Rajani A. *et al.* / *International Journal of Pharmacy & Therapeutics*, 5(1), 2014, 49-55.

e- ISSN 0976-0342
Print ISSN 2229-7456

International Journal of Pharmacy & Therapeutics

Journal homepage: www.ijptjournal.com

IJPT

ROLE OF A CLINICAL PHARMACIST IN UNDERSTANDING THE TREATMENT OF NON-ULCER DYSPEPSIA – A CASE STUDY

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ABSTRACT

To evaluate the etiological risk factors and to understand the treatment and management of Non-ulcer Dyspepsia in general population and to assess the better treatment strategies. A prospective study was conducted in Krishna Institute of Medical Sciences for a period of one year. After ruling out the organic causes of dyspepsia by an endoscopy report, the case has been taken for study. A patient data collection form was designed exclusively for the study and complete details of the patients were collected. All the patients were evaluated for their risk factors of the disease and finally treatment was started with different classes of drugs. The optimal duration of therapy was assessed with different classes of drugs used among different populations. Out of 86 patients considered for the study, the treatment strategies were evaluated. Proton pump inhibitors were found to be efficacious among other classes of drugs. The combination of Amoxicillin + Omeprazole + Clarithromycin was found to be efficacious in *Helicobacter pylori* infection. Only through effective patient counseling, treatment and management of Non-Ulcer Dyspepsia results in the best outcome.

Key Words:- Non-Ulcer Dyspepsia, Treatment strategies, Proton pump inhibitors, Patient counseling, Anti-*Helicobacter pylori* antibiotics.

INTRODUCTION

Non-ulcer dyspepsia or functional dyspepsia, describes recurrent or persistent symptoms of discomfort at the upper abdomen, mostly epigastric region, without any identifiable cause or pathology in the upper gastro intestinal tract (Anonymous 1; Dickerson MN, King DE, 2004). The actual prevalence of this condition is unknown. According to various reports, up to 20 to 30 % of the community has recurrent dyspeptic symptoms. In some published literature, the reported prevalence is as high as 60% (Dickerson MN, King DE, 2004; Talley NJ *et al*., 1992; Fisher RS, Parkman HP, 1998)). In Malaysia, one survey found 31.2% of non-ulcer dyspepsia patients were tested for Helicobacter pylori (Goh KL, 1997). The presenting symptoms of non-ulcer dyspepsia are usually nonspecific. It may be a mild discomfort which the patient commonly describes "indigestion", or a severe "burning" sensation. The dyspepsia symptom complex includes epigastric pain, bloating, early satiety, fullness, epigastric burning, belching, nausea and vomiting. Although often chronic, the symptoms in functional dyspepsia are frequently intermittent, even during a period with marked symptoms (Agreus L *et al*., 1995). In the general population, the most prevalent dyspepsia symptoms are post prandial fullness, early satiety, upper abdominal pain and nausea (Tougas G *et al*., 1999; Jones MP *et al*., 2003).

The pathophysiology of non-ulcer dyspepsia is poorly understood. About 25 – 60% of patients in investigated for non-ulcer dyspepsia demonstrated motility

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dysfunction of the upper GIT (Malagelada JR, Stanghellini V, 1995; Stanghellini V *et al*., 1996). Other postulations include visceral hypersensitivity, delayed gastric emptying and impaired gastric fundus accommodation (Keohane J, Quigley EM, 2006). Delayed emptying of the gall bladder and dysfunction of the sphincter of Oddi has also been implicated in the pathogenesis (Talley NJ *et al*., 1998). Life style habits like smoking, alcoholism and drugs like NSAID's also contribute to the symptomatology of dyspepsia. There is evidence that non-ulcer dyspepsia associated with psychological symptoms of anxiety and depression besides abdominal discomfort and pain. Some of these patients also complain multiple somatic symptoms (Cheng C, 2000; Richter JE, 1991). The most important in making the diagnosis of non-ulcer dyspepsia is that the treating physician must be sure that the patient is not suffering from any organic cause of the upper GIT symptoms. Upper GIT endoscopy for symptomatic patients is essential to exclude important disease such as esophagitis, gastritis, peptic ulcer disease and malignancy. Routine testing for Helicobacter pylori infection during endoscopy is recommended in view of the strong association between H.pylori and both peptic ulcer disease and non-ulcer dyspepsia (Moayyedi P *et al*., 2005; Moayyedi P *et al*., 2000).

MATERIALS AND METHODS

Study Site

The study was carried out at Krishna Institute of Medical Sciences (KIMS), Minister Road, Secunderabad. It is one of the largest superspeciality tertiary care hospitals in Andhra Pradesh, South India. The present cases were collected from the out-patient clinic of Gastroenterology department. The hospital also offers Nursing, Physiotherapy and M.D courses.

Study Population

A prospective study was conducted on the patients visiting the out-patient clinic of Gastroenterology department. Both males and females of all age groups were taken for the study.

Data Collection and Analysis

A well planned patient data collection format was used to take all the details of the patient. The cases were collected over a period of one year. The study subjects i.e. the general population was informed that the information collected would not be revealed to anyone, and assured them that it is a part of academic course only and participation would be their choice. The demographic details of the patient were noted. A detailed information regarding their past history of illness, past and present concomitant medications, socio-economic profile, diet history of the patient were collected upon thorough patient counseling. Their perception towards self-medication and source of information were also recorded. Analysis of etiological factors and treatment strategies were done on general analytical basis.

Ethical issues

Prior to data collection, a detailed explanation of the aim and objective of the study were given, confidentiality was ensured and consent was obtained.

RESULTS

Over 1yr period of study conducted at KIMS, out of 250 patients who have visited the out-patient clinic, 86 patients who were diagnosed with Non-Ulcer Dyspepsia were taken for the present study. Out of 86 patients with Non-Ulcer Dyspepsia, 46 (53%) were males and 40 (47%) were females [Fig-1]. This figure represents that there is no much significant difference in the occurrence of the disease in males and females. A general statistics was done on age distribution of NUD patients [Fig-2]. The occurrence of the dyspeptic symptoms was prevalent in middle aged people and past middle aged people i.e. above 30yrs of age. A varied data on etiological factors was analyzed and it was found that Alcoholics, Smokers, people with irregular dietary habits are more prone to aggravate the symptoms of dyspepsia [Fig-3]. It was also found that depression, anxiety and other psycho-social incidence do contribute for dyspepsia. Upon evaluation of treatment strategies, proton pump inhibitors are the efficacious drugs in majority of the population [Fig-5]. People who have underlying psychological disorders are given concomitant psychotropic agent i.e. Antidepressant or an Anxiolytic as per the need which mainly contributed for the decrease in the duration of therapy [Fig-6& 7]. As Helicobacter pylori is one of the aggravating factor for dyspepsia, 2 Anti H.pylori antibiotics combined with 1Proton pump inhibitor was found to be effective choice of treatment [Fig-8] in majority of H.pylori affected patients. Effective patient counseling was done in cases of Alcoholics, Cigar smokers and duration of therapy was less when compared to normal individuals. [Fig-9, 10].When patients switched on to regular dietary habits, there was symptomatic relief and duration of therapy has come down from 4-8weeks to 4-6 weeks in males and 4 weeks in females [Fig-11]. Supportive therapy was prescribed in some patients like Vitamin supplements, iron supplements, laxative etc. depending upon the requirement.

Table 1. Sex Distribution of Study Population

Sex	Frequency	% of distribution
Males	46	53
Females	40	47
Total	86	100

Table 2. Age Distribution of Study Population

Age in years	Total No. of patients(86)			% Distribution
	Males	Females	Total	
15-21	2	1	3	3%
22-30	6	5	11	13%
31-40	10	8	18	21%
41-46	12	11	23	27%
47-65	16	15	31	36%

Table 3. Most Common Reasons Presented among the Study Population

Common reasons	No. of patients
Irregular dietary habits	9
Smoking with irregular dietary habits	13
Alcoholism	18
Presence of H.Pylori bacteria	11
Drug induced	7
Stress & irregular dietary habits	12
Anxiety & Depression	10
Other unexplained reasons	6

Table 4. Sex Distribution of Causes of Non-Ulcer Dyspepsia

Cause	Males (46)	Females (40)	Total (86)
Irregular dietary habits	6	3	9
Smoking & bad food habits	12	1	13
Alcoholism	15	3	18
Presence of H.Pylori	5	6	11
Drug induced	3	4	7
Stress & bad food habits	2	10	12
Anxiety & Depression	2	8	10
Other unexplained reasons	1	5	6

Table 5. Statistics of Patients receiving different classes of drugs for Non-Ulcer Dyspepsia

Sex	Proton pump Inhibitors	H_2 receptor Antagonists	Psychotropic agents	
			Anxiolytics	Antidepressants
Males(46)	43	3	2	---
Females(40)	34	6	5	7

Table 6. Duration of therapy in Normal individuals and in depressed female patients

Duration of therapy		
In normal individuals	Therapy with a PPI only	Therapy with a PPI and an antidepressant
4-8 weeks	4-14 weeks	4-10 weeks

Table 7. Duration of therapy in Normal individuals and in Patients with Anxiety

Duration of therapy		
In normal individuals	Treatment with a PPI only	Treatment with a PPI and an anxiolytic
4-8 weeks	4-16 weeks	4-12 weeks

Table 8. Antibiotic prescription pattern in H.pylori cases (11)

2 Antibiotics + proton pump inhibitor	No. of patients	% prescribed
Amoxicillin + Pantoprazole + Clarithromycin	2	18
Amoxicillin + Pantoprazole + Metronidazole	1	9
Clarithromycin + Omeprazole + Amoxicillin	4	36
Metronidazole + Omeprazole + Amoxicillin	2	18
Amoxicillin + Tetracycline + Omeprazole	1	9
Amoxicillin + Tetracycline + Pantoprazole	0	0
Amoxicillin + Tinidazole + Omeprazole	1	9

Fig 1. SexDistribution of Study Population

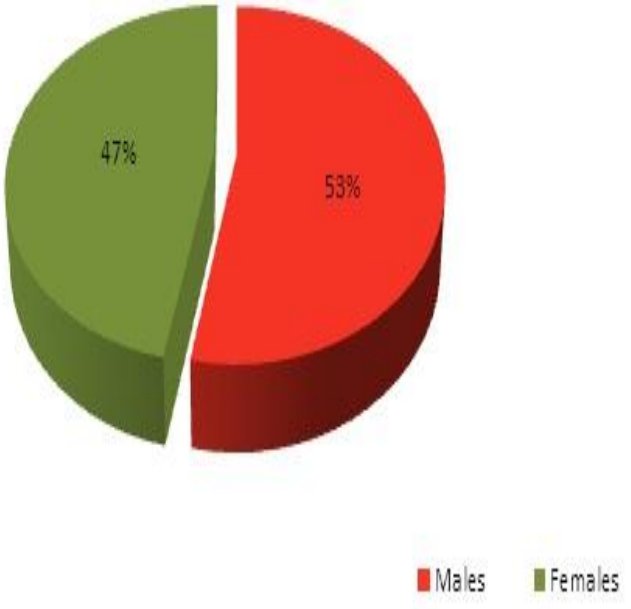


Fig 2. AgeDistribution of Study Population

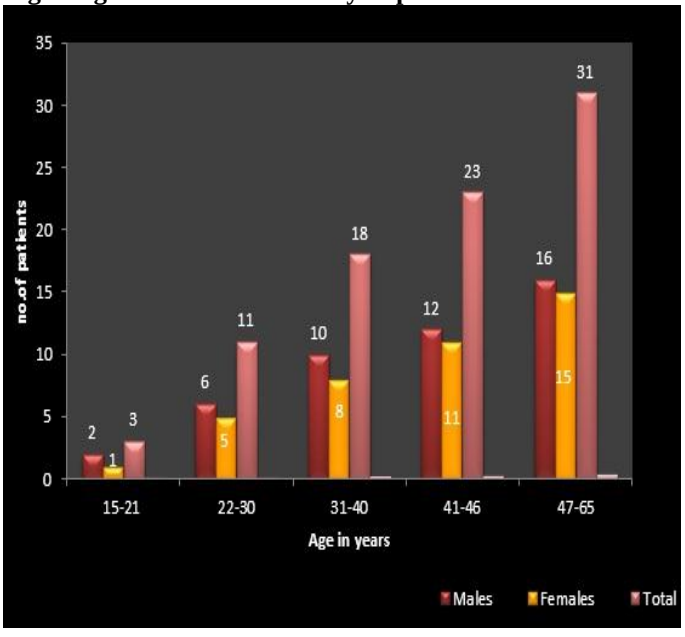


Fig 3. Common Reasons Presented in the Study Population

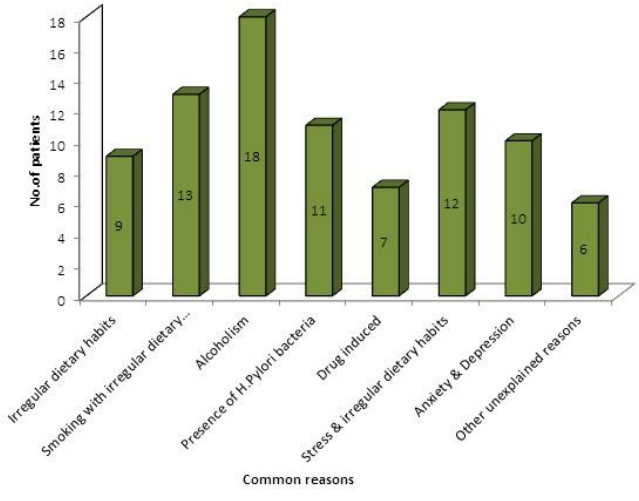


Fig 4. Sex Distribution of Causes of Non-Ulcer Dyspepsia

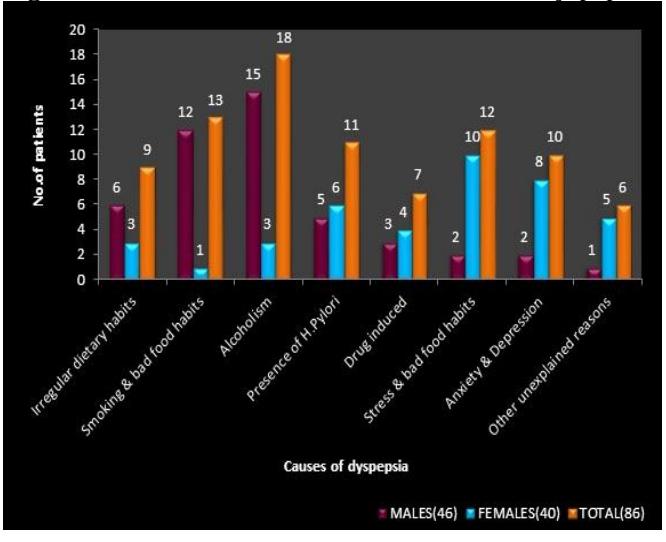


Fig 5. Statistics of Patients receiving different classes of drugs for Non-Ulcer Dyspepsia

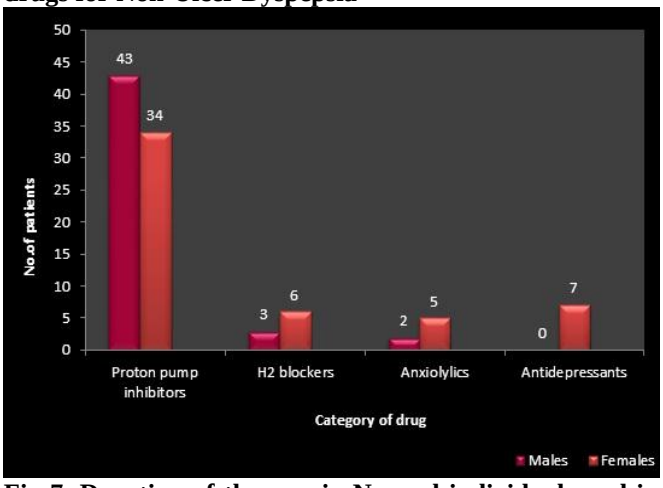


Fig 6. Duration of therapy in Normal individuals and in Depressed female patients

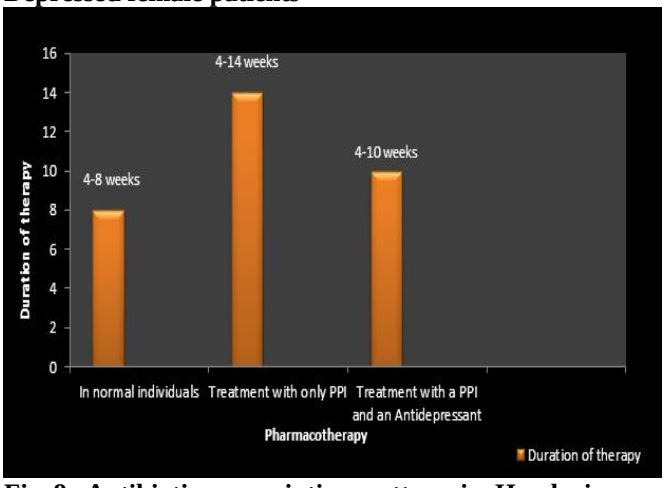


Fig 7. Duration of therapy in Normal individuals and in Patients with Anxiety

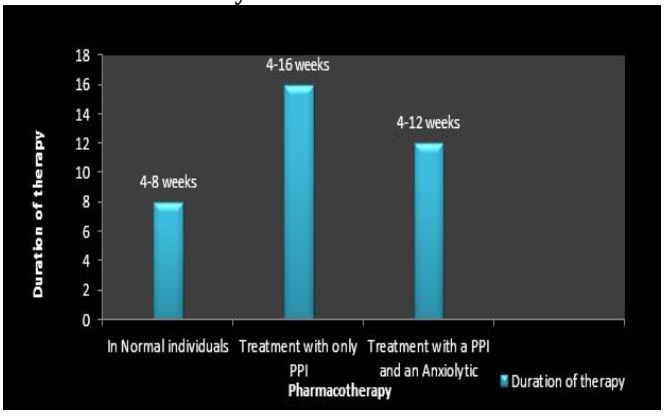


Fig 8. Antibiotic prescription pattern in H.pylori cases (11)

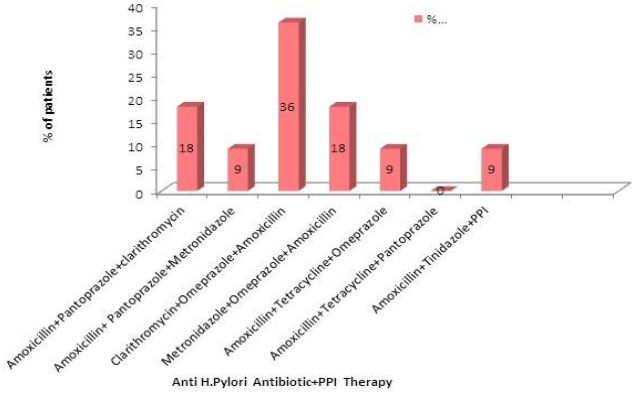


Fig 9. Duration of therapy in normal individuals and Alcoholic males and females

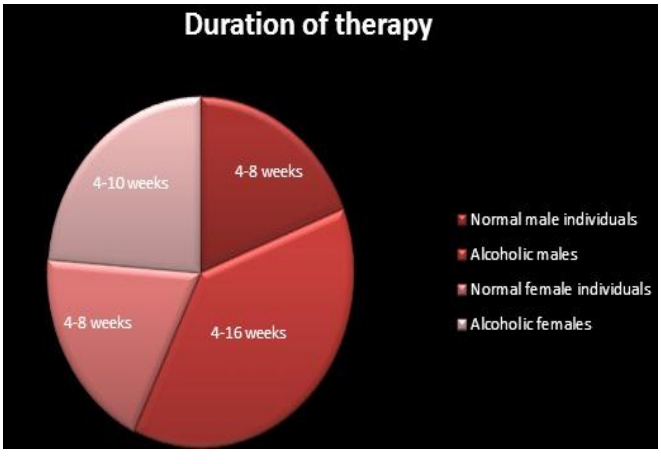


Fig 10. Duration of therapy for NUD in normal individuals and Smoking patients

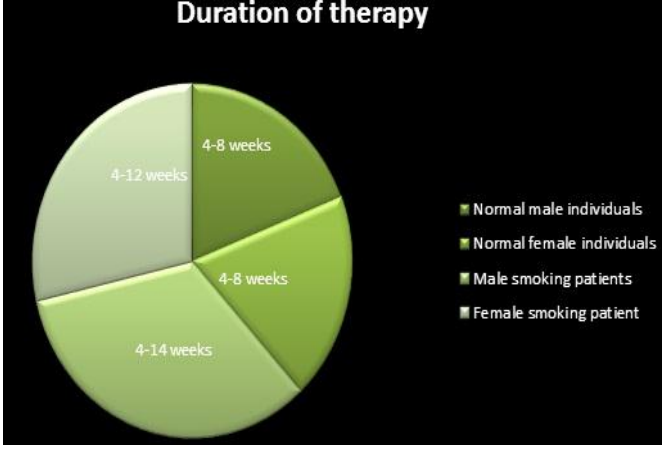
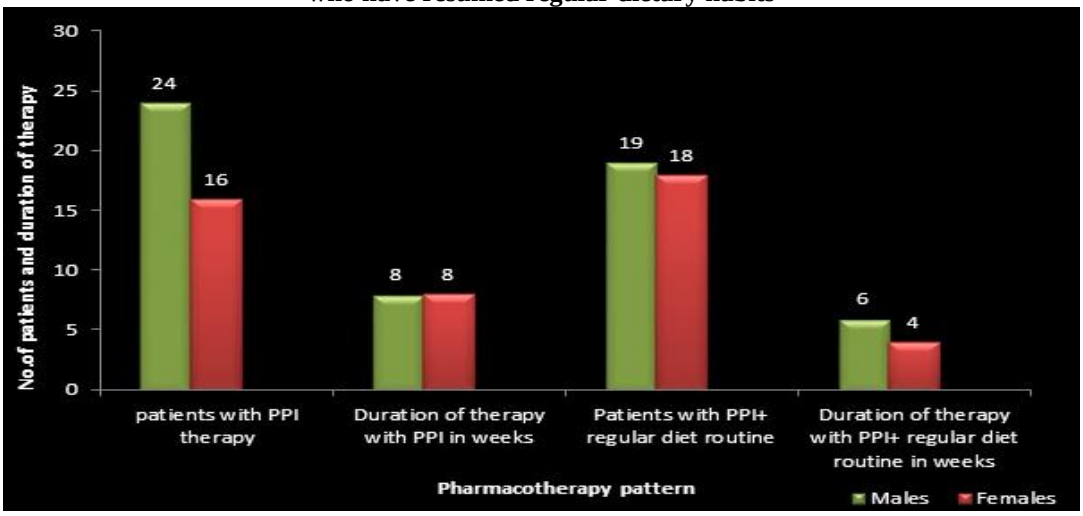


Fig 11. Statistics representing duration of therapy with only PPI and duration of therapy in patients with PPI and who have resumed regular dietary habits



DISCUSSION

Although NUD can be seen in a wide range of age distribution, patients in above 30 yrs the symptoms are more prominent. Previous studies showed that it is more prevalent at 45-55 yrs of age. But this recent study showed the symptoms of NUD are quite common in the middle age and past middle age. An interesting note of this study was psychological factors such as Anxiety, Depression, Stressful life, Low socio-economic profile were encountered in post- menopausal women beyond the age of 45yrs.In this study out of the total 86 patients, 77 patients i.e. 43 males and 34 female patients were prescribed proton pump inhibitors owing to their efficacy in acid suppression and its uses in other gastric related disorders. Proton pump inhibitors are the first choice of treatment as they would block the final step in acid production by inhibiting H^+K^+ATPase activity. Apart from Proton pump inhibitors other classes of drugs were also prescribed such as H_2 blockers, Anti H.Pylori drugs and some combination treatment was also suggested (Table 5 & 6). Non-pharmacological treatment such as appropriate patient counseling and education are the most important aspects of the management for those with chronic and recurrent symptoms Psychological intervention such as psychotherapy, cognitive behavior therapy, psycho-drama relaxation exercise and hypnosis have been found to improve patient's symptoms and quality of life. Stooping smoking and ceasing consumption of coffee, alcohol or NSAID's is commonly recommended. Antacids, H2 receptor antagonists and proton pump inhibitors are the most common therapies used by primary care physician. Prokinetics, Antibiotics for Helicobacter pylori infection and tricyclic anti-depressants and selective serotonin reuptake inhibitors are used as supportive treatment wherever whenever necessary.

CONCLUSION

A pharmacist can play an important role in the health promotion of NUD patients by thorough patient counseling, explaining them the possible causes of symptoms, assessment of regular diet routine and nutritional status and evaluation of treatment strategies. It is also important for a pharmacist to understand the complexities involved in the therapy given to the patients. The pharmacist should be able to assess each case individually to ensure that adequate necessary information is given to the patient about the foods and other agents that aggravate the symptoms of NUD Co-operation between the clinician and a pharmacist results in the best out-come. Further research on the treatment strategies can be done as there are many other drugs available in the market and it can be assessed on a wider range of population.

ACKNOWLEDMENTS

Authors are very much thankful to the Management, Medical Director and Consultants of Krishna Institute of Medical Sciences for their timely co-operation. Authors are very much thankful to the Management of Bharat Institute of Technology (Pharmacy) for providing us the facility to carry out the research work. Authors also express their sincere gratitude to the Management and Director of Sree Dattha Institute of Pharmacy for their constant support and encouragement

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