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Medication-Related Burden among Iraqi Patients with Crohn's Disease: A Cross Sectional Study

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Abstract

Crohn's disease is an inflammatory bowel disease that is characterized by chronic inflammation of any part of the gastrointestinal tract, has a progressive and destructive course and is increasing in incidence worldwide. Medical treatment of Crohn's disease is usually divided into remission induction therapy and remission maintenance therapy. Medication-related burden is a new concept focused on the negative experiences resulting from taking medicines. The aims of the current study were to measure medication-related burden among a sample of Iraqi patients with Crohn's disease, and to determine any associations between medication-related burden and some patient factors. The present study was cross-sectional conducted at "Gastroenterology and Hepatology Teaching Hospital/ Medical City / Baghdad / Iraq" during December 2022 to May 2023. The Arabic version of living with medicines questionnaire was used to measure medication-related burden experienced by the patients. Ninety-four patients with Crohn's disease were included [Males =58 (61.7%), Females=36 (38.3%)] with mean age (31.9±10.8 years). The mean of total burden score was (102.7 ± 20.6) with more than half (54.3%) of the patients experienced a minimum degree of medication burden, followed by moderate burden (29.8%), no burden (8.5%) and high burden (7.4%). Three domains showed the highest mean of burden score: "Cost Related Burden", "concerns about medicines use" and "Autonomy to vary regimen". Total burden score, "side effects of medicines" and "effectiveness of prescribed medications" domains were significantly lower in remission patients compared to active cases. In conclusion, Crohn's disease patients have experienced high medication-related burden in terms of cost, concerns and autonomy and low burden in the other terms. Disease activity was independently correlated with total burden score.

Keywords: Medication-Related Burden, Crohn's Disease, Inflammatory bowel disease, Living with Medicines questionnaire.

Introduction

Inflammatory bowel disease (IBD) is a gastrointestinal (GIT) disease characterized by chronic inflammation. It includes Crohn's disease (CD) and ulcerative colitis (UC). While CD affects the entire GIT and causes transmural inflammation, strictures, fistulas, and abscess, UC only affects the colon and causes largely superficial inflammation [(1)].

Pathologically, CD is a multi-factorial disease where the combined effects of factors such as environment triggers, and intestinal microbiota result in the dysregulated immune response, a crucial characteristic of disease pathogenesis [(2)]. A previous study suggests that genetic predisposition play a significant role in etiopathogenesis of IBD in Iraqi Arab population [(3)]. In addition, diet has an important role in the development of IBD or protection against it [(4)]. Incidence rates for CD vary from 0.1 to 16 per 100,000 people worldwide, with greater rates seen in Europe [(2)]. Over the past 20 years, the pattern of IBD incidence has changed, growing in historically low incidence areas like Asia and the Middle East while also continuing to rise in the West [(5)]. The prevalence of IBD is rising in the Arab world, and patients here may exhibit some distinct differences from those in Europe in terms of their IBD symptoms [(6)].

Patients with CD may present with diarrhea and abdominal pain, but perhaps there are many other nonspecific clinical manifestations including fever, weight loss, malnutrition, nausea, vomiting,

or rectal bleeding [7]. Unlike UC, CD is commonly resulted in complications such as abscesses, fistulas and strictures [8]. The pharmacologic treatment of CD involves different agents [aminosalicylates, corticosteroids (CSs), Immunosuppressive drugs, biologics, and antibiotics] [9]. Although medicines are the most common type of therapy in the management of various medical conditions, patients' experiences with medicines has limited consideration [10]. Coping with the side effects and having to tailor their life activities according to their therapeutic regimens puts an extra burden on the patients [11]. The concept of "medication-related burden" (MRB) has been well-described in the literature as the overall workload that is imposed on patients resulting from utilizing health care, leading to multiple negative effects in their lives [10]. The assessment of the MRB from the patient's perspective is an important step to discover any barriers that may hinder the optimum use of medications. Medication burden acts as a core factor affecting a patient's beliefs about medication adherence and health status, and to some extent reflects the patient's attitude and willingness and ability to handle medication use [12].

Although the concept of treatment burden is increasingly attracting attention from various research groups, studies that mainly focus on the MRB are scarce in Iraq and Middle East. Hawraa *et al*., studied the MRB among systemic lupus erythematosus patients and found that most patients (69.87%) had moderate MRB [13]. Ayman *et al*., studied the MRB among diabetic patients and found that patients having uncontrolled blood glucose had significantly higher medication burden [14].Similarly, Rwnk *et al*., studied the MRB among rheumatoid arthritis patients and found that women, illiterate patients, and patients with long-term medications use more than five had significantly higher medication-related burden [15].

To our knowledge, there was no published study that measure MRB among CD patients in Iraq. The aims of the current study were to measure MRD among a sample of Iraqi patients with CD, and to determine any possible association between MRB and some patient-specific factors (socio-demographic and disease characteristic including disease activity).

Patients and methods

Study design and population

The present study was cross-sectional included 94 patients which conducted at "Gastroenterology and Hepatology Teaching Hospital/ Medical City / Baghdad / Iraq" during December 2022 to May 2023. The inclusion criteria of the study were CD patients who were aged 18 years and above of either sex that have been diagnosed with CD at least 6 months before this study and use at least one medication for CD (aminosalicylates, CSs, Immunosuppressive drugs, or biologics) on a regular base. The exclusion criteria of the study were patients with a cognitive, hearing, or speech deficits that hindered their understanding, pregnancy, and patients who didn't consent to participate.

Study Questionnaire

The study questionnaire includes into two parts.1st part contain questions related to patients socio-demographic and clinical information including gender, age, durations of illness, social status, education level, residence, other chronic disease, monthly income, type of medicine, number of chronic medications currently used, and disease activity score. The CD disease activity was measured according to Harvey-Bradshaw Index (HBI) [16].

The2nd part is living with medicines questionnaire (LMQ). The Arabic version [17] of LMQ version 3 was used to explore MRB experienced by the CD patients. The LMQ-3 is a 41-item questionnaire for which the participants indicated their level of agreement using a five-point Likert scale [from (strongly agree) to (strongly disagree)]. It consisted of eight domains. A total score (LMQ-3 overall score) representing the overall level of MRB is calculated by summing all domain scores. It ranged from 41 to 205, with higher scores indicating higher medication burdens [10].

Questionnaire Administration

The researcher collected all data required for this study by him. After brief explanation about study purpose, the answers of patients on LMQ questionnaire were filled by the researcher which takes about 20-30 minutes.

Statistical analysis

Continues variable assessed for adherence to normality using Anderson Darling test, and variables followed normal distribution expressed as mean and standard deviation (SD), and those did not follow normal distribution expressed using their median and interquartile range (IQR). Independent t-test used to assess difference between remission and active disease if variables followed normal distribution, if data did not adhere to normality Mann Whitney U test is used. Linear regression analysis use to assess the relationship between LMQ and various predictors, for multivariate, analysis linear regression analysis with backward elimination (with probability of F to remove ≥0.10) was used. All analysis carried out using SPSS 27.1 (Chicago, USA) and p-value considered significant if <0.05 (2-tailed).

Results

In the present study, 94 patients with CD were included. Their sociodemographic, clinical and disease characteristics are presented in (Table 1)

Table 1. Sociodemographic, clinical and disease characteristics of CD patients.

Variable		Mean ± SD	Variable		Mean ± SD
Age (y) mean ± SD		31.9±10.8	**Disease duration (y)**		5.2±4.2
		Number (%)			**Number (%)**
Gender	**Female**	36 (38.3%)	**Source of medication**	**MOH**	42 (44.7%)
	Male	58 (61.7%)		**Private and MOH**	52 (55.3%)
Social	**Single**	42 (44.7%)	**Medication type**	**Original**	26 (27.7%)
	Married	52 (55.3%)		**Biosimilar**	68 (72.3%)
Education	**Illiterate**	2 (2.1%)	**No. of co-existing disease(s)**	**No other disease**	85 (90.4%)
	Primary	15 (16.0%)		**Single**	9 (9.6%)
	Secondary	34 (36.2%)		**Two**	0 (0.0%)
	College	43 (45.7%)	**Disease activity**	**Remission**	55 (58.5%)
Residence	**Urban**	89 (94.7%)		**Mild**	20 (21.3%)
	Rural	5 (5.3%)		**Moderate**	18 (19.1%)
Governorate	**Baghdad**	57 (60.6%)		**Severe**	1 (1.1%)
	Others	37 (39.4%)	**No. of chronic medications**	**1**	23 (24.47%)
Income	**Low (< 0.5 million ID)**	30 (31.9%)		**2**	37 (39.36%)
	Intermediate (0.5 -1.0 million ID)	40 (42.6%)		**3**	26 (27.66%)
	High (>1.0 million ID)	24 (25.5%)		**≥4**	8 (8.51%)

ID: Iraqi dinar**; MOH**: Ministry of Health

The mean of total LMQ score was (102.7 ± 20.6). The findings showed that more than half (54.3%) of the CD patients experienced a minimum degree of MRB, followed by moderate burden (29.8%), no burden (8.5%) and high burden (7.4%) (Table 2 and figure 1).

Table2. Perceived level of the medication burden.

Total LMQ score (mean ± SD)	102.7 ± 20.6	
"**Degree of burden**"	"**The range of each category**"	**Number (%)**
"**No burden**"	"41-73"	8 (8.5%)
"**Minimum burden**"	"74-106"	51 (54.3%)
"**Moderate burden**"	"107-139"	28 (29.8%)
"**High burden**"	"140-172"	7 (7.4%)
"**Extremely high burden**"	"173–205"	0.0 (0.0%)

LMQ: Living with Medicines Questionnaire.

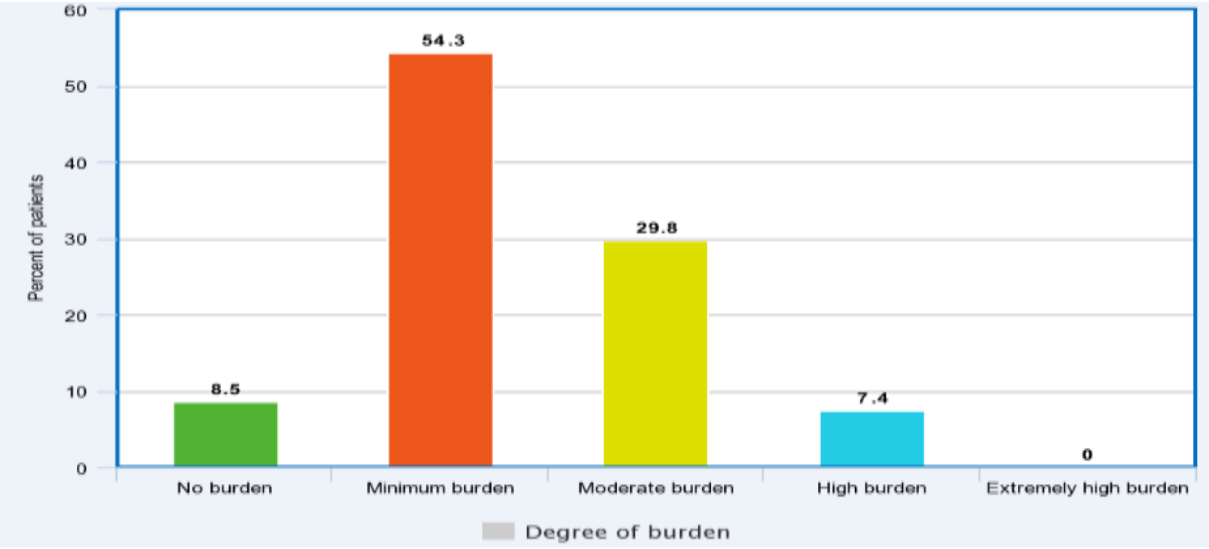

Figure1. Perceived level of the medication burden according to the total LMQ score

Five LMQ domains showed the lowest median of burden scores (below the average): domain 1 "relationships with HCPs", domain 2 "practical difficulties in using medicines", domain 4 "side effects of medicines", domain 5 "effectiveness of prescribed medications" and domain 7 "Impact of using medicines on daily life". On the other hand, 3 domains had the highest mean of burden scores: domain 3 "Cost Related Burden", domain 6 "concerns about medicines use" and domain 8 "Autonomy to vary regimen" (Table 3).

Table 3. Descriptive statistics of LMQ domains

LMQ domain	Theoretical average of the domains *	Median (IQR)
"Domain-1 (Relationships with HCPs-5 items)"	15.00	7(6)
"Domain-2 (Practical Difficulties in Using Medicines- 7 items)"	21.00	15(8)
"Domain-3 (Cost Related Burden- 3 items)"	**9.00**	**11(7) †**
"Domain-4 (Side Effects of Medicines- 4 items) "	12.00	10(7)
"Domain-5 (Effectiveness of prescribed medications- 6 items) "	18.00	10(7)
"Domain-6 (Concerns about Medicines Use- 7 items) "	**21.00**	**23(9) †**
"Domain-7 (Impact of Using Medicines on Daily Life-6 items)"	18.00	12(6)
"Domain-8 (Autonomy to Vary Regimen-3 items) "	**9.00**	**12(5) †**

IQR: interquartile range**; HCPs**: Healthcare Professionals; **LMQ**: Living with Medicines Questionnaire; *****: Theoretical average of the domains: calculated if the answers to all questions were neutral. **†:** Domains with score above the average**.**

The univariate analysis showed that there were significant relationships between total LMQ score and both age, and disease number. In addition, there was a marginal direct relationship between total LMQ and disease activity. While in multivariate analysis only disease activity were independently correlated with LMQ, as illustrated by (Table 4).

Table 4. Correlation among LMQ and other variables in CD patients

Variable	LMQ				
	Univariate		Multivariate		
	r	p-value	Partial r	Standardized β	p-value
Disease activity	0.175	0.093	**0.238**	**0.218**	**0.023 [S]**
Age	**0.323**	**0.001 [S]**	-0.052	-0.048	0.627
Gender	0.045	0.663	-	-	-
Disease duration	-0.093	0.371	-	-	-
Social	0.141	0.176	-	-	-
Education	-0.154	0.139	-	-	-
Governorate	-0.044	0.676	-	-	-
Residence	0.151	0.147	-	-	-
Smoking	-0.022	0.830	-	-	-
Medication type	0.003	0.977	-	-	-
Drug number	-0.043	0.681	-	-	-
Disease number	**0.458**	**<0.001 [S]**	-0.125	-0.115	0.238

Linear regression analysis, r: regression coefficient**, S:** significant**.**

Total LMQ score, domains 4, and 5 were significantly lower in remission CD compared to active cases as illustrate by (Table 5).

Table 5. Assessment of various score according to disease activity for CD patients

Variable	Remission (n=55)	Active (n=39)	p-value
D1, median (IQR)	8(6)	7(5)	0.565 [a]
D2, mean ± SD	14.6 ± 4.7	15.7 ± 4.8	0.242 [b]
D3, median (IQR)	10(8)	12(6)	0.194 [a]
D4, median (IQR)	**8(6)**	**11(8)**	**0.034 [S] [a]**
D5, median (IQR)	**9(6)**	**12(7)**	**0.002 [S] [a]**

D6, median (IQR)	22(10)	23(11)	0.189 [a]
D7, median (IQR)	12(6)	13(7)	0.093 [a]
D8, median (IQR)	12(5)	12(5)	0.885 [a]
LMQ, mean ± SD	**98.0 ± 19.8**	**108.5 ± 20.4**	**0.015 [S] [b]**
VAS, median (IQR)	5(3)	5(3)	0.166 [a]

a: Mann-Whitney U test**, b:** independent t-test**, S:** significant**, IQR**: interquartile range.

Discussion

The objectives of treatment for CD are to induce remission of acute flares, maintain remission, and enhance quality of life. Also, CD patients may take medicine to manage common complications. Additionally, CD patients may be given drugs to treat coexisting chronic diseases that are common in the general population [(18)]. This is exacerbated by the rising incidence and high recurrence rate following therapy in certain individuals [(19)].

The current study indicated that (91.5%) were suffering from varying degrees of MRB with more than half of the patients experienced a minimum degree of MRB. This may be partially explained by the finding of the current study that (90.4%) of the patients no other co-exiting diseases and that only (8.51%) of them were having polypharmacy (taking 4 or more medications). A previous study among Iraqi CD patients found that higher number of chronic drugs inversely correlate with Health-related quality of life (HRQOL)[(20)]. Additionally, three domains showed the highest means (above the average) ["Cost Related Burden", "concerns about medicines use" and "Autonomy to vary regimen"]. In other words, the patients had difficulty with medicine costs, high concerns about medicines use and had limitations to change the regimen. In other words, the patients had difficulty with medicine costs, high concerns about medicines use and had limitations to change the regimen. Regarding the cost; the higher burden score of this domain may be because that all patients included in the current study were using biologic drugs. The IBD has a significant financial burden [(21, 22)]. Although non-biologic, less expensive treatments have historically been used to treat IBD, the development of biologics has transformed IBD treatment while simultaneously driving up costs for healthcare systems [(23)]. Biologics are now more expensive than other IBD-related expenses like hospital stays and surgery. According to a Dutch study, the price of anti-TNF biologics was much more than the price of hospitalization, surgery, and lost productivity for both CD and UC patients [(24)]. In the USA, the cost of biologics for patients with CD accounted for about 30% of all healthcare costs, surpassing the cost of inpatient care, which was only responsible for 23% of costs [(25)].

Regarding the concerns about medicines use; all the patients involved in the current study relied on MOH (partially or totally) as a source of drug supply. The lack of constant availability of medicines and exposure to interruption from time to time together with need for life-long medications may explain the higher burden score of this domain. Regarding to "Autonomy to vary regimen"; the medication used to treat IBD (especially biologics) which were prescribed to all CD patients involved in the current study are needed to be taken regularly at definitive time which may explain the limitations to change the regimen (and hence the higher score) of this domain.

In addition, five LMQ domains had the lowest median of burden scores ["relationships with HCPs", "practical difficulties in using medicines", "side effects of medicines", "effectiveness of prescribed medications" and "Impact of using medicines on daily life"]. In other words, the CD patients had good relationships with their HCPs, low difficulties in using their medicines, low concern about side effects, good belief in their medication effectiveness, and their medicines had lower impact on their daily life. A previous study in Iraq was conducted to explore beliefs about medicines among a sample of Iraqi patients with IBD, and found (58%) of the patients had strong beliefs in the necessity of treatment (specific-necessity score greater than specific-concern) [(26)].

In multivariate analysis only disease activity was independently directly correlated with LMQ. In addition, total LMQ score, domains 4 "side effects of medicines", and 5 "effectiveness of prescribed medications" were significantly lower in remission CD compared to active cases. The IBD have a clinical course characterized by alternating relapsing-remitting periods. Disease flares occur in a random way and are currently unpredictable for most patients [(27)]. CSs are effective at inducing remission in IBD. Acute severe CD is managed with intravenous CSs. In mild-to-moderate cases, CSs can be given orally or topically. Despite their effectiveness, CSs are characterized by their serious adverse effects (including hyperglycemia, hypertension, mood disorders, gastric ulcer, and increased susceptibility to infections) [(28, 29)]. Approximately 50% of patients will develop short-term adverse effects [(28)].

Limitations

This study had some limitations that should be mentioned. First, patients were collected from a single center in Iraq. Whether they can represent the total number of CD patients in Iraq and to what extent requires further investigation. For this reason, the generalizability of the present study may be limited. Second, answers may be subject to recall bias and societal desire bias. Third, the sample size here is relatively small. In future studies, large sample and multicenter studies should be included in other regions of Iraq to show whether the results here can be confirmed in other CD patients.

Conclusion

In conclusion, the CD patients recruited in the current study reported high burden in three domains which are (cost related burden, concerns about medicines use, and autonomy to vary regimen) and low burden in other terms. Disease activity was independently correlated with total burden score.

Acknowledgment

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Conflicts of Interest

The authors did not disclose any conflicts of interest.

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Ethics Statements

The research proposal describes the goals of the current study and the proposed data collection techniques was administered to the "College of Pharmacy, University of Baghdad" and the approval was obtained from Scientific and Ethical Committee (approval name: RECAUBCP11220225, date 1-12-2022). Then approval was also obtained from the Iraqi Ministry of Health. While verbal consent was gained from the patients to participate in the study.

Author Contribution

The authors contribution as follows: study conception and design: second authors; data collection: first and third authors; draft manuscript preparation: second Author. All authors reviewed the results and approved the final version of the manuscript.

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العبء المرتبط بالأدوية بين المرضى العراقيين المصابين بمرض كرون: دراسة مقطعية

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[٣] استشاري ، مستشفى أمراض الجهاز الهضمي والكبد التعليمي ، بغداد ، العراق

الخلاصة

داء كرون هو مرض التهاب معوي يتميز بالتهاب مزمن لأي جزء من الجهاز الهضمي ، وله مسار تدريجي ومدمّر ويزداد حدوثه في جميع أنحاء العالم. ينقسم العلاج الطبي لمرض كرون عادةً إلى علاج حث الشفاء وعلاج المحافظة عليه. العبء المرتبط بالدواء هو مفهوم حديث يهتم بالتجارب السلبية الناتجة عن عملية العلاج. كانت أهداف الدراسة الحالية هي قياس العبء المرتبط بالأدوية بين عينة من المرضى العراقيين المصابين بمرض كرون ، وتحديد أي ارتباط محتمل بين العبء المرتبط بالأدوية وبعض العوامل الخاصة بالمريض. أجريت هذه الدراسة المقطعية في المستشفى التعليمي لأمراض الجهاز الهضمي والكبد / مدينة الطب / بغداد / العراق خلال الفترة من كانون الاول ٢٠٢٢ إلى مايس ٢٠٢٣. تم استخدام النسخة العربية من استبيان التعايش مع الادوية لقياس العبء المرتبط بالأدوية التي يعاني منها المرضى. تم تضمين ٩٤ مرض كرون [ذكور = ٥٨ (٦١,٧٪) ، إناث = ٣٦ (٣٨,٣٪)] بمتوسط العمر (٣١,٩ ± ١٠,٨ سنة). كان متوسط مجموع درجات العبء (١٠٢,٧ ± ٢٠,٦) مع أكثر من نصف (٥٤,٣٪) من المرضى يعانون من حد أدنى من عبء الدواء ، يليه عبء معتدل (٢٩,٨٪) ، لا عبء (٨,٥٪) وعبء ثقيل (٧,٤٪). ثلاثة مجالات لديها أعلى متوسط درجات العبء: "العبء المرتبط بالتكلفة" ، "مخاوف بشأن استخدام الأدوية" و "الاستقلالية في تغيير النظام الدوائي". كان مجموع نقاط العبء ، وعبء "الآثار الجانبية للأدوية" و "فعالية الأدوية الموصوفة" أقل بشكل ملحوظ في مرضى الشفاء مقارنة بالحالات النشطة. في الختام ، لقد عانى مرضى داء كرون من عبء كبير يتعلق بالأدوية من حيث التكلفة والمخاوف والاستقلالية والعبء المنخفض من النواحي الأخرى. وارتبط نشاط المرض بشكل مستقل مع مجموع نقاط العبء.

الكلمات المفتاحية: العبء المرتبط بالأدوية، مرض كرون ، مرض التهاب الأمعاء ، استبيان التعايش مع الادوية