ORIGINAL ARTICLE

Treatment Burden Of Non-Communicable Diseases On Patients Attending Primary Health Care In Bahrain 2020: A Cross-Sectional Study

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Abstract

Background: Adaptation to chronic disease can be challenging. Compliance with medication, adjusting to lifestyle changes, attending health care facilities, and financial costs are among many obstacles encountered. Treatment burden is defined as the effort required by the patient or caregiver to manage the medical conditions of the patient and the impact that this has on their lives. The aim of this study was to help the health care system in establishing new strategies to address the treatment burden on patients with non-communicable diseases.

Methods: A cross-sectional study was conducted among patients attending non-communicable disease clinics and central diabetic clinics in eight different primary health care centers in Bahrain, using the Treatment Burden Questionnaire through structured interviews. A value of 59 and above was considered as an unacceptable burden according to patient acceptable symptom state (PASS).

Results: Of the 411 participants, around 18% had an unacceptable burden. Female subjects reported a five times higher treatment burden. The younger population of less than 65 years scored higher treatment burden by three folds. Injectable medications were associated with a two-fold increase in treatment burden compared to other medication modalities.

Conclusion: Although treatment burden is an emerging and insufficiently addressed concept in the literature, this study revealed an overall low treatment burden. Further studies should be conducted to assess treatment burden and suggest strategies accordingly. Health care providers are encouraged to integrate all patient aspects in the management. New recommendations to formulate updated guidelines with the aim of minimizing the treatment burden are warranted.

Keywords: Bahrain, Chronic disease, Non-communicable disease, Primary health care, Surveys and Questionnaires

Introduction

Non-communicable disease (NCD), defined by World Health Organization (WHO) as a disorder of long duration due to combined genetic, physiological, environmental, and behavioral factors. There are four categories of non-communicable diseases: cancers, diabetes mellitus, chronic respiratory, and cardiovascular diseases.[1] Annually, the mortality rates of NCDs reach up to forty-one million around the globe.

According to the latest WHO country profiles, the NCD's annual mortality rates were 89%, 88%, 73% in the United States, United Kingdom, and Saudi Arabia, respectively. In comparison, a similar rate of 81.8% was found in Bahrain.[2] The 2030 United Nations agenda for Sustainable Development Goals (SDGs) considers NCDs a threat towards achieving its targets, which is reducing NCD's induced premature death by one-third by 2030 through prevention and treatment.[3]

Disease burden is the consequence of living with a disease or injury and subsequently dying prematurely due to its complications.[4] Although chronic disease burden has been well studied in the past few decades; the literature is limited in evaluating the burden of treatment. Due to the emerging novel technologies in the health care system, new management modalities are successfully unfolding.

This results in offering better control of chronic diseases and increasing the aging population. This leads to longer exposure to chronic diseases, polypharmacy, additional side effects, frequent hospital appointments, and laboratory investigations.[5] All of these factors have contributed to the concept of the treatment burden.

Treatment burden is defined as the "effort required by the patient or caregiver to manage the medical conditions of the patient and the impact that this has on their lives." [1] Prescription of monotherapy and even dual therapy is an expected outcome in the natural course of most NCDs. One study found that patients with chronic conditions take more than six medications per day, follow up with their health care providers up to six visits per month, as well as exhausting a minimum of 49.6 hours per month in health-related activities.[6]

Another study conducted in the United States between 1999 to 2012 proved that, while only 8% of US adult citizens consumed more than or equal to 5 medications in 1999-2000, this figure increased to 15% in 2011-2012, these increases persisted after accounting for changes in the age distribution of the population.[7] In Bahrain, an audit was conducted on patients with diabetes and found that around 50% of them were already on two different medications.[8]

The treatment burden includes more than just a number of medications and their side effects. It actually extends to involve the number of visits to the clinic, time spent doing laboratory tests, behavioral changes (e.g., diet, exercise, and smoking cessation), and taking care of medical equipment (e.g., cleaning the nebulizer machine).

Some patients find it overwhelming to commit to a management plan and the follow-up appointments, thereby resulting in poor disease outcomes, which in turn will negatively affect the healthcare system.[5] A study conducted in Qatar using living with medicines questionnaires V3 (LMQ V3) assessed medication-related burden among NCD patients concluded that the majority of patients reported experiencing minimal (24.1%) to moderate (66.8%) medication-related burden.[9] The 2007 Bahrain national NCD survey among the adult age group showed that high blood pressure prevalence was 38.2%, hyperglycemia 13.5%, and hypercholesterolemia was 40.6%. Since Bahrain has a high prevalence of non-communicable diseases, studying the treatment burden will help in optimizing the health care and enhance health literacy among this cohort of patients.[10]

The aim of this study was to help the health care system in establishing new strategies to address the treatment burden. The objectives were to study the treatment burden on NCD patient's lives and the factors associated with treatment burden on NCD patients attending primary health care settings.

Methods

Study Design and participants

A Cross-sectional study was conducted in primary health care centers in Bahrain. Researchers included patients attending non-communicable disease

(NCD) clinics and central diabetic clinics (CDC) during the period from February 2nd-13th, 2020. Subjects who were 18 years or older, diagnosed with at least one non-communicable disease, and able to communicate in Arabic or English were eligible for enrollment. Patients with emergency conditions and those with intellectual disabilities that hinder their ability to comprehend the questions were excluded. A sample size of at least 400 participants was agreed upon among researchers.

Data collection

• Sampling Technique:

There are four geographic governorates in Bahrain; each governorate was considered as a cluster. Two primary health care centers were selected from each governorate using simple randomization. Subsequently, all NCD patients attending the NCD and central diabetes clinics at the time of data collection were approached for enrollment. Subjects who refused to participate were counted as non-responders.

• Data collection tool

Treatment Burden Questionnaire (TBQ) consists of four domains with a total of 15 questions.[11] Burden was estimated on a scale from zero to ten in addition to a "not applicable" option. A global score out of 150 was calculated as a sum of all answers. A PASS (patient acceptable symptom state) value of 59 and above was considered as an unacceptable burden.[12]

The questionnaire is available in English and validated to be used in English-speaking countries. The corresponding author who holds the copyright was contacted for permission to use the English version, and another request was submitted to translate TBQ into Arabic. Linguistic validation was done according to the guidelines from the original developer, including two forward translations, one backward translation, and cognitive interviews.

Structured Interviews

The questionnaire was conducted in a structured interview form. The researchers agreed on a standardized format.

Data Analysis

Patient baseline characteristics (age, sex, nationality, employment status, level of education, number and types of medication(s), frequency of administration, payment for the medication(s), and need for assistance during medication administration) were collected.

SPSS 23 software was used for data entry and analysis. Frequencies and percentages were computed for categorical variables, while means and standard deviations were calculated for continuous variables. In addition, binary logistic regression was done to investigate the factors associated with the burden of treatment. A p value of less than 0.05 was considered statistically significant.

Ethics Considerations

The research was approved by the primary health care research committee, and written consents were obtained. All data were coded during analysis.

Results

Demographic Characteristics

A total of 411 structured interviews were completed, with an overall response rate of 98.3%. The majority of the research subjects were Bahraini (87.8%), with a mean age of 56.7 (Standard deviation (SD) 12.6) years. Approximately 30% of the subjects had post-secondary education, and 25% were currently employed. More than 80% of the participants were on three or more medications daily, of which tablet formulations were the most used type (95.9%), followed by injections (30.7%). (Table 1)

Table 1: Basic characteristics of participants. Values are numbers, unless otherwise stated (%) (N= 411)

Category	Sub-category	n (%)
Nationality	Bahraini	361 (87.8)
	Non-Bahraini	50 (12.2)
Age (Mean ± SD)		56.7 ± 12.6
Sex	Female	215 (52.3)
	Male	196 (47.7)
Educational level (N=410)*	No formal education	65 (15.9)
	Primary	50 (12.2)
	Intermediate	64 (15.6)
	Secondary	117 (28.5)
	Post-secondary	114 (27.8)
Employment status	Employed	104 (25.3)
	Unemployed	158 (38.4)
	Retired	149 (36.3)
Number of medications	<3	81 (19.7)
	3 – 4	121 (29.4)
	5 – 6	109 (26.5)
	>6	100 (24.3)
Type of medication	Tablets	394 (95.9)
	Nebulizers and/or inhalers	18 (4.4)
	Injections	126 (30.7)
	Others	6 (1.5)
Frequency of medication	Once per day	53 (12.9)
	Twice per day	124 (30.2)
	Three per day	167 (40.6)
	More than three per day	67 (16.3)
Need to pay for medication	Yes	127 (30.9)
	No	284 (69.1)
Need help for medication administration	Yes	39 (9.5)
	No	372 (90.5)

*During data collection, one participant's data was incomplete in terms of educational level. Therefore, this was considered as missing data and 410 samples were analyzed.

Treatment Burden Scale

As depicted in Table 2, the burden of finances and practicing the recommended physical activities scored the highest mean (3.8) when compared to other domains. While the burden of relationships with health care workers had the lowest mean (0.9). The mean overall global score of treatment burden was (32.2).

Table 2: Treatment burden scale

| Questions	Mean (± SD)
The taste, shape, or size of your tablets and/or the annoyance caused by your injections	1.8 ± 2.9
The number of times you should take your medication daily	1.9 ± 3.0
The efforts you make not to forget to take your medications	1.8 ± 3.0
The necessary precautions when taking your medication	1.8 ± 2.9
Lab tests and other exams	2.0 ± 3.1
Self-monitoring : frequency, time spent and associated nuisances or inconveniences	2.0 ± 3.3
Doctor visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers	2.1 ± 3.2
The difficulties you could have in your relationships with healthcare providers	0.9 ± 2.2
Arranging medical appointments and reorganizing your schedule around these appointments	2.0 ± 3.2
The administrative burden related to healthcare	1.7 ± 3.0
The financial burden associated with your healthcare	3.8 ± 4.1
The burden related to dietary changes	3.3 ± 3.6
The burden related to doctors' recommendations to practice physical activity	3.8 ± 3.8
Impact of Healthcare in relationships with others …	1.2 ± 2.7
The need for medical healthcare on a regular basis reminds me of my health problems	2.0 ± 3.2
Global score (**out of 150**)	32.2 ± 26.1

The scores of each question were assembled into three groups: 0 to 3, 4 to 6, and 7 to 10. The higher the number on the scale, the more the treatment

burden perceived by participants. About 132 participants (32.1%) gave the maximum score (between 7-10 points) in the financial burden question. The difficulties in relationships with healthcare providers scored the lowest (between 0-3 points) among 369 participants (89.8%). (Figure 1)
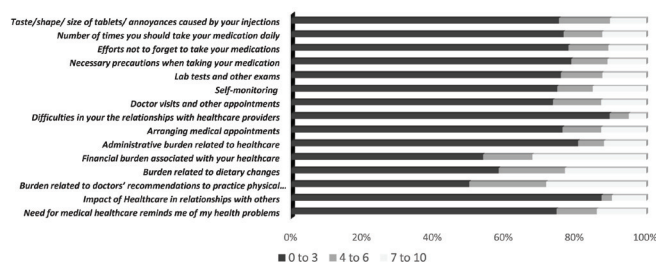
Figure 1: Treatment burden scale

Of the research population, 73, 18% (95 Confidence interval (CI), 14.1 to 21.5) scored above the PASS value considering their treatment burden as unacceptable, while treatment burden was acceptable in 338, 82% (95% CI, 78.5 to 85.9) (Figure 2).
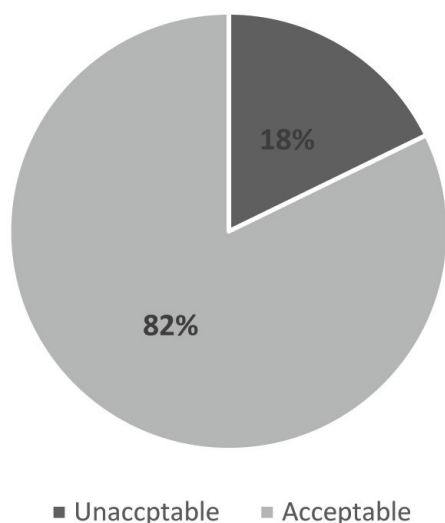
Figure 2: Overall treatment burden according to PASS score

Questionnaire items were grouped according to the burden of treatment into three contexts; treatment burden related to pharmacological treatment, comprehensive healthcare, and psychosocial-economic aspects. Therefore, analysis of the items was done for each factor separately. Results were comparable among these subscales. (Table 3)

Table 3: Treatment burden subscales (Out of 10)

	Mean	Standard deviation (SD)
Pharmacological treatment	1.3	0.5
Comprehensive health care	1.3	0.4
Psychosocial-economic	1.5	0.4

Associations between treatment burden and demographic characteristics

Logistic regression analysis revealed that the use of injectable medications and frequent administrations were significant predictors of high treatment burden ($p < 0.001$ and 0.001, respectively). We have found that the younger population (below 65 years) was around three times more likely to report higher burden, Odds ratio (OR) 2.76 (95% CI 1.2 - 6.3) p =0.016. About 5-fold greater odds of reporting a higher burden among females, OR 5.17 (95% CI 2.36 - 11.31) p <0.001 was found. Nevertheless, there was a statistically significant increase by more than two times in burden of treatment among patients on injectable medications, OR 2.37 (95% CI 1.26-4.47) p= 0.008. Those who need help in medications administration did not differ significantly when compared to those who did not. (Table 4)

Table 4: Logistic regression analysis of factors associated with burden of treatment

	OR	*p* value	95% CI for OR
Nationality			
Bahraini	Reference		
Non-Bahraini	1.07	0.890	0.41 to 2.78
Age			
65+ years	Reference		
<65 years	2.76	**0.016**	1.21 to 6.31
Sex			
Male	Reference		
Female	5.17	**<0.001**	2.36 to 11.31
Educational level			
No formal education	Reference		

	OR	*p* value	95% CI for OR
Primary	0.83	0.756	0.26 to 2.64
Intermediate	2.09	0.158	0.75 to 5.84
Secondary	1.22	0.680	0.48 to 3.10
Post-secondary	1.01	0.991	0.36 to 2.84
Employment status			
Unemployed	Reference		
Employed	1.98	0.143	0.80 to 4.91
Retired	1.89	0.133	0.82 to 4.33
Number of medication			
<3	Reference		
3-4	1.26	0.667	0.44 to 3.64
4-5	1.47	0.502	0.48 to 4.49
>6	1.32	0.647	0.40 to 4.33
Use of tablets			
No	Reference		
Yes	0.38	0.131	0.11 to 1.34
Use of injections			
No	Reference		
Yes	2.37	**0.008**	1.26 to 4.47
Frequency of medication			
Once per day	Reference		
Twice per day	2.24	0.226	0.61 to 8.21
Three per day	1.89	0.361	0.48 to 7.46
More than three per day	3.79	0.075	0.88 to 16.42
Need to pay for medication			
No	Reference		
Yes	1.18	0.593	0.64 to 2.18
Need help for medication administration			
No	Reference		
Yes	1.69	0.270	0.67 to 4.28

Discussion

In this study, treatment burden has been evaluated using TBQ, and the main findings were that (1) the overall global burden was low, (2) the financial expenses and physical activities contributed the most, and (3) the majority of subjects had scored acceptable treatment burden. These observations were consistent with other studies reported in the literature. [9, 13, 14] The low overall global burden can be attributed to several factors, including free unlimited and easy access to health care facilities for citizens, the novelty of treatment burden concept, in addition to cultural impacts on reporting treatment burden. Moreover, this cohort of the population following in the primary care may have had milder chronic diseases, thus, the lower burden.

Similar to our findings, other studies reported a higher treatment burden among females.[9, 15] Our data showed a significant inverse relationship between the treatment burden and age. Likewise, Herzig, et al. found that older people tend to accept their diseases with time and live with the burden.[13] A review article, however, found that treatment burden was higher amongst elderly participants.[15]

Our results did not reveal any association between employment status and treatment burden, whereas such association was reported in the literature. A strong positive correlation, for example, between unemployment and perceived treatment burden was reported in several studies.[9,15]

The significant association between injectables and high treatment burden is supported by a recent systematic review.[15] Polypharmacy, though reported in many studies to increase the treatment burden by several folds, was not evident in our results.[1, 16]

Despite the cultural dietary influences, diet did not yield a significant treatment burden. Tran V, et al. showed in their study that dietary interventions were the most burdensome component.[16, 17] Similar to observed trends found in other studies, our data identified physical activity as a high treatment burden.[18]

Even though our results showed some variations among the individual TBQ items, the 3-factor domain analysis did not show significant differences. These differences were not examined previously in the literature.

Addressing the treatment burden is undoubtedly challenging. While there are the majority of guidelines being generated and updated regularly, most of them are specifically developed for single diseases.[19] To recognize and subsequently

minimize treatment burden, strategies orchestrated via the minimally disruptive model (MDM) have to be integrated into the health care system.[20] Examples of strategies include assessing the patient holistically, encouraging shared medical decisions, and empowering the patient's autonomy. A study was done to reanalyze the randomized controlled trials previously done to assess chronic diseases have found that enhancing patient's capacity can remarkably reduce treatment burden.[21] Nevertheless, tailoring these kinds of strategies to the cultural and local norms of the community undeniably would serve the maximum.

Strengths and limitations

This study has several strengths, including adequate sample size and a high response rate. To the best of our knowledge, this is the first study to assess the treatment burden among patients with chronic diseases in Bahrain. The research tool (TBQ) is considered a comprehensive and commonly used tool to assess treatment burden globally.

This study has few worth-mentioning limitations. First of all, the cross-sectional design may disregard some antecedents that can affect the burden outcome. Secondly, a non-probable sampling technique could affect the accuracy of the results. Thirdly, the cohort of the population included in this study may not represent the entire population with chronic diseases. These factors can affect the generalizability of the results.

Conclusion

Even though treatment burden is a vital aspect of patient care, it has not been widely studied in the literature. The overall low treatment burden observed in this study may underestimate the actual burden. Further studies are needed to determine treatment burden in other settings and enhance the physician's patient-centered practice.

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