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Research article

ASSESSMENT OF HEALTH AND ECONOMIC OUTCOMES IN PATIENTS WITH CERTAIN GASTROINTESTINAL DISORDERS BY USING STRUCTURED EDUCATION BY PHARMACIST –A [StEP] TRIAL

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ABSTRACT

The aim of the study is to improve Health Related Quality of Life (HRQoL), mental status and to decrease economic burden of patients with certain GI Disorders. The study being a randomized controlled trial where a total of 60 patients were enrolled from which the patients were divided into 2 groups namely Control group and Interventional group. The Control group received the usual care given by the Physician and the Interventional group received Structured Education by Pharmacist; which included education about disease, drugs and importance of adhering to the therapy regimen and Upon the second visit the patients were made to fill the Quality of Life and Psychiatric forms again. Then the 2 group scores were analyzed for pre test and post test by using SPSS software by using paired sample t-test. At the end of the study the outcomes were measured in both control and interventional group and it was found among both the groups that before patient education and after patient education there was statistically significant improvement in QOL, mental status and decrease in economic burden in the intervention group than that of control group.

Keywords: Health Related Quality of Life (HRQoL), Hospital Anxiety and Depression Scale (HADS-scale), patient education, Gastrointestinal Disorder.

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INTRODUCTION

Gastro Intestinal disorders occur more frequently in the general population and which lead to severe drastic symptoms. Most GI disorders are treated successfully with medications or surgery. [1]

Examples of certain stomach disorders is GERD, dyspepsia, IBS, peptic ulcer, IBD, pancreatitis, liver disorders, GI infections, spleen disorders, appendicitis, etc.

These disorders are of major concern because when left untreated can lead to severe complications. only long term medication therapy to the patients would end up in decreased quality of life, mental status and high economic burden.

Importance is given to disorders namely GERD, dyspepsia and IBS(TYPE C) in this study particularly and it was found that there was poor QOL, Mental status and increased economic burden among them due to lack of patient education .

Patient counseling may be defined as providing medication information orally or in written form to the patients or their representative or providing proper directions of use, advice on side effects, storage, diet and life style modifications. It involves interaction between a pharmacist and a patient and/or a care giver. It is interactive in nature.

HEALTH RELATED QUALITY OF LIFE (HRQoL) : World Health Organization defined health as condition in the absence of disease and infirmity but also has the presence of physical, mental, and social well-being status. QoL can be defined as the functional level of effect of an illness and its consequent therapy upon patient. HRQoL is made up of subject perceptions and objective health status which comprised of physical, psychological and social domain. The assessment of HRQoL continues to grow in importance, as clinicians and clinical researchers have recognized the impact of the FGIDs.[8]

HRQoL QUESTIONNAIRE (HRQoL) is an instrument used to measure the impact of a disease or illness on person's life in terms of personal, marital, and employment happiness and is proposed as a measure of efficacy. Most HRQoL questionnaires assess daily function or work capability.

HADS QUESTIONNAIRE: It is a brief self reporting two dimensional questionnaire developed to screen for levels of anxiety and depression among patients .

MATERIALS AND METHODOLOGY

The approval for the conduct of the research was obtained from institutional ethics committee, K.G Hospital and Post Graduate Research Institute, Coimbatore with CTRI [Clinical Trial Registry of India] : CTRI number - CTRI/2015/07/005989

MATERIALS

a) Patient consent form.
b) Patient Data Entry Form which is specially designed for this study.
c) Standard Quality of Life Questionnaires [English & Tamil]. GERD - Health Related Quality of Life Questionnaire Short Form Leed Dyspepsia Questionnaire [SFLDQ] Irritable Bowel Syndrome – Quality of Life [IBS-QoL]
d) Hospital Anxiety and Depression Scale (HADS-scale).
e) Patient Information Leaflet [English & Tamil].

METHODOLOGY

A consent form was prepared for the study and explained to the patient about the study and got consent from the patient or legal care taker. A total of 60 patients were enrolled in the study from Inpatient and Outpatient department of Gastroenterology. [GERD – 22, DYSPEPSIA – 30, IBS - 08]. A specially designed data entry format was used to enter all patients details like patient's name, age, sex, weight, IP number, BMI, occupation, monthly income, symptoms, Diagnosis, Medication given. Study materials like Questionnaires [QoL & HAD scale] were provided to the patients and then got it filled by them. The study was conducted as a randomized controlled trial where the patients were divided into 2 groups namely Control group and Interventional group. The Control group received the usual care given by the Physician only whereas the Interventional group received both normal care by physician and also Structured Education by clinical Pharmacist; which included education about disease, drugs and importance of adhering to the therapy regimen. Upon the second visit the patients filled the Quality of Life and Psychiatric forms again. Then the 2 group scores were analyzed before and after by using SPSS software by using paired sample t-test . At the end of the study the outcomes were measured in both control and interventional group.

RESULTS

Sixty patients were enrolled in the study. Then total patients were divided into two groups, interventional and control. The following are the demographics details of the patients.

The disease wise distribution of patients

From the obtained data [fig 1], it was found that out of 60 patients, 30(50%) of study population were diagnosed with dyspepsia followed by 22(36.6%) GERD and 8(13.3%) had IBS-C.

The gender wise distribution of patients with GERD

In GERD, out of 22 patients, 15 (68%) patients were male and 7 (32%) were female which was shown in fig.2.

The gender distribution of patients with Dyspepsia

Out of 30 Dyspepsia patients, 14(47%) patients were male and 16(53%) were female which was represented in fig.3

The gender distribution for IBS-C patients

In fig.4, out of 08 IBS-C patients 04(50%) patients were male and 04(50%) patients were female.6(53%) were female which was represented in fig.3

The age wise distribution of patients

In fig.5 the data shows that 15(25%) of study population fell in age group of 18-30 years followed by 21(35%) were in age group of 31-45 years and 24(40%) were in age group of 46-60 years.

Table 1 interpretation: In terms of QoL, In GERD the MD between 1st visit and 2nd visit in control and interventional groups were 13.1 vs. 12.3 and p value shows 0.0008 & 0.0006 respectively. In Dyspepsia the MD between 1st visit and 2nd visit in control and interventional groups were 5.4 vs. 4.4 and p value shows 0.0002& 0.0001 respectively. In IBS-C the MD between 1st visit and 2nd visit in control and interventional groups were 23.0 vs. 31.8 and p value shows 0.13 & 0.04 respectively.

Table 2 interpretation: In terms of mental condition, In GERD the MD between 1st visit and 2nd visit in control and interventional groups were 2.8 vs. 3.8 and p value shows 0.004 & 0.003 respectively. In Dyspepsia the MD between 1st visit and 2nd visit in control and interventional groups were 4.2 vs. 5.9 and p value shows 0.002 & 0.0001 respectively. In IBS-C the MD between 1st visit and 2nd visit in control and interventional groups were 2.2 vs. 1.5 and p value shows 0.47 & 0.18 respectively.

Table 3 interpretation: In terms of economic burden, In GERD the MD between 1st visit and 2nd visit in control and interventional groups were 684.3 vs. 1246.0 and p value shows 0.03& 0.001 respectively. In Dyspepsia the MD between 1st visit and 2nd visit in control and interventional groups were 832.7 vs. 822.0 and p value shows 0.02& 0.03 respectively. In IBS-C the MD between 1st visit and 2nd visit in control and interventional groups were 1726.7 vs. 3236.2 and the p value shows 0.22 & 0.11 respectively.

In table 4, for QoL the total number of patients was categorized into 3 stages like Good, Fair & Poor QoL. In interventional group more patients were changed from Poor to Good QoL than the control group in terms of GERD, Dyspepsia & IBS-C.

In table 5, mental condition of the patients was categorized into Mild, Moderate & Severe. In GERD & Dyspepsia both the groups shows equal frequency distribution, but in IBS-C more patients in control group comes under Mild condition than in interventional group, this may be due to very low DOF.

The mean and p value of both groups in terms of GERD, Dyspepsia & IBS-C were consolidated in table 6.

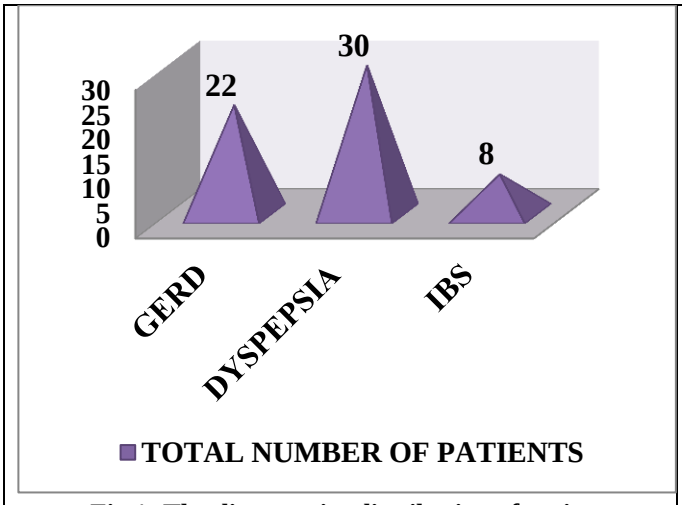

Fig 1: The disease wise distribution of patients

From the obtained data, it was found that out of 60 patients, 30(50%) of study population were diagnosed with dyspepsia followed by 22(36.6%) GERD and 8(13.3%) had IBS-C.

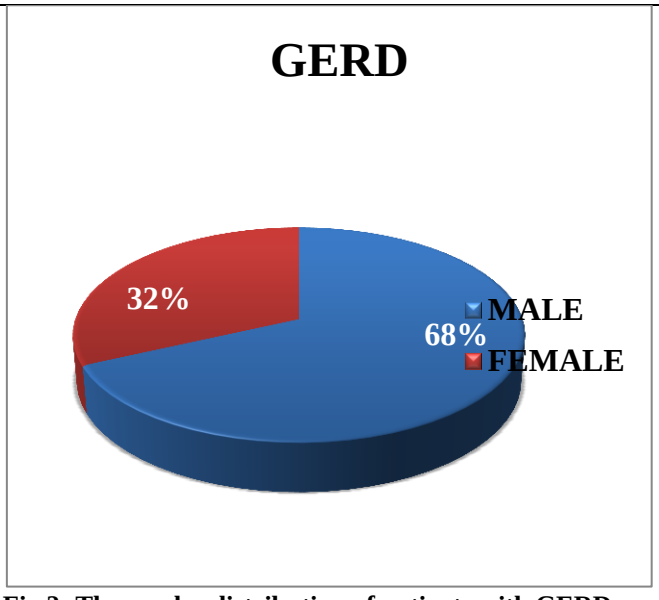

Fig 2: The gender distribution of patients with GERD

In GERD, out of 22 patients, 15 (68%) patients were male and 7 (32%) were female which was shown in fig.2.

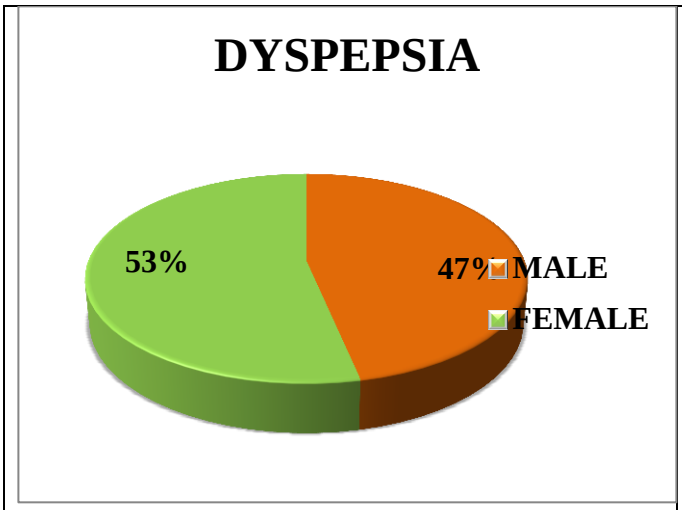

Fig 3: The gender distribution of patients with Dyspepsia

Out of 30 Dyspepsia patients, 14(47%) patients were male and 16(53%) were female which was represented in fig.3

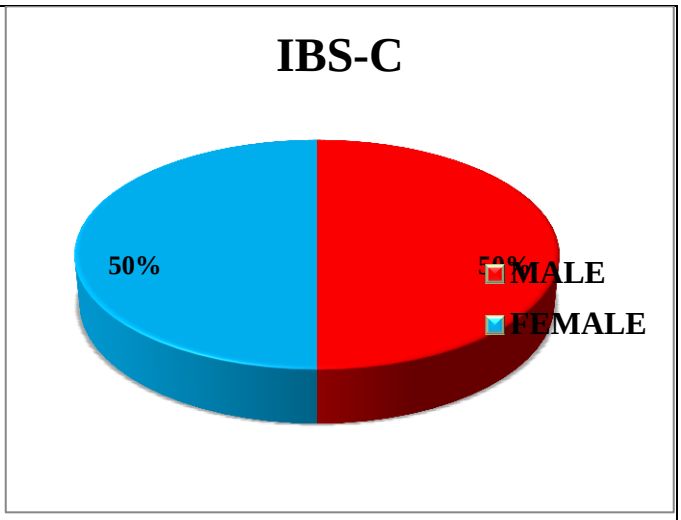

Fig 4: Represents the gender distribution for IBS-C patients

Out of 08 patients 04(50%) patients were male and 04(50%)patients were female.

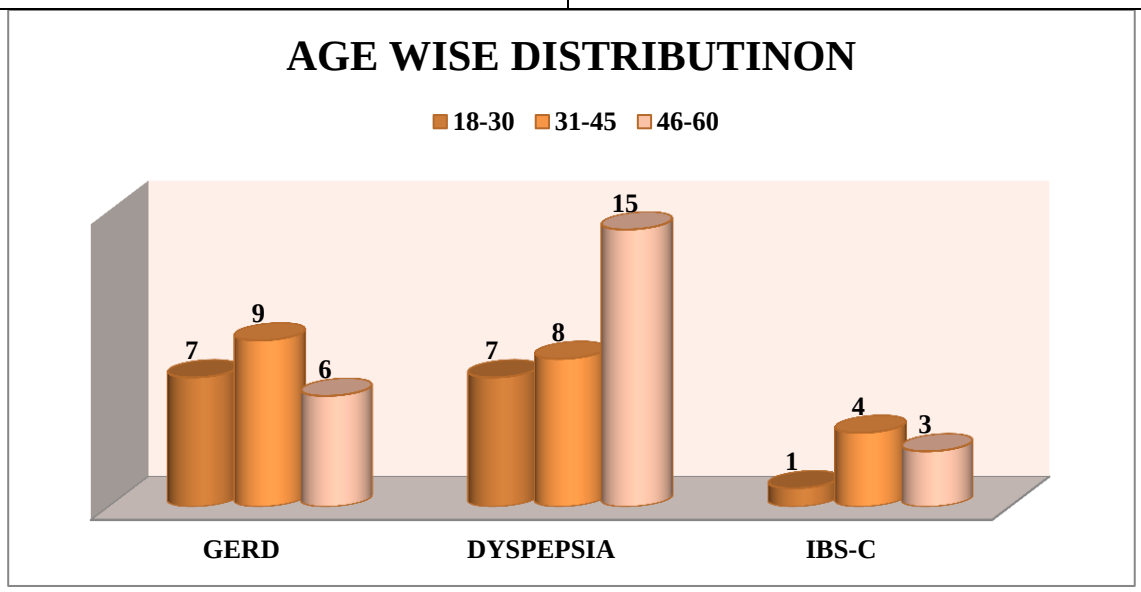

Fig 5: The age wise distribution of patients:

In fig.5 the data shows that 15(25%) of study population fell in age group of 18-30 years followed by 21(35%) were in age group of 31-45 years and 24(40%) were in age group of 46-60 years.

DISCUSSION

From the study, it can be concluded that majority of the study populations has Dyspepsia and least having IBS-C. In case of Dyspepsia and IBS-C most of them were females. According to Mark Feldman et al., (2010) the frequency of dyspepsia is slightly higher in women than men and influence of age varies among different studies, but in case of GERD males were more because, the women GERD condition may go unnoticed or many women may not report freely to General physician as men do, especially in country like India. According to Brenda Goodman (2011) men actually had more physical manifestations of acid reflux disease.

Regarding pharmacist intervention, even though there were no direct literatures quoting the applicability of pharmacist intervention in reduction of health outcomes in GI patients, there were correlating studies showing that a pharmacist can improve HRQoL, mental condition as well as economic burden in other diseased patients. This study is comparable with the study conducted by Marcia Valenstein et al., (2011) concluded that a practical pharmacy based intervention increased antipsychotic

Table 1: The QoL scores of patients in control and interventional groups

DISEASE NATURE	CONTROL GROUP								INTERVENTIONAL GROUP							
	1st VISIT		2nd VISIT		MD	t VALUE	DOF	p VALUE	1st VISIT		2nd VISIT		MD	t VALUE	DOF	p VALUE
	MEAN	SD± SEM	MEAN	SD± SEM					MEAN	SD± SEM	MEAN	SD± SEM				
GERD	20.18	14.4± 4.3	7.0	6.2± 1.8	13.1	**4.710***	10	**0.0008**	20.36	9.9± 3.0	8.0	4.5± 1.3	12.3	**6.524***	10	**0.0006**
DYSPEPSIA	7.8	3.0± 0.7	2.3	1.5± 0.4	5.4	**7.065***	14	**0.0002**	7.87	2.0±0.5	3.4	1.6± 0.4	4.4	**8.551***	14	**0.0001**
IBS-C	37.5	28.2± 14.1	14.5	11.9± 5.9	23.0	**2.040**	3	**0.13**	53.63	34.5±17.2	21.7	16.0± 8.0	31.8	**3.252***	3	**0.04**

MD = Mean Difference SD = Standard Deviation
DOF = Degree of Freedom SEM = Standard Error Mean

Table 2: The mental condition of the patients in control and interventional groups

DISEASE NATURE	CONTROL GROUP								INTERVENTIONAL GROUP							
	1st VISIT		2nd VISIT		MD	t VALUE	DOF	P VALUE	1st VISIT		2nd VISIT		MD	t VALUE	DOF	P VALUE
	MEAN	SD± SEM	MEAN	SD± SEM					MEAN	SD± SEM	MEAN	SD± SEM				
GERD	9.45	6.7± 2.0	6.6	4.8± 1.4	2.8	**3.648***	10	**0.004**	10.18	5.8±1.7	6.3	3.4± 1.0	3.8	**3.757***	10	**0.003**
DYSPEPSIA	12.07	8.3±1.5	6.80	5.9± 1.5	4.2	**6.254***	14	**0.0002**	6.36	3.4±2.1	10.2	6.6± 1.7	5.9	**6.820***	14	**0.0001**
IBS-C	9.50	5.7±2.9	7.25	4.1± 2.0	2.2	**1.711**	3	**0.47**	18.0	14.4±7.2	16.5	14.6 ±7.3	1.50	**0.812**	3	**0.18**

MD = Mean Difference SD = Standard Deviation
DOF = Degree of Freedom SEM = Standard Error Mean

Table 3: The economic burden of the patients in control and interventional groups:

DISEASE NATURE	CONTROL GROUP								INTERVENTIONAL GROUP							
	1st VISIT		2nd VISIT		MD	t value	DOF	p value	1st VISIT		2nd VISIT		MD	t Value	DOF	p Value
	MEAN	SD± SEM	MEAN	SD± SEM					MEAN	SD± SEM	MEAN	SD± SEM				
GERD	1120.0	1160.8± 299.7	435.0	252.9 ± 65.3	684.3	2.343	14	**0.03***	1849.73	1917.1 ± 495.0	603.67	221.0 ± 57.0	1246.0	2.667	14	**0.01***
DYSPEPSIA	1293.55	1219.8 ± 367.8	460.82	284.4 ± 85.7	832.7	2.646	10	**0.02***	1227.0	1183.0 ± 350.6	405.0	241.0 ± 72.6	822.0	2.399	10	**0.03***
IBS	2306.75	2538.7 ± 1269.3	580.0	503.9 ± 251.9	1726.7	1.514	3	**0.22**	3805.0	2864.7 ± 1432.3	568.0	409.9 ± 204.9	3236.2	2.216	3	**0.11**

MD = Mean Difference SD = Standard Deviation
DOF = Degree of Freedom SEM = Standard Error Mean

Table 4: The total frequencies of QoL of patients in control and interventional group

QUALITY OF LIFE	CONTROL GROUP						QUALITY OF LIFE	INTERVENTIONAL GROUP					
	GERD		DYSPEPSIA		IBS			GERD		DYSPEPSIA		IBS	
	1st VISIT	2nd VISIT	1st VISIT	2nd VISIT	1st VISIT	2nd VISIT		1st VISIT	2nd VISIT	1st VISIT	2nd VISIT	1st VISIT	2nd VISIT
GOOD	0 **(0%)**	8 **(72.72%)**	5 **(33.33%)**	15 **(100%)**	2 **(50%)**	3 **(75%)**	**GOOD**	3 **(27.27%)**	10 **(90.90%)**	4 **(26.66%)**	14 **(93.93%)**	1 **(25%)**	3 **(75%)**
FAIR	10 **(90.90%)**	3 **(27.27%)**	9 **(60%)**	0 **(0%)**	1 **(25%)**	1 **(25%)**	**FAIR**	7 **(63.63%)**	1 **(09.09%)**	11 **(73.33%)**	1 **(06.66%)**	2 **(50%)**	1 **(25%)**
POOR	1 **(09.09%)**	0 **(0%)**	1 **(06.66%)**	0 **(0%)**	1 **(25%)**	0 **(0%)**	**POOR**	1 **(09.09%)**	0 **(0%)**	0 **(0%)**	0 **(0%)**	1 **(25%)**	0 **(0%)**

Table 5: Represents the total frequencies of patients with mental status

MENTAL STATUS	GERD		DYSPEPSIA		IBS		MENTAL STATUS	GERD		DYSPEPSIA		IBS	
	1st VISIT	2nd VISIT	1st VISIT	2nd VISIT	1st VISIT	2nd VISIT		1st VISIT	2nd VISIT	1st VISIT	2nd VISIT	1st VISIT	2nd VISIT
MILD	8 (72.72%)	9 (81.81 %)	12 (80%)	12 (80%)	3 (75%)	4 (100%)	MILD	**9** (81.81%)	**11** (100%)	9 (60%)	10 (66.66%)	2 (50%)	2 (50%)
MODERATE	3 (27.27%)	2 (18.18 %)	3 (20%)	3 (20%)	1 (25%)	0 (0%)	MODERATE	**2** (18.18%)	**0** (0%)	4 (26.66%)	5 (33.33%)	0 (0%)	1 (25%)
SEVERE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	SEVERE	0 (0%)	0 (0%)	2 (13.33%)	0 (0%)	2 (50%)	1 (25%)

Table 6: The consolidation of means of Quality of life, mental condition and economic burden of patients in both groups.

DISEASE NATURE	CHARACTERISTICS OF OUTCOMES	CONTROL GROUP			INTERVENTIONAL GROUP		
		MEAN 1st VISIT	MEAN 2nd VISIT	p VALUE	MEAN 1st VISIT	MEAN 2nd VISIT	p VALUE
DYSPEPSIA	HRQOL	7.80	2.33	**0.000****	7.87	3.47	**0.0001****
	MENTAL STATUS	12.07	6.80	**0.0002****	6.36	10.27	**0.0001****
	ECONOMIC BURDEN	1293.5	460.82	**0.02***	1849.7	603.6	**0.01***
GERD	HRQOL	20.18	7.00	**0.0008****	20.36	8.00	**0.0006****
	MENTAL STATUS	9.45	6.64	**0.004****	10.18	6.36	**0.003****
	ECONOMIC BURDEN	1120.0	435.0	**0.03***	1227.0	405.0	**0.03***
IBS	HRQOL	37.50	14.40	**0.13**	53.63	21.75	**0.04***
	MENTAL STATUS	9.50	7.25	**0.47**	18.00	16.50	**0.18**
	ECONOMIC BURDEN	2306.7	580.0	**0.22**	3805.0	565.0	**0.11**

adherence among patients with SMI & according to Norma Marchetti et al., (2009) moderate or severe GERD will require pharmacists to initially refer patients to their physicians for treatment. A significant contribution to the care of patients with GERD is possible for pharmacists when we are proactive and become comfortable in our knowledge of treatment options.

This study proved that a pharmacist can play a role in improving the QoL, mental status as well as economic status of FGID's patients. According to S.L.S Halder et al., (2003) in a population-based, nested, case–control study, subjects reporting symptoms of either dyspepsia or irritable bowel syndrome and healthy controls were interviewed and completed a battery of psychological measures plus a validated, generic, health-related quality of life measure, and this study concluded that In the community, health-related quality of life is impaired in subjects with irritable bowel syndrome and dyspepsia. Thus patient education indeed has a key role in enhancing QoL.

CONCLUSION

This study concludes that, the pharmacists have an extended role of improving the Health & Economic status as well as mental status of GI disorders. From the data obtained, it was shown that, the pharmacists can improve the psychiatric score of GI disorder patients which is a prevalent and hidden condition in GI patients, which may go unnoticed if not properly analyzed. This study also proved that, when a pharmacist intervenes GI disorder patients, he/she can improve the HRQoL of the patients. Though there was no study available to prove the pharmacist's role in GI disorders, this study acts as a benchmark for other researchers to implement StEP trial in all hospitals to improve the Health and Psychiatric status in GI disorder patients. This study lacks its validity in terms of the improving economic status by pharmacist's intervention, which may be due to the lack of adequate sample size. Moreover, this study has not included all the costs involved in the treatment. Moreover, this study can provide a frame work to other hospitals to improve the mental status & Qol of patients who visits Gastroenterology Department.

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