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Compliance and adherence to drug treatment on patients with chronic kidney disease in high prevalence areas of North Central Province, Sri Lanka

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ABSTRACT

Background: Chronic kidney disease that cannot be explained by traditional factors such as hypertension, diabetes mellitus is called chronic kidney disease unexplained etiology. With limited evidence on the success of interventions in enhancing medication adherence, this study was designed to test patient compliance and adherence on taking medication in North Central Province in Sri Lanka.

Methods: A cross sectional study was conducted in a selected area of NCP to identify compliance, adherence. Data was collected using an interviewer administered questionnaire by visiting patients at their own residences.

Results: A total of 200 people participated in this study. 92.5% of the population was involved in agriculture and 63% worked more than 1 acre of farmland. Among the selected population (74%) were not educated about the side effects of medication. 60.5% had missed taking their medicines during the prescribed time period. The entire population of the study was selected among patients having a monthly income of less than 15,000 Sri Lankan rupees. There was a statistically significant association in missing doses with land extent, patient's income and stages of the disease.

Conclusions: Non adherence and compliance to the medication is common in patients that worked in largely extended lands, were in late stages of the disease and had reduced income. Compliance and Adherence to the medication can be enhanced by proper counseling and improving patient's knowledge about their medication.

Keywords: Chronic kidney disease, Compliance, Adherence towards medication treatment, Income, Stage of the disease

INTRODUCTION

Patient's compliance refers to taking medications respect to agreed recommendations made by a health care provider.¹ Adherence has been defined as the extent to which patient's behavior about taking medications following recommended prescribe medication. It is a voluntary and collaborative behavior to produce a therapeutic effect.² Inadequate adherence and compliance produces different deviations from the prescribed medication regimen. It can produce either increased risk or reduced benefits or both.¹ Chronic kidney disease (CKD) is a significant cause of morbidity and mortality worldwide.³ Outcomes of CKD include not only kidney failure but also complications of reduced kidney function and high risk of cardiovascular disease.⁴ CKD is recognized as a global public health problem.⁵ Chronic kidney disease unexplained etiology (CKDu) has been reported in Sri Lanka, Andhra Pradesh in India, in Egypt and several Central American countries including Nicaragua and El-Salvador.⁶⁻⁸ Altitude and occupational risks factors caused increase risk of CKDu in Central America whereas extensive chemical monitoring was recently reported in Sri Lanka.⁶ In these countries males are at high risk and most affected populations belong to agricultural occupations. In Central America, increased risk of disease is reported in sugarcane workers.⁹

CKD is uniformly distributed in all provinces and CKDu is restricted to a few provinces in Sri Lanka, with CKDu being more prevalent in the North Central Province (NCP) and North Western Province (NWP). Additionally, CKDu is present in a minor scale in the Uva and Eastern provinces.¹⁰ Women and children are also suffering from CKD/CKDu, with over 1,100 CKD/CKDu patients in hospitals per month in Sri Lanka and 300 deaths recorded per year.¹¹ The disease progression causes increase in symptoms. Reduction of kidney function leads to fluid accumulation and causes high blood pressure and possible heart failure. Erythropoietin deficiency causes anemia and imbalance of calcium and phosphorous homeostasis leads to metabolic bone disease.¹² Glomerular filtration rate (GFR) is a useful method to determine kidney function. A reported value of 60-90 (ml/min) may be an early sign and below 60 ml/min is considered as kidney damaged. Urine analysis is also engaged in determining kidney function. It is used to identify protein, blood and other components in urine. The presence of protein (albumin) in the urine with repeated results of 30mg or more can indicate kidney damage.13

The goals of treatment in CKD/CKDu are to delay the progression of disease, prevention and treatment of complications. Antihypertensive drugs such as angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) are used in management of patient. Non dihydropyridine calcium channel blockers are used for high blood pressure and slow the progression of CKD/CKDu. Statins are used to reduce serum cholesterol level and low dose antiplatelet therapy with aspirin is considered in all patients with stage 1-3 CKD to reduce cardiovascular risk. Anemia is commonly seen in individuals with CKD/CKDu and it is mainly related to deficiency in synthesis of erythropoietin.14 Recombinant human erythropoietin and iron supplementation are used to treatment of anemia.¹⁵

Literature shows the evidence to prove that the dialysis, medication, dietary and fluid restriction among patients with CKD contributes to issues of non-adherence.¹⁶ Personal beliefs, cultural and social characteristics, and drinking of water and certain fluids are factors influencing the treatment regimens.¹⁷ There are several physical and emotional symptoms the CKD patients experience in the course of their treatment.¹⁸ Disabling symptoms, various restrictions to food and social life, fluid restriction, associated stigma and taboos are the factors affected to daily life of the patients from the early stages of the disease to its end stage.¹⁹ End stage renal disease (ESRD) can lead to irreversible renal

impairment.¹⁷ In ESRD, renal replacement therapy (RRT) is needed to manage patients with CKD. Hemodialysis and kidney transplantation are the types of RRT.²⁰ Hemodialysis means the removal of waste products from blood by using blood plasma. It is a temporary treatment. Kidney transplantation is the preferable treatment for ESRD.²¹ Self- assessed physical and mental health has been reduced in hemodialysis patients compared to the general population.²⁰

In 2005, about 350 million rupees was spent on management of patients with kidney disease and it consumes 4.6% of the annual health budget in Sri Lanka.²² This enormous cost of treatment leads to increased economic burden to the health care system in developing countries like Sri Lanka. In the past decade one trillion dollars have been spent on dialysis treatment worldwide.²³ The cost of hemodialysis for a single session varies from 15-40 USD in government and private sector hospitals and cost of erythropoietin is approximately 150-200 USD per month in India.²⁴ Dialysis is very expensive and its availability is limited in rural areas in Sri Lanka. Patients that live in rural areas have to travel hours to referral hospital to get dialysis treatment and it causes economic burden to their families.²⁵ Development of CKD and the onset of dialysis reduce the quality of life, which affect the compliance and adherence of the patients.¹⁷ Additionally, it causes for economic burden, both directly and indirectly.²³ The information of adherence and compliance towards medications for CKD/CKDu is sparse.²⁶ Government spends and allocates a significant budget annually for management of this disease but positive outcomes have been limited. Therefore, this study was aimed to assess the factors associated with compliance and adherence towards medications in CKD/CKDu treatments in North Central Province, Sri Lanka.

METHODS

The study was conducted at high prevalence areas of CKD/CKDu in the NCP. Ethical approval was obtained from ethical review committee (ERC), faculty of medicine, General Sir John Kotelawala Defence University. In addition to, approval was received from provincial director of health services (PDHS) office. NCP is the largest province in the country and it covers 16% of total country's land area. More than 65% of population belongs to the farming population and low socio economic groups.²⁷ Agriculture is the major occupation among these areas. Paddy production is the major agricultural produce and it is cultivated under rain fed systems. NCP was selected because the prevalence of disease in NCP about 12-15% in high prevalence areas such as Mahavillachchiya, Oyamaduwa, Sandamaleliya, Randuwa, Mannarm Pemaduwa. junction, Dunumadalawa, Ethdathkall and very few literature exists about compliance and adherence of patients about medication in the NCP.

The sample size was calculated using the equation;

$$N = Z^2 P (1 - P) / d2$$

Minimal sample size was calculated as 196. 200 patients already diagnosed with CKD/CKDu were selected for this study. Confirmed CKD/CKDu diagnosed patients who are residents in selected areas of NCP and who were able to comprehend interviews were included. Patients with poor insight and patients who were unable to give the consent were excluded. Patients who were unable to comprehend the interview and unable to complete the consent form such as having recent trauma or surgery were not accepted.

An interviewer administered questionnaire was used for data collection. It was conducted by visiting patients at their own residences and interviewing them individually in order to ensure the accuracy and quality of the data. A consent form was given to the patients selected for the The study. questionnaire included three parts. Demographic details, distance from hospital to residence, family monthly income, agriculture practices and other relevant information was collected using questionnaire part A. Questionnaire part B included history of CKD and other chronic diseases, as well as the onset of the disease, duration, treatments and other medical complications. Part C included questions relevant to compliance and adherence to medications in CKD/CKDu.

Present stage of the disease was identified from the diagnostic card, investigation reports, and the clinic book given by health care professionals. It was also confirmed by present estimated glomerular filtration rate (EGFR) level. Medicines were identified by checking the name of the tablets or capsules. By checking the rest of the medicines remaining from the date of issue, it was identified whether the patient has been taking the medicines correctly and on time according to directions given by the health care professionals. Knowledge of side effects in patients regarding medicines was identified by asking common side effects of the medicines. Education level, occupation, monthly income was collected from the information given by the patients. This information was confirmed by crosschecking with the local government official and by examining their living circumstances. All data was entered to a Microsoft excel worksheet. The data was analyzed by using SPSS 23.0 and results were interpreted, with p<0.05 considered as significant value.

RESULTS

According to results, incidence in males 67.5% was higher than in females 32.5%. Mean value of the age distribution was 58.99 (SD=10.92) years with an age range of 13-88 years. The majority of the population were educated only up to primary level 60.5% and 31% of the population were found to not have attended school. Therefore, most of patients were remaining in the NCP and were involved in agricultural work as their main

occupation. Among 200 CKD patients, 92.5% of the populations were involved in agriculture and many (63%) worked more than one acre. Agrochemicals were used by the majority of the population (69.5%), with pesticides being used by 140 (70%) participants and weedicides being used by 142 (71%) participants in both yala and maha growing seasons for paddy in the Sri Lankan culture. Of the sample population of 200 patients, no patient's monthly income was found to be greater than 15000 LKR. According to results, most of the patients belong to the farming population and are in the low socio economic group. 84.5% of population was found to not be spending their money for medicines due to using medicine provided by government hospitals. However, they were spending money from their monthly income for travel because 38% of patients were found to be living more than 35 km from the hospital, in addition to 30.5% of patients living 25-35 km away (Table 1).

Table 1: Socio demographic characteristics of study participants.

Variables	Categories	Ν	%
Gender	Male	135	67.5
	Female	65	32.5
	Not attend	62	31
Education level	Primary level	121	60.5
	Up to O/L	16	8
	Up to A/L	1	0.5
Occupation	Agriculture	185	92.5
	Non Agriculture	15	7.5
Land extent	Less than 1 acres	74	37
	More than 1 acres	126	63
Monthly	Less than 5000	99	49.5
income (Rs.)	5000-15,000	101	50.5
Distance	Less than 25 km	63	31.5
from	25-35 km	31	30.5
residence to the hospital	More than 35 km	76	38
Cost of	No cost	169	84.5
medicines	Cost	31	15.5

Patients' disease information and related factors

In the present study, the most important category was based on the stage of progression of the disease, with stages 1-3 being reported in 11.1% of the participants and stage 4 & stage 5 being reported in as many as 88.9% patients. A total of 54.5% patients of CKD/CKDu had no history of chronic diseases. However, 12.5% patients already had been diagnosed with bronchial asthma and 9.5% had medical history of hypertension. Mean value of distance from residence to hospital was 30.38 km with the range of distance being 2 km to 65 km. More than half of the patients 56% had a less than 500 rupees of expenditure for transport to hospital in one clinical visit, with 44% patients having an expenditure of >500 rupees. Among the study population, 84.5% patients did not pay any money for medicines (Table 2).

Patients' adherence and compliance towards medications

A total of 38% CKD patients among the patients that were reported to be on treatments were found to have taken medicines for 1- 3 years, and 28% were found to have taken medicines for CKD for more than 5 years. Therefore, a total of 57% patients were found to have taken medicine for more than 1 year. Among the study population, 52.5% patients were reported to be taking 1-6 types of medicines at once, where 47.5% were reported to be having more than 6 types of medicines for a onetime per day. A majority of the population 95% were taking medication according to directions given by pharmacists and physicians.

Among the selected population, 74% were not educated with side effects of medications. 60.5% were found to have missed their medicines during prescribed time. Only 39.5% were found to have never missed their medicines. A majority of the population 84.5% did not stop taking medicines suddenly, with only 8% having stopped taking medicines suddenly due to occurring of side effects and 6.5% having stopped taking medicines suddenly due to feeling that their disease has worsened while being on their medication. Based on table 3, these variables have been mainly affecting compliance and adherence towards the medication (Table 2).

Table 2: Factors affecting compliance and adherencetowards the medication.

Variables	Categories	Ν	%
Years of taking Medication	Less than 1	30	15
	1-3	76	38
	3-5	38	19
	More than 5	56	28
Stage of the	Stage 1-3	22	11
disease	Stage 4-5	176	88.9
Number of	1-6	105	52.5
Medicines	More than 6	95	47.5
Taking medicines according	Yes	190	95
	No	10	5
to direction			
Knowledge of side	Yes	52	26
effects	No	148	74
Taking medicines	Yes	186	93
when travelling	No	14	7
Missing of doses	Never missed	79	39.5
	Missed	121	60.5
Reason to stop medicines suddenly	Not Stopped	169	84.5
	Not cure the disease	2	1
	Worse the condition	13	6.5
	Due to Side Effects	16	8

Among the selected participants 121 were found to have missed their doses, and 70.2% participants had more than 1 acre. 33.8% of the population were found to have more than one acre of land but had not missed the doses of medications. Present study identified that a significant association between land extent and missing of doses of medications exist. Out of 198 participants 120 missed their doses during the observed period of taking medications. Of these patients, 94.1% of those that missed their doses belonged to the CKD stages 4 and 5. 5.8% participants that missed their doses were on the stage 1 to 3 of CKD. There was a significant association between stage of CKD and the missing of doses. 55.3% patients that had missed their does had an income that was less than 5000 Sri Lankan rupees. Only 44.6% of those that had missed the doses had an income that was between Rs.5000 to Rs.15,000 Sri Lankan rupees. A significant association was found between income of participants and the missing of doses (Table 3).

Table 3: Associations between socio demographic characteristics.

		Missing doses		D
Variables	Categories	Never missed	Missed	value
Land category	less than 1 acres	38	36	< 0.05
	More than 1 acres	41	85	
Stage	Stage 1-3	15	7	< 0.05
	Stage 4-5	63	113	
Monthly income (Rs.)	Less than 5,000	32	67	<0.05
	5,000- 15,000	47	54	

DISCUSSION

CKD/CKDu is now dramatically increasing in Sri Lanka especially in NCP. The recent estimates show almost 20,000 people have died due to CKD/CKDu and the disease is more prevalent in the farming community.³ Approximately 2.5 million of the population is affected with CKD/CKDu. In the past 15 years, CKDu has increased dramatically in certain geographical locations in Sri Lanka and is not associated with diabetes, hypertension, and chronic glomerulonephritis.9 70% of CKDu patients were identified from CKD patients.⁷ Even though the government spends money annually in measures to control the disease the final result show a negative outcome. Therefore, it is essential to conduct small scale studies to assess patient's compliance and adherence to treatments of CKD in selected areas of NCP, Sri Lanka. Considering the demographics of the selected 200 participants, the male gender was more prominent compared to the female gender. 67.5% of males were already diagnosed with CKD/CKDu. According to the literature, generally the disease is more prevalent in men

and the recorded ratio between male to females was $3:1.^9$ According to the statistical findings of the present study, the mean age obtained was 58.99 years and the minimum and maximum ages were 13 and 88 years respectively. Long term kidney damage due to causative factors of CKD/CKDu has occurred by this age in their life time. The majority of participants 60.5% were educated up to primary level, and the entire population of participants of this study was found to be poor. This can be a factor for the people to remain in the NCP long term and engage in agricultural works. Lack of education may affect the compliance and adherence in CKD patients. However, no significant association between these two factors was found in our study. Patients with low levels of education have a difficulty in understanding the disease condition, treatments, and medicines which leads to poor compliance and adherence of medicines. However, giving proper education to the community in the NCP may lead to an increase in the compliance and adherence towards medications.

Many challenges are associated with the lives of CKD patients. Many of the participants in the study were engaged in agriculture. Having more land enables them to engage in long term agricultural works and many workers were not drinking enough water while engaging in agricultural activities. This can be a causative factor for CKD which is more prevalent in the farming community. In addition, many agricultural workers in the NCP were using agrochemicals, such as pesticides and weedicides without any safety precautions. The prevalence of stage 4 and 5 patients was high in the community. This is due to the fact that the people who live in the NCP do not often know they have CKD until the disease progresses to stages 4 or 5, when the disease becomes symptomatic. By the time the patients seek treatment the disease has progressed to the point where the kidney has reached ESRD. Another reason for this phenomenon can be due to a decline in adherence toward treatments. Therefore, it is suggested that the screening of CKD disease be performed before the disease progresses to its final stages, which can be beneficial to increasing the quality of life of the patients.

In the present study, a total of 38% of the participants were traveling more than 35 km for each clinical visit, and 30.5% of participants were travelling a distance of 25 km to 35 km. This also results in an additional transport cost that needs to be borne by the patients. Transportation is one of the most common problems in dialysis patients because dialysis and transplant patients are required to go to hospitals at least twice monthly. According to our findings 44% of participants were spending more than 500 Sri Lankan rupees on transportation due to lack of health care resources. This can be a cause for reduced compliance and adherence to treatment as the costs and long distances involved are very difficult for patients on hemodialysis. The possible reasons for this low adherence and compliance are less accessibility and availability of dialysis centers to continue the treatment regimes in CKD

patients. This suggests that establishing health centers of renal diseases is necessary for rural areas in NCP. As part of an initiative to alleviate these issues, the Government is issuing selected participants 5000 Sri Lankan rupees on a monthly basis which was found to be extremely helpful to those participant's families. Findings show that 49.5% of participants earned less than 5000 and 50.5% earned between 5000 to 15000 Sri Lankan rupees. Many were not able to earn money due to severity of the disease. Some patients from the group of participants were found to not be taking their medicines from the government hospital pharmacy. In some situations, medicines may not be available in the government hospital; therefore, patients may need to purchase medicines from a private pharmacy. However, majority of participants had no sufficient funds allocated for medicines, transportation, agricultural goods and house. Increasing costs can lead to a decline in patient's compliance and adherence toward medications. According to our findings, monthly income was significantly associated with the missing of doses. Patients that have less income show less compliance and adherence towards medications. This can be due to economic problems.

According to our findings on patient compliance and adherence toward medications, 47.5% participants were taking more than 6 types of medicines in a single dosage instance. Polypharmacy can also lead to reduced compliance and adherence toward medications among patients. It is suggested that giving modified release oral preparations other than immediate release oral preparations may increase patient's adherence toward medications. Many participants 74% were not aware about the side effects of medications. This finding suggests patient counseling is needed for this community in order to increase the compliance and adherence towards the medication use. 95% of participants were taking medications according to directions given by physician and pharmacists. Only 5% were not following given directions and the majority complies with the treatment regime. However, missing of doses by the participants was found to be a significant issue.

According to results; there is significant association between land extent and the missing of doses. 121 participants were missing their doses at least once of which 70.2% have more than one acre of land. Only 29.7% of participants were missing doses and have less than one acre of land. People that have more than oneacre of land can be considered to be engaged in more agricultural works. This can cause them to forget their medication doses and therefore reduce compliance and adherence towards medications. Instances of missing doses by patients belonging to CKD/CKDu stage 4 and 5 were significantly higher than that of patients belonging to stages 1-3. Capacity of working has been reduced in stage 4 and 5 which affects daily regular work and causes difficulty in comprehending normal tasks. Many challenges associated with patients living with CKD have forced them to feel that their life is short, and losing the

control of disease may also lead to poor compliance and adherence. Physical and psychological symptoms which the patients suffer were indicated in different stages. Pain is a major problem in ESRD. Therefore, pain management is required to control the pain otherwise it can affect the compliance and adherence. It is suggested that the progression of the disease can cause lower adherence to the medications and that patients belonging to early stages of the disease have more adherence to medications. Results have showed the stages of the disease were significantly associated with the missing of doses.

CONCLUSION

Non adherence and compliance to the medications is commonly found in patients who work in largely extended lands and it also depends on the stages of the disease and the income of the patients. Compliance and Adherence to medications can be enhanced by proper counseling and improving patient's knowledge about their medications. The findings provide the positive and negative factors about patient's compliance and adherence. It can be used to promote the adherence and compliance towards medications and to increase the patient quality of life even though CKD cannot be completely cured through treatments. The major outcome of treatment is increasing life time and enhancing the patient quality of life. Improving compliance and adherence to drug treatment on patients with CKD leads to a reduction in patients that need to undergo dialysis, which many patients cannot afford due to associated costs.

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