Comparison of Quality of Life between Patients Undergoing Chronic Hemodialysis with Reusable Dialyzer and Single-Use Dialyzer: A Retrospective Cohort Study

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ABSTRAK

Pendahuluan: *di Indonesia, pemakaian membran hemodialisis dengan metode reuse banyak digunakan karena hemat biaya. Diperlukan data apakah tindakan hemodialisis dengan metode reuse cukup optimal untuk kualitas hidup pasien karena metode reuse dapat menimbulkan perubahan tertentu pada tingkat molekuler tubuh yang diduga dapat meningkatkan gejala dan keluhan.* ***Metode:*** *studi ini menggunakan desain kohort retrospektif pada 39 subjek penelitian yang menjalani hemodialisis di unit hemodialisis Rumah Sakit Cipto Mangunkusumo pada Maret – September 2017. Subjek pernah menjalani hemodialisis dengan dua tipe membran, yaitu membran dialisator reuse (sebelum tahun 2015) dan membran dialisator single-use (sejak tahun 2015). Sebanyak 19 dari 39 pasien tidak mengetahui penggantian membran dialisator. Subjek diwawancara dengan kuesioner Kidney Disease Quality of Life-Short Form 36.* ***Hasil:*** *rerata dimensi kualitas hidup komponen penyakit ginjal pada kelompok single-use adalah 74,87 (SD 13,54) dan reuse 68,74 (SD 13,54) (uji Wilcoxon, p = 0,01). Rerata dimensi komponen fisik pada kelompok single-use adalah 69,38 (SD 23,07) dan reuse 63,65 (SD 27,07) (uji Wilcoxon, p = 0,217). Rerata dimensi komponen mental pada kelompok single-use adalah 75,27 (SD 22,30) dan reuse 71,78 (SD 21,54) (uji Wilcoxon, p = 0,315). Pada uji analisa bivariat dan lanjutannya dalam model regresi linear ditemukan asosiasi yang signifikan antara pendapatan dibawah 5 juta rupiah dengan kualitas hidup (p=0,048).* ***Kesimpulan:*** *dialisator reuse menurunkan kualitas hidup pasien yang menjalani hemodialisis dipengaruhi oleh faktor lain salah satunya pendapatan yang rendah.*

Kata kunci: *kualitas hidup, hemodialisis, dialisator reuse, dialisator single-use.*

ABSTRACT

Background: *in Indonesia, majority of hemodialysis centers use reusable dialyzer for cost efficiency reason. Currently, there is no available data regarding the quality of life of the end stage-renal disease patient'who use reusable dialyzer measured by a standardized questionnaire, as it was stated that at molecular level, reusable dialyzer could worsen leukocyte activity and could affect patients' complaints and symptoms.* ***Methods:*** *this was a retrospective cohort study which involved 39 subjects. All subjects underwent hemodialysis at Cipto Mangunkusumo Hospital. The study was conducted in March – September 2017. All subjects had experienced two kinds of dialyzers, the reusable dialyzers (before 2015) and the single-use dialyzers (after 2015). Of all patients, 19 patients did not know the change of dialyzers. Subjects were interviewed with Kidney Disease Quality of Life-Short Form 36 questionnaire.* ***Results:*** *in kidney disease component dimension, there was a significant mean difference between reusable group (68.74; SD 13.22) and single-use group (74.87; SD 13.54) (Wilcoxon test, p=0.01). The*

Physical Component Summary dimension, in reusable group was 63.65; SD 27.07 and in single-use group was 69.38; SD 23.07 (Wilcoxon test, p=0.217). The Mental Component Summary dimension, in reusable group was 71.78; SD 21.54 and in single-use group was75.27; SD 22.30 (Wilcoxon test, p=0.127). Bivariate analysis and further analysis showed significant association between income less than 5 million rupiah and low quality of life (p=0.048). ***Conclusion:*** *the reusable dialyzer membrane lowers the ESRD patients' quality of life influenced by another factor such as low income.*

Keywords: *kidney disease quality of life, hemodialysis, reusable dialyzer, single-use dialyzer.*

INTRODUCTION

Chronic kidney disease (CKD) is still a health burden worldwide and in Indonesia as well. The prevalence of CKD in Indonesia based on National Health Research 2013 was 0.2%.[1] According to 7th Report of Indonesian Renal Registry, there had been continuous rise in the number of new cases of patients undergoing hemodialysis (HD), from 15,128 patients in 2013 to 17,193 patients in 2014.[2]

The use of reusable dialyzer outnumbers the use of single-use dialyzer in Indonesia. Recent data from 2014 stated that a reusable membrane dialyzer could be used for more than 16 times in 40,636 patients.[2]

The utilization of reusable dialyzer remains controversial. Efficiency and cost-effectiveness are two main reasons in using reusable dialyzer. Several studies revealed no significant difference in outcome, such as insignificant mortality difference between patients who used reuse versus single-use membrane. However, there were arguments which suggested that single-use dialyzer was safer than reusable dialyzer due to the following advantages: lower possibility of pyrogen exposure, blood denaturation, and germicide residue in single-use membrane.[3,4]

Patient with chronic disease such as chronic renal failure who requires hemodialysis is bound to possibly have abnormality in mental or even social health. A study revealed that patients with renal disease had worse quality of life (i.e. lower questionnaire score), higher mortality risk and hospitalization compared to general population.[5,6]

Currently, there is no data available regarding end stage-renal disease patient's quality of life using reusable dialyzer which is measured by a standardized questionnaire as it was stated that in molecular level, reusable dialyzer could worsen leukocyte activity and could affect patients' complaints and symptoms. To our knowledge, the efficacy and safety of reuse membrane is still unknown in Indonesia due to insufficient data, but the use of reusable dialyzer keeps rising.[2]

METHODS

This study was an observational analytic study with retrospective cohort design. Inclusion criteria in this study was adults aged ≥18 years old who had been undergoing hemodialysis treatment for at least 1 year and with frequency of hemodialysis twice a week. By using a sample formula with mean difference in paired groups according to Sastroasmoro[7], α value was determined as 0.05 and research power of 0.8. The mean standard deviation (SD) based on a study by Rivara[8] was set as 10.9. Difference of value to be considered significant (d) was 4.8. By using simple random sampling method, a total of 39 subjects in Cipto Mangunkusumo Hospital who experienced both of the two different dialyzers for hemodialysis at least more than once a week were included in this study. A total of two questionnaires from each subjects were taken, each was questioned once after periods of using different dialyzer types for hemodialysis. Reusable dialyzer criteria was the dialyzers which were used for more than once and limited to 7 times of usage, according to the rules from Indonesian Committee of National Health Coverage. All patients were routinely undergoing hemodialysis since 2015, therefore wash out periods were not considered in this study. Subjects were informed whether they were switched from reusable to single-use dialyzer and only half understand the difference, all research consents were provided to the patients to be included in this study. The study protocol has been approved by Health Research Ethics Committee, Faculty of Medicine Universitas Indonesia – Cipto Mangunkusumo Hospital on March 13, 2017 with

a reference number 229/UN.2F1/ETIK/2017.

Research Instruments

Research assistants conducted the interview using Kidney Disease Quality of Life-Short Form 36 (KDQOL-SF 36) questionnaire to compare patient's current quality of life with single-use dialyzer to previous patient's quality of life when they underwent hemodialysis with reusable dialyzer. This questionnaire consists of eleven dimensions of kidney disease component (symptoms, effects of kidney disease, burden of kidney disease, work status, cognitive function, quality of social interaction, sexual function, sleep, social support, dialysis staff encouragement, and patient satisfaction), four dimensions of physical component (physical functioning, role-physical, pain, and general health perceptions), and four dimensions of mental component (emotional well-being, role-emotional, social function, and energy/fatigue). A recall method was used to answer the questionnaire regarding patient's quality of life when using reusable dialyzer membrane.

Covariates

Patients' characteristics in this study were age, sex, educational level, monthly income, ethnicity, religion, marital status, history of hospitalization, etiology of CKD, vascular access type, duration of hemodialysis, hemoglobin, albumin, and glomerular filtration rate (GFR). Age groups comprised of <35 years, 35-60 years, and >60 years. Educational level was categorized into elementary school, junior high school, senior high school, and college. Monthly income bracket (in Indonesian Rupiah or IDR) comprised of <5 million, 5-10 million, and >10 million. Ethnicity was categorized into Javanese, Betawi, and others. Religion was divided into Islam, Christian, and Buddhist. History of hospitalization in the past six months comprised of history and no history. Etiology of CKD was categorized into hypertension, diabetes mellitus, glomerulonephritis, and others. Vascular access type comprised of arteriovenous fistule, femoral, tunnel catheter, and double lumen catheter. Duration of hemodialysis was presented in numerical data. Laboratory results (hemoglobin, albumin, and GFR) were presented in numerical data.

Outcomes

Outcomes measured in this study was the each groups' mean score of quality of life dimensions.

Statistical Analysis

The categorical data are presented in frequency and proportion. The numerical data of laboratory results (hemoglobin, albumin, and GFR) and quality of life dimensions in the KDQOL-SF36 questionnaire are presented in mean and SD. Data included in this study were subjects' characteristics (age, sex, education, employment, income, ethnicity, religion, marital status, history of hospitalization, etiology of CKD, vascular access type, duration of hemodialysis, hemoglobin, albumin, and glomerular filtration rate), and mean of quality of life in reuse group and single-use group. Bivariate analysis using Spearman correlation tests (due to abnormal data distribution) were performed to correlate patients' laboratory/supporting examinations and each main components of quality of life (Kidney Disease Component, Physical Component, and Mental Component). Analysis of background and characteristics of patients with each main components of quality of life were done using independent t-test. From the bivariate analyses, an arbitrary p-value of <0.2 was used to include some characteristics into the multiple linear regression analysis for adjusting confounding factors in the relationship between subjects' characteristics and components of quality of life. Mean difference of quality of life in reuse group and single-use group was analyzed using paired t-test if the data was normally distributed and alternative Wilcoxon were used if the data was not normally distributed. The p-value of <0.05 indicates statistical significance. The statistical analysis was performed using SPSS Statistics software version 20.0 (IBM Corp., Armonk, NY).

RESULTS

Table 1 provides summary of the patients' characteristics in this study.

Table 2 provides the bivariate analysis of demographic characteristics and main components of quality of life (kidney disease component, physical component, and mental component).

Table 1. Demographic characteristics of the patients

Variables	n (%)
Age	
- <35 years	3 (7.7)
- 35—60 years	29 (74.4)
- >60 years	7 (17.9)
Sex	
- Men	18 (46.2)
- Women	21 (53.8)
Highest Educational Level Achieved	
- Elementary school	5 (12.8)
- Junior high school	2 (5.1)
- Senior high school	13 (33.3)
- College	19 (48.7)
Employment	
- Unemployed	23 (59.0)
- Employed	16 (41.0)
Monthly Income Bracket (IDR)	
- <5 millions	23 (59.0)
- 5—10 millions	11 (28.2)
- >10 millions	5 (12.8)
Ethnicity	
- Javanese	18 (46.2)
- Betawi	8 (20.5)
- Others	13 (33.3)
Religion	
- Islam	37 (94.9)
- Christian	1 (2.6)
- Buddhism	1 (2.6)
Marital Status	
- Single/Widowed/Divorced	11 (28.2)
- Married	28 (71.8)
Hospitalization History (Past six months)	
- Yes	15 (38.5)
- No	24 (61.5)
Etiology	
- Hypertension	17 (43.6)
- Diabetes Mellitus	6 (15.4)
- Glomerulonephritis	5 (12.8)
- Others	11 (28.2)
Vascular Access	
- Arteriovenous fistule	24 (61.5)
- Femoral	7 (17.9)
- Tunnel Catheter	7 (17.9)
- Double Lumen Catheter	1 (2.6)
Laboratory Results, mean (SD)	
- Hemoglobin (g/dL)	9.75 (SD 2.17)
- Albumin (g/L)	4.10 (SD 0.37)
- Glomerular filtration rate/GFR (ml/min/1.73 m^2)	5.56 (SD 3.92)

Table 2. Bivariate analysis of demographic characteristics and main components of quality of life in the single-use group

Variables	KDC p value	PC p value	MC p value
Age (Age above 60 vs other)^	0.550	0.141**	0.763
Sex (Male vs female)^	0.759	0.271	0.905
Education (Elementary school vs others)^	0.166**	0.636	0.983
Unemployed vs others^	0.079**	0.343	0.377
Income <5 million vs others^	0.189**	0.510	0.048*
Tribe (Javanese vs others)^	0.934	0.153**	0.289
Never married vs others^	0.581	0.748	0.701
History of hospitalization vs no history^	0.832	0.551	0.932
Hypertension as etiology vs other etiology^	0.835	0.245**	0.813
AV fistule vs no fistules ^	0.745	0.610	0.966
Hemodialysis duration#	0.276	0.192**	0.452
Hemoglobin#	0.987	0.624	0.798
Albumin#	0.348	0.290	0.834
eGFR#	0.617	0.638	0.882

KDC: Kidney disease component; PC: Physical component; MC: Mental component.
(^) means mean comparison between dichotomous variable using independent T-test.
(#) means correlation analyses.
(*) p<0.05; (**) p<0.25 and be involved in multivariate analysis.

Table 3 provides mean difference of quality of life between reusable and single-use group.

Table 4 provides linear regression model in single-use group, associating between patients' characteristics and quality of life dimensions. All variables with p – value of <0.25 adjusted with sample size were included in the linear regression analysis.

DISCUSSION

It is important to obtain data on how reusable dialyzers could affect ESRD patients' quality of life as the goal of hemodialysis is to maximizing the quality of life of ESRD patients.[9] Reusable dialyzer practice began in the United States

Table 3. Mean difference of quality of life between reuse dan single-usegroup

Quality of life dimensions	Reusable Group (n = 39)	Single-use Group (n = 39)	p-value
Kidney Disease Component (KDC)	68.74 (SD 13.22)	74.87 (SD 13.54)	0.01*
- Symptoms	67.18 (SD 20.53)	79.60 (SD 16.50)	0.003*
- Effects of kidney disease	72.83 (SD 23.25)	75.74 (SD 16.40)	0.43
- Burden of kidney disease	55.92 (SD 29.20)	70.59 (SD 28.74)	0.012*
- Work status	56.41 (SD 38.35)	34.61 (SD 38.30)	0.006*
- Cognitive function	77.77 (SD 21.26)	86.32 (SD 18.28)	0.038*
- Quality of social interaction	79.14 (SD 18.30)	89.57 (SD 16.87)	0.004*
- Sexual function	60.89 (SD 46.43)	58.58 (SD 42.64)	0.819
- Sleep	62.62 (SD 19.50)	76.76 (SD 19.39)	0.001*
- Social support	74.78 (SD 15.70)	84.61 (SD 16.39)	0.035*
- Dialysis staff encouragement	90.06 (SD 11.17)	92.94 (SD 13.69)	0.373
- Patient satisfaction	58.53 (SD 17.05)	64.09 (SD 14.07)	0.056
Physical Component (PC)	63.65 (SD 27.07)	69.38 (SD 23.07)	0.217
- Physical functioning	74.87 (SD 31.84)	69.87 (SD 28.38)	0.422
- Role – physical	57.69 (SD 45.93)	64.74 (SD 37.55)	0.421
- Pain	64.35 (SD 27.48)	74.48 (SD 22.47)	0.120
- General health perceptions	57.69 (SD 24.16)	68.42 (SD 19.24)	0.022*
Mental Component (MC)	71.78 (SD 21.54)	75.27 (SD 22.30)	0.315
- Emotional well-being	74.79 (SD 18.01)	80.60 (SD 17.67)	0.127
- Role – emotional	70.08 (SD 44.45)	66.67 (SD 40.46)	0.690
- Social function	77.88 (SD 26.51)	77.56 (SD 26.46)	0.982
- Energy/fatigue	64.35 (SD 19.77)	78.07 (SD 19.29)	0.001*
Overall health rating	68.33 (SD 14.92)	73.24 (SD 15.12)	0.059

(*) p<0.05

Table 4. Linear regression model between patients' characteristics and kidney disease component in the single-use group

	Parameter estimate	Standard error	CI 95% for parameter	p - value
Kidney Disease Component				
- Elementary school	-6.2	6.7	-19.7 to 7.4	0.363
- Unemployed	-6.3	4.5	-15.4 to 2.7	0.167
- Income <5 million	-2.8	4.6	-12.3 to 6.5	0.542
Physical Component				
- Men	-6.8	7.6	-22.3 to 8.5	0.372
- Javanese	11.0	7.5	-4.3 to 26.4	0.154
- Hypertension	6.2	7.6	-9.2 to 21.7	0.419
Mental Component				
- Income <5 million	-14.3	6.9	-28.4 to -0.1	0.048

since 1980 with the following advantages: cost-efficient and reducing the biomedical waste in the surrounding environment.[4] However, the report of blood contamination of germicides in reusable dialyzer was well documented.[4]

The subjects in this study had higher overall score of quality of life than a study by Al-Jumaih.[10] This study also had higher score in physical functioning and social dimension than a study by Sathvik.[11] In physical and mental component, this study had higher score than a study by Watanabe.[12]

Majority of the patients were aged 35-60 years (74.4%). More than half of the patients

were women (53.8%). Almost half of the patients' were college educated (49.8%). Majority of the patients were unemployed (59%) and had income of <5 million IDR (59%). Majority of the patients were Javanese (46.2%). Majority of patients had Islam as their religion (94.9%). More than half of the patients were married (71.8%). The majority of the patients had never been hospitalized in the past six months (61.5%). Hypertension dominated as the majority of patients' ESRD etiology (43.6%). Arteriovenous fistules were the most used vascular access by the patients (61.5%). The mean of patients' hemoglobin was 9.75 g/dL (SD 2.17). The mean of patients' albumin was 4.1 g/L (SD 0.37). The mean of patients' GFR was 5.56 mL/min/1.73 m^2 (SD 3.92). The mean of patients' duration of hemodialysis therapy was 6.31 years (SD 4.14).

There was significant association between income below 5 million Indonesian rupiah (IDR) and score of mental component of the quality of life (p=0.048). Further analysis using linear regression model showed that when income was less than 5 million IDR, as the income went lower the quality of life parameter would also be lower. This result was supported by Lemos et al which stated that low family income was significantly associated with poor mental component and social aspect of quality of life in hemodialysis patients. Socioeconomic stress could cause more burden for hemodialysis patients.[13]

The mean score of kidney disease component in single-use group (74.87; SD 13.54) was higher than reusable group (68.74; SD 13.22). The single-use group had significantly better score in dimension of symptoms, burden of kidney disease, cognitive function, quality of social interaction, sleep, and social support. In physical component, the single-use group had significantly better general health perceptions dimension than the reusable group. In mental component, the single-use group had significantly better energy/fatigue dimension than reusable group.

There was no significant difference in the summary of kidney disease component and physical component of the quality of life with other variables that were observed in this study. This study also noticed that several variables such as older age, unemployment, and education showed trend of decreasing quality of life, regardless of non-significant association. Further analysis with the linear regression model showed that potential confounding factors had insignificant association with the main components of quality of life. This was contrary to previous studies which showed that some of patients' characteristics were significant predictor of quality of life, including employment status, marital status, and sex.[14-16]

The insignificant association between patients' characteristics as confounding factor and quality of life showed that the dialyzer membrane type alone could affect the difference of scores between both groups. One study by Rao et al[17] in the molecular level concluded that there was a significant association between practice of reuse membrane process and patients' polymorphonuclear leukocyte function which may affect patients' clinical outcome. Single-use dialyzers also have advantage of avoiding "reuse syndromes" which can be caused by residual germicides used in the reuse practice, with the following symptoms of headache, nausea, or dyspnea due to formaldehyde inhalation which could affect patients' quality of life.[4,18]

The strength of this study was that half of patients did not know the change of dialyzer membrane in 2015 and this condition could avoid recall bias. To our knowledge, there had not been any study which focused on the impact of dialyzer membrane on patients' quality of life. Majority of the studies focused on the mortality and morbidity of patients regarding to the dialyzer membrane type.[19,20] A study with larger sample size with prospective design is needed in order to measure the hazardous effect of reusable dialyzer membrane.

Acceptance phase of patients was not measured in this study, which could be a bias factor, as stated by Poppe[21] that acceptance phase was a significant predictor of ESRD patients' quality of life. Time also could not be controlled by this observational study, as it was stated in Cruz[22] that it was significantly associated with quality of life.

Nowadays, the reusable dialyzer membranes are not utilized anymore in most of developed countries. However, the reusable dialyzer

membranes could be a cost-effective option in Indonesia's universal health coverage era. In fact, Indonesia's tertiary level hospitals like Cipto Mangunkusumo Hospital uses single-use dialyzer membrane. At secondary level hospitals, mainly in almost all provinces in Indonesia, the reusable dialyzer membranes are utilized in routine hemodialysis. Our results are expected to help clinicians adjusting the use of dialyzer membrane based on goals in optimizing patients' quality of life.

CONCLUSION

The reusable dialyzer membrane lowers the ESRD patients' quality of life associated with factor like low income. It is suggested for health care providers using reusable dialyzer membrane to maintain the safety of reuse processes in order to achieve the main goal of hemodialysis, which is to maximize ESRD patients' quality of life.

CONFLICTS OF INTEREST

The authors declare that there is no conflict of interest.

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