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ORIGINAL ARTICLE

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



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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

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