JOURNAL OF KENYA ASSOCIATION OF PHYSICIANS

JOKAP March 2022 Vol 5 No. 1 ISSN 2663-6484

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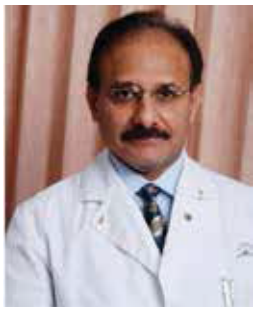

Published by Kenya Association of Physicians
P.O. Box 48397 Code 00100, Nairobi, Kenya. www.kapkenya.org

Editorial

Fibromyalgia and the Physician

Fibromyalgia (FMS), a chronic disorder defined by widespread pain, often accompanied by fatigue and sleep disturbance, affects up to one in 20 patients in primary care (1). Although most patients with FMS are managed in primary care, diagnosis and treatment continue to present a challenge, and patients are often referred to specialists. Furthermore, the lack of a clear patient pathway often results in patients being passed from specialist to specialist, exhaustive investigations, prescription of multiple drugs to treat different symptoms, delays in diagnosis, increased disability and increased healthcare resource utilisation. Fibromyalgia continues to present a challenge for Healthcare Professionals (HCPs) (1). The extensive array of symptoms associated with, and gradual evolution of, FMS make it difficult to diagnose in primary care settings (1), and the condition is often under□diagnosed. One study has shown that diagnosis of FMS might take more than 2 years, with patients seeing an average of 3.7 different physicians during this time (2). Although the American College of Rheumatology (ACR) has published diagnostic criteria for FMS , these are not widely used in clinical practice, and there remains a knowledge gap among some HCPs, particularly in the primary care setting (1,2). In addition to diagnostic complexity, therapeutic management might be problematic, and there is a lack of prescribing consistency between physicians. Many patients might not receive treatment, and for those who do, repeated therapy switching, polypharmacy and discontinuation are common. Some patients may also have unrealistic treatment expectations and difficulty coping with their symptoms, which may contribute to struggles in managing their condition.

Are most physicians comfortable treating patients with FMS, especially in set ups where there is little or non-existent multi-disciplinary teams? Several surveys have been conducted amongst physicians about this topic. Very interesting and varied opinions about the disease have arisen. Some physicians have described FMS as a 'nightmare consultation' with some even questioning the existence of the condition as a disease entity! Many see FMS as a symptom description that is slowly evolving into a spurious diagnosis! With such a wide range of opinion, it is likely that patients with fibromyalgia are receiving different levels of support, advice and treatment!

The big question thus is "How can prejudice and skepticism regarding the validity of fibromyalgia be countered?" Knowledge that FMS is grounded in neurophysiological mechanisms will reduce skepticism regarding a syndrome of subjective complaints. Physicians comfort with a biomedical paradigm, which prioritizes diagnostics, adds to the insecurity in management of these patients, with some authors contending that the label of FMS promotes poor health (4,5). Patient preoccupation with physical symptoms rather than developing control over illness invokes frustration for the healthcare professional and erodes a good therapeutic relationship (5). The construct of somatization has however never been validated in situations involving pain, and particularly in FMS. In contrast, patients with FMS report frustration with healthcare professionals, dissatisfaction with the clinic visit and seek a concrete somatic diagnosis (6,7). Although discordance between patient and physician assessment of health perceptions has been reported, physicians have expressed the desire to comply with patients' wishes and avoid frustration (8). When physicians prejudge FMS patients in moralizing terms and believe them to be illness-focused, demanding and medicalized, the patient doctor alliance will be eroded with adverse effect on patient outcome (5). Both the individual patient's concept of illness as well as perceived attitudes of the healthcare team influences global well-being. Shared decision-making between patient and physician can improve the quality of interaction (8). An early diagnosis may have pharmacoeconomic implications with reduced healthcare costs as measured by fewer investigations, less referral to specialists and reduced healthcare visits (7,8).

Whereas opinion is highly divided amongst rheumalogists as to the approach of patients with FMS, it is my opinion that holistic management of FMS patients is a very useful concept, which allows the clinician to promote beneficial lifestyle changes to patients who appear to have lost their 'pain filter', and who would otherwise resist such initiatives. The complex and multifaceted nature of FMS lends itself better to a holistic (integrative medicine) or biopsychosocial approach than the more specific bio-scientific pathways typical for a pathologically defined disease. A person-centered approach to evaluation and care more effectively addresses and encompasses the biopsychosocial aspects of this disorder than traditional bio-scientific clinical methods. Physicians should not shy away from forming multi-disciplinary teams with other colleagues e.g. psychiatrists, counselors, neurologists, nurses and pain management specialists.

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Original paper

Correlation between Disease Severity and Health-Related Quality of Life among Patients with Fibromyalgia Syndrome

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Abstract

Background: Fibromyalgia Syndrome is a rheumatological condition associated with more healthcare costs, higher prevalence of comorbidities, more workdays missed, poor productivity, early retirement, impaired function, and a poorer quality of life.

Objectives: To determine the correlation between disease severity and health-related quality of life among fibromyalgia syndrome patients.

Design: This was a prospective cross-sectional study.

Methods: The study enrolled patients diagnosed with fibromyalgia syndrome at the Aga Khan University Hospital Nairobi, Kenya. Those enrolled in the study were administered a Revised Fibromyalgia Impact Questionnaire to assess health-related quality of life and a 36 – Item Short Form Health Survey questionnaire to assess the quality of life. Spearman Ranks correlation was used to establish the correlation between the disease severity and health-related quality of life.

Results: There were 59 participants recruited to the study who met the eligibility criteria. Of the 59 participants, 54 (91.5%) were female. The median age of the participants was 41.0 years (Inter Quartile Range: 34.0, 50.0). The majority had mild disease severity (39%), followed by moderate disease (25.4%), severe disease (23.7%), and extreme disease (11.9%). The median Revised Fibromyalgia Impact Questionnaire score was 50 (moderate disease severity). There was a negative significant correlation between the Revised Fibromyalgia Impact Questionnaire domains, the overall Revised Fibromyalgia Impact Questionnaire score with all the 36 Item Short Form Survey subscales ($p<0.05$).

Conclusion: The study demonstrated a negative correlation between disease severity and quality of life in both the physical and mental components. This implies in managing patients with fibromyalgia syndrome, both physical and psychosocial and approaches should be adopted.

Key words: Fibromyalgia, Health-Related Quality of Life, FIQR, SF-36

Introduction

Fibromyalgia Syndrome (FMS) is characterized by chronic widespread musculoskeletal pain accompanied by fatigue, sleep, memory problems, and mood disturbances. Physical examination is characterized by tender points with tenderness demonstrated at insertions of tendons and muscles. It is more common in females and associated with increasing age. It is thought to result from abnormal processing of nociception with central sensitization resulting in a low threshold for pain. The cause is unknown but infectious agents have been implicated such as Hepatitis C (1), Human Immunodeficiency Virus (HIV) (2), and Lyme disease (3).

The American College of Rheumatology (ACR) 2016 updated criteria for diagnosis of fibromyalgia should include Widespread Pain Index (WPI) ≥ seven and Symptom Severity Score (SSS) ≥ five or WPI between four and six and SSS ≥ nine. Patients should exhibit generalized pain defined as pain present in at least four of five regions, symptoms being present at a similar level for more than three months, and that the diagnosis is valid irrespective of other diagnoses.

Little is known about the epidemiology of fibromyalgia syndrome in Kenya. Prevalence studies done elsewhere show it ranges between 0.4 to 4.4% in the general population. Branco *et al* (4) demonstrated a prevalence of 4.7% with most being female. A study done in Kansas on the prevalence of fibromyalgia in the general population found it to be 2% associated with increased age and more common in females (5). Local fibromyalgia studies done in Kenya have been done in clinical settings and not in the general population. A prevalence study done at Kenyatta National Hospital (KNH), Kenya was around 1%, 11% among those with chronic musculoskeletal pain (6), 27.9% among diabetics with chronic pain (7), and 17.9% among ambulatory HIV patients with musculoskeletal pain (8). This suggests that the prevalence is higher among those with comorbidities/chronic illnesses.

The Revised Fibromyalgia Impact Questionnaire (FIQR) was developed as a way to assess the severity of fibromyalgia syndrome. It is a validated tool that has

three domains to assess function, the overall impact of the disease, and symptoms (9).

The World Health Organisation (WHO) defines the quality of life as how individuals perceive their state within the framework of their culture and value systems that includes the objectives, expectations, standards, and interests of the individual (10). Health-Related Quality of Life (HRQOL) denotes the proportion of this contributed by one's health status (10).

Local studies have not directly studied the correlation between disease severity with HRQOL indicators among FMS patients. Local prevalence studies mentioned above demonstrated the disease severity to be moderate among the population studied although the HRQOL was not measured among such patients (6). This is comparable to findings by Bennet *et al* (9) who recruited participants previously diagnosed with fibromyalgia from the general population and found a mean FIQR score of 56.6.

A Brazilian study on FMS showed a negative impact on HRQOL (11). A study done in Spain by Mas *et al* (12) showed impaired functioning and poorer HRQOL among FMS patients. A study by Tander *et al* (13) comparing the HRQOL among patients with rheumatoid arthritis and FMS showed that those with fibromyalgia had poorer HRQOL. Verbunt *et al* (14) study concluded that fibromyalgia had a high impact on HRQOL especially on mental health components (14). Lee *et al* (15) study concluded that FMS patients with higher disease severity had a poor HRQOL especially the mental components.

Concerning socio-demographic characteristics, there is a female preponderance in most FMS studies. Some studies have shown a higher prevalence in people from a rural setting, with fewer years of schooling, lower social class, the unemployed, and more common among housewives (12). However other studies showed that prevalence did not correlate to marital status, level of education, or occupation (4). A study by White *et al* (16) concluded that middle age, less education, lower household income, being divorced, and being disabled were associated with the disease. A local study demonstrated that more than half of the FMS patients were unemployed and were engaged in manual activities (6). Another local study by Umar *et al* (7) found factors such as marital status, nature of employment, and activities not to be significant in influencing the disease activity.

The primary objective of this study is to determine the correlation between disease severity and HRQOL among FMS patients in Kenya. FMS contributes significantly to the burden of diseases locally, especially those presenting with musculoskeletal pains as demonstrated by the few local prevalence studies. Currently, there is no data on the local prevalence of FMS in the general population and the figures could be an underestimation due to lack of awareness or misdiagnosis. There has been no previous study to assess the correlation between the severity of FMS and HRQOL.

Materials and methods

This was a cross-sectional, analytical study carried out at the Rheumatology Clinic, Aga Khan University Hospital Nairobi (AKUHN) between April and December 2020 among those who met the 2016 updated ACR diagnostic criteria for FMS. Ethical approval was obtained from the institutional Ethics and Review Committee at Aga Khan University Hospital Nairobi (AKUHN) where the study was being conducted. A consecutive sampling technique was utilized. Consent was obtained from the respondents or appropriate surrogates. No financial incentives or gain was used to lure participants. Confidentiality was maintained throughout the study period.

Biodata and socio-demographic characteristics of the study participants were obtained. The disease severity was assessed by the FIQR questionnaire. It has a maximum score of 100 with a higher score indicating more severe disease. Further categorization of severity is based on the scores with a score of 75 to 100 being extreme, 60 to 74 being severe, 43 to 59 being moderate and 0 to 42 being mild disease. HRQOL was the dependent variable which was assessed by a standardized generic instrument the 36- Item Short Form questionnaire (SF-36) which is composed of 36 items that are grouped in eight subscales or domains. It is a validated generic instrument that measures perceived health status in different conditions. The eight domains (subscales) of the SF-36, are scored on a scale of 0–100, with a higher score indicating a better HRQOL. It is categorized into the physical and mental domains. Sample size was calculated based on the correlation formula (17) and the minimum sample size required was 52, after allowing for a 10% attrition rate using an assumption of 0.4 correlation based on previous literature (9).

Study data were collected and managed using REDCap database (17). Continuous variables were expressed as median with interquartile ranges (IQR) whereas categorical variables were expressed as frequencies and percentages. Univariate analysis was conducted using the Kruskal Wallis test for continuous variables and using Fisher's exact test for categorical variables. Spearman Ranks correlation was calculated for the dependent versus independent variables.

Results

The study recruited 59 participants who met the eligibility criteria. Of those recruited, 5 (8.5%) were male and 54 (91.5%) were female. The median age of those recruited in the study was 41.0 years (IQR: 34.0, 50.0). Fifty seven point six percent of the participants were married, 35.6% were single and 6.8% were either divorced or widowed. Most of the participants resided in Nairobi County (79.7%). The majority, 47 (79.7%) of the participants were employed while 12 (20.3%) of the participants were unemployed. The majority (52.5%) of the participants had no comorbidities whereas 47.5% had comorbidities. The most common comorbidity identified was hypertension (8.5%). Other comorbidities identified were rheumatoid arthritis and cancers. The most common level of education was a tertiary level of education (76.3%). The median duration of symptoms from onset to diagnosis was three years (IQR: 1.0, 6.0). The median duration between diagnosis and time of the study was two years (IQR: 1.0, 3.0).

Table 1 summarizes the demographic characteristics. Table 2 demonstrates the range of diseases among the participants with comorbidities.

Table 1: Demographic characteristics

Overall characteristics		N = 59
Age (years)		41.0 [IQR: 34.0, 50.0]
Gender	Male	5 (8.5%)
	Female	54 (91.5%)
Weight (Kgs)		72.0 [IQR: 63.0, 82.9]
Marital status	Single	21 (35.6%)
	Married	34 (57.6%)
	Divorced / Widowed	4 (6.8%)
Education level	Primary	1 (1.7%)
	Secondary	13 (22.0%)
	Tertiary	45 (76.3%)
Occupation	Employed	47(79.7%)
	Unemployed	12(20.3%)
Comorbidities	Yes	28(47.5%)
	No	31(52.5%)

Table 2: Range of diseases among the participants with comorbidities

	Comorbidities	Frequency No. (%)
	Diabetes	1 (3.6)
	Hypertension	5 (17.9)
	Psychiatric illness	2 (7.1)
	Cancer	2 (7.1)
	Adenomyosis	1 (3.6)
	Asthma	1 (3.6)
	Behcet's disease	2 (7.1)
	FSGS	1 (3.6)
	Grave's disease	1 (3.6)
	HIV	1 (3.6)
	Irritable bowel syndrome	1 (3.6)
	Osteoarthritis	1 (3.6)
	Pituitary adenoma	1 (3.6)
	Reactive arthritis	1 (3.6)
	Rheumatoid Arthritis	3 (10.7)
	Sjögren syndrome	1 (3.6)
	SLE, Scleroderma	1 (3.6)
	Stroke	1 (3.6)
	Varicose veins	1 (3.6)

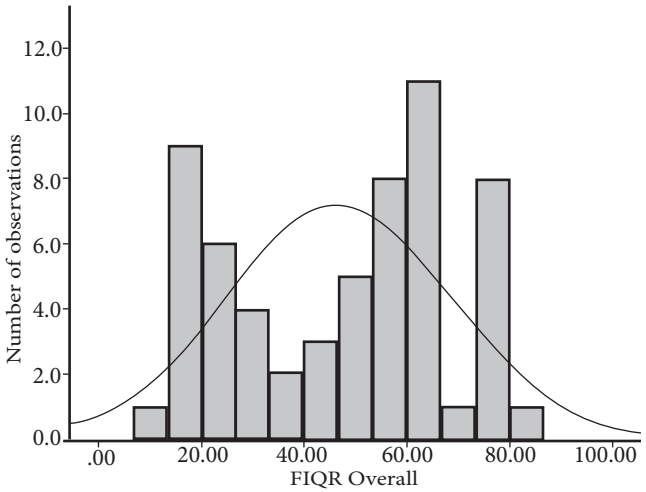
The median FIQR score among the study participants was 50.2 (IQR: 22.5, 63.0). This is in keeping with moderate fibromyalgia disease severity. FMS disease activity as measured by the FIQR score demonstrated that the majority had mild disease severity (39%), followed by moderate disease (25.4%), severe disease (23.7%), and extreme disease (11.9%).

On the FIQR domains, the median function domain score was 33.0 (IQR: 12.0, 60.0), the median overall impact domain score was 10.0 (IQR: 4.0, 15.0) and the median symptom domain score was 49.0 (IQR: 30.0, 67.0). Table 3 demonstrates the disease severity based on the FIQR categories.

Table 3: FIQR categories among study participants.

Disease severity based on FIQR categories	No. of participants (%)
Mild (0 - 42)	23 (39.0)
Moderate (43 - 59)	15 (25.4)
Severe (60 - 74)	14 (23.7)
Extreme (75 - 100)	7 (11.9)

Figure 1: Distribution of the overall FIQR scores



The HRQOL was measured by the SF-36 score which is divided into 8 subscales. A higher score usually indicates better-perceived health. The greatest impact was on the physical and emotional role limitation whereas the least impact was on social functioning. Table 4 summarizes the scores on the SF-36 subscales.

Table 4: Scores on the 8 SF-36 subscales

SF-36	Median [IQR]
Physical	55.0 [30.0, 75.0]
Physical role limitation	0.0 [0.0, 50.0]
Emotional role limitation	0.0 [0.0, 100.0]
Energy/Fatigue	40.0 [25.0, 55.0]
Emotional well being	56.0 [45.0, 72.0]
Social functioning	62.5 [37.5, 87.5]
Pain	42.5 [22.5, 57.5]
General health	45.0 [30.0, 65.0]

Correlation between FMS disease severity and HRQOL was done by comparing the FIQR domains, the overall FIQR score, and the SF-36 8 subscales. A higher domain FIQR score implies a higher disease severity. A higher SF-36 score implies a better quality of life. A negative correlation implies that with an increase in disease severity there is associated worsening HRQOL.

There was a negative correlation between the FIQR domains, the overall FIQR score with all the SF-36 subscales. This was statistically significant ($p < 0.05$) for all the SF 36 subscales. Table 5 demonstrates the correlation between the FIQR domains, overall FIQR score with the SF-36 subscales.

Table 5: Correlation between the FIQR scores and the SF 36 subscales

	SF 36 Subscales	Physical		Physical role limitation	Emotional role limitation	Energy
FIQR	Function domain	-0.619		-0.603	-0.457	-0.395
		<0.001	<0.001	<0.001	0.002	
	Overall domain	-0.374		-0.356	-0.452	-0.423
		0.004	0.006	<0.001	0.001	
	Symptom domain	-0.41		-0.466	-0.404	-0.619
		0.001	<0.001	0.002	<0.001	
	FIQR Overall	-0.555		-0.551	-0.51	-0.544
		<0.001	<0.001	<0.001	<0.001	
	SF 36 Subscales	Emotional		Social	Pain	General
FIQR	Function domain	-0.216		-0.551	-0.526	-0.463
		0.1	<0.001	<0.001	<0.001	
	Overall domain	-0.338		-0.508	-0.451	-0.47
		0.009	<0.001	<0.001	<0.001	
	Symptom domain	-0.396		-0.579	-0.5	-0.544
		0.002	<0.001	<0.001	<0.001	
	FIQR Overall	-0.365		-0.636	-0.583	-0.554
		0.004	<0.001	<0.001	<0.001	

1st Row = Correlation Coefficient
2nd Row = P-value
** Correlation method = Spearman ranks method

Multivariate logistic regression was performed to establish the association between FMS disease severity and SF-36 HRQOL domains when adjusted for other independent variables that included age, gender, level of education, and presence of psychiatric illnesses. The severity of the disease was categorized as those with a mild and moderate disease as one group and those with a severe and extreme disease as another group based on the FIQR scores.

From the results, with a one-unit increase in the various SF-36 domains, there is a reduction in the odds of being in the severe group. There was a significant negative association between the various SF-36 domains and the severity of the disease demonstrated by odds ratios of less than one ($p<0.05$). Table 6 summarizes the results of the associations.

Table 6: Multivariate logistic regression on the severity of the disease based on FIQR

SF-36 Domains	Odds Ratio	95% C.I	P-value
Physical	0.944	[0.914, 0.975]	0.001
Physical role limitation	0.964	[0.937, 0.992]	0.013
Emotional role limitation	0.971	[0.953, 0.989]	0.002
Energy	0.94	[0.9, 0.981]	0.004
Emotional	0.96	[0.925, 0.996]	0.03
Social	0.93	[0.893, 0.969]	0.001
Pain	0.931	[0.892, 0.973]	0.001
General	0.954	[0.922, 0.987]	0.007

Discussion

The study participants were enrolled at a private tertiary facility. The patients seen are likely to be referrals from other facilities and are also likely to have a more severe disease state.

There were demonstrable similar demographic characteristics with other studies. In the study, 5 (8.5%) of the study participants were male and 54 (91.5%) were female. A local study done had demonstrated a female predominance of 97.7% (6). In a study done in five European countries, 94% of the FMS participants were female (4). The mechanisms of the association between FMS and female sex have not been fully understood but the female gender is a strong predictor of disease (5). Generally, one should have a higher index of suspicion among female patients with suspected FMS.

The findings of the study demonstrated that FMS is common in the middle-aged population which is similar to what has been demonstrated in other studies. The median age of the study participants was 41.0 years. A local study had found the mean age among FMS participants to be 48.5 years (6). In a study done in the USA, the mean age of those studied was 51.0 years (9), whereas, in a study done in the Netherlands, the mean age was 40.0 years (14). The prevalence of FMS is thought to increase with age but recommendations remain that anyone presenting with widespread pain should be screened for FMS regardless of age.

Most of the participants in the study were married (57.6%). This is similar to two local studies done where the majority of the participants were married (6,8). In a study on the prevalence of FMS in Kansas, majority, 53% of the participants. were married (5). Previously FMS was thought to be more common in the single, divorced, or widowed due to psychosocial stressors but recent studies including our study show that it is more common even in the married who are perceived to be more stable psychosocially.

Most of the study participants had a tertiary level of education (76.3%). Other local studies done on FMS had not looked at the level of education. The result could be biased since most of the patients attending private clinics are from a higher social-economic status.

FMS is not a diagnosis of exclusion and can occur even in the presence of comorbidities. It plays a unique contribution to the overall burden of co-existing illnesses and treatment of each disorder contributes to the overall outcome. Hypertension was the most common co-existing illness among the participants at 17.9%. A local study did recognize hypertension as the most common comorbidity at 53.5% (6). A study done in Spain found hypertension as the most common comorbidity among FMS participants (12).

The degree of severity of FMS was assessed using the FIQR questionnaire. The majority of the study participants had mild disease severity (39%) followed by moderate disease severity (25.4%). The median FIQR score among the study participants was 50 in keeping with moderate disease severity. However, the assessment of disease severity is likely to be affected by interventions as the participants enrolled had been previously diagnosed to have FMS and were on follow-up. In a local study done on the prevalence of FMS, the average FIQR score was 55.9 implying moderate disease activity (6). In a study done in the USA, while validating the FIQR score, the average FIQR score was 56.58 implying moderate disease severity (9).

The HRQOL was assessed using the SF 36 tool. Understanding the degree of impact chronic illnesses have on the different domains of HRQOL whether physical, mental, or social functioning helps better defining the treatment strategies. The SF 36 encompasses both physical and mental health components. FMS patients are reported to have a lower HRQOL than most chronic illnesses. It also

tends to have an impact on other domains apart from the physical domains, unlike other chronic illnesses. Social factors such as depression, anxiety, fatigue play a big role in the pathogenesis of FMS.

In the study, the greatest impact was on the physical and emotional role limitation whereas the least impact was on social functioning. This is similar to a study among Brazilian women where the highest impact was on physical role limitation and the least impact was on social functioning (11). This was also found in a Turkish study where the highest impact was on physical and emotional role limitation subscales and the least impact was on the social functioning subscale (18). This demonstrates that although FMS is a chronic musculoskeletal pain disorder, the results emphasize the functional impairment as a result of the disease.

The study demonstrated a negative correlation between FMS disease severity and HRQOL. This was statistically significant in all the SF-36 subscales. Verbunt *et al* (14) demonstrated that there was a statistically significant negative correlation between FMS and disability measured by the FIQ score and SF-36 subscales apart from the energy subscale. Birtane *et al* (18) demonstrated that physical functioning, physical role limitation, and pain subscales had a statistically significant negative correlation with the overall FIQ score. Martinez *et al* (11) demonstrated a statistically significant impact on FMS on all subscales of the SF-36 compared to a healthy control group. Tander *et al* (13) demonstrated a negative correlation between the total FIQR score and the social functioning and energy subscales of the SF-36.

Multivariate logistic regression was performed and adjustment for other independent variables including age, gender, level of education, and presence of other psychiatric illnesses was done. A negative association was demonstrated between disease severity and HRQOL that was statistically significant ($p<0.05$) in all the 8 domains of the SF-36.

This means that management strategies should focus on enhancing all aspects of HRQOL and not only symptom management. Measures to raise awareness of FMS by medical personnel should be enhanced and not ignored as it has a significant impact on the HRQOL. Reduced HRQOL means less productivity by FMS patients that has a major influence on the economy. Misdiagnosis and poor management of FMS patients mean maladaptive health-seeking behavior by the patients which leads to a significant waste of health care resources.

Conclusions and recommendations

The study found a negative correlation between FMS disease severity and HRQOL. The impact was significant on most aspects of HRQOL. The strongest impact on HRQOL was on physical and emotional role limitation which results in significant functional impairment. There should be both pharmacological management approaches to manage pain and non-pharmacological strategies to address psychosocial needs including psychotherapy and exercise. Assessment of all aspects of the disease should be done during hospital visits from physical, psychosocial, emotional, and coping strategies.

Limitations: The study participants were recruited from a private tertiary facility and are generally from a higher socio-economic status which could influence the study results in terms of socio-demographic characteristics and severity of the disease. The inclusion of a control group would have given a better overall impact of the disease on HRQOL. The data was all self-reported and no objective clinical tool is available to assess disease severity. The inclusion of those with comorbidities is a confounding factor in the study. The inclusion of participants who could be receiving interventions could skew the study results on disease severity.

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Original paper

The Burden of Fibromyalgia in End-Stage Kidney Disease Patients Undergoing Maintenance Haemodialysis – A Multicentre Study

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Abstract

Background: Fibromyalgia (FMS) is a disease seen in rheumatology and is getting increasingly acknowledged. It presents with chronic widespread pain and specific tender points on clinical examination. The cause is unknown but its aetiopathogenesis is multifactorial. It has several associated symptoms which include fatigue, sleep disorders and depression. These symptoms may remarkably affect the Quality of Life (QoL) of affected individuals. The burden of Chronic Kidney Disease (CKD) is increasing in our set up due to an increase in Non-Communicable Diseases (NCDs) such as diabetes and hypertension. The prevalence of fibromyalgia in End Stage Kidney Disease (ESKD) patients undergoing maintenance haemodialysis (HD) in our setting is not known**.**

Objective: The aim of this study was to determine the burden of fibromyalgia in patients with end stage kidney disease patients undergoing maintenance haemodialysis.

Design: This was a multicenter cross-sectional study that was done at the renal units in Kenyatta National Hospital (KNH), Nairobi Hospital (NH) and the Parkland's Kidney Center (PKC).

Methods: The study participants were adults undergoing maintenance haemodialysis and a total of 167 patients were studied. Proportionate random sampling was done to recruit patients from each centre. A written informed consent was obtained. A study proforma that included demographic and clinical details was administered to patients coming in for maintenance haemodialysis. Fibromyalgia was diagnosed using the 1990 American College of Rheumatology criteria. The revised Fibromyalgia Impact Questionnaire (FIQR) was administered to the group of patients with fibromyalgia to evaluate severity of the disease. QoL was determined by administering the 36-item short form health survey. Data from the study proforma were assigned unique codes. After data cleaning and validation, data was analysed using SPSS version 25.0 with the help of a statistician. Categorical data such as gender, marital status and level of education are summarized into proportions. Continuous variables such as age, duration of dialysis in months and frequency of dialysis per week are summarized into means, medians and standard deviations. The prevalence of fibromyalgia is presented as a percentage in each center. The severity of fibromyalgia is presented as a proportion in each class (mild, moderate and severe). The QoL is expressed as a proportion of those with poor quality of life (an average score of less than 50%) in individuals with ESKD undergoing maintenance haemodialysis. Statistical differences between QoL in patients with FMS and without FMS was analysed using the Student t-test. Logistic regression analysis was applied to estimate the probability of being in good health. A P value of ≤ 0.05 was considered significant for all statistical tests.

Results: A total of 167 patients were recruited into the study. The prevalence of fibromyalgia in ESKD patients undergoing haemodialysis in the three centres was 30 (18.0%). The mean age of these patients was 53.8 with a female preponderance of 20 (66.7%). The median duration of dialysis was 22 months, and patients with fibromyalgia had dialysed 12 months longer than those without fibromyalgia. Majority of our study patients had hypertension and diabetes mellitus as the underlying aetiology for development of ESKD. There was however no relation between fibromyalgia and underlying aetiology or number of dialysis sessions per week. The mean FIQR score was 50.3. Majority of patients found to have fibromyalgia had moderate severity of symptoms. The patients found to have fibromyalgia were six times more likely to have a poorer quality of life than those without fibromyalgia and this was statistically significant ($p<0.001$).

Conclusion: The prevalence of FMS in ESKD patients undergoing HD was 18%, which was higher than that of the general population. The mean severity score of FMS was 50.3. Most patients were females. No difference between those with FMS and those without FMS was observed regarding age, marital status, level of education or frequency of weekly HD. Duration of dialysis was associated with higher incidence of FM. FMS was associated with worse quality of life in HD patients.

Key words: Fibromyalgia (FMS), End-Stage Kidney Disease (ESKD), Haemodialysis (HD), Quality of life (QoL)

Introduction

Fibromyalgia is a disorder encountered in rheumatology that presents with chronic general pain and increased sensitivity to pressure. The pain is typically accompanied by other Central Nervous System (CNS) symptoms that include fatigue, anxiety, headache and sleep disorders, in which all causes have been excluded. These factors have substantial effects on the QoL of affected individuals. Clinical exam coincides with enhanced tenderness at tendon and muscle insertion sites, known as tender points (1).

Fibromyalgia (FMS) was previously known as "fibrositis", a term developed in 1904 by Sir William Gowers on the assumption that the muscular pain was inflammatory in nature (2). He also closely related the pain with associated features that include sleep disorders and fatigue. This assumption was later disputed and Dr P.K Hench came up with the term Fibromyalgia in 1976, and it remains in use to date (3).

In 1990, a criterion for diagnosing of FMS was developed by the American College of Rheumatology (ACR) (4) based on a modification of a 1977 description by Smythe and Moldofsky (5). FMS is a condition with clearly defined clinical entities but whose aetiology is unknown. It has several underlying pathophysiological mechanisms. FMS has a preponderance to affect females more than males and tends to affect the older population more than younger individuals (6). FMS has a relapsing and remitting pattern of disease, with an increase in prevalence with increasing age.

Fibromyalgia is hypothesized to be an interplay of hereditary and environmental factors. Postulated environmental triggers are infectious agents such as Human Immunodeficiency Virus (HIV), Lyme's disease and Hepatitis C virus (7). Studies have shown that the Central Nervous System (CNS) mediates an increase in sensory input in fibromyalgia, and this is noted to be linked to central sensitization (8).

The burden of End Stage Kidney Disease (ESKD) in our set up is high with most of these patients being subjected to long-term haemodialysis (HD). It is approximated that more than 750 million people world-wide are affected by kidney disease (9), and over 2 million people are on haemodialysis for ESRD (10).

Musculoskeletal (MS) disorders have been shown to be incessant disorders of renal disease, are multifactorial and a lot of findings suggest the risk of these disorders intensify with duration on haemodialysis (11). These musculoskeletal disorders are more common in patients on chronic HD and negatively impact on QoL. They include spondyloarthropathies, amyloid deposition and osteonecrosis (12).

Pain is the commonest complaint reported by ESKD patients on HD and there is paucity of data on specific causes including FMS (13). This can be distressing to patients and it requires that adequate assessment and management of the pain is done if successful therapy is to be achieved.

The overall prevalence of FMS in the general population is 2-14% (6,13), while data in our local set-up has shown that the overall prevalence is 1% (14). Studies in the past in United States of America, Turkey, Iran, Brazil and Egypt have shown 3.9%–51% prevalence in haemodialysis patients (15-20,21). In the Brazil study done by Couto *et al* (18), where a total of 311 patients were studied, the prevalence of fibromyalgia was noted to be 3.9% and its presence contributed to a worse quality of life.

Prevalence of FMS in chronic HD patients in our set-up is unknown. The CWP and associated fatigue sleep issues and anxiety seen in FMS remarkably affects the quality of life of those with FMS. It is thus very crucial to identify FMS in this subset of patients with a goal of improving overall holistic management.

Materials and methods

This was a cross sectional study involving 167 patients aged 18 years and above on maintenance haemodialysis at the renal units of The Nairobi Hospital (NH), Kenyatta National Hospital (KNH) and Parklands Kidney Centre (PKC). The study was carried out from January 2021 to March 2021. Proportionate random sampling was used to recruit patients who met the inclusion criteria. These included patients of both sexes, above 18 years of age on maintenance haemodialysis for more than 3 months. Written informed consent were obtained from all the participants in the study. Patients were recruited daily by the principal investigator and two research assistants who are trained clinicians.

Data on the demographic variables including age, sex, presence of other comorbidities such as, human immunodeficiency virus, hepatitis B, type 2 diabetes mellitus, systemic lupus erythematosus and rheumatoid arthritis, duration of dialysis in months, and the frequency of dialysis each week.

The principal investigator (JJY) was responsible for making the diagnosis of FMS in all patients undergoing HD and evaluation of tender points using the 1990 American College of Rheumatology diagnostic criteria, after training by a consultant rheumatologist. A focused physical exam was done to demonstrate the number of tender points. A sum of 18 fixed points was examined for tenderness by digital palpation. Enough force to cause blanching of examiner's finger was applied at each point, approximately 4kgs.

The main outcomes of the study were the presence or absence of fibromyalgia, the severity of fibromyalgia in patients diagnosed to have FMS, based on the revised fibromyalgia impact questionnaire and the

QoL in HD patients with and without FMS determined by the short form health survey questionnaire. The independent variables included: age (years), sex (male or female), education levels, completed years since initiation of dialysis and number of dialysis sessions in a week. The clinical variables included hypertension (definition based on the JNC 7 classification as either being on treatment or a systolic/diastolic blood pressure of ≥ 140/90 mmHg), diabetes (self-reported, and use of anti-diabetic drugs), lupus nephritis (diagnosed on kidney biopsy) and HIV-associated nephropathy.

SPSS version 25.0 was used to analyse cleaned data. Categorical data such as gender, marital status and level of education was summarized into proportions. Continuous variables such as age, duration of dialysis in months and frequency of dialysis per week were summarized into means, medians and standard deviations.

The prevalence of fibromyalgia was presented as a percentage in each center. The severity of FMS was analysed using ordinal regression analysis and presented as a proportion in each class (mild, moderate, severe and very severe). QoL was expressed as a proportion of those with poor quality of life (an average score of less than 50%) in individuals with ESKD undergoing maintenance haemodialysis. Statistical differences between QoL in patients with FMS and without FMS were evaluated using the Student t-test. Logistic regression analysis was applied to estimate the probability of being in good health. A P value of ≤0.05 was considered significant for all statistical tests.

The study was approved by the Ethics and Research Committee of The Nairobi Hospital, The Kenyatta National Hospital and University of Nairobi.

Results

Respondent characteristics: One hundred and ninety-two patients were screened for eligibility. We excluded twenty five who did not meet the study criteria leaving us with 167 patients. The mean age of those enrolled was 53.8 years (SD 17.9) with a range of 18-95 years. There were 88 (52.7%) males with a male to female ratio of 1:0.9. A total of 141 (84.4%) study participants had post primary education. One hundred and nineteen (71.3%) participants were married (Table 1).

Table 1: Respondents characteristics

Variable	All Frequency (%) n=167	KNH Frequency (%) n=65	TNH Frequency (%) n=59	PKC Frequency (%) n=43
Age in years				
Mean (SD)	53.8 (17.9)	46.3 (15.4)	56.2 (16.7)	1.6 (18.2)
Median (IQR)	53.0 (39.5-68.0)	44.0 (32.0-56.5)	51.5(36.8-61.4)	64.5(53.2-76.7)
Min - Max	18 - 95	18 - 76	19 - 95	42 - 93
Age groups (years)				
<20	3 (1.8%)	2 (3.1%)	1 (1.7%)	-
20 – 30	14 (8.4%)	6 (9.2%)	6 (10.2%)	2 (4.7%)
31 – 40	29 (17.4%)	22 (33.8%)	5 (8.5%)	2 (4.7%)
41 – 50	28 (16.7%)	12 (18.5%)	10 (17.0%)	6 (14.0%)
51 – 60	29 (17.4%)	13 (20.0%)	14 (23.7%)	2 (4.7%)
61 – 70	27 (16.2%)	8 (12.3%)	10 (17.0%)	9 (20.9%)
>70	37 (22.1%)	2 (3.1%)	13 (22.0%)	22 (51.1%)
Gender				
Male	87 (52.1%)	42 (64.6%)	23 (39.0%)	22 (51.2%)
Female	80 (47.9%)	23 (35.3%)	36 (61.0%)	21 (48.8%)
Marital status				
Single-unmarried	28 (16.7%)	16 (24.6%)	11 (18.6%)	1 (2.3%)
Separated/Divorced	7 (4.2%)	4 (6.2%)	1 (1.7%)	2 (4.7%)
Married	119 (71.3%)	45 (69.2%)	42 (71.2%)	32 (74.4%)
Widowed	13 (7.8%)	-	5 (8.5%)	8 (18.6%)
Education level				
None	2 (1.2%)	-	1 (1.7%)	1 (2.3%)
Primary	24 (14.4%)	19 (29.2%)	1 (1.7%)	4 (9.3%)
Secondary	62 (37.1%)	30 (46.1%)	16 (27.1%)	16 (37.2%)
Tertiary	79 (47.3%)	16 (24.6%)	41 (69.5%)	22 (51.1%)

SD: Standard Deviation

Clinical characteristics: The underlying aetiology for ESKD, 89 (55.7%) had hypertension only, 4 (2.4%) had diabetes only, 60 (35.9%) had coexisting diabetes and hypertension, 4 (2.4%) had lupus nephritis, 1 had HIV-associated nephropathy, while 9 (5.4%) had no aetiology established. The duration on dialysis, 46 (27.5%) had dialysed for less than one year, 111 (66.5%) had dialysed for between one and five years, 8 (4.8%) had dialysed for between five and ten years and 2 (1.2%) had dialysed for more than ten years. The frequency of dialysis per week, 134 (80.2%) were undergoing dialysis twice a week and 33 (19.8%) were undergoing dialysis thrice a week (Table 2).

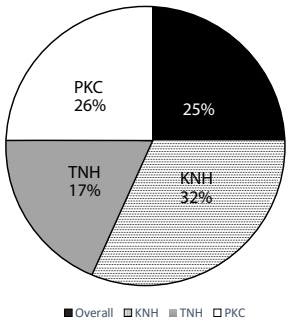
Table 2: Clinical characteristics

Aetiology	All frequency (%) n=167
Hypertension (essential)	89 (53.3%)
Diabetes mellitus	4 (2.4%)
Hypertension and diabetes	60 (35.9%)
Lupus nephritis	4 (2.4%)
HIV-associated nephropathy	1 (0.6%)
None	9 (5.4%)
Duration on dialysis in years	
<1	46 (27.5%)
1-5	111 (66.5%)
6-10	8 (4.8%)
>10	2 (1.2%)
Frequency of dialysis per week	
2	134 (80.2%)
3	33 (19.8%)

NB: The group with hypertension as an aetiology may include a number of patients with hypertension due to chronic glomerulonephritis

Prevalence of fibromyalgia in ESRD patients on haemodialysis: The prevalence of fibromyalgia in patients with end-stage renal disease on maintenance haemodialysis was 18.0% (95% CI 12.9 – 24.5). The diagnosis of fibromyalgia was made as having 11 out of 18 tender points by digital palpation and this was based on the 1990 ACR criteria. Thirty patients of the 167 were diagnosed to have fibromyalgia, and are not known to have been previously diagnosed with fibromyalgia. The prevalence of fibromyalgia by center was Kenyatta National Hospital 23.1% (95% CI 14.5 – 34.6), Parkland's Kidney Center 18.6% (95% CI 9.7 – 32.6) and Nairobi Hospital 11.9% (95% CI 5.9 – 22.5). The difference in prevalence between the three centres was not statistically significant (p=0.264). (Figure 1).

Figure 1: Prevalence



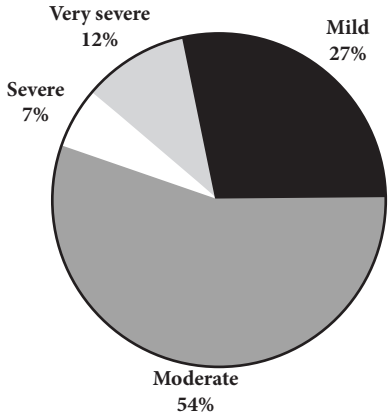
Severity of fibromyalgia among ESRD patients: The mean tender FIQR score for the thirty patients with fibromyalgia was 50.3 (SD 16.3), with the median being 47.8 (IQR 44.6-62.4). Among 30 study subjects with fibromyalgia, 7 (23.3%) had mild symptoms, 14 (46.7%) had moderate symptoms, 6 (20.0%) had severe symptoms, and 3 (10.0%) had very severe symptoms (Table 3).

Table 3: Severity of fibromyalgia

	Frequency (%)	Median (IQR)
Mild (0-42)	7 (23.3%)	28.5 (23.1 – 32.0)
Moderate (43-59)	14 (46.7%)	47.6 (46.0 – 52.0)
Severe (60-74))	6 (20.0%)	63.5 (62.4 – 66.0)
Very severe (75-100)	3 (10.0%)	76.2 (75.6 – 76.9)

*Chi-square test of association; † Fishers test; IQR; Inter-quartile range

Figure 2: Percentage distribution of the patients with fibromyalgia according to the severity in the study subjects



Factors associated with fibromyalgia in ESRD patients on haemodialysis: There was no statistical significance between the socio-demographic and clinical characteristics of the study subjects with and without fibromyalgia except for gender and duration of dialysis. Those with fibromyalgia had a median of 30 (IQR 36.0) months duration of dialysis while those

without had 18.0 (IQR 27.0) months, a difference of 12 months, which was statistically significant (p=0.040). Females were two times more likely to be affected more than males, and this showed statistical significance (OR, 2.6: 95% CI,1.1-5.9). There was no statistically significant association between underlying aetiologies and fibromyalgia (p=0.083) (Table 4).

Table 4: Associations between respondents' characteristics and prevalence of fibromyalgia

Variable	All n=167 frequency (%)	Patients with Fibromyalgia n=30 frequency (%)	Patients without Fibromyalgia n= 137 frequency (%)	OR (95% CI)	*P value
Age strata					
Mean (SD)	53.8 (17.9)	55.7 (18.4)	62.9 (17.6)	0.8 (0.2-3.4)	0.357
Median (IQR)	53.0 (39.5-68.0)	54.2(38.6-72.1)	60.5(47.5-73.0)	0.2 (0.1-2.2)	0.298
<20	3 (1.8%)	0 (0.0)	3 (2.2)	-	-
20 – 30	14 (8.4%)	1 (3.3)	13 (9.5)	0.2 (0.03-2.1)	0.239
31 – 40	29 (17.4%)	4 (13.2)	25 (18.2)	0.5 (0.1-1.8)	0.291
41 – 50	28 (16.8%)	7 (23.3)	21 (15.3)	1.2 (0.4-3.8)	0.700
51 – 60	29 (17.4%)	2 (6.7)	27 (19.7)	0.2 (0.05-1.2)	0.076
61 – 70	27 (16.2%)	7 (23.3)	20 (14.6)	0.9 (0.3-2.9)	0.845
>70	37 (22.2%)	9 (30.0)	28 (20.4)	1.0	
Sex					
Male	87 (52.1%)	10 (33.3)	77 (56.2)	1.0	
Female	80 (47.9%)	20 (66.7)	60 (43.8)	2.6 (1.1-5.9)	**0.023**
Aetiology					
Hypertension	89 (53.3%)	12 (40.0)	77 (56.2)	1.0	
Diabetes mellitus	4 (2.4%)	2 (6.7)	2 (1.5)	6.4 (0.8-50.0)	0.076
Hypertension and diabetes	60 (35.9%)	13 (43.4)	47 (34.3)	1.8 (0.7-4.2)	0.193
Lupus nephritis	4 (2.4%)	1 (3.3)	3 (2.2)	2.1 (0.2-22.2)	0.525
HIV-associated nephropathy	1 (0.6%)	1 (3.3)	0 (0.0)	-	-
None	9(5.4)	1(3.3)	8(5.8)	0.8(0.1-7.0)	0.842
Median duration of haemodialysis in months (IQR)	22.0 (10.0-36.0)	30.0 (16.0-48.0)	18.0 (9.0-36.0)	2.3 (1.02-5.4)	**0.040**
Median weekly haemodialysis (IQR)	2.0 (2.0-2.0)	2.0 (2.0-2.0)	2.0 (2.0-2.0)	0.8 (0.3-2.2)	0.638

*Chi-square test of association; † Fishers test OR: Odds Ratio CI: Confidence interval IQR: Inter-quartile range

Quality of life in patients with end-stage kidney disease undergoing maintenance haemodialysis: The average quality of life scores of the 167 patients was 82.2 (SD 20.4). Among the 167 study participants, 95 (56.9%) had scores more than 60, 44 (26.3%) had scores between 40-60 and 28 (16.8%) had scores of less than 40.

Forty four had a poor quality of life (26.3%). Among the 30 study patients with fibromyalgia, 18 (60.0%) had a poor quality of life. Patients with fibromyalgia were six times more presumably to have a poor quality of life as compared to those without the syndrome, and this was statistically significant (Odds ratio, 6.4; 95% CI, 2.7 to 14.9; p<0.001) (Table 5).

Table 5: Quality of life in patients with and without fibromyalgia

Fibromyalgia	Quality of Life		Odds Ratio (95% CI)	*P-value
	Poor	Good		
Yes	18 (60.0)	12 (40.0)	6.4 (2.7 – 14.9)	<0.001
No	26 (19.0)	111 (81.0)		

*Student t-test OR: Odds Ratio CI: Confidence interval

Discussion

In this study we evaluated the association between end stage kidney disease, fibromyalgia and quality of life. Rheumatologic conditions are common in chronic kidney disease patients, and majority of haemodialysis patients are affected by various types of musculoskeletal disorders, including but not limited to fibromyalgia (21). This study has provided further insights into the prevalence of fibromyalgia in patients on dialysis in our set-up. Our study established the prevalence of fibromyalgia among CKD patients on maintenance haemodialysis to be 18%, and it seems to be higher than other similar studies done ranging from 3.9%-12.2% (15,16,20). A study done by Yuceturk *et al* (15) in the USA noted the prevalence of fibromyalgia in CKD patients to be 7.4%, a study carried out in Iran by Samimagham *et al* (16) noted the prevalence to be 12.2%, and another study done in Turkey by Berber *et al* (20) found the prevalence to be 15.9%. These differences could be due to the contrast in population. Our study was largely carried out among black Africans, whilst the previous studies were carried out among a largely Caucasian population in the American study, and an Arabic populace in the Iranian and Turkish studies. Wolfe *et al* (6) in a random sample of 3006 adults revealed FMS prevalence rates of 3.4% in women and 0.5% in men. In accord with the literature, we found that FMS was more frequent in females, with rates of 66.7% (20 out of 30) in women and 33.3% (10 out of 30) in men. Similarly, in a review article by Malombe and Oyoo (24) published in the *African Journal of Rheumatology*, where they sought to look at the epidemiology and gender-based differences of fibromyalgia in Africa, it was noted that fibromyalgia is prevalent in middle aged females with variabilities in disease presentation.

The above mentioned study by Wolfe *et al* (6) also established that incidence of FMS increases with age, and noted that the highest rates are seen in those aged 60 to 79 years. They found a 2% prevalence rate of FMS in individuals aged 30–39 years, whereas the rate in the group aged 70–79 years was 7.4%. In accordance with literature, most of the patients with FMS (16 of the 30) in our study were older than 60 years of age. The mean age of the thirty HD patients with definite FMS was not significantly different from that of the one hundred and thirty-seven HD patients without fibromyalgia (P = 0.35). From our study, there was no statistical correlation between incidence of FMS and marital status, educational background, underlying aetiology or number of dialysis sessions in a week.

Rheumatic disorders are usual in renal disease, and data indicates that the risk of such complications increases with time on HD (21). Most other studies did not find a correlation linking duration of dialysis and incidence of fibromyalgia (15,16,18,20). As detailed above, in our study, a positive correlation linking duration of dialysis and rates of FMS was established. Subjects with FMS had dialysed for a median of 12 months longer and this was statistically significant (P=0.04).

Our study established that the largest number of our patients had moderate severity of fibromyalgia with a mean of 50.3 (SD 16.3). In the Iranian study by Samimagham *et al.* (16) majority of patients had mild severity of fibromyalgia with a mean of 39.05 (SD 23.35). This was lower in comparison to our set up. The variabilities in proportions could be due to differences in clinical characteristics such as mean duration of dialysis. In the Iranian study group, mean period of dialysis was established to be 27.9 (SD 57.1) (16), while our mean was 34 (SD 55.7). The incidence and severity of fibromyalgia is known to increase with duration on dialysis (19,21) which could be a reason for the higher severity in our set up is higher.

In Turkey, Koca *et al.* (19) established that a large number of patients had severe fibromyalgia with a mean FIQR score of 66.2 (SD 15.01). This difference could be elucidated by variations in the age. In the Turkish study, the mean age was higher at 59.5(SD 13.1), while ours had a mean of 53.8 (SD 17.1), and from studies incidence and severity of fibromyalgia is known to increase with age (6). Similarly, as mentioned above, prolonged period of dialysis predisposes to increased severity of FMS (21). For this study, only 6% of patients had dialysed longer than 5 years, while in the study by Koca *et al.* (19) 48.6% of patients had dialysed for longer than 5 years.

In comparison to local data, a similar prevalence study by Malombe *et al*. (22), found the prevalence of fibromyalgia in HIV patients to be 17.9%, and this was similar to the prevalence in our study. In yet another local prevalence study done by Dokwe *et al.* (14) in the medical outpatient clinics, the prevalence of fibromyalgia was found to be 13%. A study carried out by Umar *et al.* (23) at the diabetic outpatient clinics in

KNH found the prevalence to be 27.9%. It is noted in our study, that diabetes contributed to the largest group of patients with CKD, with the percentage of diabetics with fibromyalgia being 15.6%. This difference in prevalence could be explained by different study approaches and differences in age. The study by Umar *et al*. (23) correlated haemoglobin A1c (HbA1c) to the incidence of FMS, which our study did not as this was beyond the scope of our study. The mean age of patients in our study was 53.8 years, which was less than the study by Umar *et al.* (23) whose mean age was 59.9 years.

Poor QoL was present in 26.3% of patients with ESKD on maintenance haemodialysis. In a study done in Nepal, it was reported that 80% of study participants had a poor QoL, which is greater than our study, this could be explained by use of different tools. The Nepal study uses the World Health Organization Quality of Life questionnaire while we used the SF-36 Health survey questionnaire (25). In a study by Kamau. *et al,* (26) it was also established that patients on haemodialysis had a poor QoL with reported lower mean physical composite summary and mental composite summary scores.

A strong association between fibromyalgia and quality of life was noted in this study. It was established that FMS negatively affected quality of life in patients with ESKD on HD as compared to those without FMS (OR 6.4 (95% CI; 2.7 – 14.9)), and this was statistically significant [P <0.005]. Our study established that higher FIQR scores were linked to worse QoL. This is in line with findings in other studies, exemplified by a study done by Couto *et al.* (18) who established that patients with fibromyalgia on maintenance haemodialysis had worse quality of life than their counterparts without fibromyalgia.

Similarly, in a study by Samimagham *et al.* (16) carried out in Iran, fibromyalgia in patients on haemodialysis was strongly associated with sleep interferences and depression even after adjustment for age, sex and period of dialysis. These patients had higher FIQR scores and worse quality of life.

A study done by Yuceturk *et al.* (15) reported that fibromyalgia in ESKD patients on HD had a remarkable association with poorer health related QoL. This study also established that females with higher FIQR scores were predisposed to worse QoL.

Conclusion

The prevalence of FMS in ESKD patients undergoing HD was 18%, which was higher than that of the general population. The mean severity score of FMS was 50.3. Most patients were females. No difference between those with FMS and those without FMS was observed regarding age, marital status, level of education or frequency of weekly HD. Duration of dialysis was associated with higher incidence of FMS. FMS was associated with worse quality of life in HD patients.

Acknowledgements

The principal investigator (JJY) would like to appreciate his supervisors and the entire Department of Clinical Medicine and Therapeutics, University of Nairobi, all the staff at the Nairobi Hospital, Kenyatta National Hospital, Parklands Kidney Centre renal units and my statistician Mr. Wycliffe Ayieko for all their assistance during this entire study and all the patients who accepted to participate in the study.

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Original paper

The Burden of Depression among Patients with End Stage Renal Disease undergoing Haemodialysis at Kenyatta National Hospital, Nairobi Hospital, and Parklands Kidney Center, Nairobi, Kenya

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Abstract

Background: Depression is the commonest psychological disorder in End Stage Renal Disease (ESRD). The presence of depression has been linked with high rates of morbidity and mortality, as well as having an impact on the quality of life. Early diagnosis and treatment of depression in chronic kidney disease improves disease outcome.

Objectives: The main objective of this study was to determine the prevalence of depression in end stage renal disease patients undergoing maintenance haemodialysis at the Kenyatta National Hospital (KNH), Nairobi Hospital (NH), and Parklands Kidney Centre (PKC).

Design: This was a cross sectional descriptive study carried out over a period of two months.

Methods: The study population comprised of adults aged 18 years and above undergoing maintenance haemodialysis. Informed consent was sought from all the participants. A study pro forma was used to collect socio-demographic data. The Patient Health Questionnaire 9 (PHQ - 9) was used to establish presence and severity of depression among participants. The multidimensional scale of perceived social support was used to assess the level of social support among the study participants.

Data management and analysis: The prevalence of depression was calculated as a proportion of patients with any degree of depression and expressed as a percentage. The chi- square test was used to determine the association between presence of depression, and selected social demographic determinants. Analysis was done using SPSS version 21.0 Chicago Illinois.

Results: A total of 170 patients were recruited with a mean age of 56.44 ±13.5 years and a sex ratio (M: F) of 1.2:1. The prevalence of depression was 32.4%, mild depression 24.14%, moderate 7.06% and severe 1.17%. High social support was present for 74.12% of subjects who participated, while 23.53% and 2.35% had moderate and low social support respectively. Age (18 - 29 years, $p = 0.005$), lack of any formal education ($p = 0.048$), retirement from formal employment ($p = 0.036$) and lack of social support ($p = 0.001$) were significantly associated with depression.

Conclusion: A substantial proportion of subjects undergoing haemodialysis have concomitant depression with the majority having mild depression. Factors that increased the risk of depression were age, lack of formal education, retirement from formal employment and lack of social support. Carrying out of validated questionnaires to assess for the presence of depression in patients initiating haemodialysis may be helpful in early recognition and management. This would improve the quality of life and clinical outcomes in patients diagnosed with end stage renal disease undergoing haemodialysis.

Key words: Chronic Kidney Disease (CKD), Depression, End Stage Renal Disease (ESRD), Haemodialysis (HD), Patient Health Questionnaire – 9 (PHQ - 9), Multidimensional Scale of Perceived Social Support (MSPSS)

Introduction

End Stage Renal Disease (ESRD) represents the final stage in the spectrum of Chronic Kidney Disease (CKD); According to Kidney Disease Improving Global Outcomes (KDIGO) classification an estimated Glomerular Filtration Rate (eGFR) of < 15 ml/min/1.73 indicates ESRD (1). CKD involves the sustained gradual loss of the kidney's ability to perform its normal function, thus leading to the accumulation of metabolic waste normally excreted by the kidneys. The presence of ESRD therefore necessitates the need for Renal Replacement Therapy (RRT), to maintain life and improve the quality of life. The primary signs and symptoms of ESRD are as a result of metabolic or endocrine derangements or disturbance in water or electrolyte balance.

The estimated lifetime risk of developing depression in the general population is estimated to be between 5 – 10%, worldwide the prevalence of CKD is 10 – 15% (2-5). The rates of depression are up to three times higher than that seen in the general population for CKD/ESRD patients who are not undergoing HD. When this group of patients is compared to those who

are suffering from other chronic medical ailments the rates of depression are 2 - 3 times higher (2,6). The burden of CKD is envisaged to substantially grow owing to a worldwide pandemic of some of the aetiological factors associated with CKD e.g. Hypertension (HTN) and Diabetes Mellitus (DM). In Kenya the prevalence of DM is approximately 4.2%, (7) while that of hypertension is estimated to be 24.5% (18-69 years) (8). Therefore, with an increasing proportion of the population having risk factors for development of CKD, it is likely therefore that the number of patients requiring RRT in the near future is going to increase.

Depression is a mental disorder characterized by hopelessness, anhedonia, and a constant feeling of sadness for at least 2 weeks, according to the diagnostic and statistical manual of mental disorders (DSM – V). Other symptoms include significant weight loss, slowing down of thoughts, suicidal ideation, feeling of worthlessness, restlessness, insomnia, guilt and reduced concentration. Depression results from a complex interplay between social, biological, and psychological factors. The lifetime prevalence of depression is as high as 20% in the general population, with a female: male ratio of 1.7:1 (9). Globally approximately 350 million people are affected by depression, this has led to depression being the 4th leading cause of disability (10). Approximately 800,000 people diagnosed with depression commit suicide globally on an annual basis (10). A study carried out in the year 2002 in a rural district in Kenya showed the prevalence of depression to be approximately 6.1% (11).

The assessment of depression in patients with CKD is demanding, this is partly due to the fact that there is an overlap between the physical symptoms of uraemia and depression. Patients who have been diagnosed with ESRD show greater than five times the rate of developing depression, compared to the general population (12).

End stage renal disease/chronic kidney disease patients who are also depressed tend to be less motivated, have poor disability score and are less compliant to their treatment. The association between depression and mortality has been established in several studies. In a study published by Mapes *et al* (13) in 2004, the presence of depression was shown to have an independent association with increasing rates of mortality and hospitalization. Data compiled from 31 studies comprising of 67,000 patients on chronic maintenance HD, demonstrated a 50% increase risk of mortality with the existence of depressive symptoms (14). In CKD patients currently not on HD, the presence of depressive symptoms was associated with a higher rate of progression of CKD to ESRD (15).

Depression is associated with increasing rates of negative health behaviour such as a sedentary lifestyle, smoking and obesity which contribute to an increase in other lifestyle diseases in these patients i.e. DM and HTN. The interplay between depression and ESRD becomes a vicious cycle leading to high rates of health care utilization with increased economic cost. Depression remains largely under-diagnosed by health care providers in patients with ESRD undergoing HD thus leading to low quality of life and poor patient outcomes. Early diagnosis and intervention of depression can lead to less ESRD related morbidity and mortality.

There is no known local published data on prevalence of depression on this group of patients. The study aimed at filling in the gaps that currently exist in our set up by establishing the prevalence of depression and looking at selected determinants associated with depression among ESRD participants undergoing HD.

Materials and methods

Study design: This was a descriptive cross-sectional study.

Study sites: This study was carried out at the renal units of KNH, NH and PKC.

Study population: These were ambulatory adult patients with ESRD undergoing maintenance HD at the renal units in KNH, NH and PKC.

Inclusion criteria

(i) Patients aged 18 years and above who had ESRD and were undergoing maintenance HD.

Exclusion criteria

(i) Patients who did not give informed consent.
(ii) Patients who had any form of cognitive impairment.

Sampling method

Recruitment occurred between 0800 hours to 1800 hours every day of the week. The sampling frame was from all booked patients for HD in each of the three renal units. The principal investigator and trained medical research assistants perused the clinic booking register a day before the clinic and extracted the medical files. On the recruitment day the principal investigator and a trained medical research assistant approached each patient in order of their arrival time to the dialysis unit, each eligible patient was given an opportunity to take part in the study.

Data collection procedure

Patients who were on maintenance HD were invited to participate in the study. Those who met the inclusion criteria were given information about the study and asked to participate. Eligible patients who agreed to participate in the study were given the written informed consent to sign and consequently recruited to the study. A study pro forma filled in by the patient with the assistance of the PI/ research assistant was used to collect socio demographic and comorbidity data.

This information was then verified from the patients' medical file. The PHQ – 9 and MSPSS was administered in either English or Swahili depending on the participants' preference. Study participants with difficulty in completing the questionnaire were assisted by either the PI or research assistant. Once data had been collected, it was kept safely in a locker only accessible to the researcher.

Study variables

Dependent variable

(i) Depression

A patient with a PHQ – 9 score of 10 or more was described as having clinical depression. The severity of depression was graded as follows, depending on the PHQ – 9 scores: mild (10 – 14), moderate (15 – 19) and severe (20 – 27).

Independent variables

(i) *Age*: Described in years as at of the last birthday.
(ii) *Gender:* Described as either female/ male.
(iii) *Marital status:* This was categorized as either single, married, separated, divorced or widowed.
(iv) *Employment status:* The status of an economically active individual with respect to his/her employment. This was assessed by inquiring whether the activity one was involved in lead to a source of gainful income, or if one had retired from gainful employment that in turn had led to a decline in once source of income. It was categorized as either employed, non-employed or retired.
(v) *Level of education*: This was categorized as either having no formal education or having primary, secondary or tertiary.
(vi) *Duration of dialysis*: This was described in months/ years from the start of maintenance HD.
(vii) *Level of perceived social support:* This was graded as follows: a score 1 – 2.9 low support; 3-5 moderate support; 5.1 – 7.0 high support.
(viii) *Comorbidities:* This included a history of ever having been diagnosed with cerebrovascular accident, coronary artery disease, or peripheral arterial disease.
(ix) *Status within the family:* This concept referred to the position occupied within the family by each one of its members. It refers to the social status ascribed to each individual in the family based on individual's effort. This was assessed by inquiring who was the provider of the family or gave leadership on family matters. It was categorized as either head of the family, dependant and neither head of the family/ dependant.

Data management and analysis

All data from the study pro forma was verified by the principal investigator and coded. Data analysis was performed using the SPSS Chicago Illinois version 21. Study population was defined using socio-demographic and comorbid characteristics. Continuous variables were summarized as mean and standard deviation. Categorical variables e.g. age, sex, employment status, level of education were presented as proportions. The selected determinants associated with depression were analysed using chi – square tests. The statistical analysis was tested at 5% level of significance. A p value of less or equal to 0.05 was interpreted as significant. Results presentation was done using tables and figures where appropriate.

Results

One hundred and eighty five patients on maintenance HD were enrolled to take part in the study, 15 patients declined to give consent, while 4 patients were excluded due to cognitive impairment based on an expert opinion. A hundred and seventy patients were recruited into the study from KNH, NH, and PKC with a distribution of 70, 65 and 35 patients respectively.

Study population characteristics

A hundred and seventy participants participated in the study of whom 94 (55.3%) were males. The mean age of the respondents was 56.4 ±13.5 years, while the median age was 57.0 (IQR=19.0) years. Participants aged above 50 years accounted for 67.6%, while 72.9% were married, 32.4% were employed, a further 30% had retired from formal employment, 97.6% had attained primary, secondary or tertiary levels of education, indicating a high literacy level (Table 1).

Table 1: Participants socio demographic characteristics

Variable	Categories	Frequency	(%)
Age (years)	18 – 29	3	1.8
	30 - 39	14	8.2
	40 - 49	38	22.4
	50 - 59	43	25.3
	60 - 69	41	24.1
	≥ 70	31	18.2
Gender	Male	94	55.3
	Female	76	44.7
Marital status	Single	14	8.2
	Married	124	72.9
	Separated	3	1.8
	Divorced	6	3.5
	Widowed	23	13.5
Employment status	Employed	55	32.4
	Unemployed	64	37.6
	Retired	51	30.0
Level of education	None	4	2.4
	Primary	31	18.2
	Secondary	54	31.8
	Tertiary	81	47.6
History of alcohol use	Yes	90	52.9
	No	80	47.1
History of smoking/ tobacco use	Yes	47	27.6
	No	123	72.4
History of DM	Yes	71	41.8
	No	99	58.2
History of HTN	Yes	144	84.7
	No	26	15.3
Have you ever been diagnosed with MD	Yes	9	5.3
	No	161	94.7

Prevalence and severity of depression

Out of the study population 55 (32.4%) had clinical depression with a PHQ - 9 score =/> 10. Among these 41 (74%) had mild depression with a PHQ - 9 score of between 10 – 14, 12 (22%) had moderate depression with a score of between 15 – 19 while 2 (4%) had severe depression with a score of between 20 – 27. The mean age of those with depression was 53.0 ± 14.3 years, and the mean depression score was 12.5.

Figure 1: Prevalence of depression in ESRD participants undergoing maintenance haemodialysis

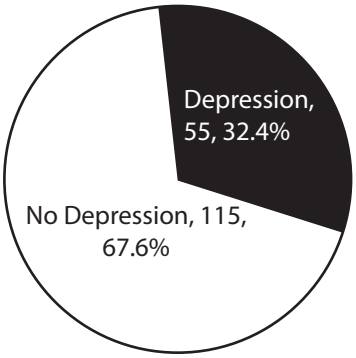
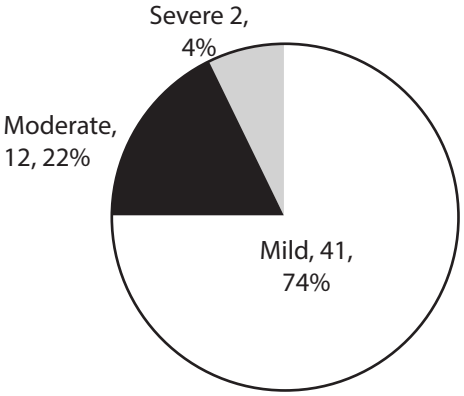


Figure 2: Severity of depression in ESRD participants undergoing maintenance haemodialysis



Factors associated with depression in participants undergoing haemodialysis

Table 2, highlights factors associated with depression among participants undergoing HD. Our study revealed an association of depression among participants who were in the age group between (18 – 29) years ($p<0.005$), retired ($p<0.036$), no form of formal education ($p<0.048$), low or moderate social support ($p<0.001$). However, this study failed to show any association of depression with marital status, duration of dialysis, comorbidities and status within the family.

Table 2: Selected determinants associated with depression in ESRD participant undergoing HD

Variable	Total	Depression	No depression	OR (95% CI)	P value
Age (years)					
18 - 29	3	3 (100.0)	0 (0.0)	-	0.005
30 - 39	14	7 (50.0)	7 (50.0)	3.4 (0.89 -13.04)	0.066
40 - 49	38	12 (31.6)	26 (68.4)	1.6 (0.54 -4.73)	0.405
50 - 59	43	15 (34.9)	28 (65.1)	1.8 (0.63 -5.14)	0.253
60 - 69	41	11 (26.8)	30 (73.2)	1.3 (0.44 -3.86)	0.680
≥ 70	31	7 (22.6)	24 (77.4)	Ref	
Gender					
Male	94	26 (27.7)	68 (72.3)	Ref	
Female	76	29 (38.2)	47 (61.8)	0.6 (0.3-1.2)	0.146
Marital status					
Single	14	7 (50.0)	7 (50.0)	Ref	
Divorced	6	0 (0.0)	6 (100.0)	-	1.000
Married	124	38 (30.6)	86 (69.4)	0.4 (0.1-1.3)	0.151
Widowed	23	8 (34.8)	15 (65.2)	0.5 (0.1-2.1)	0.363
Separated	3	2 (66.7)	1 (33.3)	2.0 (0.1-27.4)	0.604
Employment status					
Employed	55	21 (38.2)	34 (61.8)	Ref	
Not employed	64	24 (37.5)	40 (62.5)	1.0 (0.48 -2.10)	0.939
Retired	51	10 (19.6)	41 (80.4)	0.4 (0.17 -0.96)	0.036
Level of education					
None	4	3 (75.0)	1 (25.0)	7.6 (0.75 -76.89)	0.048
Primary	31	10 (32.3)	21 (67.7)	1.2 (0.49 -2.94)	0.688
Secondary	54	19 (35.2)	35 (64.8)	1.4 (0.67 -2.93)	0.404
College	81	23 (28.4)	58 (71.6)	Ref	
Duration of dialysis					
<6 months	23	10 (43.5)	13 (56.5)	Ref	
6 months – 1 year	44	17 (38.6)	27 (61.4)	0.8 (0.3-2.3)	0.701
1 year – 5 years	77	18 (23.4)	59 (76.6)	0.4 (0.1-1.1)	0.064
>5 years	26	10 (38.5)	16 (61.5)	0.8 (0.3-2.5)	0.722
Social support					
Low	4	4 (100.0)	0 (0.0)	-	0.001
Moderate	40	21 (52.5)	19 (47.5)	3.5 (1.66 -7.36)	0.001
High	126	30 (23.8)	96 (76.2)	Ref	
History of cardiovascular diseases (CAD, CVA, PAD)					
Yes	17	7 (41.2)	10 (58.8)	1.5 (0.54 -4.18)	0.412
No	153	48 (31.4)	105 (68.6)	Ref	
Status within the family					
Head of family	100	28 (28.0)	72 (72.0)	Ref	
Dependent	65	25 (38.5)	40 (61.5)	1.6 (0.82 -3.11)	0.160
Neither head of family/dependent	5	2 (40.0)	3 (60.0)	1.7 (0.27 -10.72)	0.562

Discussion

The study was designed to determine the burden of depression among ESRD patients undergoing maintenance HD at KNH, NH and PKC. This study determined the prevalence of depression among patients with ESRD undergoing HD to be 32.4% using the PHQ - 9 questionnaire. The distribution of these participants according to severity of depression was 3.6% severe, 21.8% moderate and 74.5% mild depression. There were 55.3% male participants, and the mean age of those with depression was 53.0 ± 14.3 years.

The overall prevalence in our study was similar to other studies worldwide. A study done in Nigeria by Amira (16), found a prevalence of 34.5% among patients undergoing HD using the Zung depression questionnaire. The mean age of those undergoing HD was 42.0 ± 15.0 years, no other socio-demographic categorization was done. A study done in Brooklynn USA by Cukor *et al* (17), found a 29% prevalence of depression among ESRD patients undergoing HD using the BDI screening tool. This study had 52.9% female, 88.6% black respondent, and a mean age 53.3 ± 15.0 years. A large observation study by Boulware and colleagues (18) assessed data from the choice

for healthy outcomes in caring for ESRD (CHOICE) study and found the prevalence of depression to be between 19 – 24%. A meta-analysis by Palmer *et al* (6), found a summary prevalence of 39% among ESRD undergoing HD. Despite the different tools used in all these studies, there was similarity in the prevalence of depression. This could be due to the tools used are consistent or that having the same underlying condition predisposes patients to similar disabilities and psychosocial stressors.

The prevalence of depression in this study was lower than that done by Islāmābād *et al* (19) which showed a prevalence of 76.1% using the HDRS screening tool. This study had 69.3% male participants and a mean age of 48.43 ± 12.69 years. A study done by Bhatti *et al* (20) showed a prevalence of 83.8% using the HDRS screening tool. This study had 51.96% male participants and a mean age of 46.83 ± 17.65 years. The large variability in prevalence could be as a result of the study criteria, methodology and the use of different screening tools to diagnose depression.

The severity spectrum in our study varies from other studies done worldwide. A study done by Islāmābād *et al* (19) found 31.8% had mild depression, 13.6% had moderate depression and 30.7% had severe depression using the HDRS screening tool. This study had 69.3% male participants and a mean age of 48.43 ± 12.69 years. A study by Nelson *et al* (21) showed 28.1% had mild depression, 39.7% had moderate depression and 15.7% had severe depression using the BDI screening tool. This study population had 78% male participants and the mean age of 52.89 ± 11.02 years. This difference could be as a result of the study criteria, methodology and the use of different screening tools to diagnose depression.

A study by Islāmābād *et al* (19), found no correlation between age and one developing depression. A study by Sanathan *et al* (22) found that older individuals have higher depression rates. A study by Fischer *et al* (23), found that younger patients experience more depressive symptoms than older patients. Our results are consistent with the latter findings, that young patients (18 – 29 years) are more likely to suffer from depression as compared to older patients.

Education status can be postulated in addition to undergoing HD to contribute to a patient suffering from depression. In India ESRD patients undergoing HD who had low levels of education were shown to exhibit more depressive symptoms, several other studies have shown this relationship (21,24). In our study the findings corroborate these findings and demonstrate that patients with no level of formal education were more likely to suffer from depression as compared to patients who had any form of formal education. This could be explained by the fact that lack of education makes one not follow instructions concerning their health i.e. poor dietary habits, lack of compliance to medication and poor health seeking behaviour.

The social economic status can be an important determinant of depression in patients undergoing HD, this in our study can be deduced from one's employment status. We know that ESRD brings a series of losses to the patient and requires some adaptation, including the difficulty of integration into the labour market, due to the physical condition caused by the disease and the dynamics of dialysis treatment. Other studies (23,25) reported a higher percentage of depressed patients among those who were unemployed and those without monthly income. In our study, there were more patients who were not involved in some productive economic activities, but no significant association was seen between this group of patients and development of depression. However, we observed a significant association between retirement and one developing depression. This could be explained by the loss of social links created during employment, decline in social status within the society after retirement, and a reduction in income. This aspect deserves to be better evaluated in future studies.

Turkish researchers carried out a study looking at the relationship between depression and perceived social support in ESRD patients undergoing HD. According to the study patients who had high social support were less likely to be diagnosed with depression (26). Many other studies carried out in different geographical locations and ethnic groups have established comparable results. Our results established that patients with high social support were less likely to develop depression as compared to those with moderate or low social support. Psychological issues in resource constrained setting are likely to be neglected especially in patients with ESRD undergoing HD. The knowledge that social support can have an impact on depression in patients undergoing HD presents an opportunity for early medical intervention. It would therefore be reasonable for the medical team involved in the care of this patients to recognise and stress upon the importance of social support. Physicians ought to identify patients with low social support, and offer alternative options (e.g. group therapy) to help improve the quality of life especially in patients on HD (27).

A study by Islāmābād *et al* (19), showed a relationship between gender and one developing depression in patients who were undergoing HD. In this study females were more likely to develop depression as compared to their male counterparts. Armaly *et al* (28), also demonstrated a similar pattern with females having more depression than males. The study we carried out showed no association between gender and depression.

Marital status can be an important predictor of depression in patients undergoing HD. A study done among HD patients showed being married conferred one with an even greater risk of developing depression (24). In contrast, a study done in India showed that participants who were single had more depressive symptoms than the rest of the participants (22). Our results do not demonstrate any association between one developing depression and their marital status. This variability may be explained by the fact that different cultures may have multiple sources of support and don't necessarily rely on the spouses.

Duration of dialysis has been researched as a determinant of depression in several studies and has shown conflicting results. A study, carried out in India by Sanathan *et al* (22) demonstrated that the first year after commencing HD was linked with a higher risk of developing depression. Our finding is in contrast to this studies, we did not establish any link between duration of dialysis and our participants developing depression. However, this link is still possible if screening of patients is done while commencing HD and then subsequently followed up over time.

A history of cardiovascular disease can be postulated in addition to undergoing HD to contribute to a patient suffering from depression, this can ultimately have an impact on once quality of life (23). Individually this medical conditions have been associated with one developing depression. Having multiple chronic illness is expected to put an undue socio economic burden on the patient. This multiplicity of issues could facilitate in the development of depression. However, this study did not demonstrate any significant association between having a history of cardiovascular disease and developing depression.

The status within a family set up of a patient diagnosed with ESRD undergoing HD may have an impact on one developing depression. This may be as a result of the financial implication involved in managing a chronic medical condition or self-reproach for not being able to meet the needs of the family, however our study failed to demonstrate any significant link with status within the family.

Despite the high incidence of depressive symptoms, only nine patients had ever been diagnosed with depression. This study highlights the extent of how under recognised depression is and hence the need for active screening for this disorder in ESRD patients undergoing HD. In our study about six patients who had ever been diagnosed with depression were ever put on treatment. A number of studies have looked at the use of antidepressant medication in patients diagnosed to have depression and undergoing HD and shown low levels of compliance among patients; approximately between 10% and 50% (23,29-31). The low uptake to treatment may be as a result of misdiagnosis of depression in ESRD, concern about drug toxicity in the setting of reduced kidney function as well as drug to drug interaction due to the high pill burden, drug side effects, patient non adherence to treatment, and treatment with non pharmacological treatments such as psychotherapy (31,32). Several studies indicate that treatment with antidepressant, Sertraline for 3 months, not only reduced the symptoms but also improved the quality of life (33).

This study has some implications on health care service delivery in our set up. First, this study shows that depression is a common and substantial mental health problem which is often not diagnosed in ESRD patients undergoing HD. Therefore, it's important to include screening as part of the essential health package before initiating HD. The study also creates a platform for further studies exploring the predictors and mitigating factors in depression among ESRD undergoing HD.

This study had several limitations, we relied on a history of cardiovascular disease to obtain this particular predictor of depression in relation to ESRD patients undergoing HD. The analysis of the selected predictors is not definitive because they lack the statistical power, and hence are only exploratory in nature.

Conclusion

A high percentage of patients undergoing HD suffer from depression. The vast majority of this patients have mild depression. This study highlights the extent of how under recognised depression is and perhaps suggests the need for active screening for this disorder. The quality of life and clinical outcomes in patients diagnosed with ESRD undergoing HD can be greatly improved by early diagnosis and treatment.

Recommendations

(i) We recommend routine screening of all ESRD patients for depression before commencement of HD using simple screening tools e.g. PHQ - 9 with appropriate referral.
(ii) There is need of involving a multidisciplinary team in management of ESRD patients on HD. This could include the primary physician, psychologist and psychiatrist.
(iii) There is need for research in areas revolving around mechanisms of depression and preventing and treating depression.

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Original paper

Thyroid Hormone Profile in Ambulatory Heart Failure Patients attending Adult Outpatient Clinic at Kenyatta National Hospital, Nairobi, Kenya

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Abstract

Background: Thyroid disorder affects 5–10% of the general population and can contribute to heart failure. Hypothyroidism leads to a decrease in the cardiac output by 30–50%. Heart failure affects approximately 23 to 37 million people worldwide. However, despite the known relationship between thyroid dysfunction and heart failure, there is still a paucity of evidence on the burden of thyroid dysfunction in heart failure and their association in the Kenyan population. Knowledge of the burden of thyroid dysfunction in heart failure is essential in guiding clinical decision making and improving outcomes in heart failure patients.

Objectives: To determine the prevalence of thyroid dysfunction and it's correlation with the severity of heart failure in ambulatory heart failure patients attending adult outpatient clinic at Kenyatta National Hospital, Nairobi, Kenya..

Design: A descriptive cross-sectional study design of ambulatory patients with heart failure attending the outpatient cardiac clinic at the Kenyatta National Hospital.

Methods: Ambulatory heart failure patients with a diagnostic label of heart failure based on Framingham's criteria were consecutively sampled. Patients with structural heart disease based on echocardiogram findings, on amiodarone, and those who declined consent were excluded from the study. The study included patients above 18 years. Chemiluminometric assay was used to measure free triiodothyronine, free thyroxine, and thyroid stimulating hormones levels using the Liaison test kits .Thyroid function was defined as either normal or abnormal based on thyroid function test at reference of: fT3 (2.2–4.2) pg/ml, fT4(0.8–1.7) ng/dl, TSH (0.3–3.6) Uiu/ml. The sample was characterised and overall prevalence, percentages, mean and standard deviation used. Association between severity of heart failure based on the New York Heart Association functional class, class 1 and 2 (early heart failure), class 3 (advanced heart failure) and thyroid dysfunction were assessed using Pearson's chi-square test.

Results: Three hundred and four patients were sampled, two declined consent and 302 were recruited into the study. Most of the heart failures were caused by Hypertensive Heart Disease (HHD) (53.3%) and Dilated Cardiomyopathy (DCM) (30.8%). Seventy six point two percent had heart failure in class I and II. The overall prevalence of thyroid dysfunction was 36.8% (95% CI: 31.5; 42.4). Of those with thyroid dysfunction 66.7% (95% CI: 57.1; 75.3) were women and 33.3% (95% CI: 24.7;42.9%) were men. Older adults had a higher prevalence of thyroid dysfunction with 49.6% (95% CI:39.9; 59.2) and 23% (95% CI: 15.9; 32.4) among those aged 65-79 years and 50-64 years respectively; 78.4% of patients with thyroid dysfunction were 50 years and above. Prevalence of thyroid dysfunction was 28.8% (95% CI: 20.6; 38.2), 41.4% (95% CI: 32.2; 51.2) and 29.7% (95% CI: 21.4; 39.1) for patients in heart failure class III, II and 1 respectively.

Subclinical hypothyroidism was 18.8%, (95% CI:14.6; 23.8), euthyroid sick syndrome was 9%, (95% CI: 6.0; 12.7) and primary hypothyroidism was 6%, (95% CI: 3.8; 9.7) were the most prevalent thyroid dysfunction subtypes. Secondary hyperthyroidism was 1.0%, (95% CI: 0.3; 3.1), subclinical hyperthyroidism was 1.0%, (95% CI:0.3; 3.1) , primary hyperthyroidism was 0.3%, (95% CI:0.1; 1.8) and free T3 toxicosis was 0.3%, (95% CI:0.1; 1.8) were the least subtypes of thyroid disorders. There was no significant association between thyroid dysfunction and severity of heart failure based on New York Heart Association functional class.

Conclusion: Prevalence of thyroid dysfunction in ambulatory heart failure patients is high. The most common subtype of thyroid dysfunction is hypothyroidism, with subclinical hypothyroidism being the most prevalent subtype. There is no significant association between thyroid dysfunction and severity of heart failure based on New York Heart Association (NYHA) functional class.

Key words: Ambulatory heart failure, Thyroid dysfunction, Subclinical hypothyroidism, New York Heart Association functional class, Chemiluminometric assay

Introduction

Heart failure affects approximately 23 to 37 million people worldwide (1,2). Thyroid disorder affects 5–10% of the general population (3). Thyroid dysfunctions have a higher prevalence among females, but with an increasing prevalence among males with advancing age (3). Among heart failure patients, 21%–33.3% are estimated to have thyroid dysfunction (4).

Thyroid dysfunction is related to the development of heart failure (5-7). Hypothyroidism and hyperthyroidism alter cellular and molecular pathways and lead to myocardial remodelling and heart failure (5). Overt and subclinical hyperthyroidism is linked to a high risk of heart failure and atrial fibrillation (7-10). Exposure of excess thyroid hormones leads to arterial stiffness, decreased blood pressure and increased heart rate (7-10). Hyperthyroidism is correlated with palpitations, tachycardia, exercise intolerance and exertional dyspnoea (11).

Hypothyroidism leads to a 30–50% decrease in cardiac output (12), an increase in hospital admission and deaths among heart failure patients (13). Overt and subclinical hypothyroidism are associated with bradycardia, mild hypertension, increased systemic vascular resistance and fatigue (13). Thyroid dysfunction can lead to heart failure (5-7). It can lead to atrial fibrillation resulting in acute decompensation of the heart failure (7). Hypothyroidism has been associated with mortality increase and hospitalization among heart failure patients (13). However, despite the known relationship between thyroid dysfunction and heart failure, there is still a paucity of evidence on the burden of thyroid dysfunction in heart failure and their association in the Kenyan population. Knowledge of the burden of thyroid dysfunction in heart failure is essential in guiding clinical decision making and improving outcomes in heart failure patients.

Materials and methods

This was a cross sectional study involving 302 patients aged 18 years and above with ambulatory heart failure from the cardiac clinic at Kenyatta National Hospital, and was carried out between November and January 2020. Consecutive sampling was used to recruit patients who met the inclusion criteria. Patients with a diagnostic label of heart failure based on Framingham's criteria were included. Patients with structural heart disease (congenital and rheumatic heart disease), and those on amiodarone were excluded. Written informed consent was obtained from all the participants in the study. A data collection tool was used to collect history from the patients, this included there socio-demographic, medical history and anthropometric measurements. Blood specimen for thyroid function test was collected from the patients. Laboratory measurements of the blood samples for thyroid function test were handled as per the hospital standard operating procedures and delivered to the laboratory and tested within four hours. The blood specimen for thyroid function test was taken to the University of Nairobi Paediatrics Laboratory. This laboratory undergoes both internal and external quality control measures.

The main objective of the study was to determine the prevalence of thyroid dysfunction in ambulatory heart failure patients. The secondary objectives were to determine the subtypes of thyroid dysfunction and the association between thyroid dysfunction and the degree of heart failure based on New York Heart Association functional class (NYHA).

STATA version 15 was used to analyse cleaned data. Median, interquartile ranges and percentages were used for continuous and categorical variables. Thyroid dysfunction was categorized into seven groups ; primary and secondary hyperthyroidism, primary and secondary hypothyroidism, subclinical hypothyroidism, subclinical hyperthyroidism and euthyroid sick syndrome. Association between thyroid dysfunction and severity of heart failure based on NYHA functional class was assessed using the chi square test. The study was approved by the Ethics and Research Committee of the Kenyatta National Hospital and University of Nairobi.

Results

Socio-demographic and clinical characteristics of ambulatory heart failure patients

The mean age of the respondents was 60.3 (SD 14.7) years. Sixty two point six percent of the respondents were female. Eighty eight point seven percent were married. Thirty six percent were overweight and 21% were obese. Seventy six point two percent had heart failure in class I and II. Fifty three point three percent of the patients had hypertensive heart disease with 30.8% having dilated cardiomyopathy.

Table 1: Socio-demographic characteristics of ambulatory heart failure patients

Variables	Total N=302	Male N=113	Female N=189
Age, mean (SD), years	60.3 (14.7)	60.0 (14.9)	60.4 (14.6)
19–34 n (%)	15 (5.0)	7 (6.2)	8 (4.2)
35–49	60 (19.9)	20 (17.7)	40 (21.2)
50–64	88 (29.1)	33 (29.2)	55 (29.1)
65–79	121 (40.1)	48 (42.5)	73 (38.6)
80+	18 (6.0)	5 (4.4)	13 (6.9)
Marital status n (%)			
Yes	268 (88.7)	104 (92.0)	164 (86.8)
Occupation n (%)			
Farming	91 (30.1)	34 (30.1)	57 (30.2)
Business	69 (22.9)	31 (27.4)	38 (20.1)
Unemployed	101 (33.4)	22 (19.5)	79 (41.8)
Formal employment	41 (13.6)	26 (23.0)	15 (7.9)
Family history of thyroid disease n (%)			
Yes	23 (7.6)	5 (4.4)	18 (9.5)

IQR: Interquartile range; SD: Standard deviation

Table 2: Clinical characteristics of ambulatory heart failure patients

Variables	Total N=302	Male N=113	Female N=189
Body Mass Index n (%)			
Underweight	13 (4.3)	5(4.4)	8(4.2)
Normal	119(39.4)	40 (35.4)	79 (41.8)
Overweight	108 (35.8)	50 (44.3)	58(30.7)
Obese	62(20.5)	18 (15.9)	44(23.3)
Severity of heart failure (NYHA) n (%)			
I	109 (36.1)	44 (38.9)	65 (34.4)
II	121 (40.1)	44 (38.9)	77 (40.7)
III	72 (23.8)	25 (22.1)	47 (24.9)
Causes of heart failure n (%)			
Hypertensive heart disease	161(53.3)	52(46.2)	109(57.7)
Dilated cardiomyopathy	93 (30.8)	39 (34.5)	54 (28.6)
Ischaemic heart disease	38 (12.6)	19(16.8)	19(10.1)
Cor Pulmonale	9(3.0)	4(3.5)	5(2.7)
Pericarditis	1 (0.3)	1 (0.9)	0
Medication n (%)			
ACEI	165 (54.6)	63 (55.8)	102 (54.0)
Digoxin	74 (24.5)	27 (23.9)	47 (24.9)
Beta Blockers	223 (73.8)	79 (69.9)	144 (76.2)
Aldosterone	103 (34.1)	37 (32.7)	66 (34.9)
Duration since diagnosis, median (IQR)	3 (1-5)	3 (1-5)	3 (1-5)

IQR: Interquartile range; SD: Standard deviation

Prevalence of thyroid disorders

The overall prevalence of thyroid dysfunction is 36.8% (95% CI: 31.5-42.4). Of those with thyroid dysfunction 66.7% (95% CI: 57.1 – 75.3) were women and 33.3% (95% CI: 24.7-42.9%) were men. Older adults have a high prevalence of thyroid dysfunction with 49.6% (95% CI:39.9-59.2) and 23% (95% CI: 15.9-32.4) among those aged 65-79 years and 50-64 years. Seventy eight point four percent of patients with thyroid dysfunction are 50 years and above. Prevalence was 28.8% (95% CI: 20.6-38.2), 41.4% (95% CI: 32.2- 51.2) and 29.7% (95% CI: 21.4 -39.1) for patients in heart failure class 3, 2 and 1 respectively.

Figure 1: Prevalence of thyroid dysfunction in ambulatory heart failure patients by age

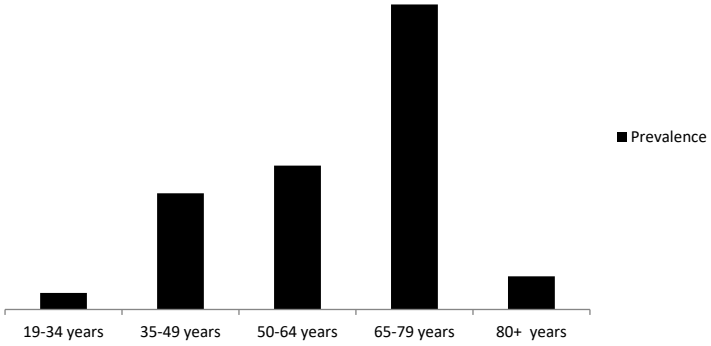

Table 3: Prevalence of thyroid dysfunction in ambulatory heart failure patients according to respondents' socio-demographic and clinical characteristics

Variables	Thyroid dysfunction		95 % Confidence Interval
	No N=191	Yes N=111	
Age, mean (SD), years	59.0 (15.1)	62.4 (13.8)	
19–34 n (%)	12 (6.3)	3 (2.7)	(0.2-2.9)
35–49	39 (20.4)	21 (18.9)	(12.1-27.5)
50–64	62 (32.5)	26 (23.4)	(15.9-32.4)
65–79	66 (34.6)	55 (49.6)	(39.9-59.2)
80+	12 (6.3)	6 (5.4)	(2.0-11.4)
Sex n (%)			
Male	79 (39.8)	37 (33.3)	(24.7-42.9)
Female	115 (60.2)	74 (66.7)	(57.1-75.3)
Body Mass Index n (%)			
Underweight	8 (4.2)	5 (4.5)	(1.48-10.2)
Normal	74 (38.7)	45 (40.5)	(31.3-50.3)
Overweight	73 (38.2)	35 (31.5)	(23.0-41.0)
Obese	36 (19.0)	26 (23.4)	(15.9-32.4)
Severity of Heart Failure (NYHA) n (%)			
I	76 (39.8)	33 (29.7)	(21.4-39.1)
II	75 (39.3)	46 (41.4)	(32.2-51.2)
III	40 (20.9)	32 (28.8)	(20.6-38.2)
Causes of heart failure n (%)			
Hypertensive heart disease	104(54.5)	57(51.4)	(41.7-60.9)
Dilated cardiomyopathy	60 (31.4)	33 (29.7)	(21.4-39.2)
Ischemic heart disease	25(13.1)	13(11.7)	(6.4-19.2)
Cor pulmonale	8(4.2)	1(0.9)	(0.00-4.9)
Pericarditis	1 (0.5)	0 (0.0)	(0)

SD: Standard deviation

Thyroid dysfunction subtypes

Subclinical hypothyroidism (18.8%, 95% CI: 14.6–23.8), euthyroid sick syndrome (9%, 95% CI: 6.0–12.7) and primary hypothyroidism (6%, 95% CI: 3.8–9.7) are the most prevalent thyroid dysfunction subtypes. Secondary hyperthyroidism (1.0%, 95% CI: 0.3–3.1), subclinical hyperthyroidism (1.0%, 95% CI: 0.3–3.1), primary hyperthyroidism (0.3%, 95 % CI: 0.1-1.8) and free T3 toxicosis (0.3% 95% CI: 0.1-1.8) are the least subtypes of thyroid disorders.

Table 4. Thyroid dysfunction subtypes

Thyroid dysfunction	(%)	Confidence interval
Subclinical hypothyroidism	18.8	95% CI :14.6-23.8
Euthyroid sick syndrome	9	95% CI: 6.0-12.7
Primary hypothyroidism	6	95% CI: 3.8-9.7
Secondary hyperthyroidsm	1	95% CI: 0.3-3.1
Subclinical hyperthyroidsm	1	95% CI: 0.3-3.1
Primary hyperthyroidsm	0.3	95% CI: 0.1-1.8
Free T3 toxicosis	0.3	95% CI: 0.1-1.8

Association between thyroid dysfunction and heart failure

There is no significant association between thyroid dysfunction and severity of heart failure based on New York Heart Association functional class, class I and II (early heart failure), class III (advanced heart failure).

Table 5. Association between thyroid dysfunction and severity of heart failure in ambulatory heart failure patients.

Variables / NYHA	I N=109	II N=121	III N=72	P-value*
Thyroid dysfunction n (SD)				
No	76 (69.7)	75 (62.0)	40 (55.6)	0.143
Yes	33 (30.3)	46 (38.0)	32 (44.4)	

SD: Standard deviation; * Chi square test of association

Discussion

The purpose of the study was to determine the prevalence of thyroid dysfunction in ambulatory heart failure patients at KNH. The study was conducted at the KNH outpatient cardiac clinic. Three hundred and two patients with heart failure based on Framingham's criteria, without structural heart disease and not on amiodarone were consecutively sampled. The study population consisted mainly of females at 62.6% with a mean age of 60.3 years and had been diagnosed with heart failure within the last 3 years. Seventy six point two percent of the patients are stable in heart failure class 1 and II and the most common aetiology of heart failure was hypertensive heart disease at 53.3%. We found a prevalence of thyroid dysfunction of 37%, higher among females at 66.7% and those above 65 years at 55%. The most common subtypes of thyroid dysfunction are subclinical hypothyroidism at 18.8% , euthyroid sick syndrome at 9% and primary hypothyroidism at 6% .

Chemiluminometric assay was used to measure thyroid hormone fT_3, fT_4, and TSH levels using the Liaison test kits. Chemiluminometric assays, have a detection limit of 0.01mU/L and thus able to detect mild thyroid dysfunction accurately. This is similar to studies done in the west, Hayashi *et al* (4) in 2016 in a study investigating the prevalence of subclinical hypothyroidism and cardiovascular outcomes in heart failure patients and, Kannan *et al* (7) in 2018 in a study investigating the prevalence of thyroid dysfunction in heart failure and cardiovascular outcomes also used the chemiluminometric assay method. The chemilumminometric assay method is more specific and sensitive than previously used radioimmunoassay (RIA) and enzyme linked immunosorbent assay (ELISA) methods with detection limits of 0.1mU/L, hence unlikely to underestimate our results. The method was chosen for our study as it is readily available and accurate. The reference ranges used were , fT3 (2.2–4.2) pg/ml, fT4 (0.8–1.7) ng/dl, TSH (0.3–3.6) Uiu/ml, this is in keeping with global reference ranges . Internal and external quality control measures were adhered to.

Ascheim *et al* (14) in 2002 in a cross- sectional study investigating the prevalence of thyroid dysfunction in ambulatory heart failure patients, sampled 132 patients, using the chemiluminometric assay method, the prevalence of thyroid dysfunction was 41%, the mean age of the patients was 67 years and majority were males, this is almost similar to our prevalence of 37%, however majority of our patients were female . Mahesh *et al* (15) in 2017 in a study to determine the prevalence of thyroid dysfunction in patients with acute decompensated heart failure and six months follow up of subclinical hypothyroidism and low T3 syndrome, sampled 114 patients, used the chemiluminometric assay method and found a prevalence of 30%, the mean age of the patients was 57 years , this is almost similar to the prevalence in ambulatory heart failure patients in our study. The global prevalence of thyroid dysfunction in heart failure is estimated at 21%-33.3% (4,15). There is no recorded data on the prevalence of thyroid dysfunction in ambulatory heart failure patients in sub-Saharan Africa.

Subclinical hypothyroidism, euthyroid sick syndrome and primary hypothyroidism were the most prevalent thyroid dysfunction subtypes in the study. Hayashi *et al* (4) in 2016 in a prospective study investigating the prevalence and prognostic impact of subclinical hypothyroidism and euthyroid sick syndrome in heart failure patients, sampled 274 patients, used the chemiluminometric assay and also found subclinical hypothyroidism and euthyroid sick syndrome as the most prevalent subtypes at 21% and 35% respectively, only 2% of the patients had subclinical hyperthyroidism. Subclinical hypothyroidism is usually asymptomatic (16) and progresses to overt hypothyroidism in only 2 – 28% of the cases (16,17). However, it is associated with coronary heart diseases (10), heart failure and stroke (18) and cardiovascular mortality (19,20). Hypothyroidism leads to a cardiac output decrease by 30–50% (12). Overt and subclinical hypothyroidism is linked to bradycardia, fatigue, death and hospital admissions in HF patients (13).

This study did not find a significant association between severity of heart failure and thyroid dysfunction. This may be due to our smaller size compared to other studies. Unlike our study, Kannan *et al* (7) in a prospective cohort study of ambulatory heart failure patients to determine the prevalence of thyroid dysfunction and associations with cardiovascular outcomes, recruited 1365 patients between 2003 and 2011, mean age of the patients was 57 years, the study included patients in heart failure class I-IV and majority were in class II and III heart failure. Chemiluminometric assay method was used for the thyroid function test, significant association was found between thyroid dysfunction and severity of heart failure based on NYHA functional class (7). This study had a smaller sample size and this may explain the difference in the results.

Use of drugs such as amiodarone could increase the risk of thyroid dysfunction, but patients using amiodarone were excluded from this study.

The prevalence of thyroid dysfunction in ambulatory heart failure patients is high. The thyroid function test should be readily available and affordable to the patients. Patients found to have thyroid dysfunction should be referred to an endocrinologist for specialised care. Early detection and treatment of overt thyroid dysfunction in ambulatory heart failure patients will slow further progression of heart failure and prevent acute decompensation.

Conclusion

Prevalence of thyroid dysfunction in ambulatory heart failure patients is high. The most common subtype of thyroid dysfunction is hypothyroidism, with subclinical hypothyroidism being the most prevalent subtype. There is no significant association between thyroid dysfunction and severity of heart failure based on NYHA functional class.

Acknowledgements

The prinicipal investigator (BOM) would like to appreciate his supervisors, the entire Department of Clinical Medicine and Therapeutics, University of Nairobi, all the staff at Kenyatta National Hospital cardiac clinic and the University of Nairobi paediatrics laboratory and my statistician Mr Samuel Gatimu for their assistance during this entire study, and all the patients who accepted to participate in the study.

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Original paper

Assessment of Guideline Concordant Antibiotic Prescribing for Patients with Community Acquired Pneumonia at The Kenyatta National Hospital Medical Wards

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Abstract

Background: Pneumonia is a major cause of morbidity and mortality globally. Despite the proven benefits of guideline concordant antibiotic prescribing, research has shown that adherence to clinical guideline recommendations is dismal.

Objectives: The study aims to determine utilization of Kenyatta National Hospital antibiotic guideline titled 'The KNH guide to empiric antimicrobial therapy 2018' in the management of community acquired pneumonia in the Kenyatta National Hospital medical wards and the perceived barriers towards the utilization of this guideline.

Materials and methods: A check list derived from the Kenyatta National Hospital (KNH) guide to empiric antimicrobial therapy 2018 was used to assess guideline concordance based on seven quality indicators: empiric antibiotic, dose and route of administration, switch to oral antibiotics, duration of antibiotics (at least 5 days), collection of microbiological samples before initiating antibiotics, review of antibiotics at 48 hours and once the culture results are out. Online self-administered questionnaires were used to determine attitude and perceived barriers towards utilization of the KNH guideline among the Internal Medicine registrars and medical officers.

Analysis: Descriptive statistics were applied in the representation of each of the seven quality indicators. These were then compared with the guideline recommendations and adherence to the guideline for each parameter was expressed as a percentage of the total number of patients admitted with community acquired pneumonia. These were then graded into the following categories based on the level of concordance: Good >90%, Intermediate 60-90%, poor <60%. Questions on the attitude and the perceived barriers towards KNH guideline utilization were answered using a 5 point Likert scale. Perceived barrier statements that were positively formulated were then recorded so that a lower score meant a lower level of the perceived barriers and vice versa. Percentages were then calculated for the total number of doctors that agreed or strongly agreed that the barrier was applicable. An open ended question on the top three barriers to the KNH guideline utilization was also included in the questionnaire.

Results: For each of the other quality indicators, adherence to the KNH guideline for patients with community acquired pneumonia was as follows: empiric antibiotic choice 48%, collection of samples for culture prior to antibiotic administration 0%, review of antibiotics at 48 hours 26.4%, review of antibiotics with culture results 45.8%, total duration of antibiotics 28.8% and time to switch to oral antibiotics 3.6%. The top three barriers towards guideline utilization among the doctors were: unavailability of drugs (52.7%), inaccessibility of the KNH guideline (45.1%) and lack of or delay of investigations (34.1%).

Conclusion: This study has demonstrated that the level of adherence to the seven quality indicators from the KNH guide is poor with the overall adherence being 35.5%. The recommendation least adhered to was collection of microbiological samples before initiation of empiric antibiotics. The most commonly identified barriers to utilization of the guideline were external and guideline related barriers.

Key words: Guide to empiric antimicrobial therapy 2018, Guideline Concordance antibiotic prescribing, Community acquired pneumonia

Introduction

Pneumonia remains one of the leading causes of hospitalization among adult patients in low and medium income economies despite advancement in the approach to disease prevention and management (1).

The absence of a microbiological aetiology when antibiotics need to be administered, the vast array of available antibiotics and increasing antimicrobial

resistance have led different infectious disease societies to publish antimicrobial guidelines to help in the selection of the appropriate initial antibiotic regimen, taking into account individual patient parameters (2).

Broad-spectrum guideline-concordant empiric therapy increases the possibility of prompt initiation of the appropriate antibiotics and has been shown to be comparable in efficacy to a pathogen-directed approach (3). Adherence to pneumonia treatment guidelines has also been shown to reduce 30 day mortality and length of hospital stay (4). Empiric antimicrobial therapy that is not concordant to pneumonia guidelines has been found to be an independent factor associated with early deaths in patients with severe pneumonia.

Adherence to guidelines for the treatment of pneumonia has been found to be alarmingly low. A study done in Garissa Provincial General Hospital, Kenya, reported 27.7% adherence to the Ministry of Health pneumonia guidelines (5). This is in contrast to studies in other countries that have reported adherence levels of 61- 97% (6).

In line with evidence based practice, the 'Kenyatta National Hospital (KNH) guide to empiric guide to antimicrobial therapy' antibiotic guideline was launched in 2018. Utilization of this guideline in the management of pneumonia is yet to be audited.

Materials and methods

This was a hospital based cross sectional study conducted in six general medical wards at the Kenyatta National Hospital (KNH). The study comprised of two population groups: 250 medical records of patients with a diagnosis of community acquired pneumonia and 91 medical doctors (Internal medicine residents, medical officers and medical officer interns at the KNH).

All the records of patients aged 18 years and above admitted to the six general medical wards in KNH with a working diagnosis of community acquired pneumonia were included in the study. Community acquired pneumonia was defined as a clinical syndrome with at least one of these "major" clinical features: or temperature > 37.8°C, cough, or sputum production, or at least two of the listed "minor" clinical features: dyspnea, deranged mental status, pleuritic chest pain, consolidation on chest examination, or leukocytosis of >12,000mm with chest X-ray showing features suggestive of pneumonia at admission or within 24 hours (7). The exclusion criteria included patients admitted in the specialized medical wards, those aged 80 years and above with multiple comorbidities (category 2 and above in the KNH antimicrobial guideline) and those who tested positive for pulmonary tuberculosis. Data was extracted from the patients' files using the study pro-forma. Information was obtained concerning their age, sex, length of hospital stay, past or current smoking history, comorbidities and hospitalization in the last 90 days. Concordance to the KNH antimicrobial guideline for community acquired pneumonia was assessed using a checklist derived from the guideline. The check list consisted of eight statements derived from the antibiotic prescribing algorithm. The domains that were assessed include: documented evidence of pneumonia, collection of microbiological samples before initiation of antibiotics, guideline concordant choice of antibiotics, review of antibiotics after reviewing results of microscopy, culture and sensitivity, time to switch to oral antibiotics and the total duration of antibiotic administration. Documentation of the evidence of pneumonia diagnosis was confirmed by ticking the positive clinical features and a chest radiograph suggestive of pneumonia. Descriptive statistics were used to represent patient demographics, evidence of pneumonia (expressed as at least two positive clinical features and a chest radiograph suggestive of pneumonia), empiric antibiotic regimen chosen, timing of collection of microbiological samples, dose, time to oral antibiotics and the total duration of antibiotic administration as well as the review of antibiotics at 48 hours and upon receiving culture results. These were then compared with the guideline recommendations. Adherence to the guideline for each parameter was expressed as a percentage of the total number of patients admitted with community acquired pneumonia.

In the second study population, the total sample was taken from the internal medicine registrars, medical officers in casualty and medical officer interns. This was done at a ratio of 7:2:1 based on the expected proportions. Enrollment was by consecutive sampling. Informed consent was sought and validated self-administered questionnaires were filled in soft copy and had a total of 20 questions. The questions assessing attitude and barriers to guideline utilization were answered using a 5 point Likert scale with the options being strongly agree, agree, neutral, disagree and strongly disagree. One open ended question is also included, where the respondents were expected to list their top 3 barriers to utilizing the KNH guideline 2018 in the management of pneumonia. The questionnaire consists of two parts: a general section on the professional characteristics of the doctors which was summarized by descriptive statistics, and a guideline specific part on the attitude towards the guideline and the perceived barriers towards guideline utilization which was answered using a 5 point Likert scale to rate the degree of agreement or vice versa. Perceived barrier statements that were positively formulated

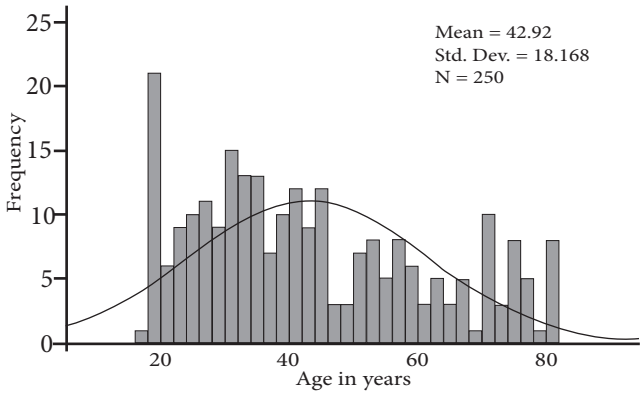
were then recorded so that a higher score meant a greater level of perceived barriers and the reverse also applied. Percentages were then calculated for the total number of doctors that agreed or strongly agreed that the barrier was applicable.

Results

During the study period, January 2020 to April 2020, a total of 282 patients admitted with pneumonia were screened for eligibility and were considered for the study. Six of these patients did not meet the case definition while 26 patients were excluded from the study due to the following reasons: 7 had healthcare associated pneumonia, 2 were treated for aspiration pneumonia, 5 tested positive for pulmonary tuberculosis while 12 patients were over 80 years of age with multiple comorbidities.

The mean age of the study patient population at the time of this study was 42.9 (±18) years. There was a slight male preponderance with male patients being 119 (52.4%). Majority, (78.8%) of the patients, were aged between 18 - 60 years. Extremes of age, represented by patients under 20 years and over 70 years were 21 (8.4%) and 35 (14%) respectively. Notably, patients aged 18 years contributed to the bulk of patients aged under 20 years at 7.2%.

Figure 1: Age distribution among patients with CAP



Past or current smoking history was reported in 55 (22%) of the study participants, predominantly male. Among the smokers, only 17 (6.8%) had a documented duration of cigarette smoking with the total number of sticks per day, giving an average of 12.29 pack years of smoking. Majority, 177 (70.9%) of the patients had at least one concurrent chronic illness. The two commonly reported comorbidities were heart failure 35 (14%) and HIV 30 (12%).

Table 1: Sociodemographic characteristics of patients with CAP (n=250)

Variable	No. (%)
Past or current smoking history	
Yes	57 (22.8)
No	193 (77.2)
Comorbid conditions	
Diabetes	10 (5.9)
HIV	17 (10.1)
Heart failure	20 (11.8)
Asthma	3 (1.8)
COPD	9 (5.3)
Other	56 (33.1)
None	54 (32.0)
Gender	
Male	128 (51.2)
Female	122 (48.8)

The length of hospital stay was defined as the time between admission into the medical ward and documentation of discharge in the patients file. The average length of hospital stay for patients admitted with CAP was 6.5 days. Majority of the patients stayed in hospital for at least 7 days (93.6%) and only 11 patients were discharged within 5 days of hospitalization.

Table 2: Length of hospital stay

Length of hospital stay in days	Number of patients (%)
2	1 (0.4)
3	1 (0.4)
4	2 (0.8)
5	6 (2.4)
6	4 (1.6)
≥ 7	236 (94.4)

Assessment of concordance to the KNH guideline was done using 7 quality indicators namely: Empiric antibiotic choice, dose, route and frequency of administration, collection of blood culture samples before starting antibiotics, review of antibiotics in 48 hours after initiation, review of antibiotics after receiving culture results, total duration of antibiotic use and time to switch to oral antibiotics in days. The degree of concordance was then graded into: Good

>90%, Intermediate 60 – 90% and poor <60%. Each of the quality indicators will be discussed below.

Empiric antibiotic concordance

The choice of antibiotic, route, dose and frequency were taken into account to fully assess the full prescribing criteria. The dose, route and frequency of administration was concordant to the KNH guideline in majority of the patients 241 (96.4%). The main reason for lack of adherence in this indicator was the erroneous dosage of ceftriaxone and ceftazidime in nine patients. Two patients received ceftriaxone 1g OD, 4 received ceftriaxone 2g BD while the remaining 3 got ceftazidime 2g TDS. There was no documented reason for the dose adjustment in these patients.

The KNH antimicrobial therapy (2018) recommends the use of either ceftriaxone, cefuroxime or amoxicillin- clavulanic acid in combination with a macrolide for the management of hospitalized patients with CAP. The empiric antibiotic choice was guideline concordant in 120 (48%) of the patients. These patients received a combination of amoxicillin- clavulanic acid or ceftriaxone with either clarithromycin or azithromycin. The most commonly prescribed empiric antibiotics were ceftriaxone (33.2%) and amoxicillin - clavulanic acid 55.6% either as monotherapy or in combination. Amoxicillin-clavulanic acid and ceftriaxone monotherapy was prescribed in 42.5% and 35.4% respectively, while dual therapy with macrolides was given in 64.4% and 23.3% respectively. Broader spectrum antibiotic use was seen in 9 (3.6%) patients, where ceftazidime, meropenem, and piperacillin tazobactam were used. Besides the combination with macrolides, a number of other antimicrobials were used in a small percentage of patients, with metronidazole being the most common in 12 (4.8%) patients.

Table 3: Antibiotic prescription patterns

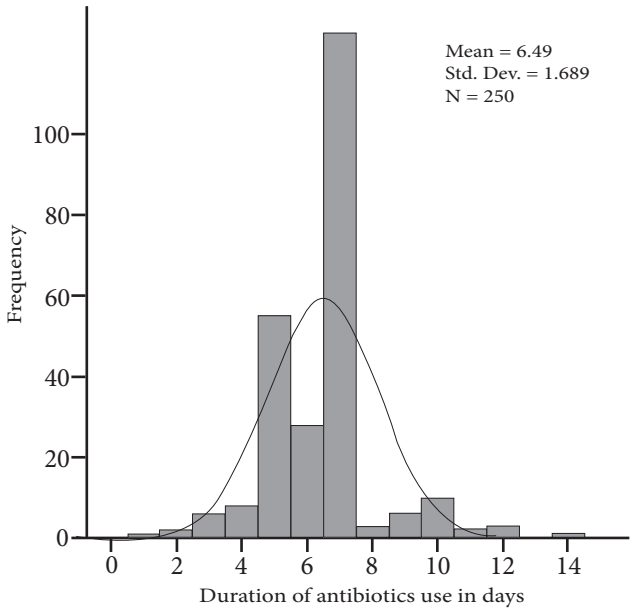
Antibiotics used	No. (%)
Single agent	113 (45.2)
	137 (54.8)
Combination therapy	
Single agent	40 (35.4)
Ceftriaxone	48 (42.5)
Amoxicillin-Clavulanic acid	16 (14.2)
Ceftazidime	3 (2.7)
Cefuroxime	2 (1.8)
Meropenem	4 (3.6)
Piperacillin tazobactam	
Combination therapy	85 (62.0)
Augmentin+Clarithromycin	3 (2.2)
Augmentin+Azithromycin	2 (1.5)
Augmentin+ Metronidazole	1 (0.7)
Augmentin+Ciprofloxacin	3 (2.2)
Ceftazidime+Clarithromycin	7 (5.1)
Ceftriaxone+Azithromycin	25 (18.2)
Ceftriaxone + Clarithromycin	10 (7.3)
Ceftriaxone+ Metronidazole	1 (0.7)
Ceftriaxone+Gentamycin	

Review of antibiotics during the course of admission

Adjustment of antibiotics after 48 hours was done for 66 (26.4%), but only 9 (3.6%) patients were reviewed with the aim of switching to oral antibiotics at 48 hours as recommended by the KNH guideline. Review of antibiotics was done mainly with the aim of adding atypical cover 65 (26.2%), with addition of clarithromycin, azithromycin or metronidazole. Ninety eight (39%) of patients had a complete change of antibiotics, with majority 45 (46%) being changed from ceftriaxone to amoxicillin- clavulanic acid.

During the course of the in-patient stay, 25 (10%) patients received oral antibiotics, with the median time to oral antibiotics being 6 days. Only 9 (3.6%) of these patients received oral antibiotics within 48 hours of admission, in line with the KNH guideline. The average duration of antibiotic administration was 6.5 (1.7) days, longer than the recommended 5 days of treatment. Guideline concordance for duration of antibiotics was only achieved in 28.8% of the study participants. Two hundred and thirty six (93.6%) of the patients received more than 7 days of antibiotics as illustrated in Figure 2. while 118 (47.2%) had comorbidities.

Figure 2: Duration of antibiotics



The KNH antimicrobial guideline recommends the collection of blood culture and sputum for TB analysis (gene Xpert) for all patients admitted with CAP. In the study cohort blood culture and sputum samples for gene Xpert test were collected for 48 (19%) and 96 (38.4%) respectively. Eighty one (32.4%) of the admitted patients presented with dry cough. There was no documentation of any attempt to induce sputum therefore no sputum sample was collected.

However, none of these microbiological samples were collected before the initiation of antibiotics. These samples were collected from day 2 of admission

onwards. Among the samples collected, over 50% of the results were not available in the patients file by day 7 therefore not reviewed. For the individual samples, blood culture results were reviewed for 21 (43.8%) while sputum gene Xpert results were only reviewed for 45 (46.9%) of the patients by day 7. Overall compliance to this quality indicator was 45.8%. The yield from these cultures was low, with 95.2% blood cultures and 93.3% sputum results being reported as negative for TB.

Assessment of attitude and barriers towards implementation of the KNH guideline

A total of 91 doctors took part in the survey. All the participants gave informed consent and proceeded to fill the online questionnaires. Seventy three internal medicine registrars, 18 medical officers and 1 medical officer intern fulfilled the inclusion criteria and proceeded to fill in the online questionnaires. Majority 59 (64.9%) of the internal medicine registrars who took part in the study were in their second and third year of training while the medical officers work in the outpatient department. Over half 48 (52.7%) the respondents reported to have worked for more than five years after graduation and only 7 (7.7%) reported to have been in practice for less than 2 years. Fifty (54.9%) of the respondents reported that they prescribe antibiotics at least once a day while only 1 (1.1%) prescribe antibiotics at least once a week. Table 4 summarizes the sociodemographic characteristics of the doctors.

Table 4: Doctors' sociodemographic characteristics (n=91)

Variable	Frequency (%)
Duration worked after school in years	
1-2	7 (7.7)
3-4	17 (18.7)
4-5	19 (20.9)
Above 5	48 (52.7)
Current position held at KNH	
Internal medicine resident	73 (80.2)
Medical officer	17 (18.7)
Medical officer intern	1 (1.1)
Year of training for Internal Medicine Residents	
Year 1	14 (15.4)
Year 2A	20 (22.0)
Year 2B	39 (42.9)
Not applicable	18 (19.8)
Times prescribed antibiotics in work week	Number (%)
More than once a day	50 (54.9)
Once a day	9 (9.9)
3-5 times per week	23 (25.3)
1-2 times per week	8 (8.8)
Less than once a week	1 (1.1)

Attitude toward the KNH guideline

To assess the attitude of the respondents towards the KNH guide to antimicrobial therapy 2018, four questions with options ranging from strongly agree to disagree were included in the survey as shown in Table 5. Eighty one (89.1%) of the doctors felt that the guideline is evidence based while 1 (1.1%) disagreed with this statement. Seventy four to eighty four percent of the participants find the guideline a useful tool in choosing the initial antibiotic, convenient and easy way to find information required. Three (3.3% of the respondents however, felt that the guideline is not useful in improving the quality of treatment given to patients with community acquired pneumonia.

Table 5: Attitude towards the KNH guideline

Question (N 91)	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Guidelines are evidence-based	37 (40.7)	44 (48.4)	9 (9.9)	1 (1.1)	0
Useful and help improve quality of treatment	40 (44.0)	36 (39.6)	11 (12.1)	3 (3.3)	1 (1.1)
Good tool for choosing initial treatment	48 (52.7)	36 (39.6)	7 (7.7)	0	0
Convenient to use and easy to find information	36 (39.6)	38 (41.8)	9 (9.9)	8 (8.8)	0

Barriers towards guideline implementation

The most commonly identified barrier toward implementation of the KNH guideline was lack of medical resources as reported by 56.1% of the respondents. The doctors reported that the guideline is accessible (67.1%), does not reduce their autonomy (61.5%) or limit treatment options (53.9%). Thirty one point nine percent however, felt that the KNH guideline is complicated and difficult to find information.

Table 6: Barriers towards guideline implementation

Question	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Hard to implement in daily practice due to lack of medical resources	19 (20.9)	32 (35.2)	13 (14.3)	24 (26.4)	3 (3.3)
Hard to implement in daily practice due to a lack of resources for patients	17 (18.7)	28 (30.8)	14 (15.4)	29 (31.9)	3 (3.3)
There is no time to search for information	3 (3.3)	16 (17.6)	12 (13.2)	45 (49.5)	15 (16.5)
Treatment guidelines are not accessible	4 (4.4)	15 (16.5)	11 (12.1)	42 (46.2)	19 (20.9)
Too complicated and it is difficult to find the information	5 (5.5)	24 (26.4)	20 (22.0)	35 (38.5)	7 (7.7)
Treatment guidelines reduce doctors' autonomy	3 (3.3)	16 (17.6)	16 (17.6)	49 (53.8)	7 (7.7)
Treatment guidelines limit treatment options	2 (2.2)	23 (25.3)	17 (18.7)	43 (47.3)	6 (6.6)
Treatment guidelines limit flexibility and individual approach	1 (1.1)	2 (2.2)	2 (2.2)	40 (44.0)	46 (50.5)
There is no need for treatment guidelines as treatment routines exist	0	1 (1.1)	12 (13.2)	42 (46.2)	36 (39.6)

Responses to the open ended question

The survey utilized an open ended question asking the respondents to list their top 3 barriers to the utilization of the KNH guideline in treating CAP. The respondents cited unavailability of drugs 48 (52.7%), inaccessibility of the guideline (45.1%) and lack of investigations or delay of results 31 (34.1%) as the most common barriers. Time constrains 8 (8.8%) and exposure to antibiotics prior to admission 7 (7.7%) were also listed among the barriers, albeit in a small percentage of respondents as shown in Table 7.

Table 7: Summary of top 3 barriers (n=91)

Barriers	Frequency (%)
Inaccessibility of guidelines	41 (45.1)
Unavailability of drugs	48 (52.7)
Lack or delay of investigative results	31 (34.1)
Conformity to routine treatment regime	10 (11.0)
Cost to the patients	12 (13.2)
Time constraints	8 (8.8)
Exposure to antibiotics prior to admission	7 (7.7)

Discussion

This audit was looking at the different aspects of adherence to the KNH guide to microbial therapy 2018 in the management of in-patient community acquired pneumonia. The quality indicators studied were: appropriate empiric antibiotic choice taking into account the dose, route, frequency of antibiotic administration, time to change to oral treatment, total duration of antibiotics and the timely collection of microbiological samples. Additionally, the attitude and barriers towards the KNH guideline were investigated.

Overall, adherence to the 7 quality indicators was poor at 35.5%, with only the route, dose and frequency of antibiotic administration achieving good adherence (96.3%).

The KNH guideline recommends the use of amoxicillin-clavulanic acid, cefuroxime or ceftriaxone with a macrolide in admitted patients with community acquired pneumonia. The main reason for discordance in the empiric antibiotic choice was the prescription of ceftriaxone or augmentin as monotherapy. Multiple studies are in favor of combination therapy with macrolides for atypical cover as this regimen has been shown to reduce both length of hospital stay and 30 day mortality of patients admitted with CAP (8). The use of monotherapy may also contribute to the increasing antimicrobial resistance in Africa, with the resistance of *Streptococcus pneumoniae* to penicillin reported at 26.7% by 2017(9).

The adherence to the recommended antibiotic in this audit (48%) was higher than the audit done in Garissa County Hospital in 2014 that revealed adherence of 27.7% to the National Paediatric protocols (5) . This may be attributed to various factors including: the greater availability of antibiotics in a referral facility like KNH compared to a remote county hospital like Garissa, the adult versus paediatric population, retrospective versus prospective study design as well as the extensive continuous medical education on antibiotic stewardship.

Globally, there is a lot of variation in the level of adherence to empiric antibiotics. Our adherence data are in agreement with other studies that investigated compliance to treatment guidelines in patients admitted with pneumonia and reported adherence rates of between 41% and 77% (10). The level of adherence is even lower in African counties with Sudan reporting up to 82% non-adherence to paediatric guidelines (11) while South Africa reported as low as 8% (12).

The study also looked at the full prescribing criteria, and it showed that the route, dose and frequency was appropriate in majority of the patients (96.4%). However, review of intravenous antibiotics at 48 hours with the aim to change to oral treatment was only done for 9 (3.6%) patients. In this audit study, only 10% of the patients received oral antibiotics during their course of hospital admission, with the median time to initiation of oral antibiotics being 6 days. This is despite the fact that the 48-hour review of antimicrobials with the aim to switch to oral treatment is a critical component of antimicrobial stewardship programs to improve judicious antibiotic use and has been shown to reduce both length of hospital stay and health care related costs (13). A study done in Venezuela as part of the CAPO study revealed that switch to oral antibiotics at 48 hours was poorly adhered to at 15% (14). Globally, the recommendation for switch to oral antibiotics is poorly adhered to and some of the reasons that have been cited include: lack of poorly stated recommendations in the clinical practice guidelines, the clinician's perception regarding patient outcome with oral antibiotics and the absence of protocols to monitor switch criteria during daily ward rounds.

The average total duration of antibiotics was 6.5 days (± 1.7) which is above the recommended duration of 5 days. This is likely as a result of the delay in early initiation of oral antibiotics as well as the patients' comorbidities. Studies done globally have shown that patients with CAP are treated with a 10 – 14 day course of antibiotics, inclusive of 6 to 8 days of oral antibiotics (15). Research done has shown that withdrawal of antibiotics after 5 days is not inferior to previously recommended fixed timelines in terms of clinical success (9). Additionally, studies have found that needless prolongation of the duration of antibiotic administration is likely to select for antibiotic resistance (16). With multiple studies favoring short courses of antibiotics for patients with CAP, the thinking is now shifting to "less is more" with regard to in-patient care of pneumonia (17).

In terms of microbiological samples, the KNH guideline recommends that both blood cultures and sputum samples for gene Xpert are taken to rule out tuberculosis due to the high prevalence of mycobacterium tuberculosis in Kenya. Blood cultures were collected for 48 (19.2%) of the patients, while sputum was collected for 96 (38.4%) of the study population. The fact that over one third of the patients with CAP 118 (32.4%) presented with a dry cough contributed to the reduced number of sputum samples collected. There was no documentation of any attempt at sputum induction in the sample population. Studies have shown that sputum induction is safe and increases the yield on sputum specimens by about two fold among HIV infected patients and admitted patients (18). Despite over half of the patients having at least either blood or sputum collected, none of these samples were collected prior to the initiation of empiric antibiotics as recommended by the KNH guideline. A similar finding was reported in a study done between 2013 to 2016 in KNH that found that the median duration of hospital stay before specimen collection for cultures was 4 days (19). The turnaround for culture results was noted to be high with results only (43.8%) and (55.2%) blood culture and sputum gene Xpert respectively available in the file by day 7. This was despite the fact that on average, blood culture results are out in about 48 hours while sputum gene Xpert test takes less than 2 hours. Factors that could explain the delay in getting the results may include a lack of initiative among the staff to follow up results, inertia from many negative blood cultures, large numbers of samples collected in a day in the referral facility leading to a back log of unattended to samples, and logistical factors like lack of reagents to run the tests.

This study also explored the factors affecting the utilization of the KNH guideline, specifically focusing on the attitude and perceived barriers among the doctors who frequently prescribe the antibiotics for patients admitted with CAP in the KNH medical wards. The participants, internal medicine residents (80.2%), medical officers in out-patient (18.7%) and medical officer interns (1.1%) reported that they routinely prescribe antibiotics for pneumonia patients, with 54.9% prescribing antibiotics at least once a day.

Overall, the attitude towards the KNH guideline is good. This was evidenced by the fact that, 89.1% felt that the KNH guideline is evidence based, a good tool for choosing initial treatment (84%) and it is convenient to use and easy to find information (84%). This is similar to what has been found in other studies, as most studies assessing clinical practice guidelines have reported a good attitude among the users (20). The reasons for the positive attitude include: the portability of the KNH guideline, the fact that it captures the commonly encountered infections not forgetting that each infection is summarized in one page for ease of reference.

In line with the overall good attitude towards the KNH guideline, it was noted that external, rather than individual barriers were cited as the main barriers to utilization of the KNH guideline. The top 3 barriers identified were: unavailability of drugs (52.7%), lack of guideline accessibility (45.1%) and lack or delay of investigations (34.1%). Other factors that featured prominently as hindrances to guideline utilization were: conformity to routine (11%), time constraints (8.8%) and previous use of antibiotics (7.7%). The

perceived barriers in our setting were different from those studied in the developed countries as patient and physician factors featured more prominently compared to KNH where external and guideline factors were cited more.

In one study done in the U.S.A, the doctor was likely to disregard the guideline if the patient was severely ill with multi-lobar disease or multiple comorbidities, male, age >65 years. Physician factors that played a key role in non-adherence include: the presence of the primary physician at the emergency department at the time of admission and the physicians level of experience. In the study done on adherence to the national paediatric protocols in Garissa County Hospital, it was reported that the presence of comorbidities did not affect adherence to the guidelines while the disease severity led to greater adherence (9).

The choice of empiric antibiotic and time to de-escalation may have been affected by other factors other than non-adherence to the KNH guideline. These include: type of antibiotic available in the hospital pharmacy, the available investigations and their turn-around time as well as comorbidities and exposure to antibiotics prior to hospital admission.

Poor documentation had direct impact on the information abstracted from patients' files and may have affected the quality of data obtained as anything not documented was considered not done.

The Hawthorne effect (observer bias) was likely to have increased the rate of compliance to the empiric antimicrobial guideline and therefore positively skewed the results.

Due to the large number of patients in KNH medical wards who are elderly and have comorbidities, it was not possible to exclude all of them as required under Category 1 of the guideline, we included only patients with one comorbidity and those over 80 years were excluded from the study.

Conclusion

This study has demonstrated that the level of adherence to the seven quality indicators from the KNH guide is poor with the overall adherence being 35.5%. The recommendation least adhered to was collection of microbiological samples before initiation of empiric antibiotics. The attitude towards the KNH guideline among the doctors was good. The most commonly identified barriers to utilization of the guideline were: unavailability of drugs, inaccessibility of the guideline and lack of or delay of results.

Acknowledgements

The principal author (PNR) would like to appreciate the supervisors and the entire Department of Clinical Medicine and Therapeutics, University of Nairobi, all the staff at Kenyatta National Hospital general medical wards, colleagues and all the medical officers who took part in this study, the statistician Mr. Mutai and all the patients who allowed us to use their medical records.

Disclosure: The authors report no conflict of interest in this work.

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Original paper

Adequacy of Glycaemic Control and Knowledge of Diabetes among Ambulatory Patients with Type 2 Diabetes at Mbagathi Hospital, Nairobi, Kenya

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Abstract

Background: Diabetes mellitus is associated with high morbidity, premature mortality and socio- economic burden globally. Its complications, morbidity and premature mortality can be delayed or prevented by optimal glycaemic control. Knowledge of diabetes plays an integral role in attaining desirable diabetes self-care and clinical outcomes. However, despite Diabetes Self-Management Education (DSME) and advances in treatment, diabetes is often inadequately controlled in clinical practice.

Objective: To determine adequacy of glycaemic control and knowledge of diabetes among ambulatory patients with Type 2 Diabetes Mellitus (T2DM) at Mbagathi Hospital, Nairobi, Kenya.

Design: Cross-sectional descriptive study.

Setting: Diabetes outpatient clinic, Mbagathi Hospital, Nairobi, Kenya.

Subjects: One hundred and sixty five patients with T2DM, aged ≥ 40 years, selected by simple random sampling, each on one anti-diabetes regimen for a period of not less than 3 consecutive months.

Methods: The study was undertaken over a period of six months from June 2015 during routine diabetes clinics. Glycaemic control and knowledge of diabetes were assessed using HbA1c assay and MDRTC diabetes knowledge test questionnaire respectively. The 4-point modified Morisky Medication Adherence Scale was used to determine adherence to medication.

Results: Of the 165 patients with T2DM recruited, 66.1% were females. Mean age (±SD) was 55.7 ± 9.5 years. Literacy level was 93.3%. The study population was largely of low socio-economic status. Mean (± SD) HbA**1**c level was high, 9.5 ± 3.1%. Mean DKT score (±SD) was satisfactory, 64.3 ± 15.3%. Levels of glycaemic control and knowledge of diabetes were 25.5% and 90.9% respectively. Adherence to medication was low (37.6%). Knowledge deficits were identified in areas related to diet, treatment of hypoglycaemia and effect of physical activity on blood glucose.

Glycaemic control was significantly associated with single (marital) status (p = 0.005), formal employment (p = 0.05), and diabetes education acquired over one year prior to study entry (p = 0.014). Knowledge of diabetes was associated with female gender (p = 0.025) and unemployment (p = 0.045). Adherence to medication was not associated with glycaemic control and knowledge of diabetes (p >0.05). However, there was association of non-adherence to medication with low family income (p = 0.043), provision of medication by spouses (p = 0.030), diabetes education gained 7-12 months prior to study entry (p = 0.031) and multiple anti-diabetes drug regimens (p = 0.004).

Sub-optimal glycaemic control was possibly due to low socio-economic status, impacting on adherence to diabetic diet and medication. Association of glycaemic control and formal employment was attributed to ability of employed patients to afford cost of medical care, while association of glycaemic control and diabetes education acquired over one year prior to study entry was likely due to adequate exposure to diabetes education and appropriate use of internalized knowledge of diabetes. Knowledge of diabetes was associated with female gender probably due to the postulated better health-seeking habits of females. Association of knowledge of diabetes and unemployment may have been because the unemployed devoted ample time to acquire knowledge of diabetes. Non-adherence to medication was associated with low family income and multiple anti-diabetes drug regimens most likely due to inability to meet cost of medication. Association of non-adherence to medication with diabetes education gained 7-12 months prior to the study entry was probably due to inadequate knowledge of diabetes acquired.

Conclusion: There was evident dissociation of glycaemic control and knowledge of diabetes. Therefore it is essential that factors affecting glycaemic control and adherence to medication as well as the identified knowledge deficits should be promptly addressed, as re-enforcement of knowledge of diabetes is maintained.

Key words: Type diabetis mellitus, Glycaemic control

Introduction

Among the environmental risk factors that predispose to T2DM, the major factors are over-nutrition and sedentary lifestyle. These predispose to overweight and obesity, which in turn lead to T2DM. Worldwide diabetes poses substantial morbidity and premature mortality, as well as public health and socio-economic burden due to its long-term complications (1,2). The risk for these complications is related to overall glycaemic burden over time (2). Diabetes treatment is based on the rationale that controlling blood glucose to near normal range is the primary strategy that reduces or prevents diabetes complications, morbidity and premature mortality (3,4). Knowledge of diabetes, an integral component in diabetes care that influences change of attitude and practice, targets glycaemic control and thus minimizes the complications. Knowledge of diabetes is gained through Diabetes Self-Management Education (DSME) program (5).

An estimated 415 million adults (aged 20-79 years) had diabetes mellitus globally in the year 2015, 75% of whom were in developing resource-poor countries. This figure was projected to rise to a staggering 642 million people by 2040 (6), if risk factors for diabetes are not addressed. Kenya with an estimated prevalence of diabetes of 3.3%, had 1.8 million people with diabetes in 2015; the prevalence of diabetes was expected to increase to 4.5 % by 2025 (7). A sum total of US$ 673.0 billion was expended on diabetes-related healthcare globally in 2015, and the expenditure was anticipated to be in excess of US$ 802.0 billion by 2040 (6).

Several studies in developing (8-12) and developed countries (13) have documented sub-optimal glycaemic control among most patients with T2DM. Poor patient knowledge of diabetes has also been demonstrated (14). This study aimed to determine adequacy of glycaemic control, knowledge of diabetes, knowledge deficits and adherence to medication among the ambulatory adults with T2DM in a managed healthcare setting as an audit of glycaemic control.

Materials and methods

Study setting and recruitment: This was a cross-sectional descriptive study conducted from June 2015 through November 2015 in the diabetes outpatient clinic at Mbagathi Hospital, an urban secondary referral healthcare facility. A total of 165 patients with T2DM were recruited by simple random sampling. Inclusion criteria were patients aged ≥ 40 years, diabetes mellitus documented by WHO diagnostic criteria (15), one continuing prescription for diabetes treatment for a period of not less than three consecutive months prior to study entry, ability to understand and speak English and or Kiswahili and a duly signed informed written consent to participate in the study. Exclusion criteria were documented T1DM, severe illness or cognitive impairment and pregnancy. Instruments used for data collection were glycosylated haemoglobin A1c (HbA1c) assay (16,17), Michigan Diabetes Research and Training Centre (MDRTC) diabetes knowledge test questionnaire (18) and the 4-point modified Morisky Medication Adherence Scale (MMAS-4) (19). The questionnaires were administered by investigators to ensure that, through standardized explanations, patients understood the questions before answering them. HbA1c assay and the MDRTC diabetes knowledge test were employed to assess glycaemic control and level of knowledge on diabetes respectively. HbA1c assay provides information about the degree of long-term glucose control; it reflects mean blood glucose over the previous 8 - 12 weeks (16,17). The MDRTC diabetes knowledge test, a two-part 23-item questionnaire developed by the Michigan Diabetes Research Training Centre (US), assesses general knowledge of diabetes. Its first 14 questions are relevant to patients not on insulin therapy (most patients with T2DM), while the entire 23-item questionnaire is applicable to insulin-treated patients. The rationale for use of the MDRTC diabetes knowledge test questionnaire includes its reliability and validity as a research instrument (20). This study used the 14-item MDRTC diabetes knowledge test, which can be administered in about 15 minutes. The MMAS-4 is a structured 4-item self-reported adherence measure that assesses medication adherence.

Data analysis: Statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) version 21.0 software. Continuous data, e.g., age and HbA1c, were summarized in means, medians and Standard Deviation (SD), while categorical data, e.g., sex, marital status were summarized in frequencies and percentages. Glycaemic control was evaluated as mean HbA1c level, categorized into good control (HbA1c ≤ 7%) and poor control (HbA1c > 7%), and presented as percentage with 95% Confidence Interval. Knowledge of diabetes was worked out as mean MDRTC diabetes knowledge test score and categorized into good knowledge (DKT score ≥ 50%) and poor knowledge (DKT score < 50%). MMAS-4 score of zero was considered good adherence to medication, and MMAS-4 score 1 - 4 as poor adherence (or non-adherence) to medication.

Results

Socio-demographic characteristics of the patients are shown in Table 1. There was female predominance (66.1%). Mean age of the patients (± SD) was 55.7 ± 9.5

years, and median duration of diabetes was 3.0 years (IQR 1.0 - 7.0). Literacy level was at 93.3%. The vast majority (85.5%) of the patients had basic education. About 61% of the patients were employed. However, the study population was largely of low income status, with only 6.7% in the family annual pre-tax income bracket in excess of Kshs.150,000.00 (US$ 1 was equivalent to Kshs. 107.00). Mean HbA1c was 9.5%, a level higher than the recommended desired target of optimal glycaemic control by ADA, HbA1c < 7%. Other demographics are shown in Table 1.

Table 1: Distribution of socio-demographic characteristics of the patients

Characteristic	Frequency, *n* (%)
Mean (±SD) age in years (range in years)	55.7 ± 9.5 (40 - 89)
Gender	
Male	56 (33.9)
Female	109 (66.1)
Marital status	
Single	21 (12.7)
Married	127 (77.0)
Divorced/separated	5 (3.0)
Widowed	12 (7.3)
Level of formal education	
Formal education	11 (6.7)
Primary School education	97 (58.8)
Secondary School education	44 (26.7)
Tertiary education (College/University)	13 (7.9)
Employment	
Unemployed	65 (39.4)
Formal employment	29 (17.6)
Informal employment	71 (43.0)
Family annual income, Ksh. *(pre-tax income from all sources)*	
≤ 50,000.00	113 (68.5)
50,001.00 - 100,000.00	31 (18.8)
100,001.00 - 150,000.00	10 (6.1)
> 150,000.00	11 (6.7)
Who buys medication	
Self	128 (77.6)
Spouse	14 (8.5)
Child	19 (11.5)
Employer/Health Insurance Company	4 (2.4)

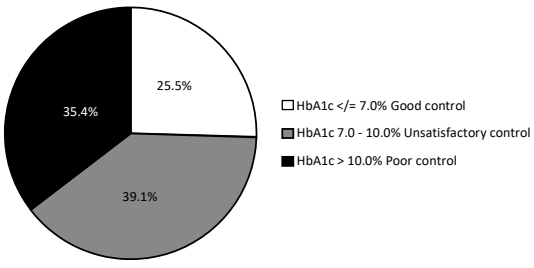
Table 2 shows diabetes-related characteristics of the patients. Most (92.1%) of the patients received DSME, the bulk of whom (70.9%) six months prior to their study entry. Almost 8% of the patients did not access diabetes education at all, while 15% did not have periodic training to re-enforce DSME for a period exceeding one year. About 85% of the patients were on oral hypoglycaemic agents (OHAs) for control of blood glucose, while only 15% were on insulin with or without metformin. Other characteristics were as shown in Table 2.

Table 2: Distribution of the diabetes-related characteristics of the patients

Characteristic	Frequency, *n* (%)
Median duration of diabetes in years (interquartile range, IQR) Range of duration of diabetes in years	3.0 (1.0 - 7.0) 3 months - 26 years
Family history of diabetes	
Yes	77 (46.7)
No	88 (53.3)
Diabetes education/update sessions	
None since diagnosis	13 (7.9)
≤ 6 months prior to recruitment into the study	117 (70.9)
7-12 months prior to recruitment into the study	10 (6.1)
> 1 year prior to recruitment into the study	25 (15.2)
Self-monitoring blood glucose (SMBG), glucometer utilization	
Yes	57 (34.5)
No	108 (65.5)
Anti-diabetic medications used	
Oral hypoglycaemic agent(s): Metformin ± Glibenclamide or Gliclazide	140 (84.9)
Insulin only	6 (3.6)
Insulin and oral hypoglycaemic agent: Insulin + Metformin	19 (11.5)
Median number of anti-diabetic drugs (interquartile range , IQR)	2 (1 - 2)

Figure 1 illustrates glycaemic control among the study patients. Adequacy of glycaemic control was low, at 25.5% (HbA1c < 7%). M:F 1:2. Females constituted 65.9% of the patients with poor glycaemic control (HbA1c > 7%). Over a third of the patients (35.4%), corresponding to nearly a half of the poorly controlled patients, had HbA1c level > 10%. Mean HbA1c (± SD) was 9.5 ± 3.1%, range 5.02% - 18.12%.

Figure 1: Glycaemic control among the study patients



Mean fasting blood glucose level was 10.9 mmol/l, range 3.7 - 32.7 mmol/l. Close to a quarter of the patients (26.1%) had normal blood glucose (<7.0 mmol/l). There were disparities in levels of HbA1c and fasting blood glucose in 20% of the patients. Slightly over one tenth of the patients (10.3 %) had normal HbA1c (≤ 7.0 %) and high blood glucose (≥ 7.0 mmol/l), while less than one tenth of the patients (9.7%) had high HbA1c (> 7.0 %) and normal blood glucose (< 7.0 mmol/l).

Table 3 describes association of glycaemic control with socio-demographic characteristics. Multivariate analysis revealed statistically significant difference in glycaemic control between the patients who were single and the married, p = 0.005 (OR 3.9, 95% CI, 1.5 to 10.1), suggesting glycaemic control was significantly associated with single (marital) status. There was also significant difference in glycaemic control between the patients in formal employment and the unemployed, p = 0.05 (OR 2.6, 95% CI, 1.0 - 6.6), suggesting glycaemic control was significantly associated with formal employment.

Table 3: Association of glycaemic control with socio-demographic characteristics

Characteristic	Controlled glycaemia (HbA1c ≤ 7.0) *n* (%)	Uncontrolled glycaemia (HbA1c > 7.0%) *n* (%)	OR (95% CI)	P-value
Gender				
Male	14 (25.0)	42 (75.0)	1.0	
Female	28 (25.7)	81(74.3)	1.0 (0.5 - 2.2)	0.923
Marital status				
Single	11 (52.4)	10 (47.6)	3.9 (1.5 - 10.1)	0.005
Married	28 (22.0)	99 (78.0)	1.0	
Separated/divorced	0 (0.0)	5 (100.0)	-	0.999
Widowed	3 (25.0)	9 (75.0)	1.2 (0.3 - 4.6)	0.814
Level of formal education				
No education Primary education Secondary education Tertiary education	2 (18.2)	9 (81.8)	1.0	
	21 (21.6)	76 (78.4)	1.2 (0.2 - 6.2)	0.790
	14 (31.8)	30 (68.2)	2.1 (0.4 - 11.0)	0.381
	5 (38.5)	8 (61.5)	2.8 (0.4 - 18.7)	0.285
Employment				
Unemployed	14 (21.5)	51 (78.5)	1.0	
Formal employment	12 (41.4)	17 (58.6)	2.6 (1.0 - 6.6)	0.050
Informal employment	16 (22.5)	55 (77.5)	1.1 (0.5 - 2.4)	0.889
Family annual income (KES)				
≤ 50,000.00	27 (23.9)	86 (76.1)	1.0	
50,001.00 - 100,000.00	10 (32.3)	21 (67.7)	1.5 (0.6 - 3.6)	0.347
100,001.00 - 150,000.00	1 (10.0)	9 (90.0)	0.4 (0.0 - 2.9)	0.335
> 150,000.00	4 (36.4)	7 (63.6)	1.8 (0.5 - 6.7)	0.367
Who buys medication				
Self	40 (31.3)	88 (68.7)	1.0	
Spouse	0 (0.0)	14 (100.0)	-	0.998
Child	2 (10.5)	17 (89.5)	0.3 (0.1 - 1.2)	0.080
Employer/Insurance Co.	0 (0.0%)	4 (100.0)	-	0.999

Table 4 shows association of glycaemic control with diabetes-related characteristics. There was significant difference in glycaemic control between diabetes education acquired over one year prior to study entry versus education acquired 6 months prior to the study, $p = 0.014$ (OR 0.3, 95% CI 0.1 - 0.8), suggesting that glycaemic control was significantly associated with diabetes education acquired over one year prior to study entry.

Table 4: Association of glycaemic control with diabetes-related characteristics

Characteristic	Controlled glycaemia (HbA1c ≤ 7.0%) No. (%)	Uncontrolled glycaemia (HbA1c > 7.0%) No. (%)	OR (95% CI)	P-values
Family history of diabetes				
Yes	21 (27.3)	56 (72.7)	1.0	-
No	21 (23.9)	67 (76.1)	0.8 (0.4 - 1.7)	0.616
Diabetes education/update sessions				
None since diagnosis	2 (15.4)	11(84.6)	0.2 (0.0 - 1.1)	0.061
≤ 6 months prior to the study	27 (23.1)	90 (76.9)	0.3 (0.1 - 0.8)	0.014
7-12 months prior to the study	1 (10.0)	9 (90.0)	0.1 (0.0 - 1.1)	0.060
> 1 year prior to the study	12 (48.0)	13 (52.0)	1.0	-
SMBG, glucometer utilization				
Yes	17 (29.8)	40 (70.2)	1.4 (0.7 - 2.9)	0.349
No	25 (23.1)	83 (76.9)	1.0	-
Anti-diabetic medications used				
Oral hypoglycaemic agent(s)[a]	39 (27.9)	101 (72.1)	1.9 (0.2 - 17.1)	0.554
Insulin monotherapy	1 (16.7)	5 (83.3)	1.0	-
Insulin and metformin combination	2 (10.5)	17 (89.5)	0.6 (0.0 - 7.9)	0.689

aMetformin ± glibenclamide or gliclazide

The study population demonstrated a high overall knowledge of diabetes, based on the 14-item MDRTC diabetes knowledge test. Mean DKT score (± SD) was 64.3 ± 15.3%, which was satisfactory; range 14% - 93%. Majority (90.9%) of the patients obtained DKT score ≥ 50%. These were presumed to have good knowledge of diabetes. Less than one tenth (9.1%) of the patients failed the diabetes knowledge test (DKT score < 50%), suggesting poor knowledge of diabetes. The female patients (62.4%) comprised the majority of the patients with good knowledge of diabetes. Other characteristics are as shown in Tables 5 and 6.

Table 5 shows association of knowledge of diabetes with socio-demographic characteristics. Female gender was associated with good knowledge of diabetes, p = 0.025 (OR 3.3, 95% CI 1.1 - 9.8). There was statistically significant difference in the knowledge of diabetes between patients who were unemployed and those in formal employment, p = 0.045 (OR 0.3, 95% CI 0.1-1.0), suggesting that unemployment was associated with good knowledge of diabetes. A trend towards poor knowledge of diabetes among patients with family annual income in excess of Kshs 150,000.00 (US$1,402) was noted, but this was not statistically significant, p= 0.054.

Table 5: Association of knowledge of diabetes with socio-demographic characteristics

Characteristic	Knowledge of diabetes, *n* (%) Good (DKT ≥ 50%)	Poor (DKT < 50%)	OR (95% CI)	P-value
Gender				
Male	47 (83.9)	9 (16.1)	1.0	
Female	103 (94.5)	6 (5.5)	3.3 (1.1 - 9.8)	0.025
Marital status				
Single	20 (95.2)	1 (4.8)	2.3 (0.3 - 18.4)	0.439
Married	114 (89.8)	13 (10.2)	1.0	
Separated/divorced	4 (80.0)	1 (20.0)	0.4 (0.0 - 4.4)	0.497
Widowed	12 (100.0)	0 (0.0)	-	0.999
Level of formal education				
No education Primary education	9 (81.8)	2 (18.2)	1.0	
Secondary education	91 (93.8)	6 (6.2)	3.4 (0.6 - 19.2)	0.171
Tertiary education	39 (88.6)	5 (11.4)	1.7 (0.3 - 10.4)	0.548
	11 (84.6)	2 (15.4)	1.2 (0.1 - 10.5)	0.855
Employment				
Unemployed	61 (93.8)	4 (6.2)	1.0	
Formal employment	23 (79.3)	6 (20.7)	0.3 (0.1-1.0)	0.045
Informal employment	66 (93.0)	5 (7.0)	0.9 (0.2-3.4)	0.835
Family annual income (KES)				
≤ 50,000.00	104 (92.0)	9 (8.0)	1.0	
50,001.00 -100,000.00	29 (93.5)	2 (6.5)	1.3 (0.3 - 6.1)	0.779
100,001.00 -150,000.00	9 (90.0)	1 (10.0)	0.8 (0.1 - 6.9)	0.882
> 150,000.00	8 (72.7)	3 (27.3)	0.2 (0.1 - 1.0)	0.054
Who buys medication				
Self	118 (92.2)	10 (7.8)	1.0	
Spouse	13 (92.9)	1 (7.1)	1.1 (0.1-9.3)	0.929
Child	16 (84.2)	3 (15.8)	0.5 (0.1-1.8)	0.263
Employer/Insurance Co.	3 (75.0)	1 (25.0)	0.2 (0.0-2.7)	0.254

* 1US$ = KShs. 107

Association of knowledge of diabetes with diabetes-related characteristics is presented in Table 6. Knowledge of diabetes was not associated with diabetes-related characteristics, $p > 0.05$. Although there was a trend towards poor knowledge of diabetes among patients not exposed to diabetes education since diagnosis, this was not statistically significant, $p = 0.086$.

Table 7 shows association of glycaemic control with knowledge of diabetes. Knowledge of diabetes was not significantly associated with glycaemic control, $p = 0.910$ (OR 0.9, 95% CI 0.3 - 3.1). Knowledge deficits, based on DKT questions incorrectly answered by more than 50% of the patients, were identified in areas related to diet, treatment of hypoglycaemia and effect of physical activity on blood glucose.

Table 6: Association of knowledge of diabetes with diabetes-related characteristics

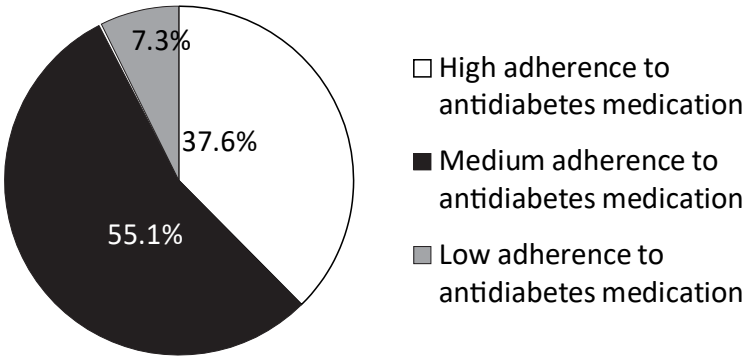
Characteristic	Knowledge of diabetes, *n* (%) Good (DKT ≥ 50%)	Poor (DKT < 50%)	OR (95% CI)	P-value
Family history of diabetes				
Yes	69 (89.6)	8 (10.4)	1.0	
No	81 (92.0)	7 (8.0)	1.3 (0.5-3.9)	0.587
Diabetes education/update sessions				
None since diagnosis	9 (69.2)	4 (30.8)	0.2 (0.0-1.3)	0.086
≤ 6 months prior to recruitment	109 (93.2)	8 (6.8)	1.2 (0.2-5.9)	0.837
7-12 months prior to recruitment	9 (90.0)	1 (10.0)	0.8 (0.1-9.7)	0.849
> 1 year prior to recruitment	23 (92.0)	2 (8.0)	1.0	
SMBG, glucometer utilization				
Yes	52 (91.2)	5 (8.8)	1.0	
No	98 (90.7)	10 (9.3)	0.9 (0.3-2.9)	0.918
Type of treatment				
Oral hypoglycaemic agent(s) [a]	124 (91.2)	12 (8.8)	1.0	
Insulin monotherapy	4 (100.0)	0 (0.0)	-	0.998
Insulin and metformin	20 (95.2)	1 (4.8)	0.6 (0.1-5.1)	0.603

[a]Metformin ± glibenclamide or gliclazide

Table 7: Association of glycaemic control with knowledge of diabetes

Characteristic	Controlled glycaemia (HbA1c ≤ 7.0%) *n* (%)	Uncontrolled glycaemia (HbA1c > 7.0%) *n* (%)	OR (95% CI)	P-value
Level of diabetes knowledge				
Good knowledge	38 (25.3)	112 (74.7)	0.9 (0.3-3.1)	0.910
Poor knowledge	4 (26.7)	11 (73.3)	1.0	

Figure 2: Adherence to medication of study patients as assessed by modified Morisky medication adherence scale



Adherence to medication among the study patients is shown in Figure 2. The level of adherence to medication was low, at 37.6%, female patients comprising 23.7%. Non-adherence to medication was high (62.4%) among these patients, female patients accounting for 42.4%. The mean age of patients with good adherence to medication was 56.1 years, while that for poor adherence to medication was 55.5 years. The median duration of diabetes for patients with adherence to medication and for patients with non-adherence to medication were 4.5 years and 5.1 years respectively.

Table 8 shows association of adherence to medication with socio-demographic characteristics of the patients. Analysis showed significant difference in non-adherence to medication between family annual income of less Ksh. 50,000.00 and Ksh. 50,001.00 - 100,000.00, p = 0.043 (OR 2.3, 95% CI, 0.0 - 5.2). There was also significant difference in non-adherence to medication between taking of medication provided by spouses of patients versus that of medication bought by patients, p = 0.030 (OR 0.1, 95% CI, 0.0 - 0.8). Family annual income of less than Ksh. 50,000.00 and provision of medications by spouses of patients were significantly associated with non-adherence to medication.

Table 8: Association of adherence to medication with socio-demographic characteristics

Characteristic	Adherence n (%)	Non-adherence n (%)	OR (95% CI)	P-value
Gender				
Male	23 (41.1)	33 (58.9)	1.0	
Female	39 (35.8)	70 (64.2)	0.8 (0.4 - 1.6)	0.507
Marital status				
Married	46 (36.2)	81 (63.8)	1.0	
Single	11 (52.4)	10 (47.6)	2.2 (0.8 - 5.6)	0.115
Separated/divorced	1 (20.0)	4 (80.0)	0.4 (0.1 - 4.1)	0.469
Widowed	4 (33.3)	8 (66.7)	0.7 (0.2 - 2.2)	0.583
Level of formal education				
No education	5 (45.4)	6 (54.6)	1.0	
Primary education	32 (33.0)	65 (67.0)	0.6 (0.2 - 2.1)	0.413
Secondary education	19 (43.2)	25 (56.8)	0.9 (0.2 - 3.4)	0.892
Tertiary education	6 (46.1)	7 (53.9)	1.0 (0.2 - 5.2)	0.973
Employment				
Unemployed	22 (33.8)	43 (66.2)	1.0	
Formal employment	13 (44.2)	16 (55.2)	1.6 (0.7 - 4.0)	0.294
Informal employment	27 (38.0)	44 (68.0)	1.2 (0.6 - 2.5)	0.577
Family annual income (KES)				
≤ 50,000.00	39 (34.5)	74 (65.5)	1.0	
50,001.00 - 100,000.00	17 (54.8)	14 (45.2)	2.3 (1.0 - 5.2)	0.043
100,001.00 - 150,000.00	1 (10.0)	9 (90.0)	0.2 (0.0 - 1.7)	0.147
> 150,000.00	5 (45.4)	6 (54.6)	1.6 (0.5 - 5.5)	0.472
Who buys medication				
Self	55 (43.0)	73 (57.0)	1.0	
Spouse	1 (7.1)	13 (92.9)	0.1 (0.0 - 0.8)	0.030
Child	6 (31.6)	13 (68.4)	0.6 (0.2 - 1.7)	0.350
Employer/Insurance Co.	0 (0.0)	4 (100.0)	-	-

Table 9 is a summary of association of adherence to medication and diabetes-related characteristics. Statistically significant difference was noted in non-adherence to medication between diabetes education gained 7-12 months prior to the study entry and diabetes education gained more than one year, p = 0.031 (OR 0.1, 95% CI 0.1 - 0.8). Diabetes education gained 7-12 months prior to study entry was associated with non-adherence to medication. There were significant differences in non-adherence to medication between use of one OHA and two OHAs, p = 0.004 (OR 0.3, 95% CI 0.1 - 0.7) and use of one OHA and combination therapy of insulin and OHA, p = 0.001 (OR 0.1, 95% CI 0.0 - 0.3). Treatment with two OHAs and combination therapy of insulin and one OHA was associated with non-adherence to medication.

Table 9: Association of adherence to medications with diabetes-related characteristics

Characteristic	Adherence No. (%)	Non-adherence No (%)	OR (95% CI)	P-value
Family history of diabetes				
Yes	32 (41.6)	45 (58.4)	1.0	
No	30 (34.1)	58 (65.9)	0.7 (0.4 - 1.4)	0.324
Diabetes education/update sessions				
None since diagnosis	4 (30.8)	9 (69.2)	0.4 (0.1 - 1.4)	0.146
≤ 6 months prior to the study	43 (36.7)	74 (63.3)	0.5 (0.2 - 1.1)	0.079
7-12 months prior to the study	1 (10.0)	9 (90.0)	0.1 (0.0 - 0.8)	0.031
> 1 year prior to the study	14 (56.0)	11 (44.0)	1.0	
SMBG, glucometer utilization				
Yes	25 (43.9)	32 (56.1)	1.0	
No	37 (34.3)	71 (65.7)	0.7 (0.4 - 1.3)	0.227
Type of treatment				
OHA (1) – metformin only	17 (68.0)	8 (32.0)	1.0	
OHAs (2)[a]	41 (35.7)	74 (64.3)	0.3 (0.1 - 0.7)	0.004
Insulin monotherapy	2 (33.3)	4 (66.7)	0.2 (0.0 - 1.6)	0.134
Insulin/metformin combination	2 (10.5)	17 (89.5)	0.1 (0.0 - 0.3)	0.001

[a]Metformin ± glibenclamide or gliclazide

Association of adherence to medication with glycaemic control and knowledge of diabetes is presented in Table 10. Almost all patients (90.5%) with good glycaemic control had good adherence to medication, while 19.5% of patients with sub-optimal glycaemic control had good adherence to medication. Thirty nine percent of the patients with good knowledge of diabetes and 20% of patients with poor knowledge of diabetes had good adherence to medication. There was no significant association between adherence to medication and glycaemic control, p = 0.061 (OR 0.2, 95% CI, 0.1 - 0.3), There was also no association between adherence to medication and knowledge of diabetes, p = 0.905 (OR 1.1, 95% CI, 0.3 - 3.4).

Table 10: Association of adherence to medication with glycaemic control and knowledge of diabetes

Characteristic	Adherence No. (%)	Non-adherence No. (%)	OR (95% CI)	P-value
Glycaemic control				
Controlled glycaemia (HbA**1**c < 7.0%)	38 (23.0)	4 (2.4)	1.0	
Uncontrolled glycaemia (HbA**1**c > 7.0%)	24 (14.5)	99 (60)	0.2 (0.1 - 0.3)	0.061
Patient knowledge of diabetes				
Good knowledge (DKT ≥ 50%)	59 (35.8)	91(55.2)	1.1 (0.3- 3.4)	0.905
Poor knowledge (DKT < 50%)	3 (1.8)	12 (7.3)	1.0	

Discussion

Despite high patient knowledge of diabetes in this study, there was evidence of low glycaemic control and adherence to medication, implying that knowledge did not translate into good diabetes practice, particularly adherence to medication for good glycaemic control. Thirty five percent of the patients had HbA1c level > 10%, reflecting possible patient non-adherence to medication and or inertia in management of diabetes by resident clinicians. Twenty per cent of the patients had disparities in HbA1c and fasting blood glucose levels, demonstrating the need to employ HbA1c assay in monitoring long-term glycaemic control as compared to blood glucose tests whose results frequently vary with food intake.

Studies in both developing and developed countries have documented sub-optimal glycaemic control among most patients with T2DM (8-13). Local studies at Kenyatta National Hospital (KNH), a university teaching and tertiary referral hospital in Nairobi, have shown low levels of glycaemic control (8-12), ranging from 13.9% to 39.5% (8,9). Vaghela (10) and Omari (11) in KNH, documented glycaemic control of 29.9% and 29.5% respectively. These levels were comparable with the finding in this study. Mwavua *et. Al* (12) in 2016 reported a much lower level of glycaemic control of 17% in a multicentre comparative study of the quality of care and glycaemic control among ambulatory patients with T2DM at KNH and Thika District Hospital (a peripheral urban secondary health facility). This suggested possible widespread sub-optimal glycaemic control countrywide. A cross-sectional multicentre study on glycaemic control among patients with T2DM in seven European countries from 2006 - 2007 by Alvarez *et al* (13) reported glycaemic control among 25.5% of the patients, a level similar to that noted in our study. Otieno *et al* (9) in a study in KNH attributed poor glycaemic control largely to poverty. In our study, poor glycaemic control was similarly due to low economic status. This impacted access to healthcare services and hence glycaemic control. Factors associated with good glycaemic control in this study were diabetes education acquired over one year prior to study entry, single (marital) status and formal employment.

Knowledge of diabetes in this study was high. It was comparable to the level of knowledge of diabetes of 77.2% in a study at KNH by Omari *et al* (11). In the study at KNH the high level of knowledge of diabetes was as attributed to the DSME offered (11). In this study, the high knowledge of diabetes (90.9%) similarly reflected quality of DSME offered at the healthcare facility. In contrast, Odili *et al* (14) in Nigeria, in a study using DKT, reported poor knowledge of diabetes (mean DKT score 39.5 % ± 16.7 %), which was attributed to patient diabetes education and cultural beliefs about diabetes. Factors associated with good knowledge of diabetes were female gender and unemployment. Association of knowledge of diabetes with female gender was possibly related to the postulated better health-seeking behaviour of females (21). The association of knowledge of diabetes with unemployment was likely due to relatively ample time the unemployed patients had to interact and acquire knowledge of diabetes; most patients who declined to participate in the study were the employed, citing need not to delay to report back to work.

Knowledge of diabetes was not associated with glycaemic control. This was not unusual as knowledge of diabetes is only a component of diabetes care, and demands of glycaemic control stretch beyond knowledge of diabetes. Dissociation of knowledge of diabetes and glycaemic control has been observed in various studies. Studies by Omari *et al* (11) and Islam *et al* (22) reported similar findings. Islam *et al* (22) in Bangladesh, attributed their findings to lack of access to healthcare by the general population. In our study, this was because of poor access to healthcare services and non-adherence to medication largely due to high healthcare costs and limited income of the patients.

Knowledge deficits in diabetes were identified in areas related to diet, physical activity and treatment of hypoglycaemia. Appropriate diet and physical activity, which constitute lifestyle modification in diabetes management, promote weight loss and

improve glycaemic control (1,2). Knowledge deficits in diet and physical activity in this study population suggested probable association of sub-optimal glycaemic control with unsuitable dietary practices and physical activity. Maina *et al* (23) in Kenya, observed knowledge gaps in adherence to both dietary practices and physical exercises, consistent with the findings in our study, suggesting possible widespread prevalence of these deficits among patients with diabetes in this country. Al-Rasheedi (24) in Saudi Arabia, also noted significant association of poor glycaemic control with poor adherence to dietary advice and physical activity. Knowledge deficits in our study were attributed to lack of knowledge about benefits of suitable diet and physical activity in glycaemic control. The deficit in treatment of hypoglycaemia was of critical significance in this study population. It posed a huge challenge, as 35.4% of the patients had HbA1c level >10%, and essentially required insulin-based therapy, which potentially predisposes to hypoglycaemia with risk of loss of life, if not promptly recognised and managed. This deficit was probably due to lack of emphasis on treatment of hypoglycaemia in DSME program and or understanding of consequences of failure to recognize and treat hypoglycaemia.

The level of non-adherence to medication was high (62.4%). Comparatively, this was higher than that reported in KNH by Omari *et al* (11) (39.8%), and Pascal *et al* (25) in Eastern Nigeria in 2012. It was lower than that in the study by Sankar *et al* (26) in rural Kerala, India. Pascal *et al* (25) documented financial constraint as a factor associated with non-adherence to medication. In our study, non-adherence to medication was similarly due to financial constraints, largely resulting from low income status.

There was no statistically significant association of non-adherence to medication with glycaemic control and knowledge of diabetes. Factors associated with non-adherence to medication were low family income, diabetes education, multiple anti-diabetes drug regimen and who bought medication (person or entity). Association of non-adherence to medication and low family income was possibly due to inability to obtain medication because of financial limitations. In a study in Kerala, India, Shaimol *et al* (27) noted low-income patients were less adherent to prescribed therapy than high-income patients. Association of non-adherence to medication and diabetes education gained 7-12 months prior to study entry (compared to diabetes education obtained more than one year) was probably due to inadequate internalized knowledge of diabetes. Sankar *et al* (26) in India, attributed high rate of non-adherence to limited diabetes education and low per capita monthly expenditure, among other factors. Association of non- adherence to medication and multiple anti-diabetes drug regimens was possibly due to inability to afford high cost of medication.

Given the evident dissociation of glycaemic control and knowledge of diabetes, it was necessary that factors affecting glycaemic control, including but not limited to non-adherence to medication and identified knowledge deficits, should be promptly addressed by the relevant authorities so as to facilitate adequate glycaemic control, as re-enforcement of quality knowledge of diabetes is maintained. Importantly, provision of free healthcare service to the unemployed and persons in low income brackets, from a publicly funded national healthcare system should be considered. Strategies to identify and resolve other potential barriers to glycaemic control should be employed to augment adequate glycaemic control in this study population with scarce financial resources.

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Commentary

The Role of Healthcare Professional Societies

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Abstract

Is healthcare a profession in its own right? And what is the role of professional bodies? Without professional bodies, there would be no professions. Profession is distinct from a job or an occupation, Profession's distinguishing features – which include accountability, self-regulation, altruism, and a commitment to continued high standards – are actualized through the work of its professional bodies (1). Healthcare educators participate in professional bodies for many reasons to do with asserting and maintaining their place as professionals. There are three main reasons why individuals join a professional body: to demonstrate and maintain their membership of a profession; to uphold their profession's ethical standards and enhance its special position within society and to maintain and develop their professional expertise. While each healthcare profession's infrastructure will vary, it is usually possible to observe within each area of professional practice one or more organizations that serve the public by maintaining a register of practitioners and ensuring that standards are met, serve members by offering them opportunities to add to, explore, and communicate their expert knowledge base; and to serve the profession by acting as a collective voice, particularly on issues that affect them.

Key words: Profession, Healthcare, Professional Association, Membership, Standards, Education

Medical societies, associations and groups comprising of doctors, pharmacists or other representatives of the medical profession have been present since the dawn of the Scientific Revolution in the 17th and 18th centuries (2,3). The Scientific Revolution was a series of events that marked the emergence of modern science during the early modern period in the 17th century, when developments in mathematics, physics, astronomy, biology (including human anatomy) and chemistry transformed the views of society about nature. It continued through the late 18th century, influencing the intellectual social movement known as the Enlightenment, which synthesized ideas concerning God, reason, nature, and humanity into a worldview that celebrated reason. This marked the dawn of modern medicine (4).

Dr John Coakley Lettsom, who founded the Medical Society of London in 1773, invited physicians, surgeons and apothecaries in its ranks, said that the association should be, "*A Society of medical practitioners of various ranks who would meet together to compare their observations and compare their thoughts mutually, taking note of new discoveries at home and abroad*"(5).

It is this noble challenge that was taken up by countless medical associations across the world, one of them being the Kenya Association of Physicians (KAP). Founded a quarter century ago (6), the aims and objectives of KAP is to maintain the highest standard of medical practice by providing continuing professional development to its members through various interactive physical and, since the advent of Covid 19, now mainly virtual activities. In addition, it incorporates other core elements of a professional society, including: defence and promotion of professional interest of its members; defining and enforcing professional standards in medical training and practice; promoting academic research and exchange, and; community extension and outreach (7).

The Kenya Association of Physicians (KAP) has experienced low membership over the years. However, this apathy towards a professional society's activities by its members is not unique to doctors (8). Quite often, members often cite lack of time or incongruence of interest for their failure to adequately participate in professional societies (9). However, it is important to appreciate the fact that professional societies provide a way for individual members to remain connected in a meaningful way by facilitating structured opportunities for networking, including formal and informal mentor-mentee relationships and continued medical education opportunities. Evidently, despite the significant competing time and activity pressures, it is in the best interest of individual professionals and, by extension, the patients and community at large, for doctors to be meaningfully engaged with their professional medical associations.

Granted, medical associations are not perfect. We also know that those who join them tend to do so for their own personal reasons, which may change over time. That said, I am a firm believer that we are always stronger personally and professionally when we work

together, and the benefit of being a part of something greater in medicine has compound benefits that cannot be gainsaid.

The noble task of sharing knowledge, exchanging thoughts and the results of the latest research was the primary task of medical societies in the 18th-19th century as the exchange of information was way more limited than today. Arising from such broad consensus, recommendations or Clinical Practice Guidelines (CPGs) have remained the cornerstones of professional medical practise ever since (10).

Clinical Practice Guidelines (CPGs) promote a progressive and responsive healthcare that is based on a combination of scientific evidence, knowledge gained from clinical experience, and patient value judgments and preferences (11). They are developed through a transparent process by a group of multidisciplinary experts screened for minimal potential bias and conflicts of interest, and supported by a systematic review of the evidence. Thus, CPGs help clinician and patient decision making by clearly describing and appraising the evidence and reasoning regarding the likely benefits and harms related to specific clinical recommendations (12).

With the advent and proliferation of technology, the original function of connecting colleagues for exchanging knowledge and creating a platform for discussions has been considerably widened (13). Beyond keeping their members informed through all available means of communication, medical associations have increasingly undertaken the causes of medical professionals by advocating for their rights and interests, assisting doctors in protecting the interests of their patients, and helping settle their disputes.

In addition, as physicians, nurses, surgeons, medical students, and other medical professionals are looking for yardsticks to smoothly take the transition from analogue to digital healthcare systems, medical associations have all the means to give a helping hand. They have the structure to educate key healthcare actors about the latest technological changes and how to integrate digital health achievements in clinical practice (14).

Perhaps one of the most valuable roles a medical professional society can play is to provide a way for individual physicians to remain connected in a meaningful way with the core principles and values that led them to medicine in the first place and to those who share them. Being a physician can be a fairly solitary enterprise, and fostering ongoing relationships with like-minded colleagues can serve to counter the growing sense of isolation that physicians often feel in the current healthcare environment. It is this inherent fellowship with our medical colleagues that may be the key to combating our feelings of loneliness, instead providing a sense of empowerment and restoring joy in the work of doctoring (12).

For professional bodies to survive into the next century, further change will be necessary. Such changes will almost certainly include closer inter-professional working and the development of multi-professional collaborations and mergers. Healthcare educators, whatever their clinical or academic specialty, need to work together to raise the status of healthcare education as a profession; it is therefore important that individuals support and participate in their professional bodies as a means of developing healthcare education for the benefit of students, patients, and society as a whole (15).

Thus, by balancing the professional against economic, commercial and social pressures, the professional society lends equilibrium to the otherwise dizzyingly changing medical landscape. Let us all maintain our membership in the KAP; let us actively participate in its programmes; and let us rejoice in the shared labour and responsibility of our hallowed calling.

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