed using the VAS. Patients were asked to circle a number on the VAS corresponding to the intensity of itching, ranging from 0 to 10, where "0" represents no itch and "10" represents the maximum itch.

Relevant laboratory investigations were prescribed at the initial visit. Patients were randomly assigned to two groups using a lottery method. Group A received oral pregabalin 75 mg on alternate nights after food for a duration of 12 weeks. Group B received NB-UVB phototherapy thrice weekly for the same duration, starting at a dose of 200 mJ/cm² and increased by 10% at each session. A total of 60 patients with uraemic pruritus were enrolled in the study after screening 82 patients for eligibility. The participants were randomly allocated into two equal groups (group A and group B). No patients were lost to follow-up. The CONSORT flow diagram is shown in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

Based on the treatment response, the phototherapy dose was adjusted as follows: the previous dose was maintained if asymptomatic erythema persisted for 24 hours; the dose was reduced by 10% if erythema was accompanied by pruritus or mild pain; NB-UVB therapy was restarted at one-third of the previous dose after recovery in cases of painful erythema or blister formation [5,11].

NB-UVB phototherapy was administered using a 24-Spiegel series chamber equipped with Philips 100 W TL-01 tube lights (DermaIndia). Patients in both groups received liquid paraffin and oral cetirizine as part of standard care. Patients were followed-up every two weeks until the end of 12 weeks and subsequently on a monthly basis until the completion of 24 weeks. At each visit, a brief history regarding symptoms and adverse effects of oral pregabalin or NB-UVB therapy was elicited. Patients were asked to indicate the intensity of pruritus using the VAS. The variables assessed in this study included age, gender, mean eGFR, mean baseline VAS score, mean duration of pruritus, CKD stage, number of haemodialysis sessions per week, mean duration of dialysis, blood urea, serum creatinine, serum calcium, and VAS scores over time. CKD staging [Table/Fig-2] [12] and reference values for laboratory parameters [Table/Fig-3] [13] are provided.

Stage	eGFR (mL/min/1.73 m ²)
1	eGFR ≥ 90 (kidney damage with normal or increased GFR)
2	eGFR 60-89 (mildly reduced GFR)
3a	eGFR 45-59 (mild to moderately reduced GFR)
3b	eGFR 30-44 (moderately to severely reduced GFR)
4	eGFR 15-29 (severely reduced GFR)
5	eGFR < 15 (kidney failure)

[Table/Fig-2]: Staging of Chronic Kidney Disease (CKD) [12].

Laboratory parameters	Normal range
Blood urea (mg/dL)	15-40
Serum creatinine (mg/dL)	0.7-1.4 (Male)
	0.4-1.3 (Female)
Serum calcium (mg/dL)	9-10.5

[Table/Fig-3]: Reference values for the laboratory parameters [13].

STATISTICAL ANALYSIS

Data comprising both quantitative and qualitative variables were entered into Microsoft Excel 2019 to create a master chart. The outcome variables of the study were VAS score and adverse effects. The data were subsequently analysed using SPSS version 23.0. Qualitative variables were expressed as percentages, while quantitative variables were expressed as mean and standard deviation. The Chi-square test was used to compare the distribution of qualitative variables between the study groups. The independent sample t-test was applied to compare mean values. Repeated Measures Analysis of Variance (RMANOVA) was used to analyse VAS scores at each visit, changes over time, and differences between the two groups. A p-value of <0.05 was considered as statistically significant.

RESULTS

Demographic characteristics and baseline parameters are summarised in [Table/Fig-4]. The mean age in group A was 47.23 ± 14.24 years, while in group B it was 48.80 ± 11.08 years. Male predominance was observed in both groups, accounting for 63.3% in group A and 53.3% in group B. The mean eGFR was 25.83 ± 15.51 mL/min/1.73 m² in group A and 23.00 ± 11.35 mL/min/1.73 m² in group B. Both groups showed a similar distribution in terms of age, gender, and mean eGFR (p-value >0.05).

Characteristics		Group A (n=30)	Group B (n=30)	Total (n=60)	p- value
Age in years (mean±SD)*		47.23±14.24	48.80±11.08	48.01±12.66	0.35
Age group (years)	(18-30)	5 (16.7)	2 (6.7)	7 (11.7)	0.38
	(31-50)	13 (43.3)	12 (40)	25 (41.7)	
	(51-70)	12 (40)	16 (53.3)	28 (46.7)	

Male	19 (63.3)	16 (53.3)	35 (58.3)	0.43
Female	11 (36.7)	14 (46.7)	25 (41.7)	
Mean eGFR* (mL/min/1.73 m ²)	25.83±15.51	23±11.35	24.41±13.43	0.42
Mean duration of itching* (in months)	3.47±2.27	3.63±1.54	3.55±1.90	0.74
Mean baseline VAS score*	8.89±0.69	8.73±1.07	8.81±0.83	0.49

[Table/Fig-4]: Demographic details and baseline parameters of group A and B. Percentage is provided inside the bracket.

*Independent sample t-test others: Pearson's Chi-square test

The mean duration of pruritus was 3.47±2.27 months in group A and 3.63±1.54 months in group B. The mean baseline VAS score was 8.89±0.69 in the pregabalin-treated group and 8.73±1.07 in the NB-UVB-treated group. Statistically, both groups had comparable intensity and chronicity of pruritus (p-value >0.05).

As shown in [Table/Fig-5], in group A, 36.7% of patients were in CKD stage 4 and in stage 5. In group B, 46.7% of patients were in CKD stage 4 and 33.3% were in stage 5. In group A, 10 patients were on haemodialysis, with a mean dialysis duration of 22.70±9.10 months. In group B, 16 patients were undergoing haemodialysis, and the mean duration was 23.81±5.10 months. Both groups showed a similar pattern with respect to the mean duration of haemodialysis (p-value=0.69).

Characteristics	Group A (n=30)	Group B (n=30)	Total (n=60)	p-value
CKD stage	n (%)	n (%)	n (%)	0.81
2	1 (3.3)	0	1 (1.7)	
3a	4 (13.3)	3 (10.0)	7 (11.7)	
3b	3 (10.0)	3 (10.0)	6 (10.0)	
4	11 (36.7)	14 (46.7)	25 (41.7)	
5	11 (36.7)	10 (33.3)	21 (35.0)	
No. of haemodialysis/week				
Nil	20 (66.7)	14 (46.7)	34 (56.7)	0.24
Once	9 (30)	13 (43.3)	22 (36.7)	
Twice	1 (3.3)	3 (10)	4 (6.7)	
Mean duration of dialysis (months)*	Group A (n=10)	Group B (n=16)	Total (n=26)	0.69
	22.70±9.1	23.81±5.1	23.25±7.1	

[Table/Fig-5]: Distribution of cases based on CKD stage and haemodialysis.

*Independent sample t-test Others- Pearson's Chi-square test

Statistical analysis of biochemical parameters revealed that in group A, 83.3% of patients had elevated blood urea levels and 86.7% had elevated serum creatinine levels, whereas in group B, 63.3% had elevated blood urea levels and 60% had elevated serum creatinine levels. Elevated serum calcium levels were observed in 34.5% and 26.3% of patients in groups A and B [Table/Fig-6].

Group	Blood urea		Serum creatinine		Serum calcium	
	Raised	Normal	Raised	Normal	Raised	Normal
Group A (n=30)	25 (83.3)	5 (16.7)	26 (86.7)	4 (13.3)	10 (34.5)	20 (65.5)
Group B (n=30)	19 (63.3)	11 (36.7)	18 (60)	12 (40)	5 (26.3)	25 (73.7)
p-value	0.06	0.08	0.06	0.07	0.55	0.50

[Table/Fig-6]: Comparison of laboratory parameters between two study groups.

Test used: Pearson's Chi-square test

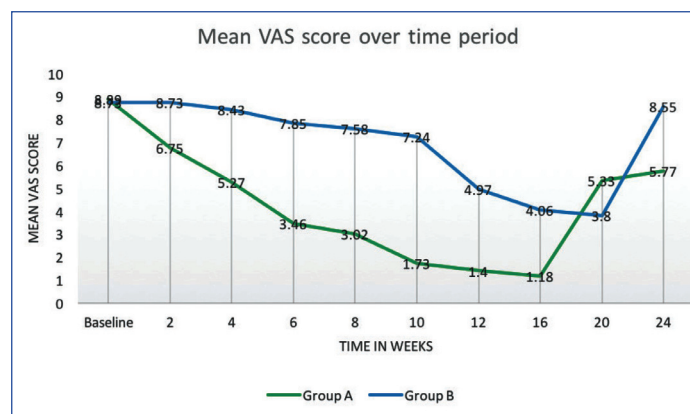
The variation in VAS scores over time in both groups is presented in [Table/Fig-7,8]. The mean baseline VAS score was 8.89±0.69 in group A and 8.73±1.07 in group B. At the second week of follow-up, the mean VAS score in group A declined by 24% from baseline, whereas it remained nearly unchanged in group B. By the end of the fourth week, both groups demonstrated a reduction in VAS

scores compared to the previous visit. At the 8th, 10th, 12th, and 16th weeks, mean VAS scores continued to show a consistent declining trend in both groups, with a more pronounced reduction observed in group A compared to group B. The maximum reduction in VAS score in group B was noted at the 20th week (3.80±0.51), while the maximum reduction in group A occurred at the 16th week (1.18±0.65). At the end of the 20th week, a slight increase in the mean VAS score was observed in group A, whereas group B continued to show a decrease. By the end of the 24th week, mean VAS scores increased in both groups, with group B exhibiting higher values. Overall, the total variation in VAS scores between the two groups was statistically significant (p-value <0.001). Although VAS scores were comparable at baseline, at each subsequent follow-up until the 16th week, group A demonstrated significantly lower VAS scores than group B (p-value=0.001). Notably, an increase in VAS score was observed one month earlier in group A.

Timeline (weeks)	Group A (n=30)		Group B (n=30)		p-value†	p-value‡, F value
	Mean	SD	Mean	SD		
Baseline	8.89	0.69	8.73	1.07	0.497	0.001, 114.97
2 nd	6.75 (24)	1.85	8.73 (0)	0.96	0.001	
4 th	5.27 (41)	1.71	8.43 (5)	0.85	0.001	
6 th	3.46 (60)	1.47	7.85 (10)	0.91	0.001	
8 th	3.02 (66)	0.97	7.58 (13)	0.78	0.001	
10 th	1.73 (81)	0.90	7.24 (17)	0.85	0.001	
12 th	1.40 (84)	0.76	4.97 (43)	0.87	0.001	
16 th	1.18 (87)	0.65	4.06 (53)	0.59	0.001	
20 th	5.33 (40)	1.29	3.80 (56)	0.51	0.001	
24 th	5.77 (36)	1.13	8.55 (2)	0.72	0.001	

[Table/Fig-7]: Pattern of change in VAS score over the time period- percentage decline from baseline given in brackets.

†p-value through parameter estimates; ‡p-value obtained through RMANOVA



[Table/Fig-8]: Line diagram showing change in VAS score over the time line.

Among participants in group A, three patients (10%) experienced dizziness, two (6.7%) reported somnolence, and the remaining patients reported no adverse events. In group B, one patient (3.3%) developed erythema, and another patient (3.3%) reported worsening pruritus. None of the adverse events observed in either group necessitated discontinuation of therapy.

DISCUSSION

Uraemic pruritus is the most common cutaneous manifestation in patients with CKD and occurs more frequently in individuals undergoing dialysis for more than three months [7,14]. The mean age of the 60 patients in the present study was 48.01±12.66 years. In contrast, Ravindran A et al., reported a higher mean age of 56.09±11.62 years in a randomised prospective interventional study conducted in Kerala [9]. In the present study, 58.3% of participants were male (n=35), which was consistent with previous studies by Ko MJ et al., Shavit L et al., and Ozen N et al., [5,10,15]. Although CKD is more prevalent among women, this male predominance

may be attributed to the multifactorial pathogenesis of uraemic pruritus. The mean duration of pruritus in this study was 3.55 ± 1.90 months, which was considerably shorter than the duration reported by Ada S et al., who observed a mean duration of 30 ± 41.7 months, and Dhaher SA and Hassan AA, who reported a median duration of 18 months [16,17]. The relatively shorter duration observed in the present study may be attributed to early recognition and prompt referral to the dermatology outpatient department by nephrologists.

Out of the 60 patients, 41.7% were diagnosed with CKD stage IV, and 35% were undergoing treatment for end-stage renal disease. However, 56.7% of the patients were not on haemodialysis. Only four patients were undergoing haemodialysis twice weekly. The mean duration of dialysis was 23.25 ± 7.10 months, which was lower than that reported in clinico-epidemiological studies by Ozen N et al., and Subach RA and Marx MA [15,18]. In the NB-UVB-treated group, none of the patients underwent haemodialysis three times per week. In contrast, in the study conducted by Ada S et al., all patients were on haemodialysis three times per week [16].

Group A patients were treated with oral pregabalin 75 mg on alternate nights, while group B received NB-UVB phototherapy thrice weekly. The dose of pregabalin used in the present study differed from that used by Shavit L et al., who administered a starting dose of 25 mg orally three times per week at the end of each haemodialysis session [10]. If no improvement was observed by the end of the first week, the dose was increased to 25 mg/day and subsequently to 50 mg/day, with treatment continued for 24 weeks. In another study by Ravindran A et al., a lower dose of pregabalin (25 mg/day) was also found to be effective in reducing symptoms of uraemic pruritus [9].

Although the present study employed a higher treatment frequency and longer duration, the initial NB-UVB dose was similar to that used by Sherjeena PB et al., [11]. In contrast, Dhaher SA and Hassan AA initiated NB-UVB therapy at a higher dose of 0.3 J/cm^2 , with incremental increases of 0.1 J/cm^2 , which was associated with improved clinical outcomes [17]. Similarly, Mahmoud WS et al., used an initial NB-UVB dose of $0.25\text{--}0.30 \text{ J/cm}^2$, adjusted according to skin type, and gradually increased the dose to reach the minimal erythema dose over a treatment period of six weeks [19].

In this study, the mean baseline VAS scores were comparable between the two groups. By the end of the second week, the mean VAS score in group A began to decline. At the end of the fourth week, the mean VAS score was 5.27 ± 1.71 , which was higher than the 3.2 ± 1.75 reported by Shavit L et al., [10]. This difference may be attributed to the lower initial dose of pregabalin and the absence of dose escalation in the present study. Additionally, by the end of the follow-up period, the mean VAS score in group A remained higher than that observed at the end of 24 weeks of treatment in the study by Shavit L et al., likely due to the longer treatment duration in the latter [10]. Similarly, Ravindran A et al., reported a marked reduction in VAS scores from 7 to 1 following six weeks of treatment with pregabalin at a dose of 25 mg/day [9]. However, follow-up was not performed in these studies to evaluate the persistence of therapeutic effects after drug discontinuation. In contrast, present study findings suggest that the antipruritic effect of pregabalin persisted for up to four weeks after the final dose.

In group B, the VAS score remained unchanged at the end of the second week, likely due to the slower onset of action of NB-UVB therapy. Thereafter, mean VAS scores showed a declining trend until the 20th week. The VAS scores at the end of the 4th, 12th, and 24th weeks in present study were higher than the mean values of 1.9 ± 0.4 , 1.9 ± 0.4 , and 2.4 ± 0.8 , respectively, reported by Sherjeena PB et al., who also noted that the therapeutic effect persisted for up to three months after the final treatment session [11]. In contrast, in the present study, the therapeutic effect persisted for up to

two months following the final NB-UVB session. Overall, group A demonstrated a greater reduction in VAS scores compared to group B as treatment progressed. This difference may be attributed to the lower baseline dose and smaller incremental increases of NB-UVB used in this study. In contrast, studies by Ko MJ et al., and Mahmoud WS et al., employed higher NB-UVB doses and reported more pronounced reductions in VAS scores over six weeks [5,19].

Relapse of pruritus was observed in both groups. In group A, an increase in VAS score was noted at the 20th week, which occurred four weeks earlier than in group B. This earlier relapse may be attributed to the limited duration of action of oral pregabalin. The delayed relapse observed in the NB-UVB-treated group may be due to its apoptotic effects on dermal mast cells, thereby reducing the release of pruritic mediators [20]. Adverse effects reported in group A included dizziness (10%) and somnolence (6.7%), neither of which interfered with treatment continuation. Shavit L et al., also reported minimal or no adverse effects associated with pregabalin therapy [10]. In group B, adverse effects included pruritus (3.3%) and erythema (3.3%), each reported in one patient. No adverse effects were reported in the study conducted by Sherjeena PB et al., [11].

Limitation(s)

This study was limited by its small sample size and relatively short follow-up period. Patient-related bias in VAS score assessment cannot be excluded. The response to higher doses of NB-UVB was not evaluated, and Kt/V calculations were not performed.

CONCLUSION(S)

The mean baseline VAS scores were comparable between the two groups. Overall, a faster and more pronounced reduction in mean VAS scores was observed in the pregabalin-treated group, likely due to the rapid onset of action of the oral medication. Adverse effects observed during the study were minimal, and none necessitated discontinuation of either pregabalin or NB-UVB therapy in any participant.

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- iThenticate Software: Sep 19, 2025 (1%)

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