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# Relationship between Self-management and Quality of Life among Patients with Diabetes Mellitus: A Cross-Sectional, Correlational Study



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# Abstract:

**Background:** Diabetes is managed by prescribed medication and dietary measures to control blood sugar, but self-management is a vital aspect of this management. Self-management is a complex bio-psycho-social phenomenon, a crucial task in monitoring the negative consequences of the condition and enhancing quality of life.

*Objective:* This study aimed to examine the relationship between self-management and health-related quality of life among Saudi patients with diabetes.

*Methods:* A descriptive, cross-sectional, comparative study design was adopted. Self-reported questionnaires were administered to 87 Saudi patients with diabetes in 2021. Data were analysed using Pearson's r and t-test.

**Results:** The total adherence mean of diabetes self-care activities was 2.84 (SD=1.83), which is considered inadequate. The mean score for the total health-related quality of life was 57.35 (SD=15.01), which is regarded as fair. Patients with higher physical and social quality of life reported more adherence to self-management activities. Older patients generally experienced poorer quality of life. Patients with higher body mass index reported statistically significantly more body pain. Male patients reported higher total quality of life and role functioning. Females reported more body pain than males.

**Conclusion:** Diabetic patients have particular challenges in controlling the disease. Nurses and other healthcare providers need to empower patients to engage in culturally appropriate self-management and physical exercise. The results reported here could be used to design a specific health promotion policy that addresses the promotion of physical exercise and self-management of diabetes care. These policies should consider cultural nuances and be tailored to different demographic groups.

**Keywords:** Diabetes mellitus, Self-management, Health-related quality of life, Cross-sectional study, Comparative study, Self-reported questionnaires.

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## 1. INTRODUCTION

#### 1.1. The Burden of Diabetes in Saudi Arabia

Diabetes mellitus (DM) is a global chronic disease that causes threats to human health [1, 2]. As estimated by the International Diabetes Federation (IDF) in 2021, the maximum incidence of diabetes overall is anticipated to occur in the Middle East and North Africa as a result of rapid economic and financial development, together with variations in lifestyle habits in these areas [3]. Diabetes is one of the most common health problems in the Kingdom of Saudi Arabia (KSA) [4]. In 2020, the prevalence of diabetes among Saudi adults was 18.3%, with 4,275,200 total adult cases [5]. This increasing disease burden results from numerous factors, including consanguine marriage, rising incidence of obesity, susceptibility to insulin resistance, aging population, and lifestyle changes [1]. Cardiovascular disease has been found to be a major cause of DM in the country [6]. Its rising incidence and prevalence in Saudi Arabia affect the elderly, adolescent, and urban populations [7].

DM is a serious, long-term chronic metabolic condition manifested by elevated blood glucose levels when the pancreas produces little or no insulin (type 1 diabetes – T1DM), cells' resistance to insulin (type 2 diabetes – T2DM), or both [8]. It affects nearly 10% of the global population above 20 years of age. Type 2 diabetes is the most prevalent, accounting for 90%-95% of all cases [3]. DM exerts a major impact on the lives and well-being of individuals, families, and societies worldwide [9], and it is one of the top ten diseases that cause death in adulthood [8].

The estimated incidence of DM in adults in Saudi Arabia is 17.7%, significantly higher than the global (8.8%) and regional (10.7%) incidences [3]. Some studies have focused on self-management by patients with diabetes in Thailand [10, 11], Egypt [12], and Taiwan [13], while others have concentrated on health-related quality of life (HRQL) in the same population in Malaysia [14] or (in Iran) combined both variables [15, 16]. However, the association between self-management and quality of life among patients with T2DM has not been studied yet in the societal and cultural context of Saudi Arabia.

# 1.2. Self-management in Diabetes

Diabetes is managed by prescribed medication and dietary measures to control blood sugar, but an Ethiopian

systematic review of 39 studies noted that self-management is a vital aspect of managing diabetes effectively [17]. Self-management is a complex bio-psychosocial phenomenon, a crucial task in monitoring the negative consequences of the condition and effecting behavioural adjustment [18]. Self-management is the cornerstone of diabetes care and includes diet, exercise, blood glucose monitoring, and foot care. Canadian research reported that it plays a significant role in influencing quality-of-life outcomes [19].

A qualitative study explored the self-management experiences of adults with diabetes through a focus group in Taiwan, emphasizing the involvement of healthcare teams in the self-management education of patients to improve their quality of life [13]. Similarly, semistructured interviews provided insight into the experiences of self-management practices among Thai people with diabetes [10]. The findings accentuated the discovery of the causes of behavioural changes before designing self-care programmes and education for patients, their families, and their friends. Moreover, experiences, barriers, and challenges of diabetes selfmanagement in Pakistan were also explored [20], and significant gender differences were identified. It was found that women were more ready to adapt and willing to integrate daily self-management, while men perceived the negative effects of stigma more acutely. Women were more interactive in seeking an understanding of the condition, whereas men preferred self-directed education. However, all complained of lack of professional support as the main barrier to self-management. This was supported by research in Saudi Arabia, which found that healthcare providers providing adequate information and empowering patients with diabetes are the essential elements of effective self-care management plans [18].

A systematic review of 10 randomized controlled trials (RCTs) was conducted in Australia to assess the effectiveness of self-management interventions on glycaemic control (HbA1c) and behaviour (exercise, healthy diet, foot care, blood glucose self-monitoring, and medication adherence) in T2DM [21]. Patient activation interventions exerted positive effects on glycaemic control, and self-management was found to be effective across different intervention approaches, methods of delivery, the extent of intervention, and the number of providers. Korean researchers conducted a systematic review and meta-analysis of self-management nursing

interventions for controlling blood glucose in diabetes [22]. This review focused on the impact of self-management on HbA1c and body mass index, quality of life, depression, and anxiety. The review reported that HbA1c was decreased significantly. However, programs are required to be personalised to patients' personal characteristics and circumstances to be effective.

#### 1.3. Quality of Life in Diabetes

A cross-sectional observational study in Malaysia determined the predictors of HRQL among 430 patients with T2DM [14]. A study revealed that patients using insulin therapy had better diabetes-related knowledge and treatment adherence characteristics that reflected positively on HRQL than non-insulin users. In Botswana, a randomised cross-sectional study of HRQL and its associated factors in 380 diabetic patients found that most patients had relatively poor HRQL, affecting both physical and mental well-being [23]. Since most patients present late with complications, policy changes are necessary to promote early diagnosis and prevent associated complications. Improving HRQL must include programs of self-management as well as medication adherence.

The Short Form 36 Health Survey (SF-36) was used to investigate HRQL among 5472 Iranian patients with T2DM in a meta-analysis [15]. Only moderate quality of life was found, with physical factors being the most problematic and social functioning of least concern. Increasing age was found to be related to worsening HRQL. Research in the Dominican Republic emphasised the importance of considering differing domains of HRQL when considering the impact of metabolic control [24]. The use of measurement (in this case, MDQoL-17) was noted in an Indian study to be central to establishing the patient's perspective as well as objective assessment of HRQL [25].

Another systematic review by Mexican researchers applied the World Health Organization Quality of Life Instrument (WHOQOL) and SF-36 to review the quality of life among patients with DM in Latin-American populations [26]. It was found that better quality of life was reported by patients who received guidance and treatment regularly to control their diabetes than by patients with severe complications, comorbidities, or foot ulcers. This population was found to experience generally poor HRQL. No improvement was seen from insulin therapy. Psychosocial support was vital to increasing HRQL, but comorbidity exerted a negative impact.

HRQL among patients with diabetes was investigated in one province of the Kingdom of Saudi Arabia [4]. The cross-sectional, multicentre study employed a validated, self-administered questionnaire. The condition exerted negative impacts on general health and daily activities in more than 70% of participants. Another randomised, cross-sectional study in primary health care centres of Saudi Arabia evaluated the quality of life in diabetic patients aged 30-60, excluding those with mental disorders, physical and cognitive disability, or gestational diabetes [27]. In relation to physical, mental, social, and work aspects, more than half of the 179 participants

showed a high quality of life in all aspects, though 3.4-16.2% reported a low quality of life in the same aspects.

## 1.4. Self-management and Quality of Life

A cross-sectional survey of 3352 patients with T2DM was conducted in the Netherlands, and it was found that self-management skills and HRQL corresponded positively with patients' mastery and perceived autonomy [28]. A 22-study systematic review and meta-analysis in China revealed that participants who received a smartphone-based self-management intervention had better self-care activities, self-efficacy, HRQL, and lower glycated haemoglobin (pooled MD=-0.55; p<0.001) [29].

A quasi-experimental pre-test post-test study was conducted to assess the impact of self-care educational programs in Iran in improving HRQL among 30 non-randomized patients with diabetes using the Iranian SF-36 [16]. A significant increase was observed in most of the domains of HRQL, including physical role, general health, social functioning, physical functioning, and body pain. A cross-sectional study in Malaysia on 266 patients with T2DM examined the effect of diabetes knowledge and attitudes on self-management and HRQL. Diabetes knowledge was found to be a significant predictor of self-management, while attitude was a significant predictor of impact on HRQL, as were self-management and diet [30].

#### 1.5. Summary

Diabetes is a serious, increasing health issue in Saudi Arabia. Self-management holds great promise for improvement in a variety of patient outcomes, while HRQL is susceptible to a host of threats, with differences between genders and across continents and cultures. Self-management itself can exert positive physical and psychological effects on HRQL. A gap was found in the knowledge to guide interventions for Saudi patients with diabetes in their particular cultural context and against the background of intractable prevalence.

#### 2. METHODS

#### 2.1. Aim

To examine the relationship between self-management and HRQL among Saudi patients with diabetes in order to develop culturally effective programs for Saudis and others in the Middle East region.

#### 2.2. Objectives

The following were the objectives of this current study:

- 1) Determine the level of self-management among Saudi patients with DM.
- 2) Determine the level of HRQL among Saudi patients with DM.
- 3) Examine gender-related differences in self-management and HRQL.  $\label{eq:constraint} % \begin{subarray}{ll} \end{subarray} % \begin{subarra$

#### 2.3. Study Design

A descriptive, cross-sectional, comparative study

design was adopted. Self-reported questionnaires were administered in 2021.

## 2.4. Setting

Data was collected from patients from 2 clinical settings, who were diagnosed with DM as affirmed by medical records from outpatient clinics in King Abdulaziz Medical City, Ministry of National Guard Health Affairs, Al Ahsa, King Abdulaziz Medical City, and Ministry of National Guard Health Affairs in Riyadh.

#### **2.5. Sample**

Convenience sampling was used. The inclusion criteria were patients with DM diagnosed at least one year previously, of at least 18 years of age, and able to speak Arabic. Only those who actively agreed to participate in the study were included. Patients diagnosed with cognitive or mental disorders were excluded because their responses could bias the result.

#### 2.6. Ethical Issues

Ethical approval was obtained from the College of Nursing at Al Ahsa and the King Abdullah International Medical Research Centre (RA20/002/A). Research assistants introduced the study and distributed the invitation letter during appointments in outpatient clinics. The nature of voluntary participation was emphasised, and anonymity was assured. All personal and study data were stored securely by the PI in a locked office with access limited to the researchers. The requirements of the Helsinki Declaration were followed for involving human subjects in the study, and formal, explicit consent was obtained from all patients before data collection.

## 2.7. Data Collection

The targeted hospitals were contacted to assign the head of the unit to the role of research liaison to facilitate approaching the patients and accessing patients' records. The nurses in charge helped to identify eligible patients. Patients with DM who agreed to participate sat with a research assistant to complete the survey, which, on average, took about 15 minutes. Clinical information was retrieved from patients' records, including weight and height (for BMI calculation), HA1C, and type of medication. The questionnaire package consisted of 3 sections. Demographic variables of age, gender, marital status, year of diagnosis, duration of living with DM, hobbies, and medical treatment were elicited. Then, the Arabic-validated version of the Summary of Diabetes Self-Care Activities - Arabic (SDSCA-Arabic) was followed. This consists of four subscales: diet, exercise, blood glucose testing, and foot care [31]. Finally, the SF-36 Health Survey was used to measure HRQL. This consists of 36 items with eight dimensions. Four subscales address the mental component summary (MCS), and four more make up the physical component summary (PCS). All item scores are coded and transformed for the PCS and the MCS into a scale of 0 (poor health) to 100 (optimal health) in both dimensions. Good internal consistency was reported [32].

#### 2.8. Data Management and Analysis

IBM SPSS Statistics was used for data analysis (version 22). Descriptive statistical analysis was used to describe the research sample and the items of the questionnaires. Pearson correlation coefficient (r) was used to examine the relationship between the variables. The t-test was used to examine the differences in self-management and HRQL mean scores between males and females. Significance was set at p=0.05.

## 3. RESULTS

#### 3.1. Characteristics of Study Participants

The sample consisted of 87 patients diagnosed with diabetes. Of these, 58 (66.7%) were female. Forty-nine patients (54%) were from Riyadh and 40 patients were from Al Ahsa (46%). The mean age was 45.18 years (SD=15.16), with a range from 18 to 70 years. The mean income was SR8808. All patients were Muslims, and most were married (n=65, 75.6%). The average time since diagnosis was 12.88 years (SD=7.80). The mean score for HA1C was 8.54 (SD=2.11), and for BMI was 30.60 (SD=7.54). Most were treated with insulin (54%), and 46 (52.9%) reported no hobbies.

#### 3.2. Diabetes Self-care Activities

The total adherence mean was 2.84 (SD=1.83). The individual item with the highest adherence rate was "test blood sugar within the previous 7 days" (M=4.27, SD=3.02), whereas the item that had the lowest adherence rate was "participation in strict exercise session" (M=1.36, SD=2.33). Table 1 presents a detailed item analysis of diabetes self-management practices.

Table 1. Diabetes self-care activities.

Diabetes Self-care Activities Subscales	Mean	SD
Diet	2.44	2.82
Exercise	1.78	2.11
Blood sugar test	3.97	2.90
Foot care	3.23	2.97
Total	2.84	1.83

## 3.3. HRQL Scores

The mean score for the total HRQL was 57.35 (SD=15.01). The *social functioning* subscale was found to be the best functioning domain, and *body pain* was the poorest functioning subscale (Table 2).

# 3.4. Relationship between Diabetes Self-management and HROL

Pearson correlation was used to examine the relationship between total diabetes self-management mean score (and subscales) and HRQL mean score (and subscales). There was a significant positive relationship between exercise self-management and both the total HRQL mean score and physical functioning subscale (r=0.330, p=0.009; r=0.485, p=0.0005). This indicated that the patients with a high level of exercise self-management had higher HRQL.

Table 2. Mean scores for HROL domains.

Domains	Mean (SD)
Physical functioning	65.05 (29.18)
Role functioning/physical	52.08 (39.42)
Role functioning/emotional	63.13 (46.29)
Social functioning	67.44 (28.52)
Body pain	28.60 (26.12)
General health	63.70 (18.94)
Mental health	66.21 (23.60)
Vitality	55.98 (23.67)
Total HRQL	57.35 (15.01)

Table 3. Relationship between diabetes self-management and HRQL.

HRQL Domains	Diabetes Self-care Activities Subscale	Exercise	Blood Sugar Test	Foot Care	Total
Physical Functioning	0.89	0.485**	0.195	-0.001	0.257
Role Functioning/ Physical	-0.014	0.209	-0.007	-0.171	-0.026
Role Functioning/ Emotional	0.107	0.171	-0.087	-0.122	0.001
Social Functioning	0.129	0.294*	0.160	0.168	0.259*
Body Pain	0.163	-0.223	0.031	0.318**	0.141
General Health	-0.069	0.131	-0.198	-0.254*	-0.185
Mental Health	0.131	0.142	0.056	-0.069	0.076
Vitality	-0.015	0.160	-0.119	-0.133	-0.068
Total HRQL	0.168	0.330**	0.054	-0.049	0.152

Note: \*\* Correlation is significant at the 0.01 level (2-tailed).

Moreover, there was a significant positive relationship between total diabetes self-management mean score and both *physical functioning* and *social functioning* HRQL mean scores (r=0.257, p=0.04; r=0.259, p=0.037). This means that patients with higher physical and social quality of life reported more adherence to self-management activities. In addition, there was a significant positive relationship between *foot care self-management* and *body pain* domain of HRQL (r=0.318, p=0.009). Higher scores in *body pain* indicate better control of pain, so better foot care results in less body pain (Table 3).

# 3.5. Relationship between Selected Demographics and Diabetes Self-management or HRQL

Correlational analysis was performed to examine the association between patients' characteristics and diabetes self-management or HRQL. There was a significant negative relationship between age and exercise self-management (r=-0.363, p=0.003). The older the patient, the less exercise was undertaken. However, there was a significant positive relationship between family income and exercise self-management (r=0.327, p=0.023), perhaps related to enhanced access to exercise facilities and more leisure time. Moreover, there was a positive significant relationship between the number of years since diagnosis and diabetes foot care self-management (r=0.25, p=0.04).

There were negative relationships between age and

total HRQL and subscales of physical role functioning and social functioning (r=-0.285, p=0.010; r=-0.433, p=0.0005; r=-0.253, p=0.019), respectively. Older patients generally experienced poorer HRQL.

There were significant negative relationships between HA1C and total HRQL (r=-0.342, p=0.002), role functioning (r=-0.371, p=0.001), general health (r=-0.224, p=0.043), vitality (r=-0.410, p=0.0005), and social functioning (r=-0.243, p=0.027). Patients with higher HA1C had lower HRQL in most fields. Moreover, there was a significant positive relationship between HA1C and body pain subscale score (r= 0.403, p=0.0005) such that patients with poorer blood glucose control reported more body pain.

Patients with higher BMI reported statistically significantly more  $body\ pain\ (r=0.259,\ p=0.020).$  Moreover, there was a significant negative relationship between BMI and  $role\ functioning\ -\ physical\ (r=-0.376,\ p=0.001).$ 

A significant negative relationship between the number of years since diagnosis and *physical role functioning* (r=-0.345, p=0.001) indicated that patients with more years since diagnosis had lower role functioning than newly diagnosed patients. On the other hand, there was a significant positive relationship between the number of years since diagnosis and *body pain*, indicating that body pain increased with time since diagnosis.

<sup>\*</sup> Correlation is significant at the 0.05 level (2-tailed).

#### 3.6. Gender Differences

A two-tailed t-test was used to examine the effect of gender on  $total\ self$ -management mean score and subscale scores. No statistical difference was found. However, there were statistically significant differences between males and females and  $total\ HRQL\ (t(78)=2.045,\ p=0.04),\ role\ functioning/physical\ (t(82)=3.02,\ p=0.003),\ and\ body\ pain\ (t(84)=-4.08,\ p=0.0005).$  This indicated that male patients reported higher total HRQL and role functioning. Moreover, females reported more body pain than males.

#### 4. DISCUSSION

The aim of the study was to explore the relationship between self-management and quality of life among Saudi patients with DM. Enhancement of HRQL requires an objective assessment of how DM affects patients' lives in multiple dimensions [33], how they respond to prescribed self-management, and to what extent they cope with the challenges.

# 4.1. Increased Exercise Enhances HRQL in Many Domains

Pearson correlation showed a significant positive relationship between the exercise self-management subscale and both the total HROL and physical functioning subscale. The ability of patients to perceive and identify the important advantages of exercise plays a significant role in improving overall health and, subsequently, HRQL. This is in line with studies conducted in Iran [34] and Hungary [35] reporting that exercise was associated with improved HRQL among people with diabetes. One plausible explanation is that physical exercise increases self-confidence, motivation, and self-acceptance. There are additional reports on the positive effects of physical exercise on the physical, psychological, and environmental aspects of HRQL in Iranian patients with T2DM [36]. This means that physical exercise improves the physical, psychological, and social well-being of patients (which are all domains of quality of life). Indeed, it was reported in a further study in Iran that physical activity was a strong predictor of quality of life in patients with T2DM [37]. A US study reported that exercise counteracts muscle weakness, which is related to physical disability, and its absence is reflected in less daily walking activity, problems in balance, and a higher risk for falls [38]. Ultimately, it can be concluded that exercise improves HRQL.

# 4.2. Lack of Engagement in Self-care and Exercise

In this study, it was found that physical and social functioning features of quality of life (each involving degrees of physical activity) were significantly associated with overall high HRQL. However, it has been found that Portuguese patients with T2DM usually show difficulty in engaging in regular programs of exercise or activity [39]. The probable reason for this may be the low level of awareness of the benefit of exercise in improving physical functioning and control of serum blood sugar. Physical activity as a form of exercise behaviour has both

physiological and psychological components that are essential for achieving effective management and rehabilitation goals in T2DM patients. Participants in this study were more likely to perform self-care management behaviours that required the least effort and lifestyle changes.

Research in other countries with majority Muslim populations (for example, Malaysia, Iran, and Pakistan) has demonstrated gender-based differences in response to diabetes management initiatives. In Saudi Arabia, physical activity and exercise are not widely pursued, particularly by women and older generations. However, this may change as more generations are exposed to other cultures, though in Saudi Arabia, it is perhaps only for males [40].

#### 4.3. Foot Care as a Particular Issue

In terms of body pain and self-care management, a significant relationship was established in Bangladesh between lack of adherence to foot care and problems with pain or discomfort, physical activity, self-care, and daily activities [41]. This is congruent with the findings reported in this study. A plausible reason for this may be increased duration of the disease, fatigue with the treatment regimen and self-care, cognitive issues in some elderly patients, and lack of reinforcement by medical professionals about the importance of foot care. However, in this study, the second most frequent behaviour was foot care, and this may be explained by Muslims performing foot-washing activities as a religious practice, which helps them to promote more frequent checking of the feet.

# 4.4. Designing Solutions

Developing interventions to increase self-care exercise safely in this vulnerable population may help patients attain control of pain, enhance self-care management, and consequently improve HROL. International literature reports that men and women are often more accepting of different modes of information and support. Due attention must be paid to population characteristics, particularly age and gender, so that strategies may be tailored to address specific barriers to exercise and self-care in this diagnostic group. Societal and cultural pressures play a part in decisions about these vital aspects of selfmanagement, so these factors must be included while designing initiatives and services. In Saudi Arabia, where mobile technology is a major factor in work, social, and family life, for example, a smartphone-based intervention, such as the one reported above, might be an effective strategy [29]. Yet both self-management and exercise must be addressed for maximum potential.

# CONCLUSION AND CONTRIBUTION TO KNOWLEDGE

Physical exercise can exert a positive impact on HRQL, but currently, this benefit is unlikely to be experienced by the Saudi Arabian population since exercise is not a common activity, particularly with increasing age and for females in general. An increase in self-management of diabetes care would also enhance HRQL, but in addition to

support for individual patients, this will require a major public health effort on the part of nurses. Due attention must be paid to population characteristics, particularly age and gender, so that strategies may be tailored to address specific barriers to exercise and self-care in differing groups. In this diagnostic group, a focus on the promotion of self-managed foot care to increase adherence to prescribed regimes will be essential.

That physical exercise improves HRQL is established in at least 3 continents, including some majority Muslim countries, but this study has identified the particular importance of cultural and societal norms in restricting physical exercise, especially for Muslim women. Similarly, other studies have recognised the issue of inadequate foot care, but this study identified ritual cleansing as an opportunity for self-screening for diabetic problems and a cost-zero solution to promoting early help-seeking. Finally, the emphasis on population characteristics, gender differences, and the impact of increasing age as contributing factors in decisions about self-help behaviour discovered in this study, considered in cultural, societal, and religious contexts, has been shown to be vital to successful initiatives and interventions.

# IMPLICATIONS FOR NURSING PRACTICE AND HEALTH POLICY

Nurses and other healthcare providers need to empower patients to engage in culturally appropriate selfmanagement and physical exercise. The results reported could be used to design a culturally effective intervention for patients with diabetes to further enhance their quality of life. Moreover, a specific health promotion policy can be designed that addresses the promotion of physical exercise and self-management of diabetes care. Such policies should consider cultural nuances and be tailored to different demographic groups. Implementation of the policies would support the creation of targeted educational programs. These programs should focus on raising awareness about the benefits of physical exercise, diabetes self-management, and the importance of selfmanaged foot care, with an emphasis on reaching diverse age and gender groups.

## **AUTHORS' CONTRIBUTIONS**

It is hereby acknowledged that all authors have accepted responsibility for the manuscript's content and consented to its submission. They have meticulously reviewed all results and unanimously approved the final version of the manuscript.

#### LIST OF ABBREVIATIONS

DM = Diabetes mellitus T1DM = Type 1 diabetes T2DM = Type 2 diabetes

RCTs = Randomized Controlled Trials
MCS = Mental Component Summary

# ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was provided by the King Abdullah International Medical Research Centre, Ministry of National Guard Health Affairs, Riyadh, Kingdom of Saudi Arabia [RA20/002/A].

#### **HUMAN AND ANIMAL RIGHTS**

The requirements of the Declaration of Helsinki were followed to involve human subjects in the study.

#### CONSENT FOR PUBLICATION

Formal, explicit consent was secured from all patients before data collection.

#### STANDARDS OF REPORTING

The STROBE guidelines were followed.

#### AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available from the corresponding author [EAG] on request.

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None.

# **CONFLICT OF INTEREST**

The authors declare no conflict of interest, financial or otherwise.

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