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Assessment of Quality of Life and Severity of Itching Pre and Post Doxepin Therapy in Dialysis Patients with Pruritus

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ABSTRACT

Objective: Chronic kidney disease (CKD)-associated pruritus is a significant clinical symptom affecting more than 50% of patients on hemodialysis. The main aim of this study was to assess the effects of doxepin treatment on the quality of life of pruritic patients.
Material and methods: This prospective-interventional study was carried out for a period of 6 months in dialysis unit of Department of Nephrology in a tertiary care teaching hospital, Chennai. Both inpatients and outpatients of both sexes ≥ 18 years on hemodialysis or peritoneal dialysis for more than 3 months with pruritus were included for the study. A total number of 39 dialysis patients with pruritus were recruited for the study. Patients were evaluated at the beginning of the study and at the end of 2 weeks of each study period. The severity, duration, degree, direction, disability and distribution of itch were evaluated using 5D- pruritus scale. The quality of life of patients was assessed using DLQI questionnaire (Dermatology Life Quality Index).
Results: There was an improvement in quality of life of patients with pruritus after doxepin therapy.
Conclusion: Doxepin is a better therapy for itching and improving the quality of life in dialysis patients. Clinicians should enquire about skin irritation and itching during consultations since patients may be reluctant to admit to these symptoms due to embarrassment.

INTRODUCTION

Pruritus (skin irritation or itching) is common in patients with Chronic Kidney Disease (CKD) stages 4 and 5. It is associated with disrupted sleep, reduced quality of life, depression and increased mortality (Rayner *et al.*, 2012). Pruritus is a common and bothersome symptom among patients with end-stage-renal-disease (ESRD) (Nolan, 2005).Chronic kidney disease (CKD)-associated pruritus is a significant clinical symptom affecting more than 50% of patients on hemodialysis (Mettang and Weisshaar, 2010). People with end-stage kidney disease have a higher incidence of skin itching than the general population, while dialysis also raises this high incidence. Therefore, patients' ESRD, dialysis treatment and phosphorus metabolic disorder all can contribute to their skin problems (Ostlere *et al.*, 1994). In rare cases, this skin problem is due to allergies. If patients notice itching occurs at the beginning of dialysis treatments, they may have an allergy to the blood tubing, dialyzer or other elements associated with dialysis (Francos *et al.*, 1991).If suffering from severe skin itching that happens all the time, the high buildup of wastes may be the root cause. In this situation, kidney function improvement is the most effective treatments to solve both your skin problem and many other symptoms. The key to achieve this purpose is to increase damaged kidney cells' self-curative ability and nourish them. As for the latter two causes, correct medicines, diet and some changes in dialysis treatment can help ease itching effectively (Ostlere *et al.*, 1994; Stockenhuber *et al.*, 1987). Scratching may lead to impetigo (skin infection), prurigo (papules) and chronic, lichenified dermatitis/eczema.

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Because of the ignorance about its pathogenesis it is not surprising that treatment of uremic pruritus is quite unsatisfactory. Treatments currently used for uremic pruritus such as antihistamines, steroids, emollients, and phototherapy (UVB) have not been investigated rigorously, and no drugs have been approved for this indication by the U.S. Food and Drug Administration (Ponticelli and Bencini, 1995). Doxepin, as a H1-receptor blocker, is an effective and safe choice not only in idiopathic pruritus, but also in uremic pruritus resistant to conventional treatments. Doxepin can help improve pruritus resistant to antihistamines in end-stage renal disease patients who undergo hemodialysis (Por-Reza-Gholi *et al.,* 2007). A low dose of doxepin is safe while effective and its main adverse effect, drowsiness, is temporary and can be easily tolerated by the patients.

Antihistamines are usually ineffective in patients with uremic pruritus (Greene *et al.,* 1985). Hence we found it logical trying an agent with histaminic activity in haemodialysis patients. Hence the main objectives of the study were to assess the effects of doxepin treatment on the quality of life of pruritic patients and the improvement in severity, distribution and frequency of pruritus related sleep disturbance after doxepin treatment.

MATERIAL AND METHODS

This prospective-interventional study was carried out for a period of 6 months in dialysis unit of Department of Nephrology in a tertiary care teaching hospital, Chennai, after getting approval from the Institutional Ethics Committee **(Ref. No. CSP/13/OCT/31/176)**. Thirty-nine patients were enrolled in the study. Both inpatients and outpatients of both sexes equal to or above 18 years on hemodialysis or peritoneal dialysis for more than 3 months with antihistamine resistant pruritus were included for the study. Patients with a history of dermatologic disease antedating renal failure and those with skin disease other than cutaneous findings of uremia and with systemic diseases like malignancy, cholestatic liver disease were excluded from the study. Informed consent was obtained from each patient before enrolling in the study. Data on patient demographics (age, sex, body weight, body surface area), stage of chronic kidney disease, drugs prescribed, co-morbidities, surgical and dialysis details were all entered in a patient data collection form. Patients were prescribed with doxepin 10mg/day at night for a period of 2 weeks. They were evaluated at the beginning of the study – before doxepin therapy and at the end of 2 weeks – after doxepin therapy. Each evaluation included a limited physical examination and assessment of severity of pruritus. Pruritus was auto-assessed by the patients. Each patient was directly asked to fill the questionnaires. The score was assessed by the investigator for all the patients and at each time of study.

The severity, duration, degree, direction, disability and distribution of itch were evaluated using 5D- pruritus scale (**Appendix 1**). The 5D- pruritus scale comprised of 5 domains that are used to assess the level of itching. The quality of life of patients was assessed using DLQI questionnaire (Dermatology Life Quality Index) (**Appendix 2**). Both are validated questionnaires. The Dermatology Life Quality Index questionnaire is designed for use in adults, i.e. patients over the age of 16. It is self-explanatory and can be simply handed to the patient who is asked to fill it in without the need for detailed explanation. It is usually completed in one or two minutes. If the patients were illiterate and were not able to understand the questionnaire we assisted them by explaining every domain of the questionnaire either or gave them the questionnaire in their vernacular language.

Statistical methods

The collected data was statistically analyzed using SPSS 16.0 version software. The results were represented as frequency, percentage, mean and standard deviation wherever applicable. Internal consistency for both the questionnaires was measured using Cronbach's alpha. In addition, Pearson correlation was used to compare the level of significance between post and prior obtained domain scores for both the questionnaires. Comparison of questionnaires before and after treatment was done using Wilcoxon signed rank test.

RESULTS

A total number of 39 dialysis patients with pruritus who were equal to or above the age of 18years and of either sex from the department of nephrology were recruited for the study. The mean age of the patients was 53.36±12.811 (Range 18 to 72 years). Majority of the patients (n=11, 28%) fall in the age group of 50-59 years followed by 60-69 years (n=10, 25%).In the study population of 39, 12(31%) were female and 27(69%) were male. Among them, 6(15%) were in the stage-3chronic kidney disease and the remaining 33(85%) were in the stage-5 chronic kidney disease. The major co-morbidity among the study population was hypertension (HTN) - 30(77%) and diabetes mellitus (DM) - 21(54%). Among the study population of 39, 30 patients (77%) had itching for a period of less than 6 months (Table 1).

Table 1: Patient characteristics.

		Frequency (number)
Age (years)	<30	8% (3)
	30-39	8% (3)
	40-49	23% (9)
	50-59	28% (11)
	60-69	25% (10)
	70+	8% (3)
Gender	Male	69% (27)
	Female	31% (12)
CKD stage	3	15% (6)
	5	85% (33)
Co-morbidities	Renal anaemia	10% (4)
	Hypertension	77% (30)
	Diabetes Mellitus	54% (21)
	Glomerulonephritis	44% (1)
	Rheumatoid Heart Disease	3% (1)
	Seizure	3% (1)
	Coronary Heart Disease	3% (1)
	Urosepsis	3% (1)
Duration of itch	<6months	77% (30)
	6months – 1 year	20% (8)
	>1year	3% (1)

Each domain in the 5D-Pruritus scale was assessed before and after doxepin therapy (Table 2). A statistically significant difference was found in each domain of 5D-Pruritus scale after doxepin therapy. This shows that the duration of itch was diminished, the intensity of itch was reduced, the itching became better, the impact of itch on sleep, social activities, housework and work was lessened and the distribution of itch on the body was greatly decreased after doxepin therapy.

Table 2: Evaluation of 5D – Pruritus scale before and after doxepin therapy.

Q1 Pre			Q1 Post			
Score	**Number**	**Percentage**	**Score**	**Number**	**Percentage**	**p value**
1	2	5	1	22	56	
2	16	41	2	15	38	
3	20	51	3	1	3	0.001*
4	0	0	4	1	3	
5	1	3	5	0	0	
Q2 Pre			**Q2 Post**			
1	0	0	1	5	13	
2	13	33	2	27	69	
3	18	46	3	6	15	0.001*
4	8	21	4	1	3	
5	0	0	5	0	0	
Q3 Pre			**Q3 Post**			
1	0	0	1	5	13	
2	0	0	2	25	64	
3	15	38	3	7	18	0.001*
4	23	59	4	2	5	
5	1	3	5	0	0	
Q4a Pre			**Q4a Post**			
1	1	3	1	1	3	
2	5	13	2	26	66	
3	12	31	3	8	21	0.001*
4	12	31	4	2	5	
5	9	23	5	2	5	
Q4b Pre			**Q4b Post**			
N/A	1	3	N/A	1	3	
1	12	31	1	25	64	
2	12	31	2	10	25	0.001*
3	10	25	3	3	8	
4	4	10	4	0	0	
5	0	0	5	0	0	
Q4c Pre			**Q4c Post**			
N/A	1	3	N/A	1	3	
1	10	26	1	25	64	
2	13	33	2	9	23	0.001*
3	9	23	3	4	10	
4	6	15	4	0	0	
5	0	0	5	0	0	
Q4d Pre			**Q4d Post**			
N/A	28	72	N/A	28	72	
1	4	10	1	5	13	
2	4	10	2	5	13	0.461
3	2	5	3	1	3	
4	1	3	4	0	0	
5	0	0	5	0	0	
Q5 Pre			**Q5 Post**			
1	7	18	1	25	64	
2	32	82	2	14	36	
3	0	0	3	0	0	0.001*
4	0	0	4	0	0	
5	0	0	5	0	0	

*p<0.05 is statistically significant, Pre – Before doxepin therapy, Post – After doxepin therapy,

The DLQI questionnaire was assessed before and after doxepin therapy (Figure 1). A statistically significant difference was found in the scores after doxepin therapy(p<0.05). This shows that the quality of life was very much improved after doxepin therapy.

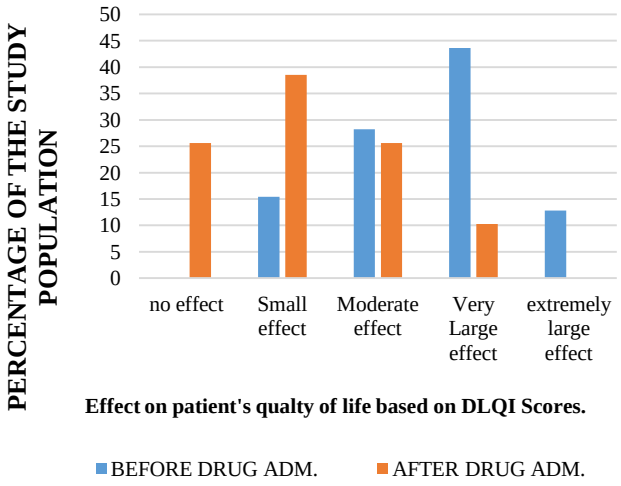

Fig. 1: Assessment of DLQI questionnaire before and after doxepin therapy.

Each domain in the 5D-Pruritus scale and each question in the DLQI questionnaire was compared before and after doxepin therapy using Wilcoxon signed rank test. Overall, there was a statistically significant difference found in almost all the questions (Table 3).Based on Wilcoxon signed rank test, positive ranks and the sum of negative ranks equals the sum of positive ranks, analysis was done to compare the significant difference in each component of both questionnaires before and after the treatment.From the table, it was inferred that there were significant positive outcomes from doxepin therapy. The questions DLQI6 and Q4D were answered "not relevant" to this particular study population and so there was no significant difference.

Table 3: Comparison of the questions before and after doxepin therapy using Wilcoxon signed rank test.

Questionnaires	Z	Asymp. Sig. (2-tailed)
Q1 Post - Q1 Pre	-5.340[b]	0.001*
Q2 Post - Q2 Pre	-4.767[b]	0.001*
Q3 Post - Q3 Pre	-5.370[b]	0.001*
Q4a Post - Q4a Pre	-4.927[b]	0.001*
Q4b Post - Q4b Pre	-4.064[b]	0.001*
Q4c Post - Q4c Pre	-4.247[b]	0.001*
Q4d Post - Q4d Pre	-0.736[b]	**0.461**
Q5 Post – Q5 Pre	-5.125[b]	0.001*
Total 5D Post – Total 5D Pre	**-5.311[b]**	**0.001***
DLQI Post1 – DLQI Pre1	-4.617[b]	0.001*
DLQI Post2 – DLQI Pre2	-4.513[b]	0.001*
DLQI Post3 – DLQI Pre3	-4.939[b]	0.001*
DLQI Post4 – DLQI Pre4	-4.450[b]	0.001*
DLQI Post5 – DLQI Pre5	-4.500[b]	0.001*
DLQI Post6 – DLQI Pre6	0.000[c]	**1.000**
DLQI Post7 – DLQI Pre7	-4.684[b]	0.001*
DLQI Post8 – DLQI Pre8	-4.082[b]	0.001*
DLQI Post9 – DLQI Pre9	-3.945[b]	0.001*
DLQI Post10 – DLQI Pre10	-3.464[b]	0.001*
Total DLQI Post – DLQI Pre	**-5.445[b]**	**0.001***

*p<0.05 is statistically significant, b. Based on positive ranks. c. The sum of negative ranks equals the sum of positive ranks.

DISCUSSION

Chronic Kidney Disease with Pruritus is the common health problem especially among elderly who undergo dialysis. In our study, a high incidence of Pruritus was observed among the mean age of 53.36 ± 12.81. It was similar to the study conducted by Khan TN *et al.,* 2013, in which the mean age was 52±17.5 years which showed no difference among the Arab population when compared to our population. In our study, the majority of the patients were men (69%) and in a study carried out by Khan *et al.,* 2013 also, the majority of sample involved were men (65%), which indicates that the incidence of pruritus is greater in men when compared to women. In our study, hypertension (n=30, 77%) and diabetes mellitus (n=21, 54%) were the common comorbid conditions, which was very much similar to the study conducted by Khan *et al.,* 2013. Greene *et al.,* 1985 compared the effect of doxepin and diphenhydramine in systemic form for the treatment of idiopathic urticaria. They used doxepin 10 mg thrice daily and recorded the subjective outcomes, whereas we used doxepin once daily at night and recorded the outcomes using questionnaires. In the present study, we found a significant ($p<0.05$) improvement in the quality of life and decrease in severity of pruritus in patients receiving haemodialysis, whereas in a study conducted by Pour-Reza-Gholi *et al.,* 2007, there was a significant effect of doxepin for the treatment of pruritus in ESRD patients receiving haemodialysis, which proves that doxepin can be used in the treatment of treatment-resistant pruritus. In a study conducted by Khan *et al.,* 2013, the reliability of the five domain 5D pruritus scale indicated first rate reliability and was found to be a reliable measure for assessment of pruritus in patients with uremic pruritus and so in our study the 5D pruritus scale was administered to assess the severity of itching. In our study population of 39 (100%), pruritus was found mild in 33%, moderate in 46% and severe in 21%, while in a study conducted by Akhyani *et al.,* 2005, pruritus was found to be mild in 51%, moderate in 11% and severe in 37% of patients.

In a study conducted by Welter *et al.,* 2008, DLQI Quality of life assessment revealed that there was no effect of pruritus in 20.3%, small effect in 37.4%, moderate effect in 13%, very large effect in 18.8% and extremely large effect in 10.1% of patients on the quality of life. Our study revealed small effect of pruritus in 6(15%), moderate effect in 11(28%), very large effect in 17(44%) and an extremely large effect in 5(13%) patients.

In a study conducted by Szepietowski *et al.,* 2002, among the demographic variables, only age was found to significantly interfere in a negative manner in the DLQI, i.e. with more severe scores for patients who were younger ($r = –0.20$, $p = 0.0003$; the mean age was 64.21 ± 0.72). The gender, ESRD causal disease, type of Minimal Renal Disease (MRD) and duration of MRD had no significant impact on DLQI, while in our study the mean age was 52±17.5 years, the male population showed greater prevalence than the female study population, also the prevalence in CKD-V (85%) patients was greater than patients in CKD-III stage (15%).

Haemodialysis patients with moderate or severe itch are significantly more likely to feel drained or depressed and have 17% higher mortality risk, statistically associated with quality of sleep. In our study, the disability caused to the patients due to sleep disturbance was severe (delays falling asleep and occasionally wakes me up at night) in 23% before the treatment but 5% of study population reported severe sleep disability after the treatment, which proves that doxepin has relatively good effect in reducing disability in pruritic patients due to insomnia. In a study conducted by Susel *et al.,* 2014, the mean score of DLQI was 3.6 ± 3.4 points (4.4 ± 4.4 points in women and 3.2 ± 2.8 points in men). There was no significant difference of DLQI score between female and male patients with Uremic Pruritus. In our study the mean DLQI score before the treatment was 2.59±0.910 and it was 1.23±0.902 after the treatment which demonstrates a significant improvement in the quality of life in pruritic patients after treatment with doxepin.

In a study conducted by Mathur *et al.,* 2010, 67% of patients were taking medications for pruritus. Those with greater Uremic Pruritus severity were somewhat more likely to take medications (56, 74, and 70% in categories A, B, and C respectively). All type C patients (representing 25% of the study population) reported that the medications "did not help at all" or only "helped a little," compared with two thirds of type A patients. Consistent with reports of medication ineffectiveness, pruritus intensity was high and associated symptoms were frequent despite medication use among most patients. Among the type C patients who were not taking pruritus medications, 100% cited "nothing works" as the reason. In our study 23(59%) patients reported that their itching was unchanged despite medications before the administration of doxepin, later reported that their itching was much better but still present after the treatment.

In our study, the mean score for disability in social activity due to pruritus was 2.10 ±1.046, which was similar to the study conducted by Khan *et al.,* 2013.

CONCLUSION

Doxepin as a H1 receptor blocker orally administered at night at a dose of 10mg, for 2 weeks in haemodialysis patients was proven to improve the quality of life and decrease duration, degree, direction, disability and distribution of pruritus.

The clinicians should enquire about skin irritation and itching during consultations since patients may be reluctant to admit to these symptoms due to embarrassment.

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Conflict of Interests: There are no conflicts of interest.

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5-D Pruritus Scale

1. **Duration**: During the last 2 weeks, how many hours a day have you been itching?

Less than 6hrs/day	6-12 hrs/day	12-18 hrs/day	18-23 hrs/day	All day
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **Degree**: Please rate the intensity of your itching over the past 2 weeks

Not present	Mild	Moderate	Severe	Unbearable
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. **Direction**: Over the past 2 weeks has your itching gotten better or worse compared to the previous month?

Completely resolved	Much better, but still present	Little bit better, but still present	Unchanged	Getting worse
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. **Disability**: Rate the impact of your itching on the following activities over the last 2 weeks

	Never affects sleep	Occasionally delays falling asleep	Frequently delays falling asleep	Delays falling asleep and occasionally wakes me up at night	Delays falling asleep and frequently wakes me up at night
Sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	N/A	Never affects this activity	Rarely affects this activity	Occasionally affects this activity	Frequently affects this activity	Always affects this activity
Leisure/Social	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Housework/ Errands	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Work/School	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **Distribution:** Mark whether itching has been present in the following parts of your body over the last 2 weeks. If a body part is not listed, choose the one that is closest anatomically.

	Present		Present
Head/Scalp	☐	Soles	☐
Face	☐	Palms	☐
Chest	☐	Tops of Hands/Fingers	☐
Abdomen	☐	Forearms	☐
Back	☐	Upper Arms	☐
Buttocks	☐	Points of Contact w/ Clothing	
Thighs	☐	(e.g waistband, undergarment)	☐
Lower legs	☐	Groin	☐
Tops of Feet/Toes	☐		

Appendix 1

DERMATOLOGY LIFE QUALITY INDEX

DLQI

Hospital No: Date:
Name: Score:
Address: Diagnosis:

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick ☑ one box for each question.

1.	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes No	❒ ❒	Not relevant ❒
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot A little Not at all	❒ ❒ ❒	
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant ❒

Please check you have answered EVERY question. Thank you.

Note: The prior consent of the copyright holder was taken.

Appendix2