

Pattern of Herbal and Dietary Supplement Usage and Conventional Medication Adherence among Patients with Chronic Kidney Disease: A Survey Finding

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ABSTRACT

Introduction: There is widespread use of herbal and dietary supplements worldwide among patients despite robust clinical evidence of its efficacy. This may lead to adverse effects, such as diabetes, hypertension, stroke, cardiovascular risk and kidney problems due to inappropriate self-prescription. This study was performed to determine the prevalence of herbal and dietary supplements usage among patients with chronic kidney disease and its association with the socio-demographic background and the conventional medication adherence. **Materials and methods:** A survey was conducted among 78 chronic kidney disease patients attending the Nephrology Clinic, Hospital Tengku Ampuan Afzan, Kuantan, Pahang. Data were collected using a questionnaire and analyzed using descriptive statistics, Chi Square Test and Fisher's Exact Test. The *p-value* was set to be less 0.05 for its level of significance. **Results:** Most of the patients aged more than 50 years (89.7%), female (53.8%), unemployed (41%) and from lower socio-economic earners (75.6%). Only 5.2% of respondents reported using herbal and dietary supplements. There was no association between socio-demographic background with the herbal and dietary supplements usage. Similarly, there was no association between herbal and dietary supplements usage and the conventional medication adherence. **Conclusion:** This study provides a good baseline on the usage of herbal and dietary supplements use among chronic disease patients. It can be concluded that the level of awareness among the patients is good. Nevertheless, a larger study shall be performed in the future to explore the pattern of association.

KEYWORDS: Herbal and dietary supplements, chronic kidney disease, conventional medication adherence

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INTRODUCTION

Complementary alternative medicine (CAM) is categorized into two types, natural products and mind and body practices. Natural products are varied and include herbs, vitamins, minerals and probiotics. On the other hand, mind and body practices include a large and diverse group of procedures of techniques administered or taught by

a trained practitioner, such as yoga, chiropractic and osteopathic manipulation.¹ In Malaysia, herbal products is found to be the most popular natural products of CAM and Malay medicine is the most popular type of alternative medicines.² As there is widespread use of CAM nowadays, Ministry of Health (MOH) of Malaysia has developed the National Policy on Traditional and Complementary Medicine (T&CM) in 2007. The main objective of this policy is to promote the correct practice and use of T&CM in Malaysia.

Herbal and dietary supplements (HDS) are considered to be “complementary” when used together with conventional medicine and as “alternative” when it is used to replace conventional medicine. A new term, “integrative medicine” is developed to bring together conventional and complementary approaches in a coordinated way.³ Previous studies found that people with chronic diseases, such as chronic kidneys disease (CKD), diabetes mellitus (DM) and stroke are more likely to use CAM or herbal and dietary supplements (HDS).^{1,4,5} However, the risks of interaction between HDS and conventional medicine are not well studied especially the adverse effects of the herbal and dietary supplement among users with multiple comorbidities.

Other than that, the use of HDS may be prompted by various factors that eventually direct patients towards HDS.⁶ The patients or consumers who are eager to maintain or improve their health status may be tempted to try various kinds of HDS that are available in the market without knowing the adverse effect to their body. They shall seek the advice from healthcare professionals (HCP), such as medical doctors, pharmacists or nurses prior to any kind of HDS intake to prevent deterioration of the health condition. Plus, HDS should not replace or taken together with the prescribed medications without the HCP’s approval, particularly from the medical doctor or registered pharmacy recommendation.

Therefore, this study is conducted to determine the prevalence of HDS usage among patients with CKD and its association with the socio-demographic background and the conventional medication adherence. To date, several researches were done on the prevalence and pattern of HDS use in Malaysia particularly in the west coast region.

However, there is limited study conducted at the east coast region of Malaysia particularly in Kuantan, Pahang. This may provide some highlight on the discussed issue above.

MATERIALS AND METHODS

Population and Setting

A cross-sectional study was conducted from May until June 2018 in the Nephrology Clinic, Hospital Tengku Ampuan Afzan (HTAA), Kuantan, Pahang. The study was approved by the Kuliyyah of Nursing Postgraduate and Research Committee (KNPGRC), Medical Research and Ethic Committee (MREC) and Clinical Research Centre (CRC), HTAA with ID: NMRR -18-374-39751.

Inclusion and Exclusion criteria

The inclusion criteria were Malaysian, diagnosed with any stage of CKD, above 18 years old and understand Malay or English. A patient was excluded from the study when he/she did not consent and undergoing renal replacement therapy (RRT), such as hemodialysis, continuous ambulatory peritoneal dialysis (CAPD) and renal transplant. Patients who met the inclusion criteria were randomly approached and consent was obtained.

Research instrument

A nineteen-item semi-structured questionnaire was adapted from previous survey study in Thailand on herbal and dietary supplement conducted by Tangkiatkumjai et al., (2013).⁴ Permission was also granted from Donald E. Morisky to use the questionnaire namely the Morisky Medication Adherence Scale (MMAS) based on the study performed by Al-Qazaz et al., (2010).⁷ The final version of the questionnaire consisted of four parts: 1) demographic characteristics, 2) HDS use, 3) experiences of benefits and adverse effects from HDS and 4) the Malay version of MMAS-8. Prior the actual survey study, a pilot study was performed which will be explained in detail in the following headings.

The demographic characteristics include the age, gender, race, marital status, educational level, occupation and income status. Meanwhile the items asked about HDS usage include types, medical

purposes, dosage forms, doses and duration of HDS use, reasons why respondents use HDS, information sources, how they obtained the HDS and the disclosure of HDS use to their doctor. For the final part, total MMAS-8 score can range from 0 to 8 and have been categorized into three level of adherence: high adherence (score equal to 8), medium adherence (6 to less than 8) and low adherence (score less than 6).⁷

Pilot study

This phase was completed before proceeding to the actual study phase. There are three procedures involved in this portion: (1) translation, (2) validation, and (3) reliability in order to check the compatibility of the items in the translated assessment tools.⁸⁻¹¹

Stage 1: Translation procedure

The original questionnaire developed by Tangkiatkumjai et al., (2013)⁴ was forward and backward translated into Malay language by two bilingual experts (Renal Nursing and Patient Education) and subsequently back-translated into English. One of the authors compared the original English instrument with the back-translated Malay instrument and edited it to obtain the matching Malay version. After some minor adjustments, the final backward translated English version was used to re-evaluate the Malay version. Several changes were made and the final Malay version was finalized to be used in the current study.

Stage 2: Validation Procedure

This study had employed content validity and face validity only which is the translational validity. The criterion validity, such as concurrent, predictive, convergent, and discriminant are not applicable in the current study. There were two evaluators involved in the content validation process from the background of Intensive Care Nursing and Urology Nursing. The result of the content validation was 0.92 which indicated that the 19-items were relevant and clear since the recommended cut-off value for content validity index is 0.75.^{8, 11} However, some of the items were modified as recommended by the experts since they were not clear and may create confusion.

Stage 3: Reliability Procedure

A cross-sectional study was performed among 30 chronic kidney disease patients attending the Nephrology Clinic, HTAA to examine the validity and reliability of the finalized Malay version instrument (Table 1). The internal consistency of the questionnaire was tested using the Cronbach's alpha. The Cronbach's alpha value obtained for the pilot study is 0.70 which considered having strong reliability of correlation as cited by Nur Ain I. (2017) from the expert's, Nyi Nyi Naing (2012) suggestion.¹²⁻¹³

Sample size and data collection procedure

The actual study was conducted at the Nephrology Clinic, HTAA. A different set of CKD patients was selected as the sample which did not involve the earlier patients in the pilot study. The total population of chronic kidney disease (CKD) patients registered the clinic is approximately 434 annually. The sample size calculated using Openepi with the margin error of 5%, confidence interval of 95% and response rate of 45%. After calculation, the recommended sample size of this study was 187 participants.

However, only 82 patients were recruited for this study due to late ethical approval and shorter duration was left for data collection. Nevertheless, this sample size is still considered adequate for a new survey study. The range between 5 to 10% of a survey sampled from the actual population is considered acceptable.^{8, 14}

During recruitment, brief explanation about the study was given to the CKD patients before handing the consent form and questionnaire. The time given for the respondent to complete answering all items in the questionnaire was 15 to 20 minutes.

Data analysis

IBM Statistical Package Social Science (SPSS) version 23.0 is used for data management and analysis. Frequency and percentage are used for descriptive statistics. The inferential statistics used is Chi Square Test and Fisher's exact test to determine the associations between socio-demographic background of patients with CKD and HDS usage and also the associations between HDS usage and the conventional medication adherence.

Level of significance was set at *p-value* less than 0.05.

RESULTS

Total number of patients participated in the study was 82 but 4 (4.9%) were excluded due to being younger than 18 years old ($n = 1$) and incomplete patient details ($n = 3$). The results are presented descriptively according to the four parts of the section in the questionnaire: 1) demographic characteristics, 2) HDS use, 3) experiences of benefits and adverse effects from HDS and 4) the Malay version of MMAS-8, followed by the results of association findings for socio-demographic backgrounds towards HDS usage as well as association findings for HDS usage and adherence to conventional medicine.

Socio-demographic backgrounds of patients with CKD

Most of the CKD patients are female (53.8%), Malay (83.3%), married (66.7%) and more than 50 years old (89.7%) with mean age of 62.88 (12.7). In terms of education level and occupation, majority of them had only completed primary school (64.1%) and 42.3% were unemployed. This result accounts for 75.6% of the respondents have the monthly income of below RM 150.00 with mean monthly income around RM 443.59 (835.20).

Prevalence and Factors of Herbal and Dietary Supplements Usage

Table 1 presents the information on the prevalence of HDS usage. From 78 CKD patients, only 4 (5.2%) of them are using HDS. Most of them utilized both the herbal supplement and dietary supplement. When asked further, the supplement taken was in the form of solution or drinks and taken daily. The main factor of using HDS was recommendation by family and friends and they even provided the HDS supply for the consumers (75%). In terms of disclosure to the HCP, all of the consumers told their HCP about their HDS usage.

Experiences of Herbal and Dietary Supplements Usage

Table 2 presents the benefits and adverse effects of the HDS experienced by CKD patients who used HDS.

75.0% of the users said that they benefited from the HDS use to maintain wellness while the other 25.0% experienced the adverse effects of the HDS and they immediately stop from using it after that. For the non-HDS users, none of them were planning to use HDS in the future.

Conventional Medication Adherence

The conventional medication adherence is assessed using the Morisky's Medication Adherence Scale 8-items (MMAS-8). The score was rated as high (= 8), medium (6 to <8) and low (<6).⁷ Most of the respondents obtained high score (59.0%), followed by medium score (37.2%) and low score (3.8%). The mean score is 7.5 (SD \pm 0.7). The descriptive results are presented in Table 3.

Association between Socio-Demographic Backgrounds and Herbal and Dietary Supplements Usage

There were seven variables measured for socio-demographic background, including age, gender, race, marital status, educational level, occupation and monthly income. Overall, all the variables measured for socio-demographic background was found not significantly associated with the HDS usage among patients with CKD. Since the *p-value* is more than 0.05, the study must accept the null hypothesis (Table 4).

Association between Herbal and Dietary Supplements Usage and Adherence to Conventional Medicine

Overall, HDS usage and adherence to conventional medicine were found not significantly associated with the HDS usage among patients with CKD. Since the *p-value* is more than 0.05 ($p=0.731$), the study must accept the null hypothesis which means patients with CKD were adhered to their medication prescriptions.

DISCUSSION

There are limited studies conducted in identifying patterns of CAM use among patients with chronic disease globally and locally. Most studies were done among patients with cancer, cardiovascular risk, diabetes, stroke or focused on the general population as a whole.¹⁵⁻¹⁹

Table 1: Prevalence of Herbal and Dietary Supplements Usage among CKD patients (n = 78)

Variables	Categories	Frequency (Percentage) n (%)
HDS usage (n = 78)	Yes	4 (5.2)
	No	74 (94.9)
If Yes (n = 4), Type of HDS used	Herbal supplement	2 (50.0)
	Dietary supplement	2 (50.0)
	Both	0 (0.0)
Name of product	Whitening collagen brand A	1 (25.0)
	Energy liquid brand A	1 (25.0)
	Pomegranate extract brand A	1 (25.0)
	Leaf A	1 (25.0)
Indication	Treatment of CKD	0 (0.0)
	Well-being	3 (75.0)
	Long life expectancy	0 (0.0)
	Others*	1 (25.0)
Dosage form	Pills	0 (0.0)
	Capsules	0 (0.0)
	Tablets	0 (0.0)
	Powder	1 (25.0)
	Solution	2 (50.0)
	Crude Herbs	1 (25.0)
	Swallow	2 (50.0)
Route of administration	Topical use	0 (0.0)
	Make into a drink / food using hot water	2 (50.0)
	Other	0 (0.0)
	Once / day	4(100.0)
	Two times / day	0 (0.0)
Dosage (categorical)	Three times / day	0 (0.0)
	More than three times/day	0 (0.0)

Note:

*Indication: to become fairer

Table 1: Prevalence of Herbal and Dietary Supplements Usage among CKD patients (n = 78) (Cont)

Variables	Categories	Frequency (Percentage) n (%)
If Yes (n = 4), Frequency of day per week (categorical)	Once / week	0 (0.0)
	Two times / week	0 (0.0)
	Three times / week	0 (0.0)
	More than three times / week	4 (100.0)
Frequency of month per year (categorical)	One month / year	0 (0.0)
	Two month / year	0 (0.0)
	Three month / year	0 (0.0)
	More than 3 months / year	4 (100.0)
Factors of using HDS	Willing to try anything that works	1 (25.0)
	Hope HDS will work	1 (25.0)
	HDS is safer than modern medicine	0 (0.0)
	Modern medicine doesn't work	0 (0.0)
	HDS cheaper than modern medicine	0 (0.0)
	HDS are easily accessed	0 (0.0)
	Recommended by healthcare providers	0 (0.0)
	Recommended by family and friends	2 (50.0)
	Used by family and friends	0 (0.0)
	Others	0 (0.0)
Sources related to HDS usage	Family and friends	3 (75.0)
	Television	1 (25.0)
	Internet	0 (0.0)
	Radio	0 (0.0)
	Newspaper	0 (0.0)
	Pamphlets	0 (0.0)
	Others	0 (0.0)
	Buy from:	
	Pharmacy / Drug store	0 (0.0)
	Folk remedy shop	1 (25.0)
Health food store	0 (0.0)	
Hospital	0 (0.0)	
Direct sale	0 (0.0)	
Methods of obtaining supply for HDS	Provided by family / friends	3 (75.0)
	Collecting from their garden / planted by your own-self	0 (0.0)
	Others	0 (0.0)
	No:	
	They don't ask	0 (0.0)
Disclosure about HDS usage to the HCP	No need to inform	0 (0.0)
	Other	0 (0.0)
	Yes	4 (100.0)

Therefore, this study was performed to determine the prevalence of herbal and dietary supplements usage among patients with chronic kidney disease and its association with the socio-demographic background and the conventional medication adherence. A set of questionnaires was adopted from previous researcher related to CAM usage and

conventional medication adherence.^{4, 7} The translated Malay version instrument was found to have good content validity index (0.92) and strong reliability (0.70) when tested in the pilot study. Thus, the instrument is considered valid and reliable to be used in the actual study.

Table 2: Experiences of Herbal and Dietary Supplements Usage among CKD patients (n = 78)

Variables	Categories	Frequency (Percentage) n (%)
If Yes (n = 4),		
Benefits	No	1 (25.0)
	Don't know	0 (0.0)
	Not sure	0 (0.0)
	Yes*	3 (75.0)
Adverse effects	No	3 (75.0)
	Don't know	0 (0.0)
	Not sure	0 (0.0)
	Yes [#]	1 (25.0)
Stop medication after adverse effects (n = 1)	No	0 (0.0)
	Yes*	1 (100.0)
Duration of continuing HDS usage (n = 3) [‡]	Don't know	0 (0.0)
	Not Sure	3 (100.0)
	Month / Year	0 (0.0)
If No (n = 74),		
Intention of using the HDS in the future (n = 74)	No	74 (100.0)
	Not Sure	0 (0.0)
	Don't know	0 (0.0)
	Others	0 (0.0)

Note:

*Benefits: increased energy

[#]Adverse effect: kidney disease

[‡]Missing information (n=1)

Most of the CKD patients recruited from Nephrology Clinic, HTAA, Kuantan, Pahang for the current study are Malay, female and married with age more than 50 years old. These findings are supported with another study done in the west coast region at Nephrology Clinic, National University of Malaysia Medical Centre (HUKM), which highlighted the mean age of their patients as 59.3 years (SD 14.5), most are Malays (66.5%), followed by Chinese (26.5%), Indian (6.5%) and others (0.5%).¹⁸ A similar pattern was observed in general population, cancer patients, patients attending outpatient clinics or primary care settings whereby the common users of HDS product are female, Malays and married either at the global or local setting.^{15-17, 20-23} Nevertheless, a study on CAM among stroke patients in a tertiary hospital in the east coast of Malaysia involved more male than female⁵

The prevalence of HDS usage among CKD patients is only 5.2% for the current study which can be considered as low, similar to a study in Spain

(18.8%) but contradicted with a study done in Thailand among CKD patients (45.0%) which is considered high. The current rate of HDS usage is also considered low in comparison to the population standard which is rated at 29.3% as highlighted in the National Health and Morbidity Survey (2015) on T&CM report.¹⁶ Nevertheless, the national study was conducted among general population had excluded those staying in hotels, hostels and hospitals.¹⁶ A study in Turkey found that the use of HDS among kidney patients undergoing hemodialysis increased from 47.0% (before dialysis) to 63.1% (after started dialysis).²² Therefore, this current study had at least provided a baseline finding for the HCP on the importance to obtain information on HDS usage among the current CKD patients in a way of more open-minded manner and not being judgmental.

Most of HDS users in the current study mentioned that the main factor influencing them to consume HDS are due to the recommendation by family and friends followed by the hope that HDS will work and gain benefits from it.

Table 3: Conventional Medication Adherence Measured by Morisky's Medication Adherence Scale 8-items (MMAS-8items) (n = 78)

No.	Categories	Frequency (Percentage) n (%)																			
		Yes				No															
1	Do you sometimes forget to take your kidney pills?	27 (34.6)				51 (65.4)															
2	People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your kidney medicine?	1 (1.3)				77 (98.7)															
3	Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	1 (1.3)				77 (98.7)															
4	When you travel or leave home, do you sometimes forget to bring along your kidney medication?	6 (7.7)				72 (92.3)															
5	Did you take your kidney medicine yesterday?	76 (97.4)				2 (2.6)															
6	When you feel like your kidney disease is under control, do you sometimes stop taking your medicine?	1 (1.3)				77 (98.7)															
7	Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your kidney treatment plan?	4 (5.1)				74 (94.9)															
8	How often do you have difficulty remembering to take all your medications?	<table border="1"> <thead> <tr> <th colspan="5">Frequency (Percentage) n (%)</th> </tr> <tr> <th>Never/Rarely</th> <th>Once in a while</th> <th>Sometimes</th> <th>Usual-ly</th> <th>All the time</th> </tr> </thead> <tbody> <tr> <td>71 (91.0)</td> <td>7 (9.0)</td> <td></td> <td>0 (0.0)</td> <td></td> </tr> </tbody> </table>					Frequency (Percentage) n (%)					Never/Rarely	Once in a while	Sometimes	Usual-ly	All the time	71 (91.0)	7 (9.0)		0 (0.0)	
Frequency (Percentage) n (%)																					
Never/Rarely	Once in a while	Sometimes	Usual-ly	All the time																	
71 (91.0)	7 (9.0)		0 (0.0)																		

Furthermore, the CAM users were willing to try anything that works on their body and these reasons were similarly highlighted in several study done globally and locally.^{15-17, 20-21, 23} Among the purpose and benefits of taking the HDS, such as food supplement or drinks informed by the CKD patients in the current study is to maintain their wellness as their daily remedy. This is in accordance to a study done among the general population which indicates the similar reason ranges from 60.0% to 68.0% in using the herbs or nutritional therapy.^{15, 16}

Other than those reasons, all HDS users in the current study were found to inform their healthcare practitioner (HCP) about their HDS usage similarly as the respondents in the study done among hypertensive patients in USA.²⁴ This contraindicated with studies done in Thailand, Japan and Spain in which more than half and one third respectively of the respondents did not inform their HCP about the usage.^{4, 20, 23} Several

studies in Malaysia highlighted that CAM users who never reported about the use of CAM to their doctors ranges between 57.1% to 68.5% because they think it is not important for any HCP to know about it.⁶ Since there were only four reported known cases on CAM usage in the current study, the result may be under-reported due to recall bias. Overall, there was no association found between the socio-demographic background and the prevalence of HDS usage.

Most of the respondents in this study scored high for the conventional medication adherence level. Likewise, there is no significant association found between the prevalence HDS usage and the level of conventional medication adherence in the current study measured using Morisky's Medication Adherence Scale 8-items (MMAS-8). Even if there is any association between the variables, there is no clear pattern of this association and the reason for the association was not investigated, so further studies are needed before firm conclusions can be made.^{4, 23}

Table 4: Association between socio-demographic backgrounds and Herbal and Dietary Supplements Usage among CKD Patients (n = 78)

Variables	Categories	Frequency (Percentage) n (%)		p value [#]
		Yes (n = 4)	No (n = 74)	
Age	<50	1 (25.0)	7 (9.5)	0.357
	>50	3 (75.0)	67 (90.5)	
Gender	Male	2 (50.0)	34 (45.9)	0.855
	Female	2 (50.0)	40 (54.1)	
Race	Malay	3 (75.0)	62 (83.8)	0.372
	Chinese	1 (25.0)	9 (12.2)	
	Indian	0 (0.0)	1 (1.4)	
	Others	0 (0.0)	2 (2.7)	
Marital status	Widow/widower	0 (0.0)	17 (21.8)	1.000
	Married	4 (100.0)	60 (76.9)	
	Divorce	0 (0.0)	0 (0.0)	
	Single	0 (0.0)	1 (1.3)	
Education level	Bachelor/Master/PhD	0 (0.0)	0 (0.0)	0.136
	Certificate/ Diploma	1 (25.0)	2 (2.7)	
	Secondary school	1 (25.0)	25 (32.1)	
	Primary school	2 (50.0)	48 (64.9)	
Occupation	Unemployed	1 (25.0)	31 (41.9)	0.166
	Housewife	1 (25.0)	25 (33.8)	
	Private servant	1 (25.0)	10 (13.5)	
	Retired	0 (0.0)	4 (5.4)	
	Government servant	1 (25.0)	4 (5.4)	
Income (RM)	First tertile (RM0-150)	2 (50.0)	57 (77.0%)	0.111
	Second tertile (RM151-1100)	0 (0.0)	0 (0.0)	
	Third tertile (RM1101-38000)	2 (50.0)	17 (23.0)	

Note:

* Significant level is set at $p < 0.05$ (95% CI)

[#] Fisher's Exact Test

Poor adherence towards conventional medication is observed when one is using CAM among hypertensive patients in UK.²¹ However, a small number of CKD patients in the current study reported on the use of CAM and the majority of them still preferred the conventional medication as their main mechanism for treatment modalities.

CONCLUSION

Overall, only a small portion of CKD patients attended Nephrology Clinic, HTAA were using HDS. Most of them reported that family and friends had an influence on the usage. However, no significant association between the sociodemographic background towards HDS usage among CKD patients. It was also found that most of the respondents scored high in the MMAS-8 questionnaire which highlights good medication adherence. Nevertheless, there was no association between the HDS usage and the conventional medication adherence level among patients with CKD in HTAA. This study had highlighted there is a tendency of HDS usage among CKD patients in the future which require an open discussion between the patients and HCPs involved.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest in this study.

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