

## Relationship between Knowledge, Medication-Adherence, and Quality of Life among Gastro-esophageal Reflux patients.

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### Abstract :

**Background:** Gastro-esophageal reflux disease is a chronic disease that is widespread globally. This disease negatively affects the patient's productivity and quality of life. Therefore, the patient's adherence to treatment based on his health knowledge of the disease and its complications, as well as following a healthy lifestyle positively affects their quality of life. Quite limited studies explored adherence of esophageal reflux patients and their quality of life separately. Therefore, **our study was aimed to determine the relationship between GERD patients' knowledge, medication-adherence, and their quality of life.** **Research design:** We used a quantitative correlational design. **Subjects:** a convenience sample of 320 GERD patients who were met the inclusion criteria were selected randomly. **Setting:** The study conducted at medical outpatient clinics at Beni-Suef and Zagazig University Hospitals. **Tools:** Socio-demographic data-sheet, Knowledge assessment sheet, Mourisky Medication-Adherence Scale, Quality of Life in Reflux, and Dyspepsia Questionnaire, and Visual Numeric Pain Scale were used to collect relevant data. **Results:** The participants' total knowledge score was poor with a mean score of  $68 \pm 2.42$ . A positive correlation with a highly statistically significant difference was shown between the total medication-adherence score and QoL of the participants ( $p=0.04$ ).

**Conclusion and recommendation:** The participants' overall knowledge about GERD was poor. A positive, statistically significant relationship was detected in-between the participants' total knowledge score, their affected QoL, and their adherence level to medication. Obviously further research is needed to gain GERD patients' knowledge about their disease and the importance of adherence to medication.

**Key words:** Medication-Adherence, Compliance, Gastro-Esophageal Reflux [GERD], Knowledge, Lifestyle, Quality of Life.

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### I. Introduction

Gastroesophageal Reflux Disease (GERD) is a worldwide spread disease, numerous survey studies showed the prevalence of GERD that was 27.8% in North America, 25.9% in Europa, 11.6% in Australia, and 23% in South America; while GERD was less than 10% in East Asia. Moreover, 7.1% of South Korean was affected by GERD. Obviously, GERD prevalence based on individuals' awareness of its symptoms ranged from 2.5% to 25% (Du Jeong et al., 2017). Additionally, a recent study carried on Egyptian Patients attending Al-Azhar University Hospital has shown 54% of patients were complaining of GRED classic symptoms (El-Shafei, El-Tiby, Abdelaziz, Abdel-Fatah, & Gaafar, 2017).

Numerous studies have defined GERD as a chronic disease result from retrograde gastric acid into the esophageal tube, causing structural damage of the esophageal lining mucosa. GERD symptoms take several forms like heartburn, reflux of gastric food contents, regurgitation, dyspepsia, Pyrosis, tissue damage of the pharynx, larynx, and trachea. Moreover, GERD manifestations are classified into non-erosive and erosive reflux. The erosive reflux ends with a pre-cancerous disease known as Barrett-Esophagus (López-Colombo et al., 2017). Various risk factors are result in GERD like unhealthy dietary patterns, obesity, aging, incorrect recumbent position, smoking, inactivity, stress, and consumption of deep-frieddiets. In the past two decades, considering, Egyptians have experienced lifestyle changes that include dietary changes like processed foods high in salt, sugar, and saturated lipids (Çela et al., 2013; Galal, 2003).

In a summary of the comprehensive review article of (Savarino et al., 2017), diagnosis, surveillance, and treatment of GERD are highly expensive. (Peers et al., 2012) added that GERD is the most out-patient clinical problem requiring gastroscopy. The GERD symptoms and its diagnostic tests are in a direct bad effect on the patients' Quality of Life (QoL) and their productivity. Additionally, previous literature pointed to GERD impaired significantly daily living activities, burdens patients psychologically, physically, vitality, and disturbed their sleep (Bjelović, Babič, Dragičević, Ćorac, & Trajković, 2015).

Change QoL carry an important role in the eradication of GERD's complications. These changes require a major change in daily activities of self-care, follow healthy nutrition, smoking cessation, and reduce body weight, high quality of night sleep, and exercise program (Kaltenbach, Crockett, & Gerson, 2006). Likewise, (Maradey-Romero, Kale, & Fass, 2014) recommended using lifestyle modification besides the medical-management of GERD. These recommendations emphasized elevating the head of the bed at sleeping, avoid coffee drinking, spicy and fatty diet, and rest at least three hours post eating and prior to bedtime, and medication-adherence. (Lam & Fresco, 2015) defined medication regimen adherence as the degree to which patients take drugs as given by their physician. By contrast, non-adherence is associated directly with poor cure outcomes, cost, and increased use of medical resources, such as physician visits, laboratory investigations, and hospital charges. Additionally, noncompliance to medications has also a negative influence on the patients' QoL. Accordingly, medication adherence is affected by several factors such as economic, social, psychological, and physical status, knowledge about the disease, and medication adverse effects (Jin, Sklar, Oh, & Li, 2008).

The previous literature shows a majority of patients had non-adhering to the prescribed medications, and nearly 40-50% of those patients are either taking medication improperly or takes it in a routine that contrasts to the given dose (Dal-Paz et al., 2012). There are restricted data that reports on why they take the medication that way and explore patient compliance with the prescribed medicine. That non-adherent may relate to inadequate knowledge or economic status. In addition, data about QoL of the Egyptian GERD patients have been scarce. Egyptians view the QoL as well-being and GERD as considerably less severe than other chronic diseases that they suffer from it like diabetes, kidney failure, and liver disease. So, achieving good QoL requires changes in the behavioral, cognitive, and emotional patterns via acquiring the correct knowledge. Therefore, assessing the patient's knowledge about his disease is necessary to understand the patient's needs and designing an effective educational session to promote his health (Wang, Chuang, & Bateman, 2012).

All previous studies looked at the impact of esophageal reflux on patients' quality of life and some examined patients' adherence to treatment. After the researchers reviewed these studies, it turns out that there is a research gap on the linking between the patients' knowledge, medication adherence, and their QoL. **Hence, our study was aimed** to determine the relationship between GERD patients' knowledge, medication-adherence, and their quality of life.

***The study Research Questions were:***

1. What is the participants' knowledge level regarding GERD?
2. What is the degree of medication-adherence among GERDS' patients?
3. How does the GERD affect in Patients' QoL?
4. Is there a relation between both patients' knowledge, QoL, and their medication adherence?
5. Does the reflux patients' demographic data affect their Knowledge, QoL, and medication-adherence?

## **II. Subjects And Methods**

***Technical design***

***Research design:*** A Quantitative correlational research design was used in this study. This design involves a description of the variables and the systematic investigation of relationships between the study's variables.

***Research Setting:*** This study was conducted in the outpatient clinics of the medical department of both Beni-Suef and Zagazig University Hospitals, Egypt.

***Study's participants:***

A convenience sample of 320 adult patients newly diagnosed with Gastro-esophageal reflux disease was included in this study and selected randomly by using SPSS software, by random select case. They were selected according to the following **inclusion criteria:** adult patients aged between 18 and 65 years, confirmed diagnoses by a positive result of 24-hour PH monitoring and Esophageal-gastro-duodenoscopy, and agree to participate in the study. While patients who have communication barriers, cognitive impairments, Gastroesophageal bleeding, and Sleeve gastrectomy were excluded from the study (Fig 1). We calculated sample size by using Rao-soft based on the total populations (570 GERD's patients), with a response rate of 50 %, at a confidence level of 95% with a 5% margin of error to be 230 but we increased the sample to 320 to overcome non-response (<http://www.raosoft.com/samplesize.html>)

***Tools for data collection:*** we used the following tools to collect the study's data:

***Tool I:*** A structured Interview Questionnaire adapted by the researcher after reviewing the literature (Maradey-Romero et al., 2014). It has consisted of two parts: **Part 1:** Socio-demographic data-sheet as age, gender, residence, marital status, educational level, occupation, and monthly income.

**Part 2:** The knowledge assessment sheet has consisted of 31 closed-end questions covered: a. Knowledge about the disease (definition, causes, risk factors, diagnostic tests, and complications); b. Diet regimen, medication

regimen, exercise regularly and follow up. For example: which of the following caused in GERD?; Do you practice exercises regularly?; are you follow a diet regimen?; Etc.

**Knowledge scoring system:**

Patients' response was scored (one) for the correct answer and (zero) for incorrect answer. Mean and standard deviation was calculated and then converted into percent score. The knowledge was considered "Good" if the percent score was 75% or more, "Fair" if percent score ranged from 60 to less than 75%, and "Poor" if percent score was less than about 60%.

**Tool II:** Mourisky Medication Adherence Scale (MMAS) adopted from (Morisky et al., 2008) and translated to Arabic. It was a structured self-reported 8 closed-end items response. Each response scored as (zero) for "no" and (one) for "yes". The total score was calculated and the result is categorized into two groups; the patient whose score was less than 4 categorized as non-adherent while whose score was 4-8 categorized as adherence.

**Tool III:** Quality of Life in Reflux and Dyspepsia Questionnaire (QoLRDQ). It measures the symptoms of heartburn adopted from (Wiklund et al., 1998) and translated to Arabic. The QoLRDQ contained 25 questions specific to gastrointestinal symptoms. Questions were rated on a five-point Likert scale; the lower the value, the more severe the impact on daily activities. The questions categorized into five directions: emotional distress (6 questions), sleep disturbance (5 questions), vitality (3 questions), food/drink problems (6 questions), and (5 questions) to physical/social aspect.

**Quality of life scoring system:**

Patients' responses were ranged from "Zero" for the "Not all the time" responses to "Four" for the "All the time" responses. The total score was 125. Mean and standard deviation was calculated and then converted into percent score. Quality of life was considered "Sever affecting" if percent score was 75% or more, "Moderate affecting" if percent score ranged from 60 to less than 75%, and "Mild affecting" if percent score was less than from 60%.

**Tool IV:** Visual Numeric Pain Scale (VNPS): developed by (Ritter, González, Laurent, & Lorig, 2006) to assess the pain intensity. The patient was asked to circle the number below VNS grade to clarify his pain intensity. The VNS has ten points rating scale from zero for no pain to ten for worst pain. The point zero pointed to no pain, mild pain (point 1-3), moderate pain (point 4-6), and severe pain (point 7-10).

**Official approval:**

The researchers obtained an official permission from the official personnel in both Beni-Suef and Zagazig University hospitals to conduct the study and collect the necessary data. Simple explanation was given to them about the nature of the study, its aim, benefits and study data collection tools, full explanation of the nursing intervention and its benefits to patients.

**Ethical considerations:**

The study was conducted with careful attention to ethical standards of research and the rights of participants. Oral informed consent was taken from each patient. They informed that the data collected will be used for the research only, and confident manner is assured, and they can withdraw at any time from the study without explanation.

**Data Collection Procedure**

**Tools developments:** Tools were developed by the researchers after reviewing the literature to collect the necessary data. The tools validity test was done through five expertise for checking tools' clarity, relevance, and applicability. They were Faculty members of the medical, surgical department.

**Test reliability** of the proposed tools was done by the alpha Cronbach test. The internal consistency of the tools was high and ranged from 0.77 to 0.85.

**Pilot study:** of 320 patients a pilot study was carried out on 32 patients (10%) to test the clarity and applicability of the tools; estimate the time needed for each subject to fill in the questions. The pilot study sample was excluded from the study.

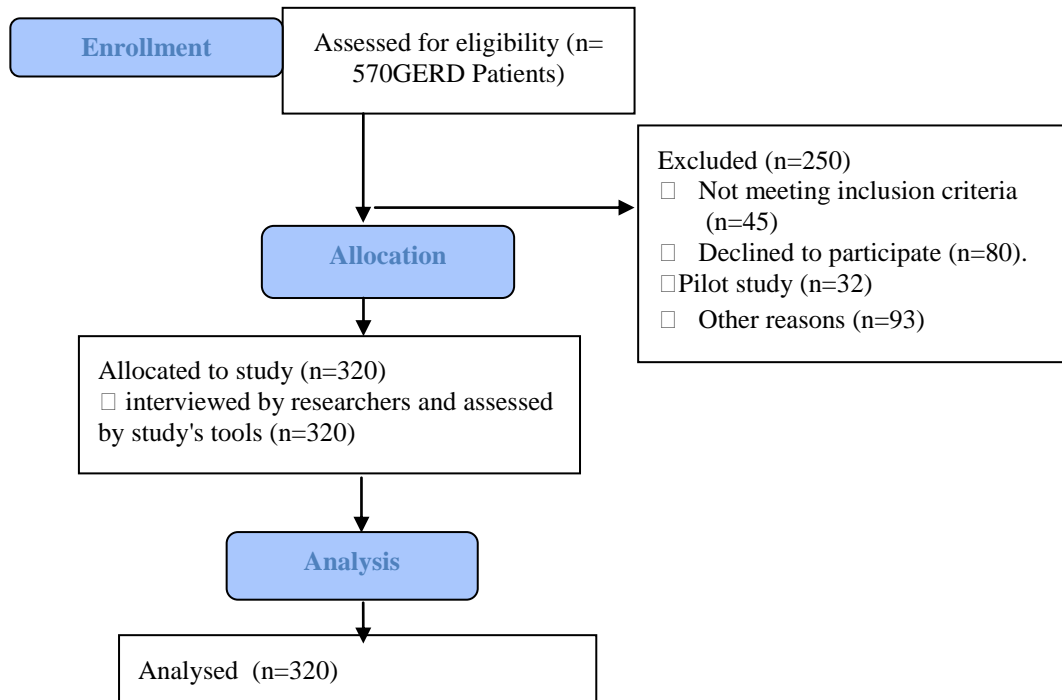
**Field work:** The actual fieldwork started from June 2020 to November 2020. A formal letter was issued from the Beni Suef and Zagazig Faculty of Nursing to the directors of Beni-Suef and Zagazig University hospitals. Oral consent was taken from the patients who agreed to participate in the study before filling the questionnaire. The researchers gave the questionnaire sheet to the participants and asked them to write their responses freely. For those who can't read and write the researchers read the sheet to them and wrote their exact answer. The time consumed to fill the demography, history, and knowledge sheet was about 10-15 minutes, for medication adherence and quality of life; it was about 15-20 minutes.

**Statistical Design:**

Data entry and statistical analysis were done using (IBM SPSS statistics ver23). Quality control was at the stage of coding and data entry. Data were presented using descriptive statistics in the form of frequencies and

percentage for qualitative variables; mean and standard deviation for quantitative variable. Qualitative categorical variables were compared using Chi-square (X<sup>2</sup>) test. Pearson correlation co-efficient (r) was used for assessment of the inter-relationship among quantitative variables. The confidence level chosen for the study was 95%. Statistical significance was considered at p value <0.05.

Fig (1) Flow Diagram of study subjects



### III. Results

#### Demographics:

Our sample was composed of 320 GERD' Patients; 218 men and 102 women, 40.9% of them aged between 45-<55 years with mean age 36±4.28. Also, 82.2% of the participants were married, 75.3% of them were from rural areas. Regarding Education, 37.5% of the participants have a secondary education. Additionally, 64.1% of the participants were working and 8.1% were retired. About income, 62.2% of the participants, their income were enough.

**Table1. Frequency and percentage distribution of the participants' knowledge Scores (n=320).**

Items	Good		Faire		Poor	
	No.	%	No.	%	No.	%
knowledge about disease	33	10.3	64	20	223	<b>69.7</b>
knowledge about diet regimen	20	6.2	110	34.4	190	<b>59.4</b>
knowledge about medication	169	<b>52.8</b>	75	23.4	76	23.8
knowledge about Exercise	56	17.5	155	<b>48.4</b>	109	34.1
knowledge about Follow-up and investigation	52	<b>16.3</b>	65	20.3	203	63.4
<b>Total knowledge</b>	18	5.6	40	12.5	262	<b>81.9</b>
<b>Mean ± SD</b>	13.68 ± 2.42					

*Data presented in number, Percentage, mean, and standard deviation.*

**Table 1** reveals that 52.8%, 48.4%, 69.7%, and 59.4% of the participants had good knowledge about medication, fair knowledge about exercise, and poor knowledge about both GERD's disease and diet regimen. Only 16.3% of them had good knowledge about follow-up and investigation. Additionally, the total knowledge score of the participants was poor (81.9%) with a mean score of 13.68±2.42.

Medication adherence score (n=320).

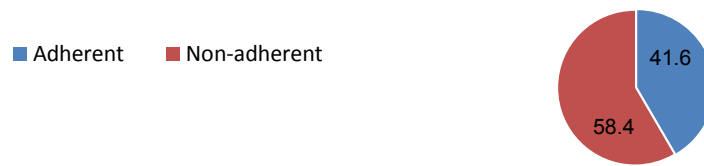


Figure2. Percentage distribution of the participants' medication adherence (n=320).

Figure 2 clarifies that 58.4% of the participants were non-adherent to GERD's medications.

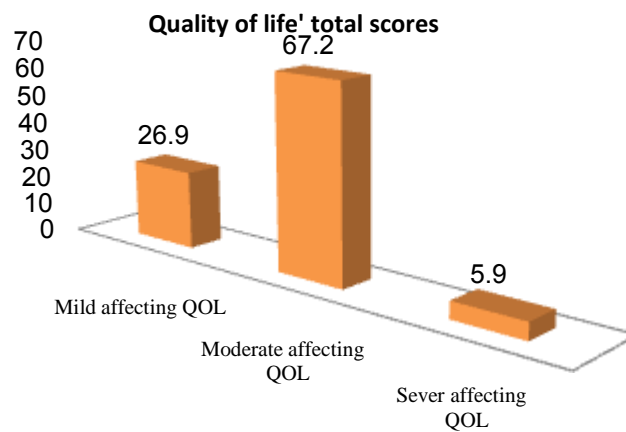


Figure3. Percentage distribution of the Participants' quality of life total scores (n=320).

Figure 3 shows that the participants' quality of life was moderately affected by GERD's disease (67.2%).

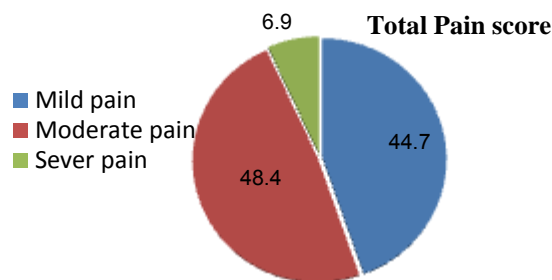


Figure4. Percentage distribution of the participants' total Pain score (n=320)

Figure 4 reveals that 48.4% of the participants' pain levels were moderate.

Table2. Correlations between the participants' total score of knowledge, medication-Adherence, and Quality of life.

Variable	Total knowledge Score		Total Adherence score	
	r	P	r	P
Total Adherence score	.229	.000**	1	-
Total QoL score	.147	.000**	0.083	0.041*

Significant levels: \* $p < 0.05$ . \*\* $P < 0.01$ .  $r$  = Person correlation. Quality of Life (QoL)

Table 2 shows that there was a positive correlation with highly statistically significant differences between the total knowledge score of the participants and each of their total medication-adherence score and total quality of life score ( $p < 0.01$ ). Moreover, there was a positive correlation with a highly statistically significant difference between the total medication-adherence score and QoL of the participants ( $p = 0.04$ ).

**Table3. The correlation between the participants' demographic data and the total scores of their knowledge, medication adherence, and quality of life (n=320 patients).**

Demographic characteristics	No	Total Knowledge			X <sup>2</sup> P-Value	Total Adherence		X <sup>2</sup> P-Value	Total Quality of Life affected			X <sup>2</sup> P-Value	
		Good n=18	Faire n= 40	Poor n=262		Adherence n=133	Non-adherence n=187		Mild n=86	Moderate n=215	Severe n=19		
		%	%	%		%	%		%	%	%		
Age	20 - <30 years	36	0.9	5.0	8.4	6.18 .044*	1.6	9.7	18.3 .000**	3.1	7.5	0.6	23.5 .000**
	30 - <45 years	107	1.3	5.3	26.9		23.4	10.0		8.8	23.4	1.3	
	45 - <55 years	131	2.2	5.0	33.8		17.2	23.8		7.2	30.0	3.8	
	>55 years	46	1.3	0.3	12.8		5.0	9.4		7.8	6.3	0.3	
Gender	Male	218	3.4	5.0	59.7	16.6 .000**	25.9	42.2	3.42 .047*	20.6	43.4	4.1	4.12 .029*
	Female	102	2.2	7.5	22.2		15.6	16.2		6.3	23.8	1.9	
Marital status	Single	27	0.6	1.9	5.9	7.48 .018*	5.0	3.4	36.1 .000**	0.3	7.5	0.6	17.6 .000**
	Married	263	3.8	10.6	67.8		31.9	50.3		25.3	52.5	4.4	
	Widowed	18	0.9	0.0	4.7		0.6	5.0		0.9	4.4	0.3	
	Divorced	12	0.3	0.0	3.4		3.8	0.3		0.6	2.5	0.6	
Residence	Urban	79	2.2	3.4	19.4	3.84 .091	10.6	14.1	4.16 .049*	1.6	20.6	2.5	46.3 .000**
	Rural	241	3.4	9.1	60.9		30.9	44.4		25.3	46.6	3.4	
Education	Illiterate	84	1.3	1.9	23.1	3.72 .315	9.7	16.6	8.51 .093	13.4	11.9	0.9	44.9 .000**
	Read and write	63	0.6	3.4	15.6		10.0	9.7		1.6	15.9	2.2	
	Secondary	120	2.8	5.0	60.9		13.4	24.1		10.3	25.3	1.9	
	University	53	0.9	2.2	13.4		8.4	8.1		1.6	14.1	0.9	
Job	Working	205	2.5	6.6	55.0	13.4 .004*	29.7	34.4	22.1 .000**	22.2	38.1	3.8	29.3 .000**
	Not working	53	1.6	2.2	12.8		5.3	11.2		1.56	13.8	1.3	
	Retired	26	0.6	0.3	7.2		0.3	7.8		3.1	4.7	0.3	
	Housewife	36	0.9	3.4	6.9		6.2	5.0		0.3	10.3	0.6	
Income	Enough	199	2.8	6.6	52.8	17.8 .000**	30.9	31.2	19.6 .000**	19.0	39.7	3.4	4.33 .192
	Not enough	78	1.6	5.3	17.5		5.3	19.1		4.7	17.8	1.9	
	More than enough	43	1.3	0.6	11.6		5.3	8.1		3.1	9.7	0.6	

Significant levels: \*p <0.05. \*\*P <0.01. (X<sup>2</sup>) Chi-square

Table 3 shows that there was a statistically significant relation between the participants' total knowledge score and their demographic characteristics at p<0.01, except for residence and education. Additionally, a statistically significant relation was found in-between the participants' total medication adherence score and their demographic characteristics except for education p=0.093. Moreover, there was a relation with statistical significance between the participants' QoL affected with GERD and their demographic characteristics except for income p=0.192.

#### IV. Discussion

The (GERD) is a common gastrointestinal disorder that is linked to a lower QoL and a higher risk of complications worldwide. To provide GERD's patient education about his disease the relationship between patients' knowledge, medication adherence, and quality of life must be identified. So, our study was aimed to determine the relationship between GERD patients' knowledge, medication-adherence, and their quality of life. Of 320 GERD' Patients more than half of them were men and one-third were women. Their mean age was  $36\pm 4.28$ . The almost of the participants were married, and two-third of them was from rural areas. Additionally, almost all of the participants were working. More than half had enough income, and one-third of them had a secondary education. Our results are consistent with what (**Zaman et al., 2016**) reported in their study of 300, (54.7%) were female, (35.3%) were illiterate. The mean age was  $35.9\pm 9.6$  years. And 33.3% of people were unemployed. The frequency of GERD was higher in rural (57.3%). From point of view this results may due to low education level and improper health teaching about this disease.

In answer to the study's question of the participants' knowledge about GERD, The results showed that the Participants' overall knowledge about GERD was poor; above half of the participants had good knowledge about medication while their knowledge about practicing exercise was fairly less than half. Additionally, two-third of them had poor knowledge about disease and diet regimens. Also, the minority of them had good knowledge about the importance of follow-up and investigations. These findings underscore the patients' need for educational programs on their disease and how to improve their quality of life. This result agrees with (**Ahamed, Elalem, & Mohamed, 2018**), they reported that, more than two-thirds of the patients in both studied groups' total knowledge was unsatisfactory at the pretest, the deficiency was most evident concerning exercise, disease complication, and treatment regimen. This study was intervention study about the efficacy of lifestyle modification sessions.

In answer to the study question of the participants' medication adherence, the results showed more than half of them that were non-adherent to the prescribed medications. A potential explanation for this finding may be due to a lack of knowledge about the importance of adherence and their fear of the adverse effect of medications or economical factor. Our results are in agreement with (**Azzam, 2018**) who is evaluate the degree of adherence to Proton Pump Inhibitor (PPI) treatment in 240 patients with GERD, revealed (53.8%) of the participants that were forgetting to take PPI. Additionally GERD patients on PPI were poorly compliance with medication.

About the participants' QoL that affected by GERD, the results clarified that approximately half of the participants' QoL was moderately affected. This result could explain by the chronicity of this disease, adverse effect of the prescribed medication, lack of motivation, economic status, and gastric pain sensation. This is confirmed by the results of the current study, which is that almost half of GERD patients have a moderate level of pain. This result is similar to the study of (**Bjelović et al., 2015**). They concluded GERD that impairs largely patients' daily lives proportion dependently on variables resembling education, age, and sex. The present study showed a significant positive correlation between the participants' total knowledge, total adherence and their QoL scores. This finding is an answer to the study research question about the nature of the relationship between each of patients' knowledge about GERD, QoL, and their adherence to medications. Similarly, a study of (**Kroch & Madanick, 2017**) reported that GERD patients with infrequent mild symptoms must be counseled to modify their lifestyle and compliance to PPI. Consequently, the GERD patients' quality of life is impacted.

To answer the study research question regarding the relationship between various aspects of the participants' sociodemographic and each of their total knowledge, adherence degree, and the affected QoL, the present study results cleared the participants' demographic characteristics that were a highly significant relationship with their total knowledge, adherence to medication score, and the affected QoL with GERD. Likewise in a systematic review of (**Nafradi, Nakamoto, & Schulz, 2017**) clarifies four out of six studies declared a positive association between self-efficacy that in general and adherence compared to only two studies denied this relationship. Furthermore, a different research topic fulfilled by (**Heggy, Galal, Shrief, & Elalem, 2018**); found a relation with statistical significance between the gouty patients' knowledge, adherence, and their demographic as age, marital status, and education while no relation between their demographic data and QoL score. Also, a study carried in Egypt to estimate the relation between hypertensive patients' knowledge, QoL, and their management-compliance reported that, 65% of 600 patients had a fair compliance level, their compliance level affected by education, gender, age, and employment. Additionally, the majority of the hypertensive patients had a poor score of HRQoL related to a limited role, impaired emotional trouble, and physical activity (**Eldessouki, Keryakos, & Gamal, 2019**). It is impossible to compare this study to the present study because of the difference in the scope and topics of research.

From our view and after hard research that showed the paucity of studies that deal with the relationship between the demographic characteristics of reflux patients and their knowledge, adherence, and quality of life. This supports the originality and novelty of the present study. Lack of similar studies is one of the study limitations.

## V. Conclusion:

Based on the study results we concluded that the participants' overall knowledge about GERD was poor, more than half of them were non-adherent to the prescribed medication, and approximately half of the participants' QoL was moderately affected. Additionally, a positive, statistically significant relationship was detected in-between the participants' total knowledge score, their affected QoL, and their adherence level to medication. Moreover, a highly statistically significant relationship was detected between the participants' demographic data and each of their knowledge, QoL, and medication-adherence.

**Recommendation:** Obviously further research is needed to gain GERD patients' knowledge about their disease and the importance of adherence to medication. Additionally, future intervention research is needed to enhance GERD patients' QoL.

### **Acknowledgment:**

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### **Conflicts of interest:**

The authors have declared no conflict of interest, no financial received support with regard to this research.

### **Authors' contribution:**

Both Laila A, and Sheren S, was involved in the study's idea, design, data collection, and analysis. Also both authors revised, drafted the manuscript, and approved the final copy for publication.

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