

A Study of Patients with Risk of Gastro Intestinal Complications among Users of Nsaids and Cox Inhibitors in General Population among Patients Attending Tertiary Care Center

Anusha Narayanam¹ , Sowmya Papagari² , Sadia Sultana³ ,Veena Janumpally⁴,
Dr. Naresh Kunta⁵.

Malla Reddy Pharmacy College , Maisammaguda ,Telangana 500014 India.

Corresponding Author: Anusha Narayanam

Abstract:

INTRODUCTION: Non steroidal anti- inflammatory drugs (NSAIDs) are effective anti-inflammatory and analgesic agents and are among the most commonly used classes of medications worldwide. However, their use has been associated with potentially serious dose- dependent gastrointestinal (GI) complications. The risk of GI complications can occur even with short-term NSAID use, and the rate event is linear over time with continued use.

OBJECTIVE: To study the patients profile with GI complications occurred due to long-term use of NSAIDs and COXIBs. To identify and determine the risk factors, co-morbidity , illness associated in patients with GI complications. To assess the better therapeutic outcome.

METHODOLOGY: A prospective cohort study was conducted for 6 months at Mallareddy hospital and Narayana hrudayalaya hospital. The patients who met the study criteria were enrolled into the study and following information was collected:

Patient demographic data, present medication history, present medical history , past medication history, family history , social history, various parameters , laboratory data . The data collected manually was reviewed and entered into Microsoft Excel database.

RESULTS: In our study, 200 patients were enrolled, among which 110 were male and 90 were females. The prevalence of GI complications was found more in patients with Lower GI complications 49 patients in males and 39 patients in females. The prevalence of GI complications was found more in patients with age group between 30-40 years. The patients with the risk of lower GI complications were found to be more. The patients administered with Diclofenac (81 patients) were present with more GI complications.

CONCLUSION: The long-term use of NSAIDS continues to increase at any age which is not only risk in elderly. NSAIDS may have GI complications in any part of gastrointestinal tract: oesophagus, stomach , duodenum , small intestine , or colon . Prevalence of lower GI complications are more in both male and female and 30-40 years are more affected compared to remaining age groups . Risk factor is more with lower GI complications than other complications. Endoscopic finding revealed with lower GI complication. Complications with Diclofenac (40.5%) is more when compared to other drugs. So, long term use of NSAIDS may affect all the age groups and gender equally . Lower GI complications are prone to GI complications than other. Diclofenac causes higher risk than other drugs.

Key Words: NSAIDs , COXIBs , GI complications.

Date of Submission: 22-06-2019

Date of acceptance: 10-07-2019

I. Introduction

A complication is a secondary disease or condition aggravating an already existing one. They may be caused by the disease procedure or treatment or may have other causes. The risk of GI complications usually occurring by the use of NSAIDs and COXIBs include: GI bleeding, peptic ulcer, gastroparesis, bowel obstruction, non alcoholic fatty liver disease. Gastrointestinal complications are one of the most prevailing cause of use of NSAIDs, and it is seen mostly in elderly patients (>60 years) ⁽¹⁾. NSAIDs can increase the risk of developing nausea, an upset stomach, or an ulcer. They may also interfere with kidney function. NSAIDs include the risk of lower GI bleeding and perforation to similar extent as seen in upper GI tract. COX 2 inhibitors have the same beneficial effects as non selective NSAIDs but with less GI toxicity in upper GI tract and probably in lower GI tract⁽²⁾.

NSAIDs are widely used for the pain, fever and inflammation. Some NSAIDs (aspirin, naproxen, ibuprofen) are among the most popular over the counter drug. Chronic NSAID treatment effectively reduces the

symptoms of many painful arthritic syndromes, but induces adverse gastrointestinal complications ranging from abdominal discomfort to life threatening GI ulceration, bleeding and perforation⁽³⁾. The most common clinical manifestation of NSAID related GI damage to tissue are a combination of gastroduodenal erosions and ulceration often called NSAIDs induce gastropathy affecting chronic NSAID users. A synergism was found between NSAIDs and H-pylori infection in the risk of peptic ulcer. NSAIDs are on the common class of analgesics used chronically for persistent pain due to osteoarthritis and other musculoskeletal disorders in older adults. These agents are effective in treating inflammation and pain⁽⁴⁾.

NSAIDs are among the most frequently prescribed drugs worldwide. Because of their over the counter (OTC) availability, they are also consumed on non prescription basis as well . Though reasonably safe in most cases prescribed dosages and for short durations, these drugs causes gastrointestinal toxicity in a large number of cases⁽⁵⁾. They can affect all segments of the gastrointestinal tract. Felix Hoffman synthesized acetyl salicylic acid (ASA) the first NSAID.NSAIDs inhibit prostaglandin production by inhibiting cyclooxygenase (COX) ⁽⁶⁾. Two iso forms of the COX enzyme are known to be involved in prostaglandin synthesis. COX-1 is constitutively expressed and generates prostaglandins involved in GI mucosal protection and platelet function while at the sites of inflammation; COX-2 is induced to generate prostaglandins which mediate inflammation and pain⁽⁷⁾.

NSAIDs are the most common pain relief medicines in the world. They prevent clotting of blood. So because of their reducing clotting action, some NSAIDs especially aspirin may have a protective effect against heart disease. A single dose of aspirin 650mg causes haemorrhages and gastric erosions⁽⁸⁾.

Symptoms of GI Complications:

Constipation , Faecal impaction , Bowel obstruction , Bloating , Belching , Dyspepsia , Heart burn , Indigestion , Vomiting , Diarrhoea and acid reflux⁽⁹⁾ .

Table:1.1: List of various GI Complications.

Upper GI Complications	Lower GI Complications
Perforation	Constipation
Dyspepsia	Diarrhea
Dysphasia	Malena
Acid reflux	Burning micturation
Chest tightness	Intestinal ulcers

Table:1.2: List of GI complications at a particular organ.

ORGAN	GI Problems
Mouth	Oral Ulcerations.
Oesophagus	Ulceration, Oesophagitis, Stricture formation.
Stomach and Duodenum	Ulcers, Erosions, Perforation, Obstruction.
Small intestine	Ulcers, Erosions, Protein loss , Strictures.
Colon	Non – specific colitis, Exacerbation of ulcerative colitis , Chron’s disease.

The GI tract is the main target of NSAID toxicity⁽¹⁰⁾. It is also most common drug induced toxicity that can be fatal. NSAID associated with GI problems include: Gastric and duodenal ulceration , Haemorrhage or perforation, other events which may lead to hospitalization or death .

- Patients with small intestinal damage associated with chronic NSAID use may be present with chronic iron deficiency anaemia or hypoalbuminemia due to blood or protein loss, and may develop over bleeding, perforation or strictures⁽¹¹⁾.
- In the oesophagus, chronic NSAID use may be associated rarely with oesophagitis ,ulceration or stricture formation.
- In the large bowel, NSAID use may lead to the development of non – specific colitis (with abdominal discomfort , bloody diarrhoea and weight loss) ⁽¹²⁾.

NSAID – related gastrointestinal adverse events can be classified into three broad categories: nuisance symptoms such as heartburn, nausea, dyspepsia and abdominal pain ; mucosal lesions(which may or may not be

symptomatic) such as ulcers, and serious gastrointestinal complications such as perforated ulcers and bleeding. Nuisance or minor gastrointestinal side effects including nausea, abdominal pain, flatulence and diarrhea are common and affect between 10 % and 60 % of NSAID users⁽¹³⁾

II. Materials and Methodology

A data collection form was prepared to study the GI complications among the patients who are administering NSAIDs at Malla Reddy Health Care Centre, Suraram, Secunderabad. A total of 200 GI complicated patients were involved in this research. From the total, 88 (44%) patients had only Lower GI complications, 65(32%) patients had both Upper and Lower GI complications and 50 (25%) patients had only Upper GI complications. Among which 110 were male and 90 were females. The prevalence of GI complications was found more in patients with age group between 30-40 years. The patients with the risk of lower GI complications were found to be more. The patients administered with Diclofenac (81 patients) were present with more GI complications.

III. Results

Among 200 patients , in Males the Upper GI complications were found to be in 34 patients (31%) , Lower GI complications were found to be in 49 patients (45%) and Upper and Lower GI complications were found to be in 27 patients (25%).

In Females , 16 patients (17%) were found with Upper GI complications , 39 patients (42%) were found with Lower GI complications and 38 patients (41%) were found with both Upper and Lower GI complications.

GI complications is more age dependent . The mean age of the study population was found to be 40± . This clearly indicates that age older than 40 years seems to be the most common risk factor 30-40 age group were more affected 59 patients.

The risk factor profile of the patients in the study was recorded. Among 200 patients 88 (44%) patients had only Lower GI complications.

The prevalence of 65(32%) patients had both Upper and Lower GI complications and 50 (25%) patients had only Upper GI complications.

Males are more effected than female with lower GI complications 49 patients The patients in the study who underwent the endoscopic procedure were found to be in 2 patients out of 200.

The patients out of 200 in the study administered with Diclo 81 (40.5%) patients , Signoflam 41 (20.5%) patients , Hifenac 50 (25%) patients , Zerodol 17(8.5%) patients , Naproxyn 3 (1.5%) patients , Aceclo 7 (3.5%) patients and Ecospirin 1 (0.5%) patients.

Table:1 Patient distribution based on Age, Gender, Risk factor, Clinical examination

Variables		No.of patients	Percentage(%)
Gender	Upper GI	M-34	31%
		F-16	17%
	Lower GI	M- 49	45%
		F- 39	42%
Upper and Lower GI	M-27	25%	
	F-38	41%	
Age	20-30	35	17.5%
	30-40	59	29.5%
	40-50	35	17.5%
	50-60	45	22.5%
	>60	26	13%
Risk factors	Upper GI	50	25%
	Lower GI	88	44%
	Upper and Lower GI	65	32%

Clinical Examination			
	Diclo	81	40.5 %
	Signoflam	41	20.5%
	Hifenac	50	25%
	Zerodol	17	8.5%
	Naproxyn	3	1.5%
	Ecosprin	1	0.5%

Fig.1: Diagrammatic Representation of GI complications in Males and Females.

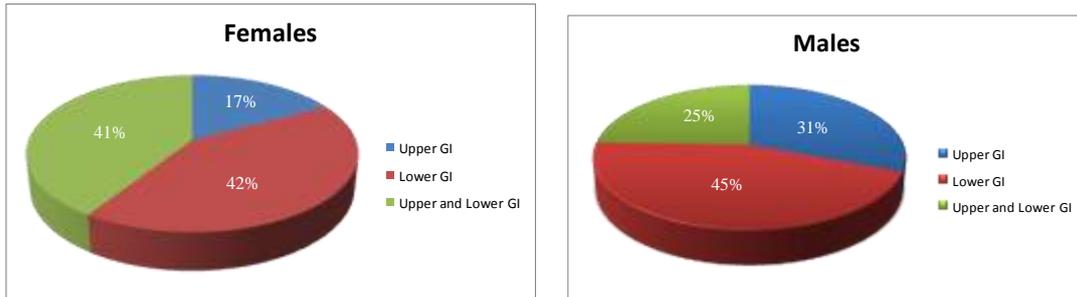


Fig.2: Representation of age groups affected with GI complications.

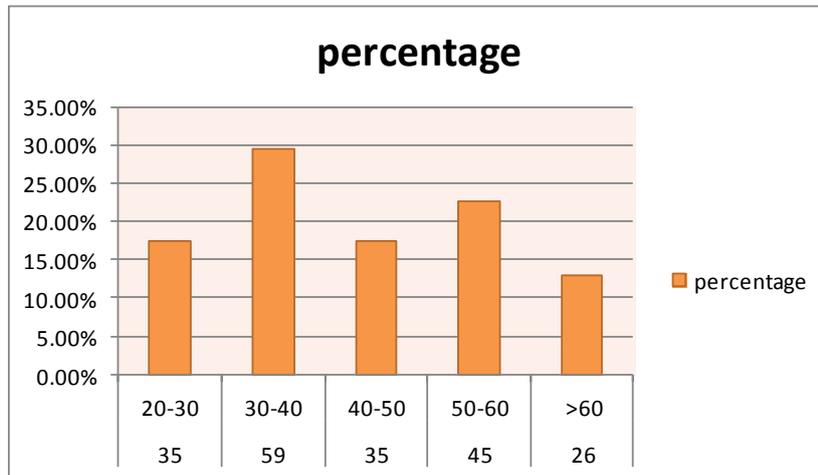


Fig.3: Diagrammatic representation of percentage of patients with risk of GI complications.

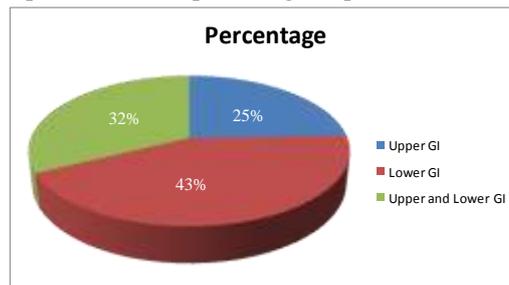


Fig.4: Graphical representation of GI complications in males and females.

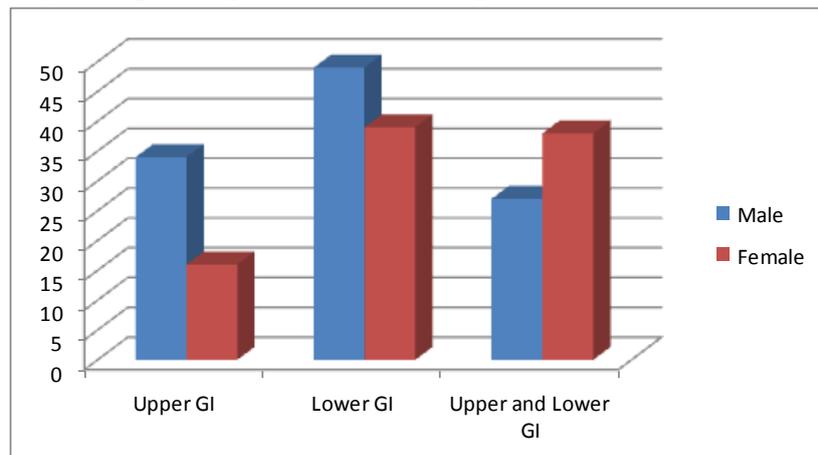
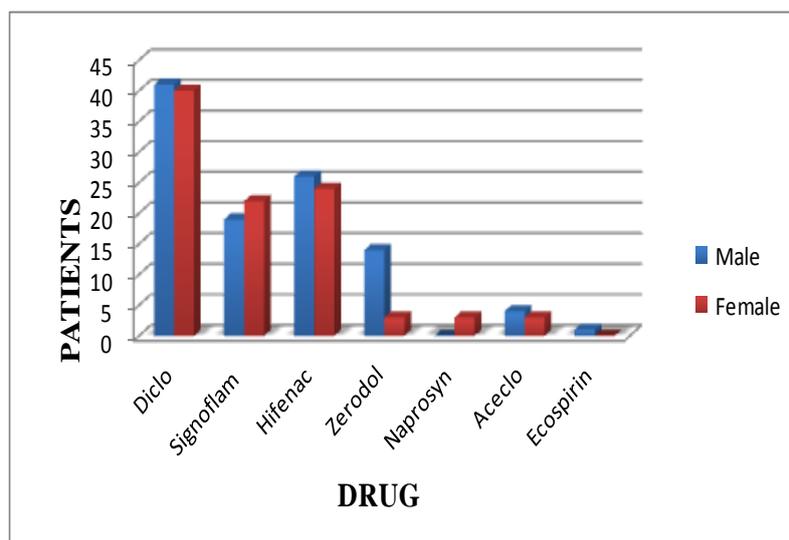


Fig.5: Graphical representation of Patients differentiated based on gender according to drugs



IV. Discussion

Risk of GI complications are seen by long term usage of NSAIDs. For improving patients quality of life dose adjustment of NSAIDs and withdraw of drug or alternative therapy is administered based on patient's requirement of drug.

Here in our study we found some common complications like constipation, acid reflux, dyspepsia, diarrhoea, belching, bloating of stomach and malena.

Our results revealed that prevalence of Lower GI complications is seen more in Male- 49 patients (45%) than in Female- 39 (42%) patients. Where as in Upper GI complications Male-34(31%) patients and Female- 16 patients(17%) were seen. In upper and lower GI complications females 38 (41%) patients are more prone than in Males- 27 patients(25%).

In our study, the prevalence of GI complications is seen more in age group between 30-40 years patients.

In our study, risk factors were found to be more with lower GI complications i.e., 88 (44%) patients among 200patients.

65(32%) patients had both Upper and lower GI complications and 50(25%) patients had only upper GI complications

Endoscopic procedure is done in two patients which revealed GI complications.

Clinical Examination is done to reveal GI complications by interviewing patients and by every day follow up.

In our study we found complications with Diclo 81 (40.5%) patients, Signoflam 41(20.5%) patients, Hifenac 50 (25%) patients , Zerodol 17(8.5%) patients , Naprosyn 3(1.5%) patients , Aceclo 7 (3.5%) patients and Ecospirin 1 (0.5%) patients among 200 patients.Our study showed that risk factors for lower GI complications are more than Upper GI complications. This data is based on the patients who underwent complications by using NSAIDs. Prevalence with Diclo 81patients (40.5%) is more than other drugs.

V. Conclusion

The long-term use of NSAIDS continues to increase at any age which is not only risk in elderly. NSAIDS may have GI complications in any part of gastrointestinal tract: oesophagus, stomach , duodenum , small intestine , or colon .

Prevalence of lower GI complications are more in both male and female and 30-40 years are more affected compared to remaining age groups.

Risk factor is more with lower GI complications than other complications. Endoscopic finding revealed with lower GI complication.

Complications with Diclofenac (40.5%) is more than compared to other drugs.

So, long term use of NSAIDS may affect all the age groups and gender equally . Lower GI complications are prone to GI complications than other. Diclofenac causes higher risk than other drugs.

References

- [1]. Hernandez –Diaz S, Garcia Roriguez LA (2002). Association between NSAIDS an GI bleeding and perforation : An overview of epidemiological studies published in 1990's (PUBMED)

- [2]. Gabriel SE, Jaakkimaunen L, Bombarier C (2007). Risk of serious gastrointestinal complications related to use of NSAIDS Drugs : a meta analysis.
- [3]. Goldstein JL, Esien GM, Lewis B, Gralenk IM, Zlotmik S, Fort JG (2006). Video capsule endoscopy to prospectively assess small bowel injury with celecoxib and placebo
- [4]. Harirfoorsh S, Asghar W, Jmail, F . Adverse effects of NSAIDS (2015) : An update of GI , Cardiovascular and renal complications.
- [5]. McCarthy DM (2001) NSAIDS: reduing the risk to GI tract .
- [6]. Langman MJS, Morgan L, Worrall A (1985) : Use of NSAIDS by patients admittedwith small and large bowel perforations and haemorrhage.
- [7]. Chang C.H., Chen H.C., Lin J.W(2012): Risk of hospitalization for upper GI andverse events associated with NSADS.
- [8]. Henry ., Dobson A., Turner C (1993) : Variability in the risk of major GI Complications from nonaspirin NSAIDS .
- [9]. Nicolette L. de Groot (2014): Upper GI Bleeing in NSAIDS and low dose aspirin users.
- [10]. Gurkirpal Singh (1996): GIT Complications of NSAIDS treatment in orthro patients .
- [11]. Gurkripal Singh G, Triadafilopoulos G (1999): Epidemiology of NSAID induced gastrointestinal complications.
- [12]. Gabriel SE, Jaakkimainen L,Bombarier C (1991): risk of serious gastrointestinal complications related to use of NSAIDS - A meta analysis .
- [13]. Langman ,MJ Jensen DM, Watson DI, Harper SE, Zhao PL, Quan H, et al (1999) . Adverse upper gastrointestinal effects of rofecoxib compared with NSAIDS .

Anusha Narayanam. " A Study of Patients with Risk of Gastro Intestinal Complications among Users of Nsaids and Cox Inhibitors in General Population among Patients Attending Tertiary Care Center" .IOSR Journal of Nursing and Health Science (IOSR-JNHS), vol. 8, no.04 , 2019, pp. 01-06