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ORIGINAL ARTICLE

Preparation, validation and user-testing of pictogram-based patient information leaflets for hemodialysis patients



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KEYWORDS

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Abstract *Background:* Patient information leaflets are universally-accepted resources to educate the patients/users about their medications, disease and lifestyle modification. *Objectives:* The objective of the study was to prepare, validate and perform user-testing of pictogram-based patient information leaflets (P-PILs) among hemodialysis (HD) patients. *Methods:* The P-PILs are prepared by referring to the primary, secondary and tertiary resources. The content and pictograms of the leaflet have been validated by an expert committee consisting of three nephrologists and two academic pharmacists. The Baker Able Leaflet Design has been applied to develop the layout and design of the P-PILs. *Results:* Quasi-experimental pre- and post-test design without control group was conducted on 81 HD patients for user-testing of P-PILs. The mean Baker Able Leaflet Design assessment score for English version of the leaflet was 28, and 26 for Kannada version. The overall user-testing knowledge assessment mean scores were observed to have significantly improved from 44.25 to 69.62 with p value < 0.001 . *Conclusion:* The overall user opinion of content and legibility of the

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leaflets was good. Pictogram-based patient information leaflets can be considered an effective educational tool for HD patients.

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1. Introduction

Verbal communication often fails because the information may be misunderstood and/or forgotten (Renuka and Pushpanjali, 2013). Patient information leaflets (PILs) are universally-accepted materials to educate patients/users about the medications, disease and lifestyle modification (Newton et al., 1998; Al-Maskari et al., 2013). Therefore, PILs may be considered as a tool for supplementing health education. PILs can be preserved and gladly passed from person to person without getting crumpled (Meillier et al., 1999). Pictogram-based patient information leaflets (P-PILs) are the advanced version of PILs. The information presented in P-PILs with suitably validated pictograms is used for better patient understanding. The ideal P-PILs can be validated by subject experts with good readability, legibility and content (Kenny et al., 1998).

P-PILs are the best tools for patients with chronic diseases such as diabetes, hypertension, asthma and chronic kidney disease. To achieve the positive therapeutic outcome for these diseases, self-care becomes inevitability (Mateti et al., 2013). The PILs study conducted by Adepu and Swamy (2012) has shown the improved the levels of knowledge, attitude and practice of the patients. Several studies have revealed that there is a lack of knowledge regarding the drugs, disease and lifestyle modification among chronic kidney disease patients on hemodialysis (HD) (Sathvik et al., 2007 and Schmid et al., 2009). The self-care regarding fluid management, managing the thirst, salt management, nutritional information is very much important in HD patients (Mateti et al., 2013). The objective of the study was to prepare, validate and perform user-testing of P-PILs in HD patients.

2. Methods

2.1. Study design, setting and patients

A quasi-experimental pre- and post-test design without control group was conducted for a period of 12 months between June 2013 and May 2014 at three different HD units of academic, government and corporate hospitals. Approval of the Institutional Ethics Committee (IEC) was obtained prior to the initiation of the study. The present study was carried out as part of a larger study on the impact of pharmaceutical care plan on health-related quality of life among HD patients. HD patients on pharmaceutical care group with minimum primary educational background were selected from the out-patient HD unit from all the three units. The inclusion criterion was based on the patients undergoing HD continuously for 3 months in the age group of 18–75 years, with a written informed consent. The socio-demographic details such as age, gender, educational status, economic status, length of time spent on HD and co-morbidities were collected from the patients. The socio-economic status of the patients was calculated using the Kuppaswamy socio-economic scale (Kumar et al., 2012).

2.2. Sample size

The sample size was calculated on the basis of the change in patient's knowledge of user-testing scores from baseline to post-intervention scores by using the following formula.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2}{d^2} + 2$$

$\sigma = 10$, $Z_{1-\alpha/2}$ is 1.96 (for $\alpha = 5\%$).

$Z_{1-\beta}$ is 0.84 for 80% power and $d = 5$.

σ is the mean of the two standard deviations.

d is the minimum significant difference in the two groups.

The minimum sample required for this study is 40.

2.3. Preparation, validation and translation of P-PILs

The patient information leaflets were prepared by referring to the primary, secondary and tertiary resources. Tertiary resources included textbooks on nutritive values of Indian foods and textbook of Pharmacotherapy and guidelines of National Kidney Foundation, Kidney Disease Outcomes Quality Initiative Clinical Practice guidelines, Indian Association of Nephrology guidelines and publications from National Kidney Disease Education Program and Renal Nutrition Forum. The secondary resources were various databases such as Micromedex, Up-to-date, Medscape, Medline and Web MD. The primary resources include various articles related to HD. Content of the leaflet includes information on fluid, thirst, salt, potassium and anemia management, energy and proteins turnover, phosphorous and calcium balance, micro-nutrient supplements, drugs to be avoided, vaccinations, monitoring of laboratory tests based on monthly, tri-monthly and half-yearly and annual, and the information of commonly prescribed medications has been included. The content and pictograms of the leaflet have been validated by an expert committee consisting of three nephrologists and two academic pharmacists. The changes were made as per the directions of the expert committee and the leaflet was prepared after assessing the characteristics of layout and design of P-PIL by using Baker Able Leaflets Design method (Baker, 1997; Gibbs et al., 1989). The validated English version of leaflet was translated into Kannada by using a three-step process of forward translation, backward translation and patient-testing.

2.4. Readability testing of P-PILs

Readability was assessed by user-testing questionnaire. For this user-testing, 10 multiple-choice questions have been prepared based on the content of the leaflet. The questionnaire was validated and readability was checked. During the user-testing, questionnaire was administered to the HD patients on pharmaceutical care group for assessing baseline knowledge followed by provision of leaflet (English or Kannada) to the

patients depending on the choice. After allowing the patients to read for 20 min, patients were again administered the same questionnaire to assess the knowledge. At the end of the study, the response was evaluated using the following formula.

$$\text{Response Evaluation} = \frac{\text{Total number of correct responses patient}}{\text{Total number of actual responses}} \times 100$$

After knowledge assessment, opinion of the patients was elicited about the content, layout and design in a rating form containing 4 questions and the scores were ranged on 5–1 scale. The interpretation of the scores is as follows:

- Good = If the score of legibility and content of the P-PILs is '20-14'.
- Average = If the score of legibility and content of the P-PILs is '14-9'.
- Poor = If the score of legibility and content of the P-PILs is 'Less than 9'.

2.5. Validation and reliability of user-testing and user-opinion testing questionnaire

Validation and reliability of user-testing and user-opinion testing questionnaire were checked before assessing the knowledge and user opinion from the patients. The user-testing and user-opinion questionnaire was validated by an expert committee. Test re-test reliability was assessed with a sub-sample of 24 randomly selected HD patients by administering Kannada and English versions twice of user-testing and user-opinion questionnaire a week apart.

2.6. Statistical analysis

In order to assess the test–retest reliability of user-testing and user-opinion questionnaire, the intraclass correlation coefficients (ICC) were computed among randomly selected HD patients. An ICC ≥ 0.9 has been considered highly reliable while ICC between 0.7 and 0.89 as moderately reliable and an ICC < 0.7 as having low reliability. Descriptive Statistics has been used to summarize the data and the user-testing data of baseline and after 20 minutes, scores were computed by using 'paired student *t* test' with '*p*' value less than 0.05 considered as statistically significant. Data were analyzed using SPSS version 15 software, Bangalore, South Asia.

3. Results

3.1. Test-retest reliability of user-testing and user-opinion questionnaire

Out of 24 patients, 12 were assessed for Kannada and remaining 12 were assessed for English version of the questionnaire. The intraclass correlation coefficient (ICC) reliability for both the versions of the questionnaire ranged from 0.92 to 0.98. The ICC reliability values, 95% confidence intervals, means and standard deviation scores of both the versions of Kannada and English results are summarized in [Table 1](#).

3.2. Scores of Baker Able Leaflet Design

The mean Baker Able Leaflet Design assessment score for English version of leaflet was 28 and 26 for Kannada version.

3.3. Socio-demographic details of the Patients

A total of 100 patients were in the pharmaceutical care group. Eighty one of these patients were included in the study and 19 patients were excluded from the study. As these 19 patients were illiterate the patient information leaflets were provided to the attendants of the patients. Out of 81 patients, 45 were selected from academic hospital, 28 from corporate hospital and 8 from government hospital. Most of the patients were men (77.77%) with high school educational background (29.62%) and had lower middle socio-economic status (34.56%). The results of socio-demographic details of the patients are summarized in [Table 2](#).

3.4. User-testing and user-opinion scores of leaflets

The Kannada leaflet users outnumbered the English leaflet users, of which 50 Kannada users constitute 61.72% while 31 English users, 38.27%. The overall user-testing knowledge assessment mean scores significantly improved from 44.25 to 69.62 with *p* value < 0.001 . The detailed user-testing scores of Kannada and English versions of leaflets are summarized in [Table 3](#). The overall user opinion of legibility and content of the leaflets was good i.e., 81.14%. The detailed user-opinion scores of Kannada and English versions of leaflets are summarized in [Table 4](#).

Table 1 Test re-test reliability of user-testing and opinion questionnaire.

Type of questionnaire	Test 1 (Day 1 scores) (Mean \pm SD)	Test 2 (Day 7 scores) (Mean \pm SD)	Mean difference \pm SD, (range) [Significance]	ICC value	95% CI
User testing Kannada version (<i>n</i> = 12)	45.83 \pm 13.72	44.25 \pm 10.83	1.57 \pm 5.98, (–11, 10), [NS, <i>p</i> 0.38]	0.93	0.79–0.98
User testing English version (<i>n</i> = 12)	48.79 \pm 10.76	49.62 \pm 12.75	–0.83 \pm 2.88 (–10, 0), [NS, <i>p</i> 0.33]	0.98	0.95–0.99
User opinion Kannada version (<i>n</i> = 12)	16.08 \pm 2.23	16.41 \pm 2.19	–0.33 \pm 1.15 (–2, 2), [NS, <i>p</i> 0.33]	0.92	0.75–0.97
User opinion English version (<i>n</i> = 12)	14.66 \pm 1.92	15.25 \pm 1.86	–0.58 \pm 0.79, (–2, 0), [significant, <i>p</i> 0.02]	0.95	0.68–0.98

SD – standard deviation; NS – not significant; ICC – intraclass correlation coefficient; CI – confidence interval.

Table 2 Socio-demographic details of patients.

Socio-demographic details	Number of patients (%)
Age, Mean \pm SD	52.37 \pm 12.80
<i>Gender</i>	
Male	63 (77.77)
Female	18 (22.22)
<i>Educational status</i>	
Primary School	8 (9.87)
Middle School	11 (13.58)
High School	24 (29.62)
Intermediate	16 (19.75)
Graduate	22 (27.16)
<i>Socio-economic status</i>	
Upper	3 (3.70)
Upper middle	27 (33.33)
Lower middle	28 (34.56)
Upper lower	22 (27.16)
Lower	1 (1.12)
<i>Length of the time spent on hemodialysis (months)</i>	
Median (IQR)	48 (72,16)
<i>Hypertension</i>	
Yes	100 (100)
No	–
<i>Diabetes mellitus</i>	
Yes	24 (29.62)
No	57 (70.37)
<i>Anemia</i>	
Yes	100 (100)
No	–

SD – standard deviation and IQR – interquartile range.

4. Discussion

The present study is the first of its kind in India conducted on preparation, validation and user-testing of pictogram-based patient information leaflets for HD patients. The previous studies were conducted on preparation, validation and reliability of patient information leaflets for diabetes, hypertension, diabetic foot ulcer, rheumatoid arthritis, asthma, peptic ulcer, and tuberculosis (Adepu and Swamy, 2012; Hill and Bird, 2003; Roy et al., 2013; Rajan et al., 2013). The mean Baker Able Leaflet Design score of English version leaflet was better than the leaflets prepared by the similar studies (Adepu and Swamy, 2012; Roy et al., 2013). When compared the leaflets prepared by Rajan et al. (2013) had better score for English version and lesser score for Kannada version leaflet. The previously conducted studies were tested for readability of

Table 4 User-opinion scores of P-PILS.

Type of leaflet user-opinion rating	Number of patients (%) ($n = 81$)
<i>Kannada</i>	
Good	40 (80)
Average	10 (20)
Poor	–
<i>English</i>	
Good	26 (83.87)
Average	5 (16.12)
Poor	–
<i>Overall P-PILs users</i>	
Good	66 (81.14)
Average	15 (18.51)
Poor	–

the leaflets by using the western developed formulas such as Flesch Reading Ease, Flesch–Kincaid grade level and Simplified Measure of Gobbledygook index readability (Flesh, 2014; Flesch and Kincaid, 2014; McLaughlin, 2014). In the present study, user-testing was used to assess the readability of the leaflets. User-testing is the accurate method to assess the readability of the leaflets in any language. The readability assessed by formulas can only be applied to the English version leaflets and readability of other language leaflets was hitherto unknown. The validity and readability of western developed readability formulae for Indian languages were also unknown. The study also collected the user-opinion of the leaflets in addition to the user-testing. Most of the published studies did not assess the user-opinion on the leaflets which the present study attempted as they are one of the important stakeholders in patient education. The results of the study reveal that more than 80% patients rated the leaflets content, legibility and design as good. The reliability of the present study in user-testing and user-opinion of the questionnaire is found to be ≥ 0.9 and is considered highly reliable.

It is evident from this study that the post-interventional P-PILs knowledge-based user-testing scores significantly improved from baseline scores from 44.25 to 69.62 with p value < 0.001 . The impact of pictograms in PILs in recalling the information conducted by the Leija and Ros (2003) has shown similar improvements. The pre- and post-interventional PIL study conducted in the community pharmacy observed that the recall drug information significantly improved from 30% to 65% (Carina et al., 1996). The verbal advice along with PIL is shown to have improved knowledge levels in recognizing the uses and side effects of medications from 40% to 67% (Gibbs et al., 1990). Similar studies conducted by others with patient information leaflets as an educational intervention

Table 3 User-testing scores of P-PILS.

Type of users	Pre-test scores (Mean \pm SD)	Post-test scores (Mean \pm SD)	Mean difference \pm SD, (range)
			[Significance]
English ($n = 31$)	48.13 \pm 11.63	77.92 \pm 18	–29.78 \pm 13, (–50, 0), [significant, $p = 0.000$]
Kannada ($n = 50$)	41.84 \pm 11.93	64.48 \pm 18.97	–22.64 \pm 12.75, (–60, 10), [significant, $p = 0.000$]
Overall P-PILs users ($n = 81$)	44.25 \pm 12.14	69.62 \pm 19.62	–25.37 \pm 13.24, (–60, 10), [significant, $p = 0.000$]

SD – standard deviation.

have significant impact on the knowledge, attitude and practice among the patients suffering from diabetes, hypertension, asthma peptic ulcer and rheumatoid arthritis (Adepu and Swamy, 2012; Sathvik et al., 2007; Hill and Bird, 2003; Louis and Halparin, 1979).

5. Conclusion

The present study showed significant improvement in knowledge levels after reading the validated leaflets. More than 80% of patients rated the leaflets content, legibility and design as good. The pictogram-based patient information leaflets have been found to be an effective educational tool in HD patients.

Contributors

Uday Venkat Mateti contributed toward concept, design, literature search, data acquisition, data analysis and wrote the first draft of the manuscript. Anantha Naik Nagappa, Ravindra Prabhu Attur, Manohar Bairy, Shankar Prasad Nagaraju, Surulivelrajan Mallayasamy, Rajesh Vilakkathala, Rajesh Balkrishnan contributed toward concept, design and manuscript preparation. Vasudeva Guddattu contributed toward design, data analysis and manuscript preparation.

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