Bismillahir Rahmanir Rahim

A Study on Drug's Side Effects due to Using GIT Drugs Without Prescription in Lower Class People in Bangladesh

A Research Report submitted to the Department of Pharmacy, East West University in partial fulfillment for the requirements of the degree of Bachelor of Pharmacy

Submitted by

Md. Nazmul Hassan

ID # 2013 – 3 – 70 – 051

Submitted To

Department Of Pharmacy

East West University

Aftabnagar, Dhaka.

Declaration by the Research Candidate

I, **Md. Nazmul Hassan (ID # 2013 – 3 – 70 – 051)** , hereby declare that the Research entitled **"A Study on Drug's Side Effects due to Using GIT Drugs Without Prescription in Lower Class People in Bangladesh"** , submitted by me to the Department of Pharmacy, East West University, Aftabnagar, Dhaka, Bangladesh in the partial fulfillment of the requirement for the award of the degree of Bachelor of Pharmacy is a bonafide record of original Project work carried out by me during 2013 under the supervision and guidance of **Ms. Nazia Hoque**, Assistant Professor, Department of Pharmacy, East West University, Aftabnagar, Dhaka, Bangladesh and it has not formed the basis for the award of any other Degree/Diploma/Fellowship or other similar title to any candidate of any University.

Signature of the Candidate

……

Md. Nazmul Hassan
ID# 2013 – 3 – 70 – 051

Certificate by the Supervisor

This is to certify that the Research entitled **"A Study on Drug's Side Effects due to Using GIT Drugs Without Prescription in Lower Class People in Bangladesh"** submitted to the Department of Pharmacy, East West University, Aftabnagar, Dhaka in partial fulfillment of the requirements of the Degree of Bachelor of Pharmacy was carried out by **Md. Nazmul Hassan** (ID # 2013 – 3 – 70 – 051) under our guidance and supervision and that no part of the project has been submitted for any other degree. We further certify that all the sources of information and facilities availed of in this connection duly acknowledged.

Signature of Research Supervisor

Ms. Nazia Hoque

Supervisor and Assistant Professor

Department of Pharmacy

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Aftabnagar, Dhaka.

Certificate by the Chairperson

This is to certify that the Research entitled **"A Study on Drug's Side Effects due to Using GIT Drugs Without Prescription in Lower Class People in Bangladesh"** submitted to the Department of Pharmacy, East West University, Aftabnagar, Dhaka in partial fulfillment of the requirements of the Degree of Bachelor of Pharmacy was carried out by **Md. Nazmul Hassan** (ID # 2013 – 3 – 70 – 051). We further indorse that all the sources of information and facilities availed of in this connection duly acknowledged.

Signature

_____

Dr. Chowdhury Faiz Hossain

Chairperson and Professor

Department of Pharmacy

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Dhaka, Bangladesh.

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First, all praise and glory are to **Allah** for all the bounties granted to me and only with His guidance and help this achievement has become possible.

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Dedication

This Research Paper is dedicated to my beloved Parent,

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Abstract

A survey was conducted in various place of Dhaka in Bangladesh. Which is entitled by "A study on drug's side effects due to using GIT drugs without prescription in lower class people in Bangladesh". The aim and objective of this research were to identify the drug's side effects due to using GIT drugs without prescription in lower class people in Bangladesh. This survey was based on questioner and had a sample in size of 400 lower class people in Bangladesh who used GIT drugs without prescription from drug shop or experience drug's side effects due to use of those drugs. After this study it is seen that, drugs using without prescription tendency of lower class people various on age, experience, and monthly household income. Most of the people are suffer from various side effects like constipation, abdominal pain, liver disease, vomiting etc. number of people who brought GIT drugs without prescription where (93.2%) and number of people who consulted doctor for the disease and brought medicine according to prescription where (6.8%) and (95.5%) people were go to pharmacy shop for the treatment. All the people were using omeprazole in this survey and (13.25%) were taking over dose and were (66.5%) were facing severe pain in stomach as a side effect. About (48%) people were using clozapine and (69.27%) faced constipation. About all the lower class people are using NSAIDs in various condition and (98.25%) did not know about NSAIDs. In the NSAIDs users (13.25%) were facing problem like ulcers. About 80% were used ciprofloxacin and (88.75%) did not complete the dose of ciprofloxacin. In the observed people they faced many common side effects due to use drugs without prescription which is treated for various GIT disease or problems (69.5%) faced nausea, (64.75%) faced vomiting, (49.5%) faced fever, (55.25%) faced abdominal pain,(28%) faced dryness of mouth, (14%) faced problem of vision, and (7.75%) faced kidney disease. Because many of them don't know about the side effects of various GIT drugs. So people should be aware of the side effects of the drugs and stopped prescribing self-medication or using without prescription drugs. And health ministry of government should take proper initiative and ensure the rules and regulation for prescribing and dispensing the drugs and government should take proper step for available health checkup for the lower class people in public health cares of Bangladesh.

Keywords: Side effects, GIT drugs, without prescription, lower class people, constipation, kidney disease. Self-medication.

Chapter 1

Introduction

1.1 Physiology of the gastrointestinal tract (GIT)

Main function: The GIT provides the body with a supply of water, nutrients, electrolytes, vitamins. Actions:
1) Digestion of the food, 2) Absorption of the products of digestion
Digestive processes: - mechanical - chemical Mechanical methods: - mastication (chewing) - swallowing (deglutition) - movements of the GIT (motor functions) Chemical means (secretions): - saliva - gastric juice - pancreatic juice - intestinal juice – bile.

1.2 Basic GI physiology

The human body is doughnut shaped therefore the surface of the gut is continuous with the surface of the skin and composed of the same cell type i.e. epithelia. This is true for all organs which make direct contact with the outside world e.g. kidney, salivary glands, pancreas etc. however, the gut is the only one which connects through to other side to have an entrance and an exit. Everything more evolved than flatworms has an internalised digestive system to increase the surface area for absorption and allow a specialised environment for digestion. One advantage of being a flatworm is that you can swim (or wriggle) up to you food, digest it and then swim away from your waste products. If you have an internalised digestive system you have to move the food to the correct part of the gut for digestion and absorption and then move the waste products away for excretion. This important digestive function is achieved by co-ordinate waves of contraction or peristaltic movements of the gut which forces food to move along.

Given that the outermost (that in contact with the food) layer of the gut is composed of epithelial cells we can deduce that underlying layers must include muscle (because the gut can contract) and nerves (because the contractions are co-ordinate: enteric nervous system). In fact the gut has a uniform structure throughout (except that the esophagus and rectum lack serosa & mesentery.).

As food passes through the gut, activity in one part is communicated to the next by a combination of nerves and hormones. Hormonal activity can be either endocrine (via

bloodstream) or paracrine (in local area). Hormones can have simultaneous endocrine and paracrine activity. (Pcliv.ac.uk, 2017)

1.3 Component of the digestive system:

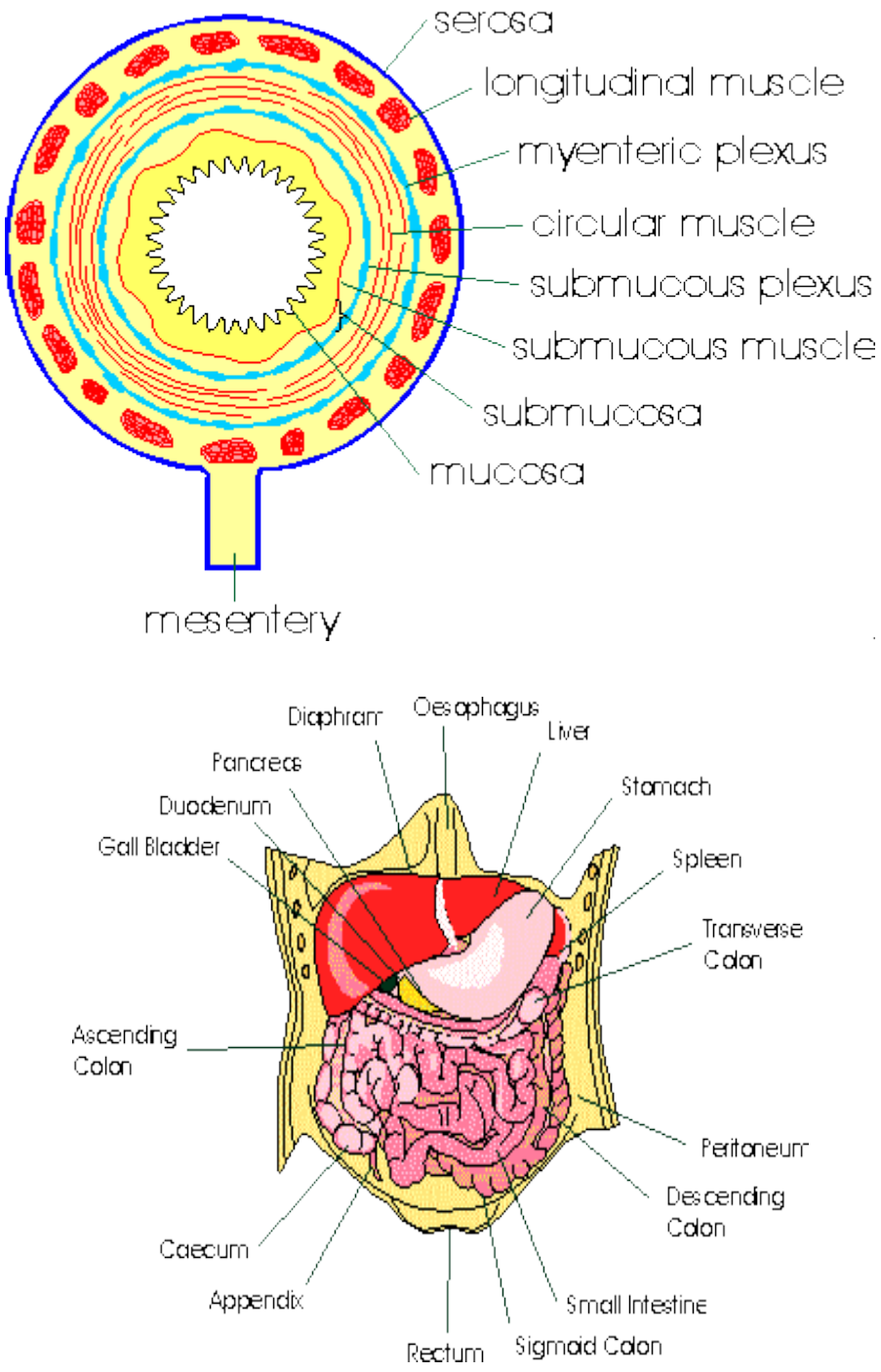


Figure 1.1: Component of the digestive system.

1.4 Oral cavity physiology of mouth

1.4.1 Functions of oral cavity:

1/ Mechanical and chemical digestion of the food
2/ the source of the unconditioned reflexes
3/ Control of physical and chemical properties of the food

The salivary glands produce saliva (1500 ml/day) containing digestive enzymes (primarily salivary amylase) and mucous. Mastication breaks the food into small particles for swallowing, coats the particles with mucous and mixes amylase inside the bolus where it can continue to act even when the bolus passes to the stomach.

1.4.2 Functions of saliva:

Keeps the mouth moist, aids speech

Facilitates swallowing

Serves as a solvent for the molecules that stimulate the taste buds

Serves a solvent for irritating foods

Helps wash away the pathogenetic bacteria,

Destroy bacteria (thiocyanate ions, proteolytic enzymes), by proteins antibodies 3 can destroy oral bacteria, lysozyme = antibacterial - keeps the mouth and teeth clean.

1.5 Stomach (anatomy and histology)

Cardiac
Fundus
Corpus
Antrim
Pyloric sphincter

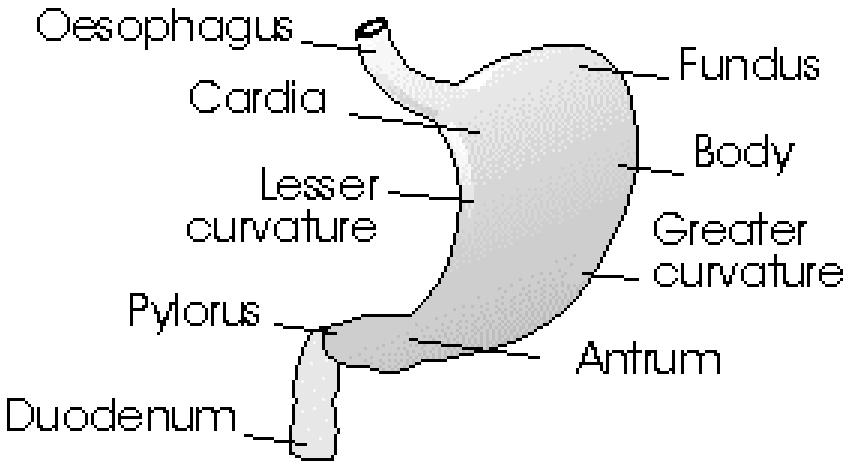


Figure1.2: Stomach (anatomy and histology)

Acid secretion (parietal cells).Pepsinogen secretion (Chief cells) Secretion of hormones, e.g. gastrin (G cells). Stomach pH 1.0 low enough to cause tissue damage except mucous is also secreted (Aspirin inhibits prostaglandin synthesis which inhibits mucous production). Acid kills bacteria helps protein digestion provides environment for pepsin to digest protein. Helps stimulate bile and pancreatic juice. (2500 ml gastric juice/day)

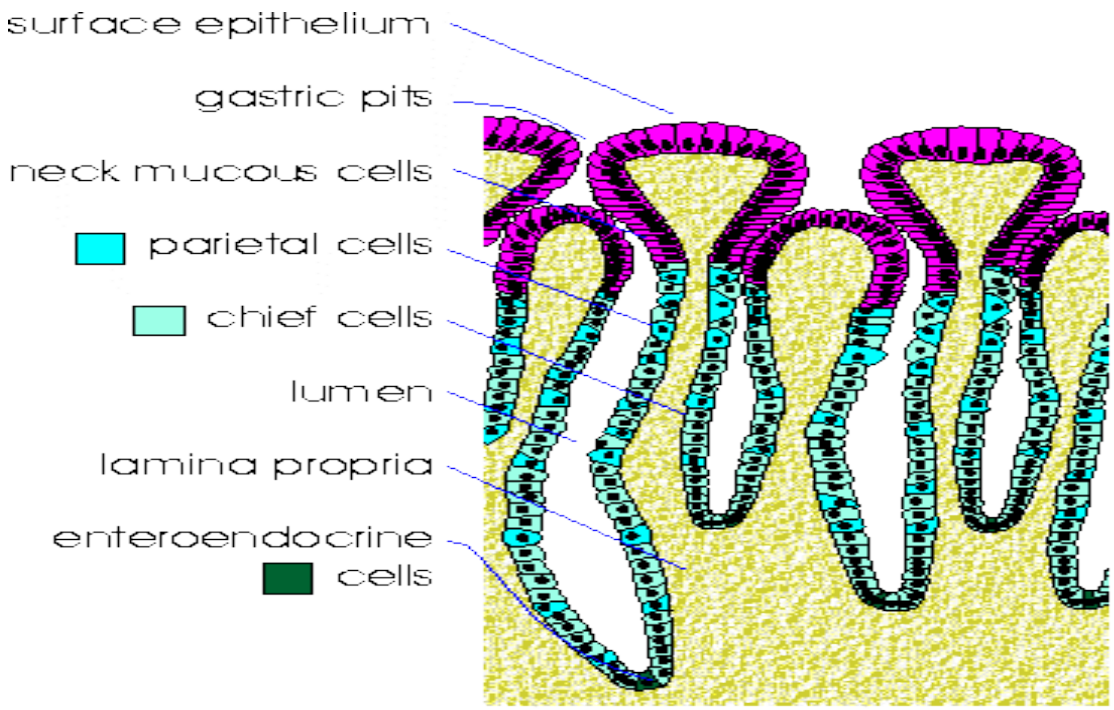
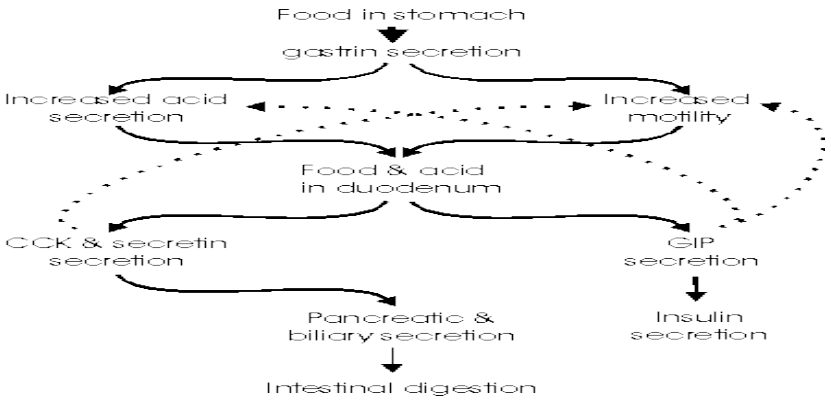


Figure1.3: Stomach (anatomy and histology).

1.6 Small intestine

Movements of the small intestine Anatomy of the intestinal wall:

- Layers (from the outer surface inward):
- the serosa - a longitudinal muscle layer
- myenteric nerve plexus
- a circular muscle layer Meissner´s plexus – the submucosa the mucosa
- 2 layers of the smooth muscles, 2 neural plexus



1.6.1 Motility of Small intestine:

Local contractions: - segmentation – ring like – circular muscle layer - pendular – circular + longitudinal muscles - villious Propulsive

Peristalsis: Peristaltic waves – analward at a velocity 0.5 – 2 cm/s to 3.5 – 10 cm.

Absorption of sugars, amino acids, water etc. Hormone secretion e.g. CCK (pancreozymin). Input from pancreas (1500 ml/day), bicarbonate (neutralise stomach acid), trypsin (as trypsinogen, autocatalysis in intestine to active form). Input from liver (500 ml/day), bile salts, important in emulsification of fat and subsequent digestion. Total of 7-9 l/day of fluid enter the small intestine (2 l with food rest from saliva pancreas etc.), all but 1-2 l/day absorbed. Small intestine also contains lymph nodes (Peyer's patch) involved in immune response.

Large intestine, Water reabsorption. 1-2 l/day enter colon <100 ml lost in faeces. The colon

has massive absorptive powers & can reabsorb water against a large hydrostatic gradient. Colon contains bacteria, mainly E.coli. Route of choice for administration of drugs etc. because they can be absorbed very rapidly.

The passage of food through the gut activates each part of the gut in turn. Negative feedback (dotted lines) helps to inactivate higher gut sections as the food passes ever onwards.

Peristaltic waves Gastric slow wave in stomach from fundus to pyloris, 3/min, regulated by vagus.Helps co-ordinate gastric emptying.

Small bowel slow wave 12/min duodenum, 9/min ileum. No need for extrinsic innervation but myenteric plexus must be intact.Large bowel slow wave 2/min ileocaecal valve up to 6/min at sigmoid. Colon also also has 'mass action contraction', simultanous contraction of large area of smooth muscle. Involved in moving material to rectum. Rectal distension initiates defecation reflex.

1.6.2 Enteric nervous system of Small intestine:

Controls motility & involved in regulation of secretion. Composed of myenteric (Auerbach's) and submucous (Meissner's) plexi. Contains motor neurones, secretory neurones and sensory neurones (stretch, tonicity, glucose or amino acids). > 1 million neurones.Sometimes called 3rd division of autonomic nervous system (along with sympathetic and parasympathetic).Neurones contain ACh, noradrenaline, serotonin (5-HT), enkephalins, VIP, substance P, somatostatin, gastrin-releasing peptide (GRP), neurotensin and maybe angiotensin II. Some substances released as neurotransmitters (some putative neurotransmitters), some as neuromodulators some have paracrine actions.Extrinsic innervation from both parasympathetic and sympathetic systems. Preganglionic Parasympathetic efferents (mainly from vagus) release ACh (onto cholinergic enteric) nerves and increase activity of the gut. Postganglionic Sympathetic efferents release noradrenalin which decrease activity of the gut, Sypatheticefferents terminate on postganglionic AChneurones and act by inhibiting ACh release. (Pcliv.ac.uk, 2017).

1.6.3 Blood supply of Small intestine:

Splanchnic circulation. Arterial supply to intestine pancreas and spleen from mesenteric

arteries. Drainage unusual via hepatic portal vein which goes straight to liver. Blood flow in intestine regulated by metabolic activity i.e. doubles after a meal. Therefore throughput to liver also doubles.

1.6.4 Transit time of Small intestine:

4 hours after meal first shows up in caecum. Everything, including undigested parts by 8-9 hours. Up to 70% through and excreted in 72 hours, may take up to a week for everything. Brown color of stools due to bile pigments. Transit time.

1.6.5 Digestive enzymes of Small intestine:

Table 1.1: Digestive enzymes of Small intestine.

Source	Enzyme	Activator	Substrate	function or products
Salivary glands	salivary α-amylase	Cl^-	starch	hydrolyzes α1-4 linkages dextrins, maltotriose, maltose
Lingual	lingual lipase		triglycerides	fatty acids & 1,2 diacylglycerols
Stomach	pepsins	HCl	proteins	cleave peptide bond adjacent to aromatic amino acid
	gastric lipase		triglycerides	fatty acids or glycerol
Exocrine Pancreas	trypsin	entero-peptidase	proteins & polypeptides	cleave peptide bond adjacent to arginine or lysine
	chymotrypsins	trypsin	proteins & polypeptides	cleave peptide bond adjacent to arginine or lysine
	elastase	trypsin	elastin,some other proteins	cleave peptide bond adjacent to aliphatic amino acids
	carbopeptidase A	trypsin	Proteins & polypeptides	cleaves carboxy terminal amino acids with aromatic or branched aliphatic side chains

	carbopeptidase B	trypsin	proteins & polypeptides	cleaves carboxy terminal amino acids with basic side chains
	pancreatic lipase		triglycerides	monoglycerides& fatty acids
	Colipase	trypsin	fat droplets	helps lipase
	cholesteryl ester hydrolase		cholesteryl esters	cholesterol
	pancreatic α amylase	Cl^-	starch	as salivary α amylase
	ribonuclease		RNA	nucleotides
	deoxyribonuclease		DNA	nucleotides
	phospholipase A_2	trypsin	phospholipids	fatty acids lysophospholipids
Intestinal mucosa	enteropeptidase		trypsinogen	trypsin
	aminopeptidases		polypeptides	cleave N-terminal amino acid from polypeptide
	dipeptidases		dipeptides	two amino acids
	glucoamylase		maltose/maltotriose	glucose
	lactase		lactose	galactose& glucose
	sucrase		sucrose	fructose & glucose
	a-limit dextrinase		a-limit dextrans	glucose
cytoplasm of mucosal cells	various peptidases		di- tri &tetrapeptides	amino acids

1.7 Composition of Bile

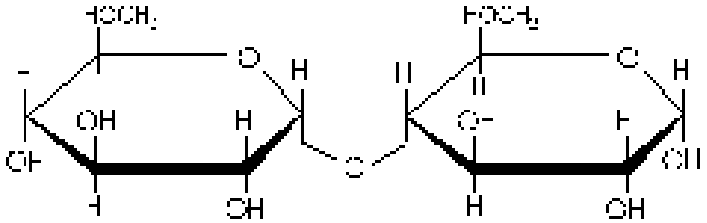
Water	97%
Bile salts	0.7%
Bile pigments	0.2%
Cholesterol	0.06%

Inorganic salts	0.7%
Fatty acids	0.15%
Lecithin	0.1%
Fat	0.1%
Alkaline phosphatase	0.01%
1, 25 dihydroxycholecalciferol (vitamin D)	0.01%
Steroid hormones	0.01%

Bile salts: (Na+ or K+ salt conjugated with taurine or glycine)

Cholic acid	50%
Chenodeoxycholic acid	30%
Deoxycholic acids	15%
Lithocholic acid	5%

1.8 Salivary α-amylase:



The main digestive enzyme in saliva is α-amylase, a glycoprotein with a weight of 62-67000 daltons. α-amylase hydrolyzes the α1:4 glycosidic bond between glucose units in the polysaccharide chain of starch. Digestion can occur anywhere along the chain except at branches, however α-amylase is very slow at cleaving off terminal glucose molecules and therefore most of the end product is maltose (2-glucose residues) or maltotriose (3 glucose residues) with a little free glucose and partially digested oligosaccharides.

Relatively little digestion actually occurs in the mouth because the food isn't there very long. The pH of the stomach is much lower than the pH optimum of α-amylase (6.8) and so it might be expected that the enzyme becomes inactive shortly after the food is swallowed. However, it can take a relatively long time for the low pH of the stomach to penetrate the inside of a bolus of food, so digestion can continue in the centre of the bolus.

The starch in potatoes and cereals is in the form of granules that are not attacked by α-amylase. Fortunately cooking destroys the granules so cooked potatoes and cereals can be digested.

1.9 Common problems or disease of GIT

1.9.1 Chest pain: gastro esophageal reflux disease (GERD)

When stomach acid backs up into your esophagus — a condition called acid reflux — you may feel a burning pain in the middle of your chest. It often occurs after meals or at night .While it's common for people to experience acid reflux and heartburn once in a while, having symptoms that affect your daily life or occur at least twice each week could be a sign of GERD, a chronic digestive disease that affects 20 percent of Americans, according to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). If you experience persistent heartburn, bad breath, tooth erosion, nausea, pain in your chest or upper part of your abdomen, or have trouble swallowing or breathing, see your doctor. Most people find relief by avoiding the foods and beverages that trigger their symptoms and/or by taking over-the-counter antacids or other medications that reduce stomach acid production and inflammation of the esophagus; however, some cases of GERD require stronger treatment, such as medication or surgery.

1.9.2 Gallstones

Gallstones are hard deposits that form in your gallbladder — a small, pear-shaped sack that stores and secretes bile for digestion. Twenty million Americans are affected by gallstones,

according to the NIDDK. Gallstones can form when there's too much cholesterol or waste in your bile or if your gallbladder doesn't empty properly. When gallstones block the ducts leading from your gallbladder to your intestines, they can cause sharp pain in your upper-right abdomen. Medications sometimes dissolve gallstones, but if that doesn't work, the next step is surgery to remove the gallbladder.

1.9.3 Celiac Disease

An estimated 1 in 133 Americans has celiac disease, according to the National Foundation for Celiac Awareness, but it's also estimated that 83 percent of people who have celiac disease don't know they have it or have been misdiagnosed with a different condition. Celiac disease is a serious sensitivity to gluten, a protein found in wheat, rye, and barley. Eat gluten, and your immune system goes on the attack: It damages your villi, the fingerlike protrusions in your small intestines that help you absorb nutrients from the foods you eat. Symptoms of celiac disease in kids include abdominal pain and bloating, diarrhea, constipation, vomiting, and weight loss. Symptoms in adults also can include anemia, fatigue, bone loss, depression, and seizures. However, some people may not have any symptoms. The only treatment for celiac disease is to completely avoid eating gluten. Common cooking alternatives to gluten include brown rice, quinoa, lentils, soy flour, corn flour, and amaranth.

1.9.4. Crohn's Disease

Crohn's disease is part of a group of digestive conditions called inflammatory bowel disease (IBD). Crohn's most commonly affects the end of the small intestine called the ileum, but it can affect any part of the digestive tract. As many as 700,000 Americans may be affected by Crohn's, according to the Crohn's and Colitis Foundation of America.This chronic condition is an autoimmune disease, meaning that your immune system mistakenly attacks cells in your own body that it thinks are foreign invaders. The most common Crohn's symptoms are abdominal pain, diarrhea, rectal bleeding, weight loss, and fever. "Treatment depends on the symptoms and can include topical pain relievers, immunosuppressants, and surgery," Dr. Bamji says. (EverydayHealth.com, 2017)

1.9.5 Ulcerative Colitis

Ulcerative colitis is another inflammatory bowel disease that affects about 700,000 Americans. The symptoms of ulcerative colitis are very similar to those of Crohn's, but the part of the digestive tract affected is solely the large intestine, also known as the colon.

If your immune system mistakes food or other materials for invaders, sores or ulcers develop in the colon's lining. If you experience frequent and urgent bowel movements, pain with diarrhea, blood in your stool, or abdominal cramps, visit your doctor.

Medication can suppress the inflammation, and eliminating foods that cause discomfort may help as well. In severe cases, treatment for ulcerative colitis may involve surgery to remove the colon.

1.9.6 Irritable Bowel Syndrome

Is your digestive tract irritable? Do you have stomach pain or discomfort at least three times a month for several months? It could be irritable bowel syndrome (IBS), another common digestive condition.Ten to 15 percent of the U.S. population suffers from irritable bowel syndrome, according to the International Foundation for Functional Gastrointestinal Disorders. Signs of IBS can vary widely: You can be constipated or have diarrhea, or have hard, dry stools on one day and loose watery stools on another. Bloating is also a symptom of IBS.

What causes IBS isn't known, but treatment of symptoms centers largely on diet, such as avoiding common trigger foods (dairy products, alcohol, caffeine, artificial sweeteners and beans, cabbage, and other foods that produce gas), or following a low-fat diet that's also high in fiber. (EverydayHealth.com, 2017)

1.9.7 Anal Fissure

Anal fissures are tiny, oval-shaped tears in the lining of the very end of your digestive tract called your anus. The symptoms are similar to those of hemorrhoids, such as bleeding and

pain after moving your bowels. Straining and hard bowel movements can cause fissures, but so can soft stools and diarrhea.A high-fiber diet that makes your stool well-formed and bulky is often the best treatment for this common digestive condition. Medications to relax the anal sphincter muscles as well as topical anesthetics and sitz baths can relieve pain; however, chronic fissures may require surgery of the anal sphincter muscle. (EverydayHealth.com, 2017)

1.9.8 Diarrhea

Diarrhea is defined as an alteration in the normal pattern of defecation resulting in the passing of soft, unformed faces, with an increased water content, or an increased frequency of defecation. If your pet is lethargic, won't drink, has vomiting as well, or blood in the diarrhea, you should take him or her to your local Green cross Vet.

Causes of Diarrhea

Diarrhea is not a disease; rather, it is a sign of many different diseases. Diarrhea may be due to primary gastro-intestinal disorders (parasites, bacterial or viral infections, dietary indiscretions, cancer, inflammatory bowel disease etc.) or may be secondary to other disease conditions such as liver disease, diabetes or pancreatic disorders.

Many mild cases of diarrhea can be resolved quickly with simple treatments. Others may be the result of potentially serious illnesses. Even diarrhea caused by mild illnesses may become serious if treatment is not begun early enough to prevent severe fluid and nutrient losses.

1.10 Gastrointestinal Disorders

Gastrointestinal disorders include such conditions as constipation, irritable bowel syndrome, hemorrhoids, anal fissures, perianal abscesses, anal fistulas, perianal infections, diverticular diseases, colitis, colon polyps and cancer. Many of these can be prevented or minimized by maintaining a healthy lifestyle, practicing good bowel habits, and submitting to cancer screening. (Slideshare.net, 2017)

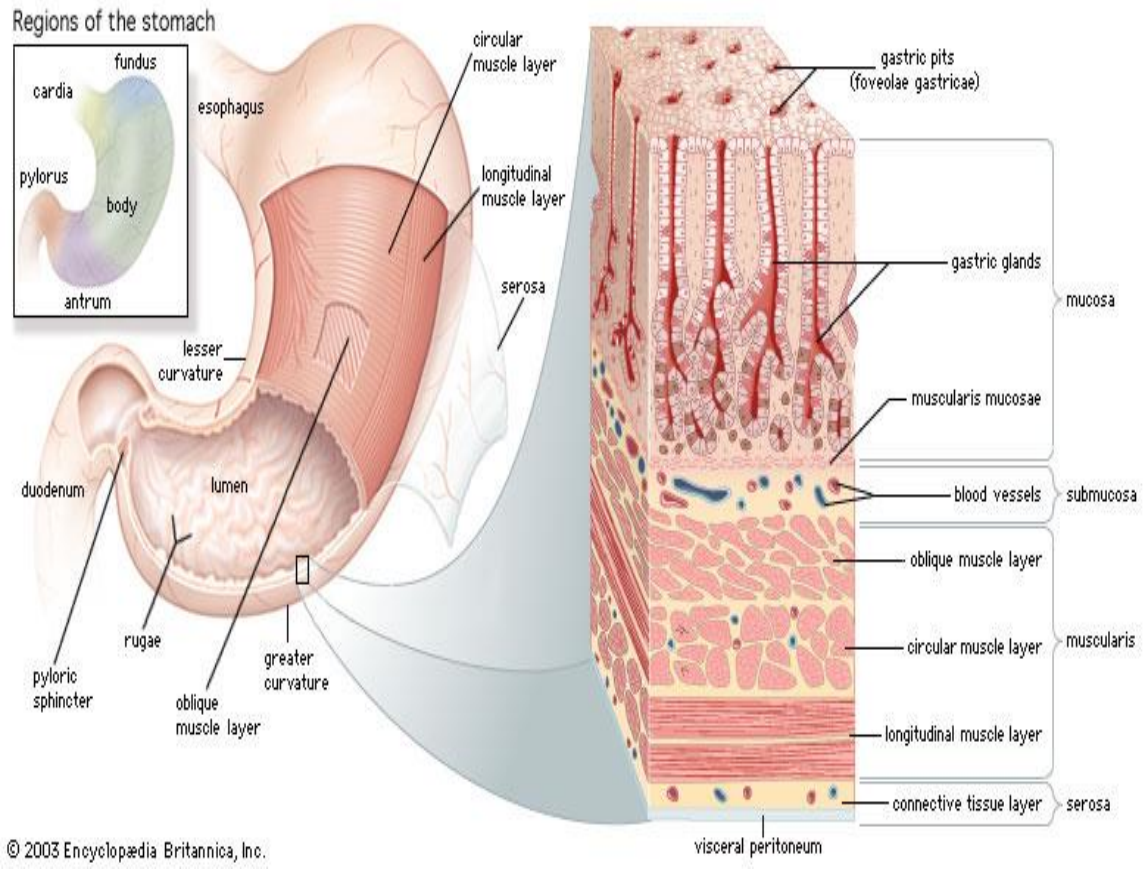


Figure 1.4: Gastrointestinal Disorders with regions of the stomach.

Many factors may upset the GI tract and its motility (or ability to keep moving), including:

- Eating a diet low in fiber
- Not enough exercise
- Traveling or other changes in routine
- Eating large amounts of dairy products
- Stress
- Resisting the urge to have a bowel movement
- Resisting the urge to have bowel movements due to pain from hemorrhoids
- Overusing laxatives (stool softeners) that, over time, weaken the bowel muscles
- Taking antacid medicines containing calcium or aluminum
- Taking certain medicines (especially antidepressants, iron pills, and strong pain medicines such as narcotics)
- Pregnancy

1.10.1 Constipation

Constipation means it is hard to have a bowel movement (or pass stools), they are infrequent (less than three times a week), or incomplete. Constipation is usually caused by inadequate "roughage" or fiber in the diet, or a disruption of the regular routine or diet.

Constipation causes a person to strain during a bowel movement. It may cause small, hard stools and sometimes anal problems such as fissures and hemorrhoids. Constipation is rarely the sign of a more serious medical condition.

You can treat your constipation by:

- Increasing the amount of fiber you eat
- Exercising regularly
- Moving your bowels when you have the urge (resisting the urge causes constipation)

If these treatment methods don't work, laxatives are a temporary solution. Note that the overuse of laxatives can actually make symptoms of constipation worse. Always follow the instructions on the laxative medicine, as well as the advice of your doctor.

1.10.2 Irritable bowel syndrome (IBS)

Irritable bowel syndrome (also called spastic colon, irritable colon, or nervous stomach) is a condition in which the colon muscle contracts more often than in people without IBS. Certain foods, medicines, and emotional stress are some factors that can trigger IBS.

Symptoms of IBS include:

- Abdominal pain and cramps
- Excess gas
- Bloating
- Change in bowel habits such as harder, looser, or more urgent stools than normal
- Alternating constipation and diarrhea

Treatment includes:

- Avoiding caffeine
- Increasing fiber in the diet
- Monitoring which foods trigger IBS (and avoiding these foods)
- Minimizing stress or learning different ways to cope with stress
- Sometimes taking medicines as prescribed by your healthcare provider

1.11 The structural gastrointestinal disorders

Structural disorders are those in which the bowel looks abnormal and doesn't work properly. Sometimes, the structural abnormality needs to be removed surgically. Common examples of

Structural GI disorders include hemorrhoids, diverticular disease, colon polyps, colon cancer, and inflammatory bowel disease.

1.12 Anal disorders

1.12.1 Anal fistula

An anal fistula often follows drainage of an abscess and is an abnormal tube-like passageway from the anal canal to a hole in the skin near the opening of the anus. Body wastes traveling through the anal canal are diverted through this tiny channel and out through the skin, causing itching and irritation. Fistulas also cause drainage, pain, and bleeding. They rarely heal by themselves and usually need surgery to drain the abscess and "close off" the fistula.

1.12.2 Other parietal infections

Sometimes the skin glands near the anus become infected and need to be drained. Just behind the anus, abscesses can form that contain a small tuft of hair at the back of the pelvis (called a pilonidal cyst).

Sexually transmitted diseases that can affect the anus include anal warts, herpes, AIDS, chlamydia, and gonorrhea.

1.12.3 Diverticular disease

Diverticulosis is the presence of small outpunching's (diverticula) in the muscular wall of the large intestine that form in weakened areas of the bowel. They usually occur in the sigmoid colon, the high-pressure area of the lower large intestine.

Diverticular disease is very common and occurs in 10% of people over age 40 and in 50% of people over age 60 in Western cultures. It is often caused by too little roughage (fiber) in the diet. Diverticulosis rarely causes symptoms.

Complications of diverticular disease happen in about 10% of people with outpunching's. They include infection or inflammation (diverticulitis), bleeding, and obstruction. Treatment of diverticulitis includes antibiotics, increased fluids, and a special diet. Surgery is needed in about half the patients who have complications to remove the involved segment of the colon.

1.12.4 Colon polyps and cancer

Each year 130,000 Americans are diagnosed with colorectal cancer, the second most common form of cancer in the United States. Fortunately, with advances in early detection and treatment, colorectal cancer is one of the most curable forms of the disease. By using a variety of screening tests, it is possible to prevent, detect, and treat the disease long before symptoms appear.

The importance of screening

Almost all colorectal cancers begin as polyps, benign (non-cancerous) growths in the tissues lining the colon and rectum. Cancer develops when these polyps grow and abnormal cells develop and start to invade surrounding tissue. Removal of polyps can prevent the development of colorectal cancer. Almost all precancerous polyps can be removed painlessly using a flexible lighted tube called a colonoscopy. If not caught in the early stages, colorectal cancer can spread throughout the body. More advanced cancer requires more complicated surgical techniques.

Most early forms of colorectal cancer do not cause symptoms, which makes screening especially important. When symptoms do occur, the cancer might already be quite advanced. Symptoms include blood on or mixed in with the stool, a change in normal bowel habits, narrowing of the stool, abdominal pain, weight loss, or constant tiredness.

Most cases of colorectal cancer are detected in one of four ways:

- By screening people at average risk for colorectal cancer beginning at age 50
- By screening people at higher risk for colorectal cancer (for example, those with a family history or a personal history of colon polyps or cancer)
- By investigating the bowel in patients with symptoms
- A chance finding at a routine check-up

Early detection is the best chance for a cure.

1.12.5 Colitis

There are several types of colitis, conditions that cause an inflammation of the bowel. These include:

- Infectious colitis
- Ulcerative colitis (cause not known)
- Crohn's disease (cause not known)
- Ischemic colitis (caused by not enough blood going to the colon)
- Radiation colitis (after radiotherapy)

Colitis causes diarrhea, rectal bleeding, abdominal cramps, and urgency (frequent and immediate need to empty the bowels). Treatment depends on the diagnosis, which is made by colonoscopy and biopsy. Can gastrointestinal disease be prevented, many diseases of the colon and rectum can be prevented or minimized by maintaining a healthy lifestyle, practicing good bowel habits, and submitting to cancer screening.

Colonoscopy is recommended for average risk patients at age 50. If you have a family history of colorectal cancer or polyps, colonoscopy may be recommended at a younger age. Typically, colonoscopy is recommended 10 years younger than the affected family member. (For example, if your brother was diagnosed with colorectal cancer or polyps at age 45, you

should begin screening at age 35). (Orinon, 2017).

If you have symptoms of colorectal cancer you should consult your doctor right away.

Common symptoms include:

- A change in normal bowel habits
- Blood on or in the stool that is either bright or dark
- Unusual abdominal or gas pains
- Very narrow stool
- A feeling that the bowel has not emptied completely after passing stool
- Unexplained weight loss
- Fatigue

1.13 Drugs used for GIT disease

1.13.1 Antacids

Definition:

Drugs antacids or topical antacid products are salts of aluminum and magnesium, which have the property of reducing gastric acidity by buffering and neutralizing them.

Mechanism of Action:

Antacids aluminum salts and magnesium antacids are contact; they decrease the acidity of gastric secretion, and by their buffer by direct neutralization of the hydrochloric acid present in the stomach. This action is limited at upper gastrointestinal reflux disease, there is no systemic alkalization that is in the blood.

- ☐ Forms: carbonate, hydroxide
- ☐ Have constipating effects
- ☐ Often used with magnesium to counteract constipation
- ☐ Examples
    - ■ Aluminum carbonate: Basally

- Hydroxide salt: Alternately
- Combination products (aluminum and magnesium): Gaviscon, Maalox, Mylanta, Di-Gel

Among the various products of this class.

- The aluminum hydroxide has a significant and prolonged neutralizing power, it can cause constipation and phosphorus depletion by uptake of dietary phosphate.
- Magnesium hydroxide is an antacid action fast and short, it can cause diarrhea.
- The aluminum phosphate has an antacid slow, it is also a protector of the gastric mucosa.
- The combination of derivatives of magnesium and aluminum, is designed to avoid the effects on intestinal transit and adding their actions and topical antacids.

Antacids are administered 1 hour 30 minutes to 2 hours after the start of each meal.

Objectives:

Prescription antacids aims to relieve the patient, the disappearance or reduction of symptoms.

Indications:

Antacids are indicated in the symptomatic treatment of pain and burns, upper gastrointestinal disorders esophageal.

Adverse:

These are some complications that can occur when taking the drug, knowing that induced side effects vary among individuals. Under treatment with antacids:

- There is a possibility of occasional constipation in bedridden people, or older and, due to the presence of magnesium;
- There is also a possibility of phosphorus depletion in prolonged use or in high doses, because of the presence of aluminum.

Precautions:

Due to alkalizing foods, it is unnecessary to administer antacids during meals.

Patients with renal failure and chronic dialysis, must take into account the presence of aluminum, and the risk of encephalopathy.

Interactions:

As a precaution, it should take antacids away from other drugs, due to a decrease in intestinal absorption of drugs taken at the same time.

The association with quinidine is not recommended due to risk of overdose.

There is need for a period of 2 hours or more between shots with H2 blockers, NSAIDs, beta-blockers, chloroquine, digitalis, bisphosphonates, fluoroquinolones, and inhibitors of the proton pump, the salicylate, and penicillamine.

1.13.2Antidiarrheal:

Mechanism of Action:

Diphenoxylate activates presynaptic opioid receptors in the enteric nervous system to block acetylcholine release & decrease peristalsis.

Adsorbents:

- Coat the walls of the GI tract
- Bind to the causative bacteria or toxin, which is then eliminated through the stool

Examples: bismuth subsalicylate (Pepto-Bismol), kaolin-pectin, activated charcoal.

Anticholinergic:

- Decrease intestinal muscle tone and peristalsis of GI tract
- Result: slowing the movement of fecal matter through the GI tract
- Examples: belladonna alkaloids (Donnatal), atropine

Intestinal flora modifiers:

- Bacterial cultures of Lactobacillus organisms work by:
  - Supplying missing bacteria to the GI tract
  - Suppressing the growth of diarrhea-causing bacteria
- Example: L. acidophilus (Lactinex)

Opiates:

- Decrease bowel motility and relieve rectal spasms
- Decrease transit time through the bowel, allowing more time for water and electrolytes to be absorbed

Examples: paregoric, opium tincture, codeine, loperamide (Imodium), diphenoxylate (Lomotil)

Uses:

This medication is used to treat sudden diarrhea (including traveler's diarrhea). It works by slowing down the movement of the gut. This decreases the number of bowel movements and makes the stool less watery. Loperamide is also used to reduce the amount of discharge in patients who have undergone an ileostomy. It is also used to treat on-going diarrhea in people with inflammatory bowel disease.

Loperamide treats only the symptoms, not the cause of the diarrhea (e.g., infection). Treatment of other symptoms and the cause of the diarrhea should be determined by your doctor.

Do not use in children younger than 6 years unless directed by your doctor. See also Warning section.

Side Effects:

Dizziness, drowsiness, tiredness, or constipation may occur. If any of these effects persist or worsen, contact your doctor promptly.

If your doctor has prescribed this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this

medication do not have serious side effects.

Stop taking this medication and get medical help right away if you have any very serious side effects,including:severe constipation/nausea/vomiting, stomach/abdominalpain,uncomfortable,fullness,severe,dizziness, fainting.Antidiarrheal drugs are medicines that relieve diarrhea.

Purpose:

Antidiarrheal drugs help control diarrhea and some of the symptoms that go along with it. An average, healthy person has anywhere from three bowel movements a day to three a week, depending on that person's diet.

Normally the stool (the material that is passed in a bowel movement) has a texture something like clay. With diarrhea, bowel movements maybe more frequent, and the texture of the stool is thin and sometimes watery.

Diarrhea is not a disease, but a symptom of some other problem. The symptom may be caused by eating or drinking food or water that is contaminated with bacteria, viruses, or parasites, or by eating something that is difficult to digest. People who have trouble digesting lactose

for example, may get diarrhea if they eat dairy products. Some cases of diarrhea are caused by stress, while others are brought on by taking certain medicines.

The dose depends on the type of antidiarrheal drug. Read and follow the directions on the product label. For questionsabout dosage, check with a physician or pharmacist. Never take larger or more frequent doses, and do not take the drugfor longer than directed.

Side effects:

Diarrhea usually improves within 48 hours. If the problem lasts longer or if it keeps coming back, diarrhea could be asign of a more serious problem. Anyone who has any of the symptoms listed below should get medical attention as soonas possible:

- diarrhea that lasts more than two days or gets worse
- fever
- blood in the stool
- vomiting
- cramps or tenderness in the abdomen

- signs of dehydration, such as decreased urination, dizziness or lightheadedness, dry mouth, increased thirst, or wrinkled skin.

Do not use antidiarrheal drugs for more than two days unless told to do so by a physician. Severe, long-
lasting diarrhea can lead to dehydration. In such cases, lost fluids and salts, such as calcium, s odium, andpotassium, must be replaced.
People older than 60 should not use attapulgite (Kaopectate, Donnagel, Parepectolin), but ma y use other kinds ofantidiarrheal drugs. However, people in this age group may be more likel y to have side effects, such as severeconstipation, from bismuth subsalicylate. Ask the pharm acist for more information.
Bismuth subsalicylate may cause the tongue or the stool to temporarily darken. This is harmle ss. However, do notconfuse this harmless darkening of the stool with the black.

Interactions:

Attapulgite can decrease the effectiveness of other medicines taken at the same time. Changin g the times at which theother medicines are taken may be necessary. Check with a physician or pharmacist to work out the proper doseschedule.
Bismuth subsalicylate should not be taken with aspirin or any other medicine that contains sal icylate. This drug may alsointeract with other drugs, such as blood thinners (warfarin, for exa mple), methotrexate, the antigout medicine probenecid,and the antidiabetes drug tolbutamide. In addition, bismuth subsalicylate may interact with any drug that interacts withaspirin. Anyo ne taking these drugs should check with a physician or pharmacist before taking bismuth subs alicylate.

1.13.3 H_2 Antagonists

- Reduce acid secretion
- All available OTC in lower dosage forms
- Most popular drugs for treatment of acid-related disorders
  - cimetidine (Tagamet)
  - famotidine (Pepcid)
  - ranitidine (Zantac)

Mechanism:

- Block histamine (H_2) at the receptors of acid-producing parietal cells
- Production of hydrogen ions is reduced, resulting in decreased production of HCl

What are H2 antagonists:

- H2 antagonists competitively inhibits histamine at the H2 receptors and leads to a reduction in secretion of gastric acid.
- Histamine stimulates the secretion of gastric acid by action on H2 receptors, which are found in the parietal cells of the gastric mucosa.
- H2 antagonists are used to treat gastroesophageal reflux disease (GERD), gastrointestinal ulcers and other gastrointestinal hypersecretory conditions.
    - GERD
    - PUD
    - Erosive esophagitis
    - Adjunct therapy in control of upper GI bleeding

Pathologic gastric hypersecretory conditions (Zollinger-Ellison syndrome

H_2 Antagonists: Side Effects:

- Overall, less than 3% incidence of side effects
- Cimetidine may induce impotence and gynecomastia
- May see:
    - Headaches, lethargy, confusion, diarrhea, urticaria, sweating, flushing etc.

Drug Interactions:

- Cimetidine (Tagamet)
    - Binds with P-450 microsomal oxidase system in the liver, resulting in inhibited oxidation of many drugs and increased drug levels
    - All H_2 antagonists may inhibit the absorption of drugs

SMOKING has been shown to decrease the effectiveness of H_2 blockers (increases gastric acid production).

Nursing Implications:

- Assess for allergies and impaired renal or liver function
- Use with caution in patients who are confused, disoriented, or elderly (higher incidence of CNS side effects)
- Take 1 hour before or after antacids
- For intravenous doses, follow administration guidelines

1.13.4 Proton Pump inhibitors

- The parietal cells release positive hydrogen ions (protons) during HCl production
- This process is called the "proton pump"
- H_2 blockers and antihistamines do not stop the action of this pump

Mechanism of Action:

- Irreversibly bind to H^+/K^+ ATPase enzyme
- Result: achlorhydria—ALL gastric acid secretion is blocked

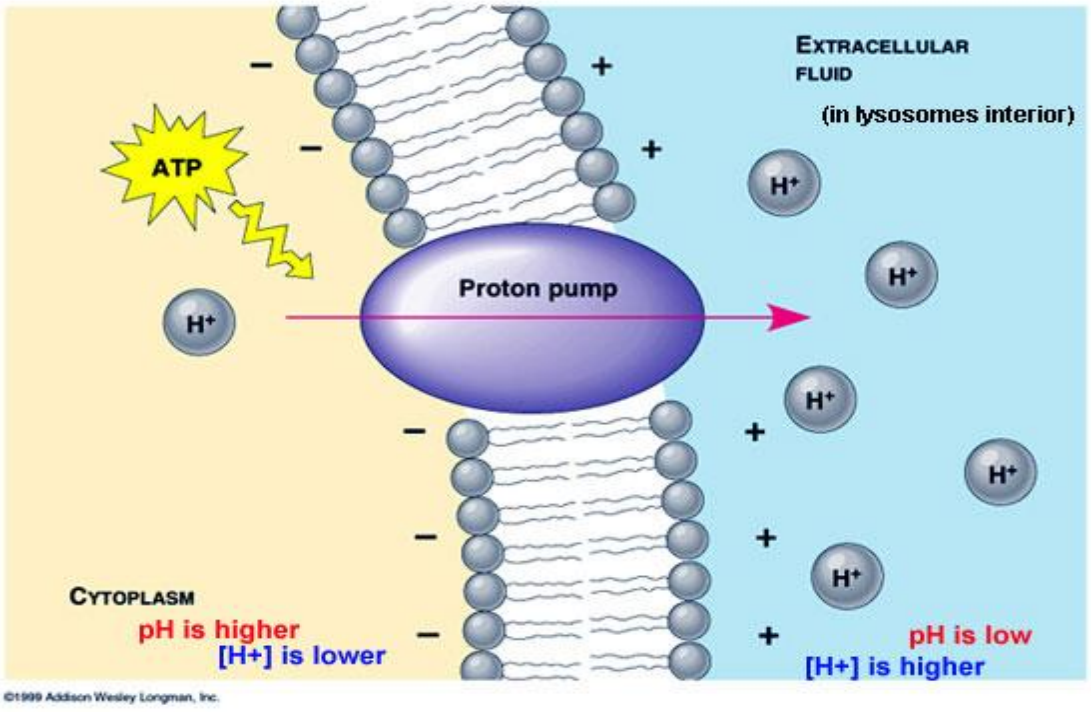


Figure 1.5: mechanism of action of Proton Pump inhibitors.

Drug Effect:

- Total inhibition of gastric acid secretion
  - Lansoprazole (Prevacid)
  - Omeprazole (Prilosec)
  - Rabeprazole (aciphex)
  - Pantoprazole (Protonix)
  - Esomeprazole (Nexium)

Indications:

- GERD maintenance therapy
- Erosive esophagitis
- Short-term treatment of active duodenal and benign gastric ulcers
- Zollinger-Ellison syndrome
- Treatment of H. pylori–induced ulcers

Side Effects:

- Safe for short-term therapy
- Incidence low and uncommon

Nursing Implications:

- Assess for allergies and history of liver disease
- pantoprazole (Protonix) is the only proton pump inhibitor available for parenteral administration, and can be used for patients who are unable to take oral medications
- May increase serum levels of diazepam, phenytoin.

1.13.5 Other drugs:

Misoprostol (Cytotec)

Synthetic prostaglandin analog Prostaglandins have cytoprotective activity

- Protect gastric mucosa from injury by enhancing local production of mucus or bicarbonate
- Promote local cell regeneration

Help to maintain mucosal blood flow.

- Used for prevention of NSAID-induced gastric ulcers
- Doses that are therapeutic enough to treat duodenal ulcers often produce abdominal cramps, diarrhea

Sucralfate (Carafate)

- Cytoprotective agent
- Used for stress ulcers, erosions, PUD
- Attracted to and binds to the base of ulcers and erosions, forming a protective barrier over these areas
- Protects these areas from pepsin, which normally breaks down proteins (making ulcers worse)
- Little absorption from the gut
- May cause constipation, nausea, and dry mouth
- May impair absorption of other drugs, especially tetracycline

1.13.6 Laxatives

Mechanism of Action:

Bulk forming

- High fiber
- Absorbs water to increase bulk
- Distends bowel to initiate reflex bowel activity
- **Examples:**
  - psyllium (Metamucil)
  - methylcellulose (Citrucel)
  - Polycarbophil (FiberContaininr)]

Emollient:

- Stool softeners and lubricants
- Promote more water and fat in the stools
- Lubricate the fecal material and intestinal walls
- **Examples:**
  - Stool softeners: docusate salts (Colace, Surfak)
  - Lubricants: mineral oil

Hyper osmotic:

- Increase fecal water content
- Result: bowel distention, increased peristalsis, and evacuation
- **Examples:**
  - polyethylene glycol (GoLYTELY)
  - sorbitol (increases fluid movement into intestine)
  - glycerin
  - lactulose (Chronulac)

1.13.7 Saline

- Increase osmotic pressure within the intestinal tract, causing more water to enter the intestines
- Result: bowel distention, increased peristalsis, and evacuation
- Saline laxative examples:
  - magnesium sulfate (Epsom salts)
  - magnesium hydroxide (MOM)
  - magnesium citrate
  - sodium phosphate (Fleet Phospho-Soda, Fleet enema)

Stimulant

- Increases peristalsis via intestinal nerve stimulation
- Examples:
  - castor oil (Granulex)
  - senna (Senokot)

Use

- Acute and chronic constipation
- Irritable bowel syndrome
- Diverticulosis
- Acute and chronic constipation
- Softening of fecal impaction; facilitation of BMs in anorectal conditions
- Chronic constipation
- Diagnostic and surgical preps
- Constipation
- Diagnostic and surgical preps
- Removal of helminths and parasites
- Acute constipation
- Diagnostic and surgical bowel preps

Side Effects

- Bulk forming
  - Impaction
  - Fluid overload
- Emollient
  - Skin rashes
  - Decreased absorption of vitamins

- Hyperosmotic
  - Abdominal bloating
  - Rectal irritation
- Saline
  - Magnesium toxicity (with renal insufficiency)
  - Cramping
  - Diarrhea
  - Increased thirst
- Stimulant
  - Nutrient malabsorption
  - Skin rashes
  - Gastric irritation
  - Rectal irritation

All laxatives can cause electrolyte imbalances

- Obtain a thorough history of presenting symptoms, elimination patterns, and allergies
- Nursing Implications
- Obtain a thorough history of presenting symptoms, elimination patterns, and allergies
- Patients should not take a laxative or cathartic if they are experiencing nausea, vomiting, and/or abdominal pain.

1.13.8 Antiemetic and Antinausea Agents

Mechanism of Action:

- Many different mechanisms of action
- Most work by blocking one of the vomiting pathways, thus blocking the stimulus that induces vomiting

Indications:

- Specific indications vary per class of antiemetics
- General use: prevention and reduction of nausea and vomiting

1.13.9Anticholinergic agents (ACh blockers)

- Bind to and block acetylcholine (ACh) receptors in the inner ear labyrinth
- Block transmission of nauseating stimuli to CTZ
- Also block transmission of nauseating stimuli from the reticular formation to the VC
- Scopolamine
- Also used for motion sickness

☐ **Antihistamine agents (H_1 receptor blockers) :**

- Inhibit ACh by binding to H_1 receptors
- Prevent cholinergic stimulation in vestibular and reticular areas, thus preventing N&V
- Diphenhydramine (Benadryl), meclizine (Antivert), promethazine (Phenergan)
- Also used for nonproductive cough, allergy symptoms, sedation

☐ **Neuroleptic agents :**

- Block dopamine receptors on the CTZ
- chlorpromazine (Thorazine), prochlorperazine (Compazine)
- Also used for psychotic disorders, intractable hiccups

☐ **Prokinetic agents :**

- Block dopamine in the CTZ
- Cause CTZ to be desensitized to impulses it receives from the GI tract
- Also stimulate peristalsis in GI tract, enhancing emptying of stomach contents
- Metoclopramide (Reglan)

☐ **Serotonin blockers :**

- Block serotonin receptors in the GI tract, CTZ, and VC

- Dolasetron (Anzemet), granisetron (Kytril), ondansetron (Zofran)
- Used for N&V for patients receiving chemotherapy and postoperative nausea and vomiting

- **Tetrahydrocannabinoids (THC) :**
  - Major psychoactive substance in marijuana
  - Inhibitory effects on reticular formation, thalamus, cerebral cortex
  - Alter mood and body's perception of its surroundings
  - dronabinol (Marinol)
  - Used for N&V associated with chemotherapy, and anorexia associated with weight loss in AIDS patients

Side Effects:

- Vary according to agent used
- Stem from their nonselective blockade of various receptors

Nursing Implications:

- Assess complete nausea and vomiting history, including precipitating factors
- Assess current medications
- Assess for contraindications and potential drug interactions
- Many of these agents cause severe drowsiness; warn patients about driving or performing any hazardous tasks
- Taking antiemetics with alcohol may cause severe CNS depression
- Teach patients to change position slowly to avoid hypotensive effects
- For chemotherapy, antiemetics are often given ½ to 3 hours before a chemotherapy agent
- Monitor for therapeutic effects
- Monitor for adverse effects

- ☐ For chemotherapy, antiemetics are often given ½ to 3 hours before a chemotherapy agent
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- ☐ Monitor for adverse effects

1.13.10 Non-steroidal Anti-inflammatory Drugs (NSAIDs)

Prostaglandins are a family of chemicals that are produced by the cells of the body and have several important functions. They promote inflammation that is necessary for healing, but also results in pain, and fever; support the blood clotting function of platelets; and protect the lining of the stomach from the damaging effects of acid.

Mechanism:

Prostaglandins are produced within the body's cells by the enzyme cyclooxygenase (COX). There are two COX enzymes, COX-1 and COX-2. Both enzymes produce prostaglandins that promote inflammation, pain, and fever. However, only COX-1 produces prostaglandins that support platelets and protect the stomach. Non-steroidal anti-inflammatory drugs (NSAIDs) block the COX enzymes and reduce prostaglandins throughout the body. As a consequence, ongoing inflammation, pain, and fever are reduced. Since the prostaglandins that protect the stomach and support platelets and blood clotting also are reduced, NSAIDs can cause ulcers in the stomach and promote bleeding.

The following list is an example of NSAIDs available:

- aspirin
- paracetamol
- celecoxib (Celebrex)
- diclofenac (Cambia, Cataflam, Voltaren-XR, Zipsor, Zorvolex)
- diflunisal (Dolobid - discontinued brand)
- etodolac (Lodine - discontinued brand)
- ibuprofen (Motrin, Advil)

- indomethacin (Indocin)
- ketoprofen (Active-Ketoprofen [Orudis - discontinued brand])
- ketorolac (Toradol - discontinued brand)
- nabumetone (Relafen - discontinued brand)
- naproxen (Aleve, Anaprox, Naprelan, Naprosyn)
- oxaprozin (Daypro)
- piroxicam (Feldene)
- salsalate (Disalsate [Amigesic - discontinued brand])
- sulindac (Clinoril - discontinued brand)
- tolmetin (Tolectin - discontinued brand)

Side effects of NSAIDs:

NSAIDs are associated with several side effects. The frequency of side effects varies among NSAIDs.

Common side effects are:

- Nausea,
- Vomiting,
- Diarrhea,
- Constipation,
- Decreased appetite,
- Rash,
- Dizziness,
- Headache, and
- Drowsiness.

Other important side effects are:

- Kidney failure (primarily with chronic use),
- liver failure,
- Ulcers, and
- Prolonged bleeding after injury or surgery.

NSAIDs can cause fluid retention which can lead to edema, which is most commonly manifested by swelling of the ankles.

Some individuals are allergic to NSAIDs and may develop shortness of breath when an NSAID is taken. People with asthma are at a higher risk for experiencing serious allergic reaction to NSAIDs. Individuals with a serious allergy to one NSAID are likely to experience a similar reaction to a different NSAID.

Use of aspirin in children and teenagers with chickenpox or influenza has been associated with the development of Reye's syndrome, a serious and sometimes fatal liver disease. Therefore, aspirin and non-aspirin salicylates (for example, salsalate [Amigesic]) should not be used in children and teenagers with suspected or confirmed chickenpox or influenza.

NSAIDs increase the risk of potentially fatal, stomach and intestinal adverse reactions (for example, bleeding, ulcers, and perforation of the stomach or intestines). These events can occur at any time during treatment and without warning symptoms. Elderly patients are at greater risk for these adverse events. NSAIDs (except low dose aspirin) may increase the risk of potentially fatal heart attacks, stroke, and related conditions. This risk may increase with duration of use and in patients who have underlying risk factors for heart and blood vessel disease. Therefore, NSAIDs should not be used for the treatment of pain resulting from coronary artery bypass graft (CABG) surgery.

NSAIDs interaction:

NSAIDs reduce blood flow to the kidneys and therefore reduce the action of diuretics ("water pills") and decrease the elimination of lithium (Eskalith, Lithobid) and methotrexate (Rheumatrex, Trexall). As a result, the blood levels of these drugs may increase as may their side effects.

NSAIDs also decrease the ability of the blood to clot and therefore increase bleeding. When used with other drugs that also increase bleeding (for example, warfarin [Coumadin]), there is an increased likelihood of serious bleeding or complications of bleeding. Therefore, individuals who are taking drugs that reduce the ability of blood to clot should avoid prolonged use of NSAIDs.

NSAIDs also may increase blood pressure in patients with hypertension (high blood pressure) and therefore antagonize the action of drugs that are used to treat hypertension.

NSAIDs increase the negative effect of cyclosporine on kidney function.

Persons who have more than three alcoholic beverages per day may be at increased risk of developing stomach ulcers when taking NSAIDs. (MedicineNet, 2017)

1.13.11 Antidiarrheal:

Side Effects:

Adsorbents

- ☐ Increased bleeding time
- ☐ Constipation, dark stools
- ☐ Confusion, twitching
- ☐ Hearing loss, tinnitus, metallic taste, blue gums

Anticholinergic

- ☐ Urinary retention, hesitancy, impotence
- ☐ Headache, dizziness, confusion, anxiety, drowsiness
- ☐ Dry skin, rash, flushing
- ☐ Blurred vision, photophobia, increased intraocular pressure
- ☐ Hypotension, hypertension, bradycardia, tachycardia

Opiates

- ☐ Drowsiness, sedation, dizziness, lethargy
- ☐ Nausea, vomiting, anorexia, constipation
- ☐ Respiratory depression

- ☐ Bradycardia, palpitations, hypotension
- ☐ Urinary retention

1.13.12 Clozapine

Clozapine side effects:

Get emergency medical help if you have signs of an allergic reaction to clozapine**:** hives, skin pain, rash that spreads and causes blistering or peeling; difficult breathing; swelling of your face, lips, tongue, or throat.

Serious and sometimes fatal infections may occur during treatment with clozapine. Call your doctor right away if you have signs of infection such as: weakness, fever, swollen gums, sore throat, painful mouth sores, pain when swallowing, skin sores, cold or flu symptoms, cough, trouble breathing.

High doses or long-term use of clozapine can cause a serious movement disorder that may not be reversible**.** Symptoms of this disorder include uncontrollable muscle movements of your lips, tongue, eyes, face, arms, or legs. The longer you take this medicine, the more likely you are to develop a serious movement disorder. The risk of this side effect is higher in women and older adults.

Also call your doctor at once if you have:

- headache with chest pain and severe dizziness, pounding heartbeats or fluttering in your chest;
- a light-headed feeling, like you might pass out;
- sudden cough, rapid breathing, coughing up blood;
- tight feeling in your neck or jaw, twitching or uncontrollable muscle movements;
- a seizure (blackout or convulsions);
- kidney problems - little or no urination, swelling in your feet or ankles, feeling tired or short of breath;

- liver problems - nausea, upper stomach pain, loss of appetite, tiredness, confusion, unusual bleeding, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- severe nervous system reaction - very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, feeling like you might pass out;
- high blood sugar - increased thirst, increased urination, hunger, dry mouth, fruity breath odor, drowsiness, dry skin, blurred vision, weight loss; or
- signs of inflammation in your body - easy bruising or bleeding, severe tingling or numbness, muscle weakness, upper stomach pain, jaundice (yellowing of the skin or eyes), chest pain, new or worsening cough, trouble breathing.

Common clozapine side effects may include:

- weight gain;
- tremor, dizziness, spinning sensation;
- headache, drowsiness;
- nausea, constipation;
- dry mouth, or increased salivation;
- blurred vision; or
- fast heart rate, increased sweating. (Drugs.com, 2017)

1.13.13 Ciprofloxacin

Ciprofloxacin is a fluoroquinolone (flor-o-KWIN-o-lone) antibiotic that fights bacteria in the body. Ciprofloxacin is used to treat different types of bacterial infections. It is also used to treat people who have been exposed toanthrax or certain types of plague.

Fluoroquinolone antibiotics can cause serious or disabling side effects. Ciprofloxacin should be used only for infections that cannot be treated with a safer antibiotic.

Before taking this medicine

One should not use ciprofloxacin if you are allergic to a fluoroquinolone antibiotic, or if you are also taking tizanidine (Zanaflex).

To make sure ciprofloxacin is safe for you, tell your doctor if you have:

- tendon problems, arthritis or other joint problems (especially in children);
- a history of myasthenia gravis or other nerve-muscle disorder;
- a heart rhythm disorder (especially if you take medication to treat it) or history of long QT syndrome;
- trouble swallowing pills;
- liver or kidney disease;
- a history of seizures;
- diabetes (especially if you take oral diabetes medication);
- low levels of potassium in your blood (hypokalemia)

Ciprofloxacin side effects:

Get emergency medical help if you have signs of an allergic reaction to ciprofloxacin: hives, or the first sign of a skin rash; fast heartbeat, difficult breathing; swelling of your face, lips, tongue, or throat.

Ciprofloxacin may cause swelling or tearing of (rupture) a tendon. This medicine can also have serious effects on your nerves, and may cause permanent nerve damage.

Stop using ciprofloxacin and call your doctor at once if you have:

- severe stomach pain, diarrhea that is watery or bloody;
- headache with chest pain and severe dizziness, fainting, fast or pounding heartbeats;
- muscle pain or weakness;
- a seizure (convulsions);
- signs of tendon rupture - sudden pain, swelling, bruising, tenderness, stiffness, movement problems, or a snapping or popping sound in any of your joints (rest the joint until you receive medical care or instructions);
- nerve symptoms - numbness, weakness, tingling, burning, pain, or being more sensitive to temperature, light touch, or the sense of your body position;

- changes in mood or behavior - depression, confusion, hallucinations, paranoia, tremors, feeling restless or anxious, unusual thoughts or behavior, insomnia, nightmares;
- liver problems - upper stomach pain, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- increased pressure inside the skull - severe headaches, ringing in your ears, vision problems, pain behind your eyes; or
- Severe skin reaction - skin pain followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling. (Anon, 2017)

Common ciprofloxacin side effects may include:

- nausea, vomiting, diarrhea;
- rash; or
- Abnormal liver function tests.

Other drugs will affect ciprofloxacin:

- cyclosporine, methotrexate, metoclopramide, omeprazole, pentoxifylline, phenytoin, probenecid, ropinirole, sildenafil, theophylline;
- a diuretic or "water pill";
- heart rhythm medication - amiodarone, disopyramide, dofetilide, dronedarone, procainamide, quinidine, sotalol, and others;
- medicine to treat depression or mental illness - amitriptylline, clomipramine, clozapine, desipramine, duloxetine, iloperidone, imipramine, nortriptyline, and others; or
- NSAIDs (nonsteroidal anti-inflammatory drugs) - aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve), celecoxib, diclofenac, indomethacin, meloxicam, and others.

1.13.14 Metronidazole

Metronidazole is an antibiotic. It fights bacteria in your body.

Metronidazole is used to treat bacterial infections of the vagina, stomach, skin, joints, and respiratory tract. This medication will not treat a vaginal yeast infection.

Metronidazole may also be used for purposes not listed in this medication guide.

Contraindications:

You should not use this medication if you are allergic to metronidazole, or if you are in the first trimester of pregnancy. Tell your doctor if you are pregnant or plan to become pregnant during treatment.

Before taking metronidazole, tell your doctor if you are allergic to any drugs, or if you have:

- Liver disease;
- A stomach or intestinal disease such as Crohn's disease;
- A blood cell disorder such as anemia (lack of red blood cells) or leukopenia (lack of white blood cells);
- Epilepsy or other seizure disorder; or
- Nerve disorders.

Metronidazole side effects:

Get emergency medical help if you have any of these signs of an allergic reaction to metronidazole: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. At once if you have any of these serious side effects:

- numbness or tingling in your hands or feet;
- white patches or sores inside your mouth or on your lips;
- pain or burning when you urinate;
- diarrhea that is watery or bloody;
- vision problems, pain behind your eyes;

- trouble concentrating, slurred speech, mood or behavior changes, tremors, muscle twitching, seizure (convulsions);
- fever, chills, muscle pain, confusion, headache, sore throat, neck stiffness, increased sensitivity to light, drowsiness, nausea and vomiting; or
- severe skin reaction -- fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

Less serious metronidazole side effects may include:

- stomach pain, diarrhea;
- dizziness, loss of balance;
- vaginal itching or discharge;
- dry mouth or unpleasant metallic taste;
- cough, sneezing, runny or stuffy nose; or
- swollen or sore tongue

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

Other drugs will affect metronidazole:

Tell your doctor about all other medicines you use, especially:

- cimetidine (Tagamet);
- seizure medication such as phenytoin (Dilantin) or phenobarbital (Luminal, Solfoton);
- a blood thinner such as warfarin (Coumadin, Jantoven);
- lithium (Lithobid, Eskalith, others); or
- Disulfiram (Antabuse).

Major side effects:

You should check with your doctor immediately if any of these side effects occur when taking metronidazole:

More common:

- Agitation
- back pain
- blindness
- blurred vision
- burning, numbness, tingling, or painful sensations in the hands or feet
- changes in speech patterns
- confusion
- convulsions
- decreased vision
- depression
- dizziness
- drowsiness
- eye pain
- fever
- hallucinations
- headache
- irritability
- lack of coordination
- nausea
- seizures
- shakiness and unsteady walk
- slurred speech
- stiff neck or back
- trouble speaking
- unsteadiness, trembling, or other problems with muscle control or coordination
- unusual tiredness or weakness
- vomiting

Less common:

- Black, tarry stools
- blood in the urine or stools
- body aches or pain
- chills
- clumsiness or unsteadiness
- difficulty with breathing
- ear congestion
- feeling of pelvic pressure
- frequent or painful urination
- loss of voice
- nasal congestion
- pinpoint red spots on the skin
- runny nose
- skin rash, hives, redness, or itching
- vaginal irritation, discharge, or dryness not present before taking the medicine

Incidence not known:

- Blistering, peeling, or loosening of the skin
- bloody or cloudy urine
- burning while urinating
- continuing diarrhea
- continuing stomach pain
- diarrhea
- feeling of warmth
- increased volume of pale, dilute urine
- joint or muscle pain
- loss of bladder control
- red skin lesions, often with a purple center
- red, irritated eyes
- Redness of the face, neck, arms, and occasionally, upper chest.(Drugs.com, 2017)

1.13.15 Environmental pollution and gastrointestinal diseases:

Air pollution events well in excess of the National Ambient Air Quality Standards. Most of the events are due to an accumulation of particulate matter during persistent cold air pools in winter from both direct emissions and secondary chemical reactions in the atmosphere. High wintertime ozone concentrations are occasionally observed in the Uintah Basin, in addition to particulate matter. At other times of the year, blowing dust, wild land fires, fireworks, and summertime ozone formation contribute to local air pollution. The objective of this dissertation is to investigate one facet of the health effects of Utah's air pollution on its residents: the acute impacts of air pollution on gastrointestinal (GI) disease.

To study the health effects of these episodic pollution events, some measure of air pollution exposure must be matched to the health data. Time and place are used to link the health data for a person with the pollution data. This dissertation describes the method of kriging data from the sparse pollution monitoring network to estimate personal air pollution history based on the zip code of residence. This dissertation then describes the application of these exposure estimates to a health study on GI disease.

The purpose of the GI study is to retrospectively look at two groups of patients during 2000-2014: those with autoimmune disease of the GI tract (inflammatory bowel disease, IBD) and those with allergic disease of the GI tract (eosinophilia esophagitis, EoE) to determine whether disease exacerbations occur more commonly during and following periods of poor air quality compared to periods of good air quality. The primary analysis method is case crossover design. In addition to using the kriged air pollution estimates, the analysis was repeated using simpler empirical estimation methods to assess whether the odds ratios are sensitive to the air pollution estimation method.

The data suggests an association between particulate matter smaller than 2.5 microns and prednisone prescriptions, gastrointestinal infections in general, clostridium difficult infections specifically, and hospitalizations among people who have at least five entries of IBD diagnosis codes in their medical records. EOE exacerbations appear to be associated with high concentrations of particulate matter as well as ozone.

Microbiological pollution

Post infectious IBS (PI-IBS) is a particular case of IBS, which is caused by acute infectious

gastroenteritis; in fact, it is considered as the most common cause of IBS. It was shown in prospective studies that 4% to 36% patients suffer from PI-IBS because of previous infection. Noteworthy, the first reports on the disease date back already to 50 years ago. The pathogens that contribute to PI-IBS are Campylobacter jejuni, Salmonellaenterica, Shigellasonnei, Escherichia coli O157:H7, noroviruses and *Giardia lamblia*. The disease symptoms are not immediate, it takes approximately 8-10 years to develop a full-blown PI-IBS. The duration of infection is crucial; for example, a fortnight-long *Shigellasonnei* infection was considerably more associated with PI-IBS than a week-long one.

Air pollution and gut microbiome

Despite the well-studied effects of environmental pollutants on several health conditions, little is known on how air pollution impacts the gut microbiome. Kish et al showed that pollutant particles ingested with chow altered gut microbiota composition by significant changes in the relative amounts of *Bacteroidetes*, *Firmicutes* and*Verrucomicrobia*. Moreover, mice exposed to polychlorinated biphenyls from contaminated food had decreased levels of *Proteobacteria* and increased levels of *Bacteroidetes.*

Environmental factors are important mediators of many diseases of the digestive system, defined as the alimentary tract and the accessory organs of digestion, the liver and pancreas. In this review, we principally focus on the action of chemical agents which are classified as

(1) Naturally occurring compounds, (2) occupational hazards, (3) therapeutic drugs, and (4) constituents of substances of abuse.

Chapter2

Literature Review

2.1 Gastrointestinal Side Effects of Prescription Medications in the Older Adult.

Gastrointestinal (GI) symptoms resulting from either prescription medications or over-the-counter drugs are frequently encountered in geriatric practice but often mistaken for symptoms of an organic disease leading to multiple diagnostic studies. The morbidity, mortality, and medical costs associated with drug toxicity, even when restricted to the GI tract, are probably underestimated. The consequences of drug toxicity are quite variable and range from a symptom of mild discomfort (e.g., drug-induced diarrhea) at one end of the spectrum, to fatal GI hemorrhage or perforation. Better awareness of the possibility of drug-induced GI tract pathology by primary care physicians improves the recognition of these adverse effects, and ultimately, improves patient care. This review focuses on the most common and well-described drug-related side effects of the GI tract. (Jain et al., 2009).

2.2 Migraine Associated with Gastrointestinal Disorders: Review of the Literature and Clinical Implications.

Recent studies suggest that migraine may be associated with gastrointestinal (GI) disorders, including irritable bowel syndrome (IBS), inflammatory bowel syndrome, and celiac disease. Here, an overview of the associations between migraine and GI disorders is presented, as well as possible mechanistic links and clinical implications. People who regularly experience GI symptoms have a higher prevalence of headaches, with a stronger association with increasing headache frequency. Children with a mother with a history of migraine are more likely to have infantile colic. Children with migraine are more likely to have experienced infantile colic compared to controls. Several studies demonstrated significant associations between migraine and celiac disease, IBS. Possible underlying mechanisms of migraine and GI diseases could be increased gut permeability and inflammation. Therefore, it would be worthwhile to investigate these mechanisms further in migraine patients. These mechanisms also give a rationale to investigate the effects of the use of pre- and probiotics in patients. (Van Hemert et al., 2014).

2.3 Gastrointestinal Side Effects Associated With Novel Therapies in Patients With Multiple Myeloma: Consensus Statement of the IMF Nurse Leadership Board.

The novel immunomodulatory drugs lenalidomide and thalidomide and the novel proteasome inhibitor bortezomib can cause gastrointestinal side effects, including constipation, diarrhea, nausea, and vomiting, which can have a deleterious effect on quality of life and interfere with optimal therapy. The International Myeloma Foundation's Nurse Leadership Board developed this consensus statement for the management of gastrointestinal side effects associated with novel therapies to be used by healthcare providers in any medical setting. It includes grading criteria and general recommendations for assessing and managing the side effects. Although constipation, diarrhea, nausea, and vomiting are expected side effects associated with novel therapies for multiple myeloma, they are manageable with appropriate medical interventions (Smith et al., 2008)

2.4 Understanding the gastrointestinal tract of the elderly to develop dietary solutions that prevent malnutrition.

Although the prevalence of malnutrition in the old age is increasing worldwide a synthetic understanding of the impact of aging on the intake, digestion, and absorption of nutrients is still lacking. This review article aims at filling the gap in knowledge between the functional decline of the aging gastrointestinal tract (GIT) and the consequences of malnutrition on the health status of elderly.Changes in the aging GIT include the mechanical disintegration of food, gastrointestinal motor function, food transit, chemical food digestion, and functionality of the intestinal wall. These alterations progressively decrease the ability of the GIT to provide the aging organism with adequate levels of nutrients, what contributes to the development of malnutrition. Malnutrition, in turn, increases the risks for the development of a range of pathologies associated with most organ systems, in particular the nervous-, muscoskeletal-, cardiovascular-, immune-, and skin systems. In addition to psychological, economics, and societal factors, dietary solutions preventing malnutrition should thus propose dietary guidelines and food products that integrate knowledge on the functionality of the aging GIT and the nutritional status of the elderly. Achieving this goal will request the identification, validation, and correlative analysis of biomarkers of food intake, nutrient bioavailability, and malnutrition. (Rémond et al., 2015).

2.5 Gut microbiotic of healthy and malnourished children in Bangladesh.

Poor health and malnutrition in preschool children are longstanding problems in Bangladesh.

Gut microbiota plays a tremendous role in nutrient absorption and determining the state of

Health. In this study, met genomic tool was employed to assess the gut microbiota composition of healthy and malnourished children. DNA was extracted from fecal samples of seven healthy and seven malnourished children (n = 14; age 2–3 years) were analyzed for the variable region of 16S rRNA genes by universal primer PCR followed by high-throughput 454 parallel sequencing to identify the bacterial phyla and genera. Our results reveal that the healthy children had a significantly higher number of operational taxonomic unit in their gut than that of the malnourished children (healthy vs. malnourished: 546 vs. 310). In malnourished children, bacterial population of the phyla Proteobacteria and Bacteroidetes accounted for 46 and 18%, respectively. Conversely, in healthy children, Proteobacteria and Bacteroidetes accounted for 5% and 44, respectively ($p < 0.001$). In malnourished children, the phylum Proteobacteria included pathogenic genera, namely *Klebsiella* and *Escherichia*, which were 174-fold and 9-fold higher, respectively, than their healthy counterpart. The predominance of potentially pathogenic Proteobacteria and minimal level of Bacteroidetes as commensal microbiota might be associated to the ill health of malnourished children in Bangladesh. (Monira et al., 2011)

2.6 A prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital.

Adverse reactions are the recognized hazards of drug therapy and they can occur with any class of drugs and many studies revealed that the incidence is more in case of antibiotics. The main aim of this study was to detect and analyze Adverse Drug Reactions of antibiotics in inpatients of a tertiary care hospital. A prospective spontaneous reporting study by active and passive methods was carried out for a period of six months. A total of 49 ADRs were reported during the study period with male predominance (53.06%) and geriatric age group. More number of ADRs was from General Medicine and Pediatric departments in which the most affected organ systems were the GIT (38.77%) and the skin (30.61%). The antibiotic classes mostly accounted were cephalosporin's (34.69%) followed by fluoroquinolones and others in which type A reactions were more compared to type B and 59.18% of them were predictable. The severity assessment revealed that most of them were moderate (63.26%) followed by mild and severe reactions. Of the reported reactions, 55.10% were definitely

preventable and causality assessment was done which showed that 71.42% of the reactions were probable, possible (18.36%), definite (10.20%) and no reactions were unlikely. The study concluded that Adverse Drug Reactions to antibiotics are common and some of them resulted in increased healthcare cost due to the need of some interventions and increased length of hospital stay. The health system should promote the spontaneous reporting of Adverse Drug Reactions to antibiotics, proper documentation and periodic reporting to regional pharmacovigilance centers to ensure drug safety. (Shamna et al., 2014)

2.7 Irritable Bowel Syndrome in a Bangladeshi Urban Community: Prevalence and Health Care Seeking Pattern.

Although irritable bowel syndrome (IBS) is a common gastrointestinal disorder, its prevalence is unknown, especially in the urban population of Bangladesh. This community-based study aimed to find out the prevalence of IBS and healthcare-seeking patterns using the Rome-II definition.

Results: A response rate of 97.2% yielded 1503 questionnaires for analysis. The prevalence of IBS was found to be 7.7% (n = 116) with a male to female ratio of 1:1.36 (49 *vs*. 67). "Diarrhea-predominant IBS" (50%, n = 58) was the predominant IBS subgroup. Symptoms of abdominal pain associated with a change in stool frequency (100%) and consistency (88.8%) were quite common. All IBS symptoms were more prevalent among women ($P <$ 0.000). In the past one year, 65.5% (n = 76) IBS subjects had consulted a physician with a slightly higher rate of women consulters (68.6 *vs.* 61.2%). The main predictor for healthcare-seeking was the presence of multiple dyspeptic symptoms.

Conclusions: The prevalence of IBS in the urban community was found to be similar to that in rural communities. A higher rate of consultation was found among urban IBS subjects than in the rural subjects, with sex not seen to be a discriminator to seek consultation. (Perveen et al., 2009)

2.8 Gut microbiome in health and disease: linking the microbiome-gut-brain axis and environmental factors in the pathogenesis of systemic and neurodegenerative diseases.

The gut microbiome comprises the collective genome of the trillions of microorganisms

residing in our gastrointestinal ecosystem. The interaction between the host and its gut microbiome is a complex relationship whose manipulation could prove critical to preventing

or treating not only various gut disorders, like irritable bowel syndrome (IBS) and ulcerative colitis (UC), but also central nervous system (CNS) disorders, such as Alzheimer's and Parkinson's diseases. The purpose of this review is to summarize what is known about the gut microbiome, how it is connected to the development of disease and to identify the bacterial and biochemical targets that should be the focus of future research. Understanding the mechanisms behind the activity and proliferation of the gut microbiome will provide us new insights that may pave the way for novel therapeutic strategies. (Ghaisas, Maher and Kanthasamy, 2016)

2.9 Psychological disorders in gastrointestinal disease: epiphenomenon, cause or consequence.

Psychological disorders have been associated with irritable bowel syndrome (IBS) for decades in the absence of other objective etiology. However, such associations are also evident in other chronic diseases with more clearly defined pathogenesis such as ulcerative colitis. In this study, we examined the prevalence and severity of psychological disorders among IBS and ulcerative colitis (UC) patients relative to healthy controls.

Results: Seven case-control studies evaluating IBS and three evaluating UC were included. All IBS and UC studies reported excess prevalence and severity of depression. The prevalence of depression in excess of healthy controls was 39% in UC case-control trials and 33% in IBS studies, and excess anxiety was present in UC (42%) and IBS (19%) case-control trials as well. Anxiety and depression scores were higher (representing more severe symptoms) in both UC and IBS patients compared to healthy controls.

Conclusions Anxiety and depressive disorders are associated with both IBS and UC. The non-specific association between and gastrointestinal disorders could suggest that chronic gastrointestinal illness might affect psychosocial behavior. (Suarez et al., 2010).

2.10 Drug-induced side effects affecting the gastrointestinal tract.

Out of 249 patients undergoing surgery (106 women, 57,6 years (16-90)), 35 (14%) had GIR (mean age 58 years (24-84)). 15 (42,8%) had total/partial colectomy, 14 (40%) partial gastrectomy, 3 (8,6%) rectum resection, 2(5,7%) small bowel resection and 1 (2,9%)

oesophagectomy. 7 (20%) patients were treated with oral medication which pharmacological effect may be reduced after GIR: 1(14.7%) had small bowel resection and received hydrochlorothiazide, 6(85.7%) had gastrectomy: one received Metformin which decreases B12 levels and 2 received enalapril and cotrimoxazole respectively which absorption may be decreased. Other 3 patients received drugs formulations which couldn't be absorbed because of the gastrectomy. To avoid a decrease in pharmacological effect patient's medication was switched to a correct formulation or to an active substance with an appropriate absorption site. Conclusions There were few patients treated with drugs affected by GIR, however, they should be closely monitored. There is limited and scarce updated literature regarding clinical outcome of drug efficacy in these patients. The authors should keep in mind those patients with GIR and poor pharmacological response. (Leong and Chan, 2006)

2.11 NSAID-induced gastrointestinal damage: current clinical management and recommendations for prevention.

Gastrointestinal toxicity is a common adverse effect of traditional non-steroidal anti-inflammatory drugs (NSAIDs) and patients at risk should receive prevention therapies. Selective cyclooxygenase-2 (COX-2) inhibitors (coxibs) are safer to the gastrointestinal tract than traditional NSAIDs. Current prevention strategies in patients who need NSAIDs should also take into account the presence of cardiovascular risk factors, as coxibs and probably most traditional NSAIDs increase the incidence of serious cardiovascular events. Patients without risk factors should be treated with traditional NSAIDs, whereas patients at risk may receive cotherapy with a proton pump inhibitor (PPI) or misoprostol, or a coxib alone. However, patients with a previous bleeding ulcer should receive the combination of a coxib plus a PPI, and Helicobacter pylori should be tested for and treated if present. Coxib and NSAID therapy should be prescribed with caution in patients with increased cardiovascular risk and should be prescribed at the lowest possible dose and for the shortest period of time. These patients will probably be treated with low-dose aspirin or other antiplatelet agents, which puts them at increased risk of upper gastrointestinal complications. The risk of gastrointestinal toxicity with combined therapy of aspirin and coxib may be lower than that with traditional NSAIDs plus aspirin, but all these patients may benefit from PPI cotherapy. When the lower gastrointestinal tract is of concern, coxib instead of NSAID therapy should be considered. Coxib therapy has better gastrointestinal tolerance than traditional NSAIDs and who develop dyspepsia during NSAID or coxib therapy. (Lanas and Ferrandez, 2006)

2.12 Gastrointestinal side effects of drugs.

Drugs can have adverse effects on any part of the gastrointestinal (GI) tract from mouth to colon. It is essential that a detailed and accurate drug history is taken in patients presenting with GI complaints. Many drug-induced effects will regress or heal on cessation of treatment. NSAIDs are usually associated with gastric and duodenal ulcers but are also recognised to cause lichen planus in the mouth, oesophageal inflammation and strictures, and small bowel and colonic ulcers and strictures. A newer class of anti-inflammatory drugs, the cyclooxygenase-2 (COX-2)-selective inhibitors, have been developed and have a more favourable GI safety profile than standard NSAIDs. Acute diarrhoea, relapse of inflammatory bowel disease (IBD), microscopic colitis and acute pancreatitis are also induced by ingestion of standard NSAIDs. The calcium antagonists, phenytoin and cyclosporin, induce gum hyperplasia, particularly in patients with poor oral hygiene. Alendronate, a bisphosphonate, has been associated with development of esophageal ulcers, and specific recommendations are now given to reduce this complication. Of the many different forms of colitis associated with drug ingestion, the most frequent is pseudomembranous colitis. This is a complication of antibiotics and is caused by the toxin produced by Clostridium difficile. Many drugs have been associated with the development of acute pancreatitis, although a definite cause and effect relationship has been shown for only a few drugs. These include didanosine, furosomide, corticosteroids, azathioprine and sodium valproate. (Makins and Ballinger, 2003)

2.13 Drug-induced Gastrointestinal Disorders.

The gastrointestinal tract is frequently the site of complications resulting from prescription and over-the-counter drug use. If unrecognized or untreated, over time, these complications have the potential to affect nutritional status. Healthcare professionals need to be aware of the drugs commonly implicated in causing gastrointestinal complaints in order to prevent long-term complications. Patients should be alerted to the early warning signs of drug-induced gastrointestinal disorders so that they can seek care and prevent long-term complications. (Hyson, et al., 1977)

2.14 Prevention of anti-inflammatory drug-induced gastrointestinal damage: benefits and risks of therapeutic strategies.

Patients who take non-steroidal anti-inflammatory drugs (NSAIDs) may develop serious

gastrointestinal (GI) side effects in both the upper and lower GI tract. Those at risk should be considered for prevention with misoprostol, proton pump inhibitor (PPI) or COX-2 selective inhibitor (coxib) therapy. A coxib or an NSAID+PPI combination is considered to have comparable GI safety profiles, but evidence from direct comparison is limited. PPIs are effective in the prevention of upper GI events in endoscopy trials and in a few, small, outcome trials in patients at risk. Coxibs have been evaluated in endoscopic ulcer studies and clinical outcome trials, and shown to significantly reduce the risk of upper GI ulcer and complications. Moreover, unlike PPIs, coxibs significantly reduce toxicity in the lower GI tract compared with NSAIDs. Coxibs and possibly some NSAIDs also increase the risk of developing serious cardiovascular events, an effect which may depend on the drug, dose and duration of therapy. It is not known whether concomitant low-dose aspirin use, which occurs in more than 20% of patients, will reduce the incidence of cardiovascular events, although concomitant aspirin increases the risk of developing serious GI events in patients taking either an NSAID or a coxib. Such patients may require additional PPI co-therapy. Current prevention strategies with an NSAID+PPI, misoprostol or a coxib must be considered in the individual patient with GI and cardiovascular risk factors. A PPI+coxibis indicated in those at highest risk (e.g. previous ulcer bleeding). PPI therapy must be considered for the treatment and prevention of NSAID-induced dyspepsia.(Lanas and Hunt, 2006)

2.15 Secondary and primary prophylaxis of gastropathy associated with non-steroidal anti-inflammatory drugs or low-dose-aspirin: a review based on four clinical scenarios.

Based on current references four clinical scenarios were discussed and different management strategies were compared for secondary and primary prophylaxis of ulcer or peptic ulcer bleeding under continuous therapy with non-steroidal anti-inflammatory drugs (NSAID) or low-dose-aspirin, for Helicobacter pylori-positive and Helicobacter pylori -negative patients. Used as secondary prophylaxis eradication alone is insufficient in preventing recurrent peptic ulcer or recurrent ulcer bleeding for Helicobacter pylori-positive patients who continue to take unselective NSAIDs. Maintenance therapy with PPIs or switching from nonselective NSAID to COX-2-inhibitors is required after eradication of Helicobacter pylori or primary Helicobacter pylori-negative patients. Further evaluation is needed of what kind of secondary prophylaxis - maintenance therapy with PPI or switching to COX-2-inhibitor - is more (cost-) effective. It is sufficient to use eradication of Helicobacter pylori alone as secondary

prophylaxis in preventing recurrent peptic ulcer or recurrent ulcer bleeding for Helicobacter pylori-positive patients, who continue to take low-dose-aspirin. Maintenance therapy with PPI is not generally required. However it can be considered for patients with increased risk for gastrointestinal complications (previous history of peptic ulcer, age over 65 years, concomitant use of corticosteroids, anticoagulants or individual NSAID with higher risk for gastrointestinal complications, serious cardiovascular disease). Switching from low-dose-aspirin to clopidogrel is not required. Used as primary prophylaxis in preventing peptic ulcer or ulcer bleeding before starting long-term therapy with NSAIDs, COX-2-inhibitors or unselective NSAIDs concomitant with PPIs are recommended for patients with increased risk for gastrointestinal complications. Patients starting long-term therapy with unselective NSAIDs should be screened for Helicobacter pylori and eradicated. There are no valid data supporting screening for Helicobacter pylori and eradication for patients starting long-term therapy with low-dose-aspirin. Further studies are needed to evaluate a possible benefit for patients with increased risk for gastrointestinal complications. (Ricotta, 1993)

2.16 Current approaches to prevent NSAID-induced gastropathy--COX selectivity and beyond.

Gastrointestinal (GI) toxicity associated with non-steroidal anti-inflammatory drugs (NSAIDs) is still an important medical and socio-economic problem--despite recent pharmaceutical advances. To prevent NSAID-induced gastropathy, three strategies are followed in clinical routine: (i) coprescription of a gastro protective drug, (ii) use of selective COX-2 inhibitors, and (iii) eradication of Helicobacter pylori.

Proton pump inhibitors are the comedication of choice as they effectively reduce gastrointestinal adverse events of NSAIDs and are safe even in long-term use. Co-medication with vitamin C has only been little studied in the prevention of NSAID-induced gastropathy. Apart from scavenging free radicals it is able to induce haeme-oxgenase 1 in gastric cells, a protective enzyme with antioxidant and vasodilative properties. Final results of the celecoxib outcome study (CLASS study) attenuated the initial enthusiasm about the GI safety of selective COX-2 inhibitors.

Especially in patients concomitantly taking aspirin for cardiovascular prophylaxis. Helicobacter pylori increases the risk for ulcers particularly in NSAID-naive patients and therefore eradication is recommended prior to long-term NSAID therapy at least in patients at high risk.

New classes of COX-inhibitors are currently evaluated in clinical studies with very promising results: NSAIDs combined with a nitric oxide releasing moiety (NO-NSAID) and dual inhibitors of COX and 5-LOX. These drugs offer extended anti-inflammatory potency while sparing gastric mucosa. (Becker, Domschke and Pohle, 2004)

2.17 Interaction or relationship between Helicobacter pylori and non-steroidal anti-inflammatory drugs in upper gastrointestinal diseases.

According to a meta-analysis, H pylori and non-steroidal anti-inflammatory drugs (NSAID) independently and significantly increase the risk of gastro duodenal ulcer and ulcer bleeding. Their coincidence is frequent, demonstration of a possible relationship and consequent attitude is of important implications. But unfortunately, no consensus has been approved in the past years and their interactions are still controversial. H pylori and NSAID are known to share a number of pathogenic mechanisms, but there is no evidence for the significant synergic action between these two risk factors. Their relationship is independent including the definition of a NSAID user as well as the types, doses, duration and their indications for NSAID use, as well as their end-points, definition of dyspepsia and regimes used for eradication of H pylori. These might contribute to the conflicting results and opinions. H pylori infection in humans does not act synergistically with NSAID on ulcer healing, and there is no need to eradicate it. This notion is supported by the finding that the eradication of H pylori does not affect NSAID-induced gastropathy treated with omeprazole and that H pylori infection induces a strong cyclooxygenase-2 (COX-2) expression resulting in excessive biosynthesis of prostaglandin which in turn counteracts NSAID-induced gastropathy and heals the existing ulcer. Other investigators claimed that H pylori infection acts synergistically with NSAID on ulcer development, and H pylori should be eradicated, particularly at the start of long-term NSAID therapy. Eradication of H pylori prior to NSAID treatment does not appear to accelerate ulcer healing or to prevent recurrent ulcers in NSAID users. Some recommendations can be drawn from the results of clinical trials. (Ji, k. ., 2006)

2.18Clinical features of gastro duodenal injury associated with long-term low-dose aspirin therapy.

Low-dose aspirin (LDA) is clinically used for the prevention of cardiovascular and cerebrovascular events with the advent of an aging society. On the other hand, a very low dose of aspirin (10 mg daily) decreases the gastric mucosal prostaglandin levels and causes significant gastric mucosal damage. The incidence of LDA-induced gastrointestinal mucosal

injury and bleeding has increased. It has been noticed that the incidence of LDA-induced gastrointestinal hemorrhage has increased more than that of non-aspirin non-steroidal anti-inflammatory drug (NSAID)-induced lesions. The pathogenesis related to inhibition of cyclooxygenase (COX)-1 includes reduced mucosal flow, reduced mucus and bicarbonate secretion, and impaired platelet aggregation. The pathogenesis related to inhibition of COX-2 involves reduced angiogenesis and increased leukocyte adherence. The pathogenic mechanisms related to direct epithelial damage are acid back diffusion and impaired platelet aggregation. The factors associated with an increased risk of upper gastrointestinal (GI) complications in subjects taking LDA are aspirin dose, history of ulcer or upper GI bleeding, age > 70 years, concomitant use of non-aspirin NSAIDs including COX-2-selective NSAIDs, and Helicobacter pylori (H. pylori) infection. Moreover. It has been shown that the ratios of ulcers located in the body, fundus and cardiac are significantly higher in bleeding patients than the ratio of gastro duodenal ulcers in patients taking LDA. Proton pump inhibitors reduce the risk of developing gastric and duodenal ulcers. In contrast to NSAID-induced gastrointestinal ulcers, a well-tolerated histamine H2-receptor antagonist is reportedly effective in prevention of LDA-induced gastrointestinal ulcers. The eradication of H. pylori is equivalent to treatment with omeprazole in preventing recurrent bleeding. Continuous aspirin therapy for patients with gastrointestinal bleeding may increase the risk of recurrent bleeding but potentially reduces the mortality rates, as stopping aspirin therapy is associated with higher mortality rates. It is very important to prevent LDA-induced gastro duodenal ulcer complications including bleeding, and every effort should be exercised to prevent the bleeding complications. (Iwamoto et al., 2013).

Chapter 3

Methodology

Methodology

3.1 Type of the Study

It was a survey based study.

3.2 Study Population

In this study, lower class people were the study population. The study was carried out on 410 people of difference occupation inside Dhaka city. The places were:

- Gazipur
- Tongi
- Rampura
- Chamur khan
- Kamalapur
- Dhakkin khan
- Abdullah pur
- Uttarkhan

3.3 Inclusion Criteria

- Lower class people
- Both males and females

3.4 Data Collection Method

The data was collected through questionnaire that is formed in English language. It is a questionnaire consists of multiple choice type questions. The data was collected by both face to face interview and by questionnaire supply.

After explaining the purpose of the study to the respondents and obtaining their verbal consent, the researcher interviewed all the respondents by asking questions in Bangla and their prescriptions consisting of list of drugs prescribed with their dosing schedule.

3.5 Development of the Questionnaire

The questionnaire was developed based on different findings in available journal and research paper. Also from the observation of different behavior of Bangladeshi lower class people and how they take drugs how they use drugs and how they collect drugs.

3.6 Sampling Technique

In this study random sampling was followed.

3.7 Data collecting period

The duration of data collection was about five months that started from October, 2016 up to March, 2017.

3.8 Data Analysis

After collecting, all the data were checked and analyzed with the help of Microsoft Excel 2010.

Chapter 4

Results

4.1 People of different Gender.

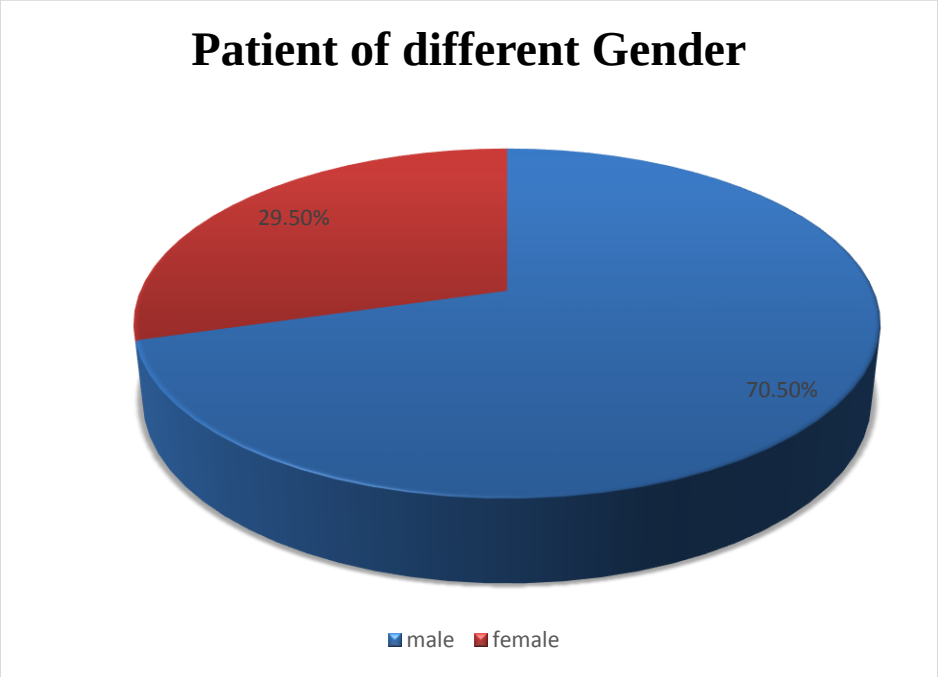

Figure 4.1: Graphical Representation of lower class Patients according to gender.

In this survey about 29.50% people are female and 70.50% people are male.

4.2 Percentage of Age distribution.

Age	Percentage
10-20	7.25%
20-30	30.50%
30-40	37.75%
40-50	16.50%
50-60	8%

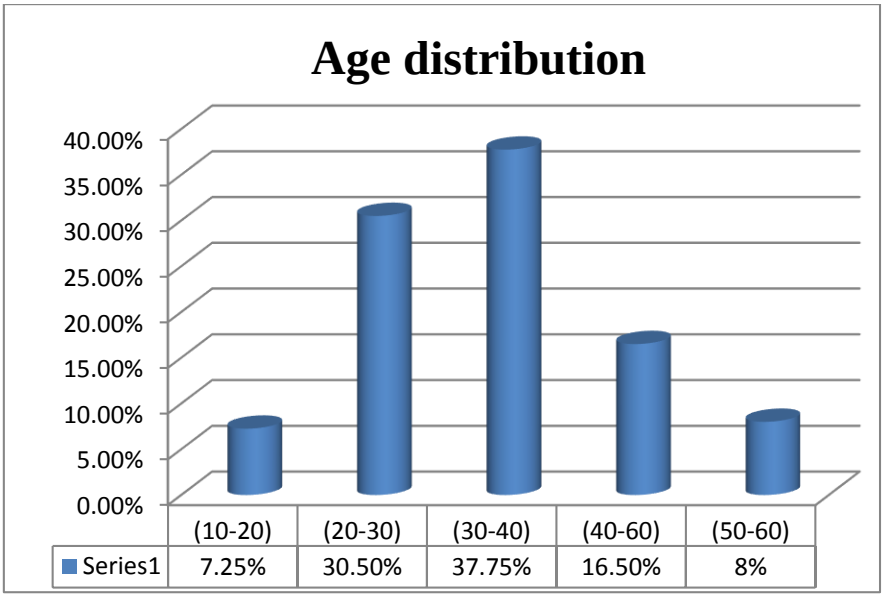

Figure 4.2: Graphical Representation of age distribution.

4.3 Percentage of Occupation distribution.

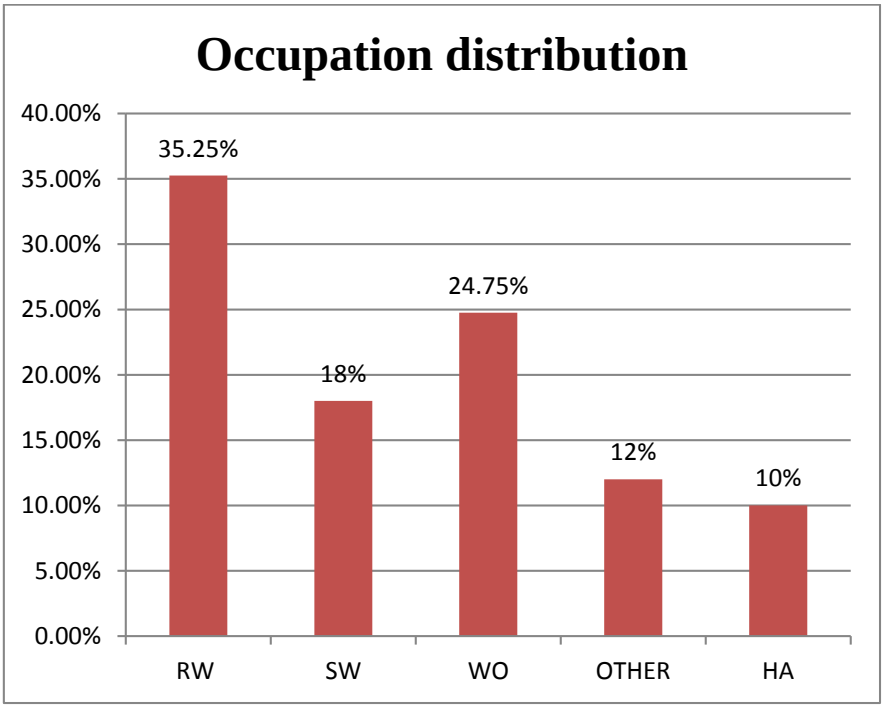

Figure 4.3: Graphical Representation of occupation distribution.

In this study there are about 35.25% people are rishka puller, 18% people are sweeper, 24% worker, and 12% other and 10% people are hoker.

4.4 Percentage of source of treatment.

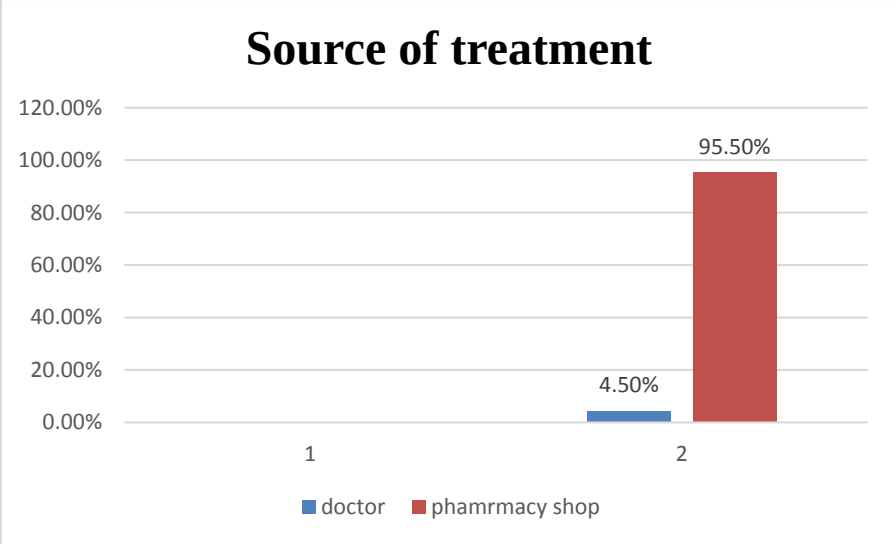

Figure 4.4: Graphical Representation of source of treatment.

In this study, about 95.50% lower class people are take their treatment from pharmacy shop and 4.50% are going to the doctor for treatment.

4.5 Pattern of treatment.

Pattern	**Percentage**
With prescription	6.80%
Without prescription	93.20%

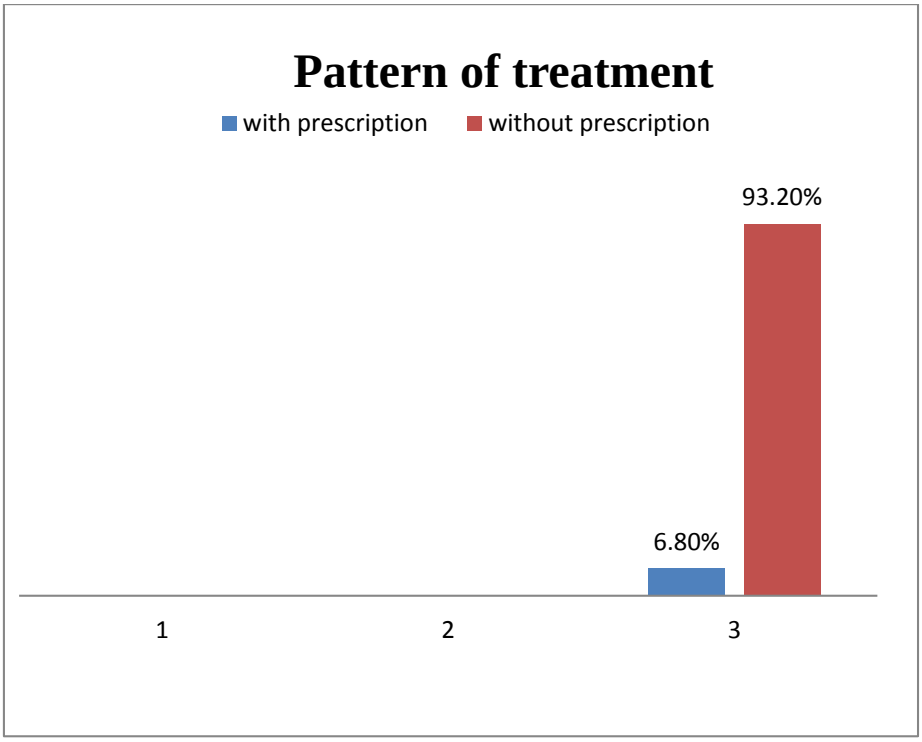

Figure 4.5: Graphical Representation of pattern of treatment.

4.6 Percentage of Use of various Omeprazole.

Used brand	**Percentage**
Seclo	33.50%
Losectil	37.25%
Stoseck	20%
Other	9.25%

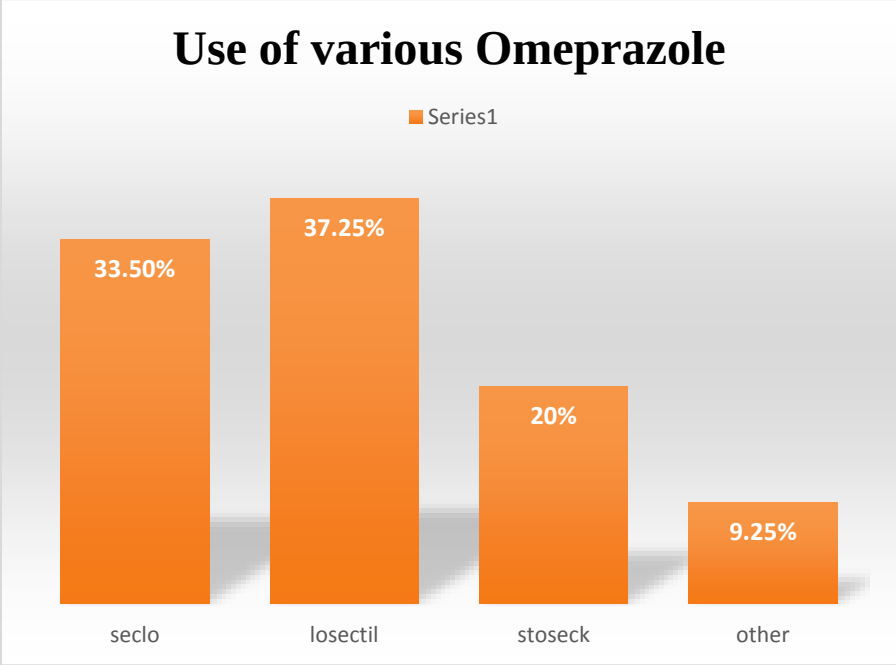

Figure 4.6: Graphical Representation of use of various Omeprazole.

4.7 Number of time dose taken (Omeprazole).

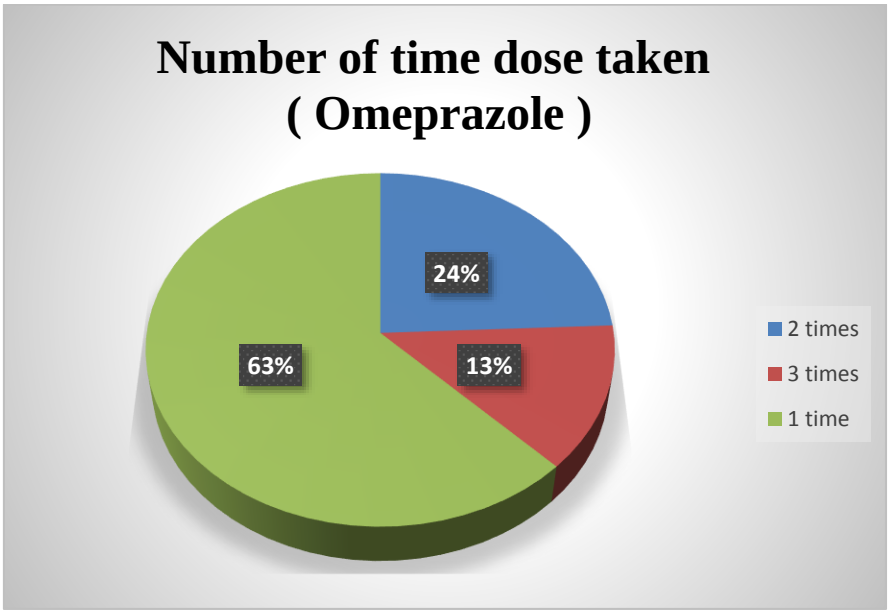

Figure4.7: Graphical Representation of number of time dose taken (Omeprazole).

In this study there are about 63% people take Omeprazole 1 time in a day, 24% people take 2 times and 13% people take 3 times in a day.

4.8 Severe pain in stomach in Omeprazole users (over dose).

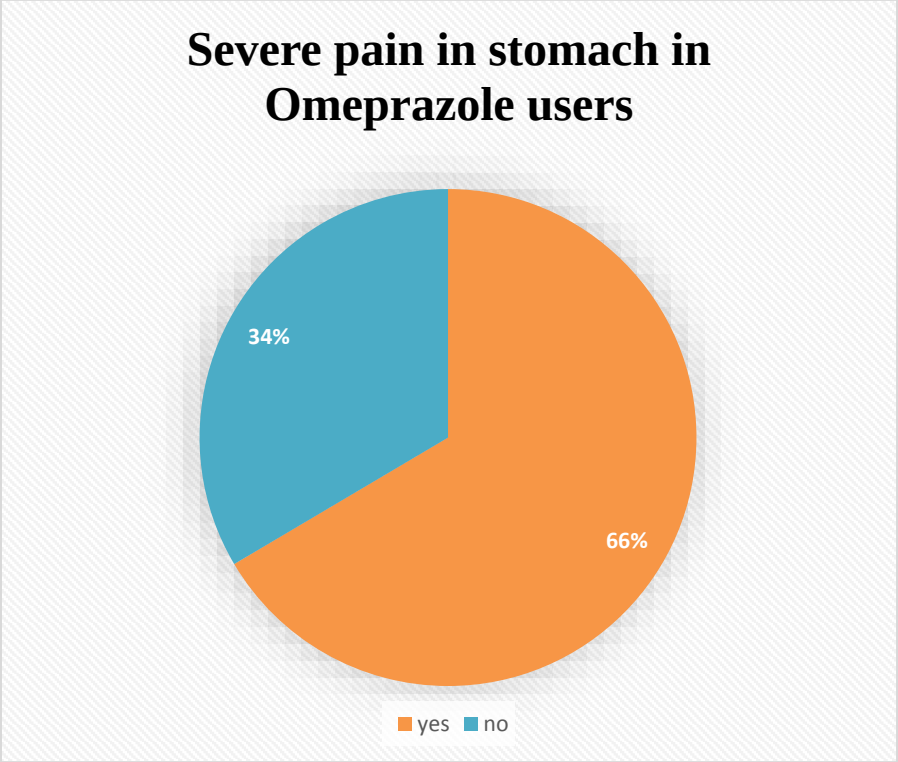

Figure 4.8: Graphical Representation of Severe pain in stomach in Omeprazole users (over dose).

In this study there are 66% people have severe pain in stomach in Omeprazole users (over dose) and 34% people have no problem.

4.9 Use of different dosage form of Clozapine.

Brand (clozapine)	Percentage
Clon	10.42%
Rebortin	38.54%
Disopen	50%

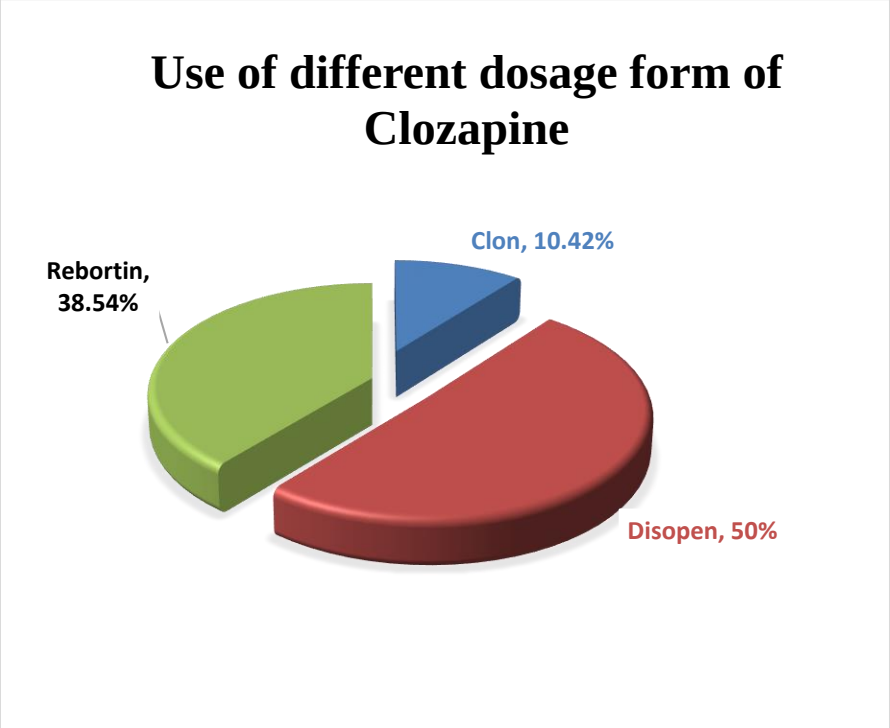

Figure 4.9: Graphical Representation of use of different dosage form of Clozapine.

4.10 Constipation in Clozapine users.

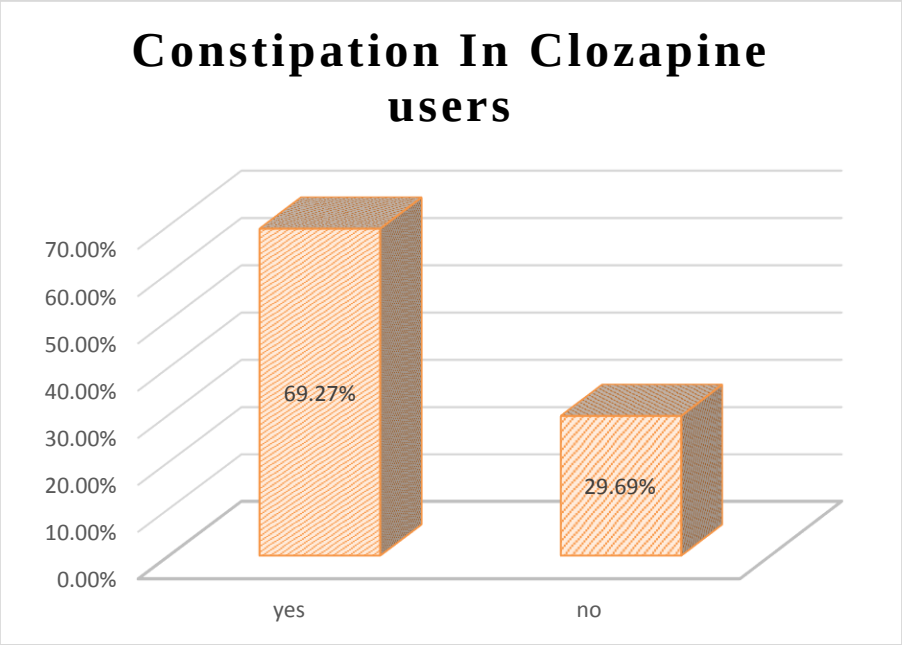

Figure 4.10: Graphical Representation of Constipation in Clozapine users.

In this survey, about 69.27% people face constipation in Clozapine users and 29.69% people are not face constipation.

4.11 Weight gaining in Clozapine users.

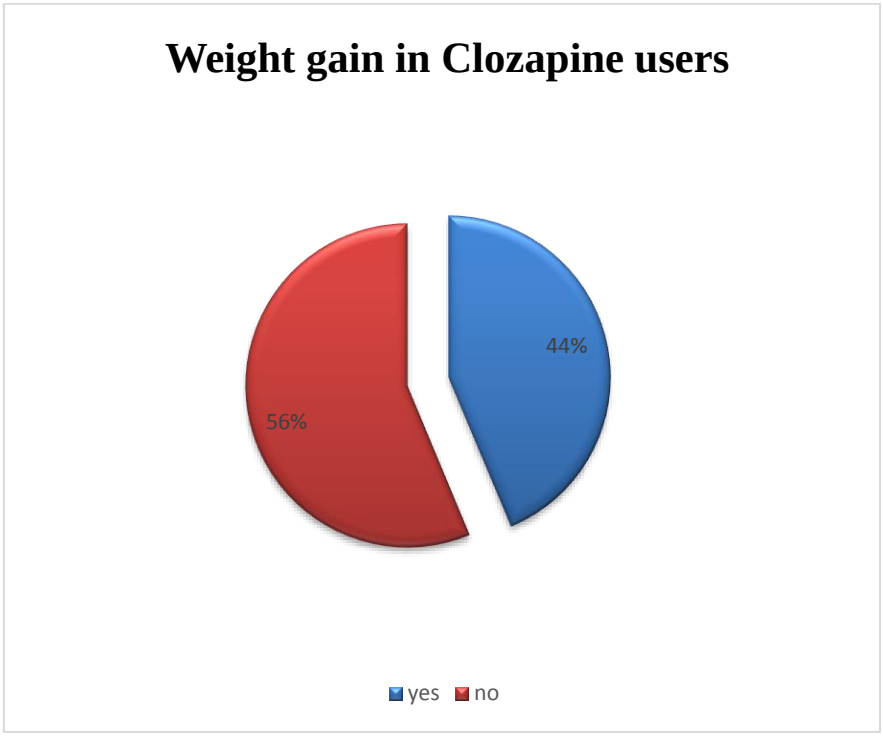

Figure 4.11: Graphical Representation of weight gain in Clozapine users.

In this study about 56% people are face weight gain and other 44% people are not face weight gain due to use Clozapine.

4.12 Use of various brands of NSAIDs.

Used brands	Percentage of people
Paracetamol	38%
Aspirin	17.75%
Dichlofenac	14%
Ibuprofen	17.25%
Naproxen	13%

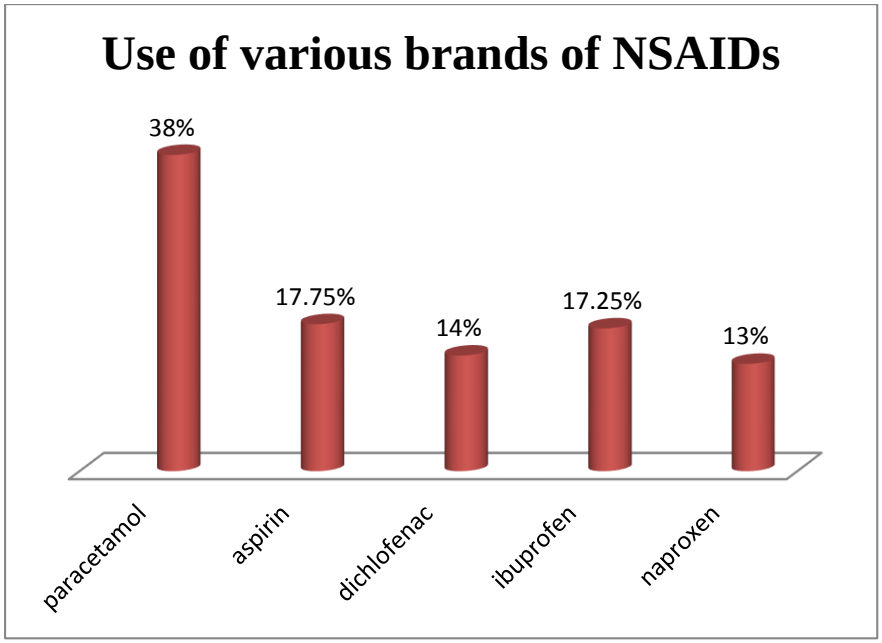

Figure 4.12: Graphical Representation of use of various brands of NSAIDs.

4.13 Percentage of people Know about NSAIDs.

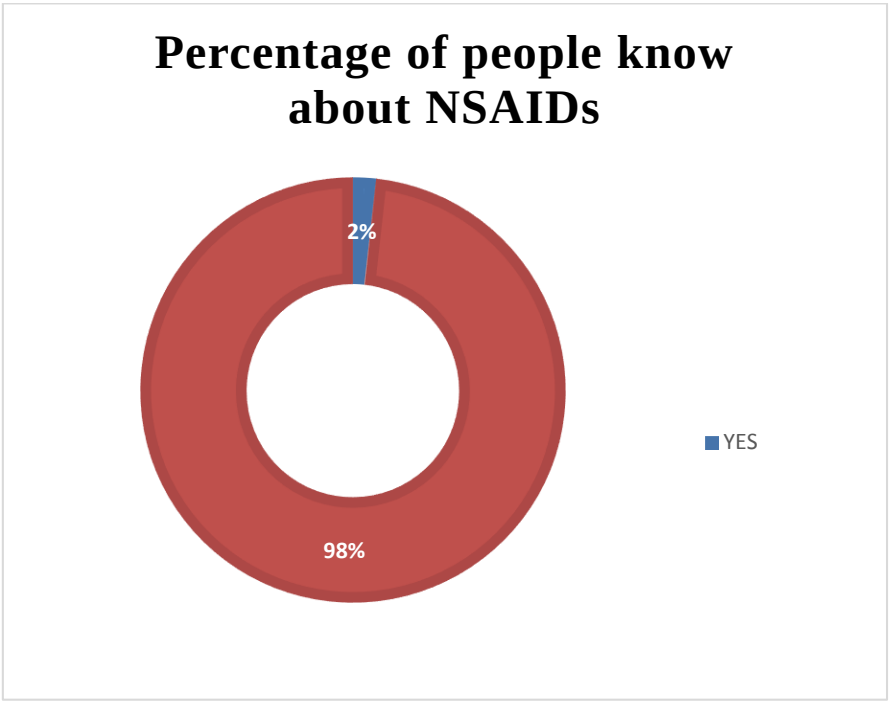

Figure 4.13: Graphical Representation of percentage of people Know about NSAIDs.

About 2% people know about NSAIDs and about 98% people don't know about this.

4.14 Adverse effects in NSAIDs users.

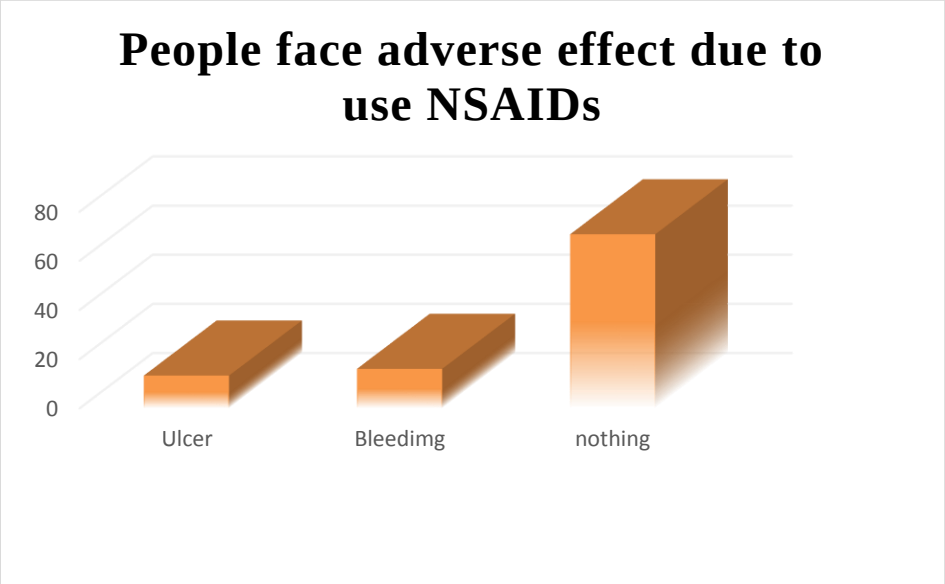

Figure 4.14: Graphical Representation of people face adverse effect due to use NSAIDs.

In this study there are about 13.25% people have ulcer, 16% people are face bleeding and 70.75% people face nothing in NSAIDs users.

4.15 Percentage of people use Ciprofloxacin.

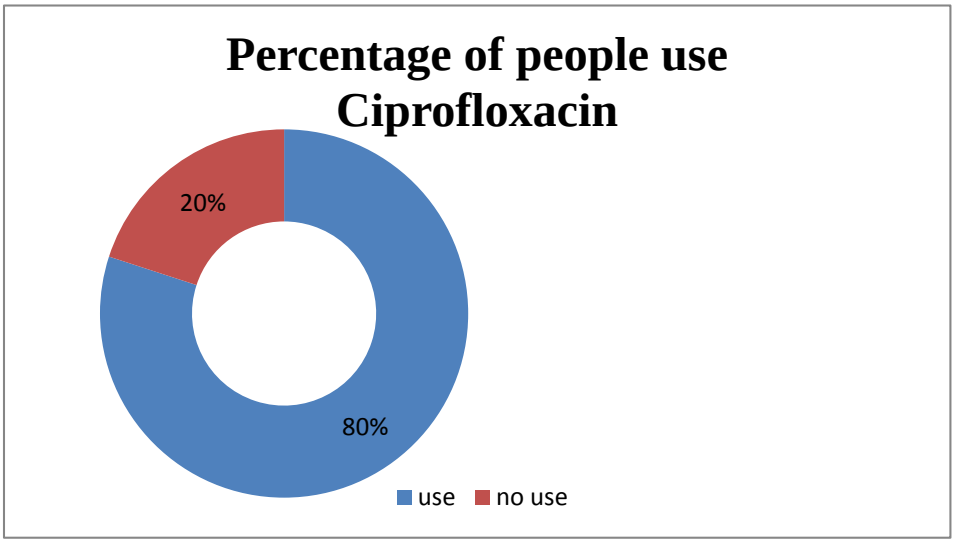

Figure 4.15: Graphical Representation of percentage of people use Ciprofloxacin.

In this study about 80% people use ciprofloxacin and 20% people are not use Ciprofloxacin**.**

4.16 Use of brands of Ciprofloxacin.

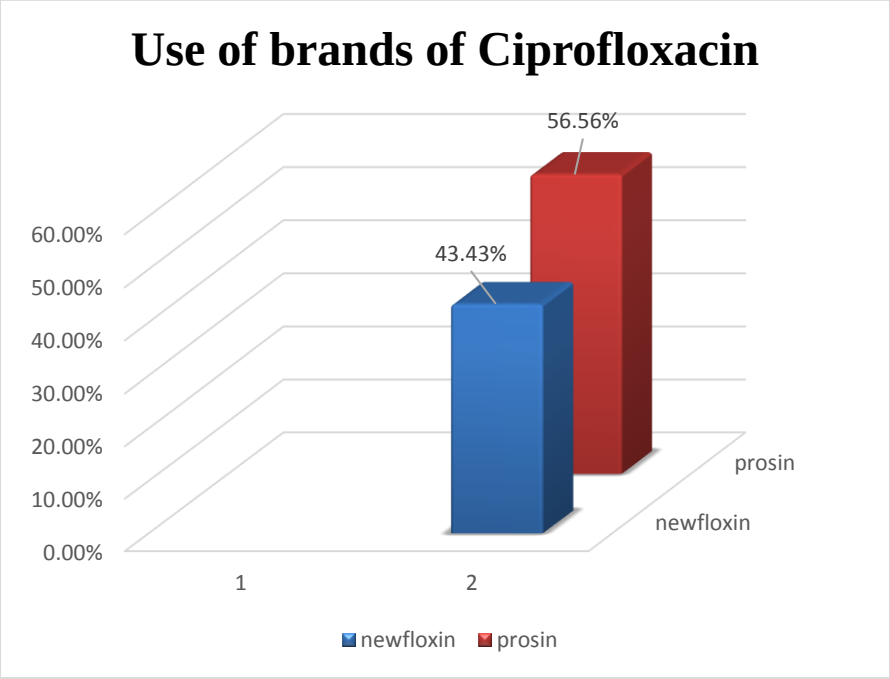

Figure 4.16: Graphical Representation of use of brands of Ciprofloxacin.

4.17 Percentage of people complete dose of Ciprofloxacin.

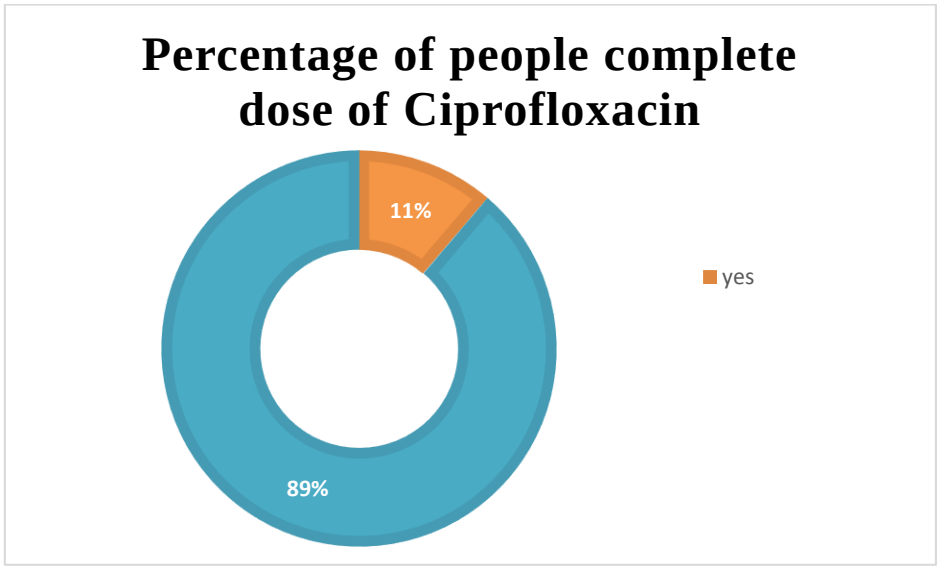

Figure 4.17: Graphical Representation of percentage of people complete dose of Ciprofloxacin.

About 11% are complete the dose of antibiotic and 89% are not complete.

4.18 Percentage of people use various brands of Metronidazole.

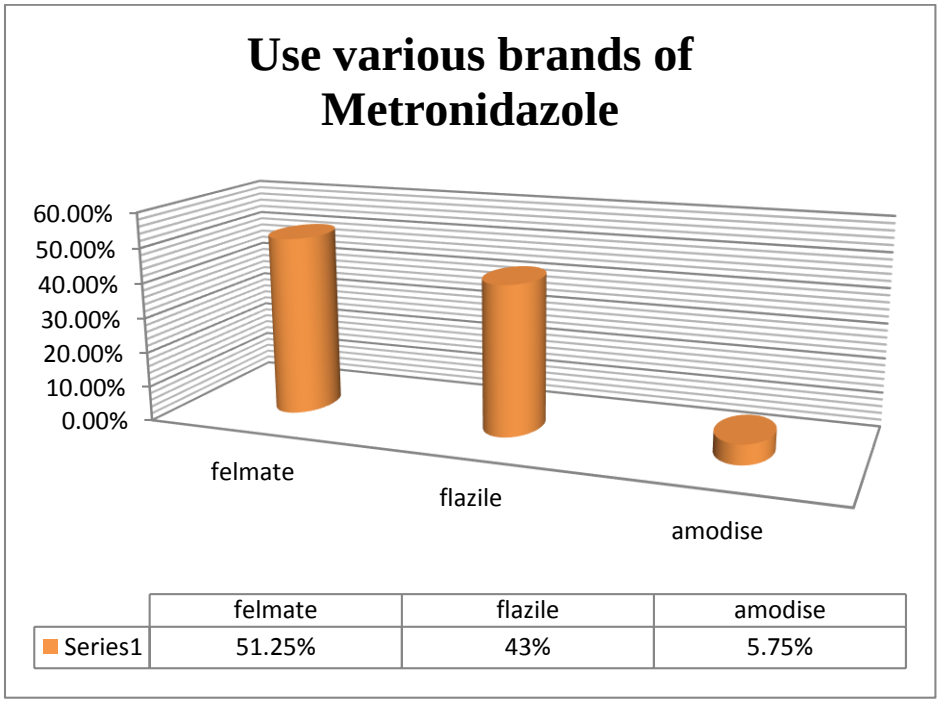

Figure 4.18: Graphical Representation of percentage of people use various brands of Metronidazole.

4.19 Constipation in Metronidazole users.

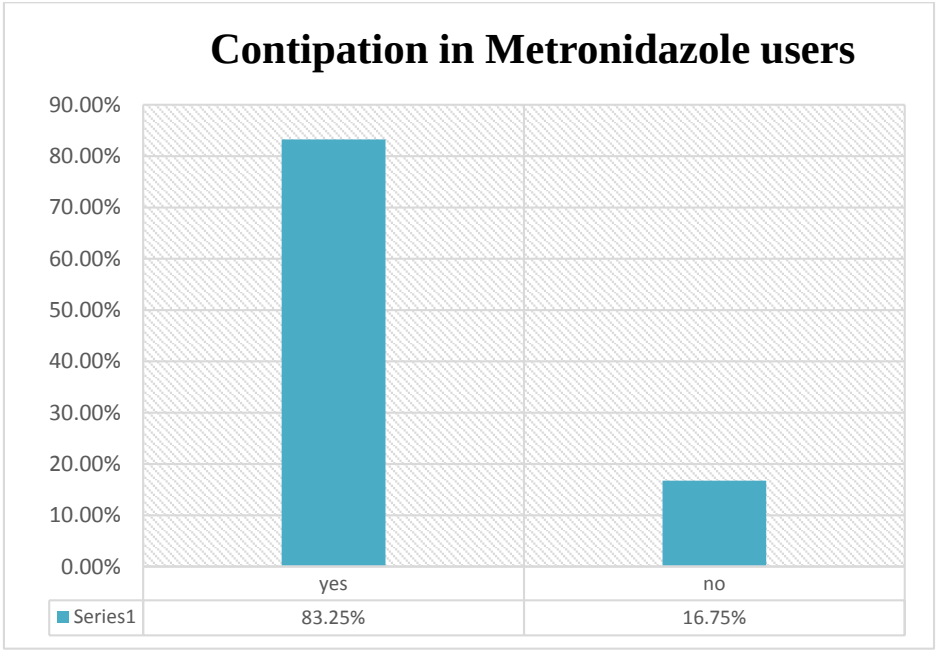

Figure 4.19: Graphical Representation of People face constipation in Metronidazole users.

4.20 Liver disease in Metronidazole users (over dose).

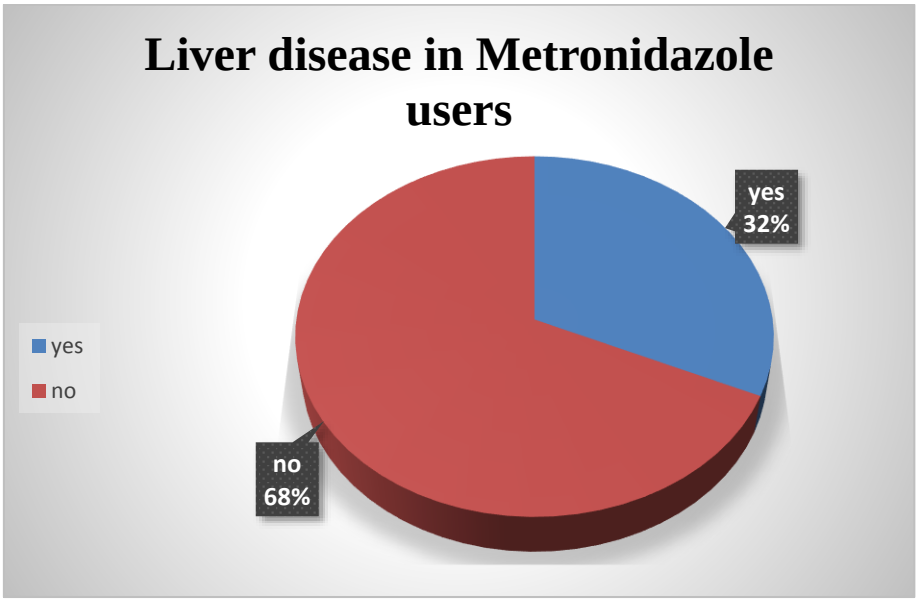

Figure 4.20: Graphical Representation of people face liver disease in Metronidazole users (over dose).

4.21 Anemia in Metronidazole users (over dose).

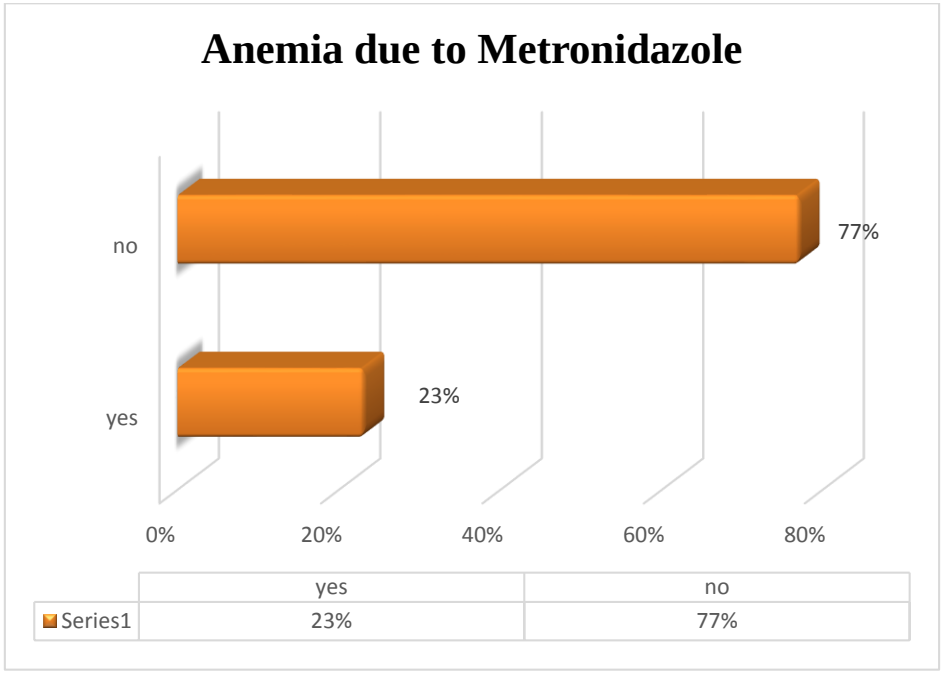

Figure 4.21: Graphical Representation of people face anemia in Metronidazole users (over dose).

About 23% People have anemia in Metronidazole users (over dose) and 77% people have no anemia.

4.22 Various use of dosage form of Antacids.

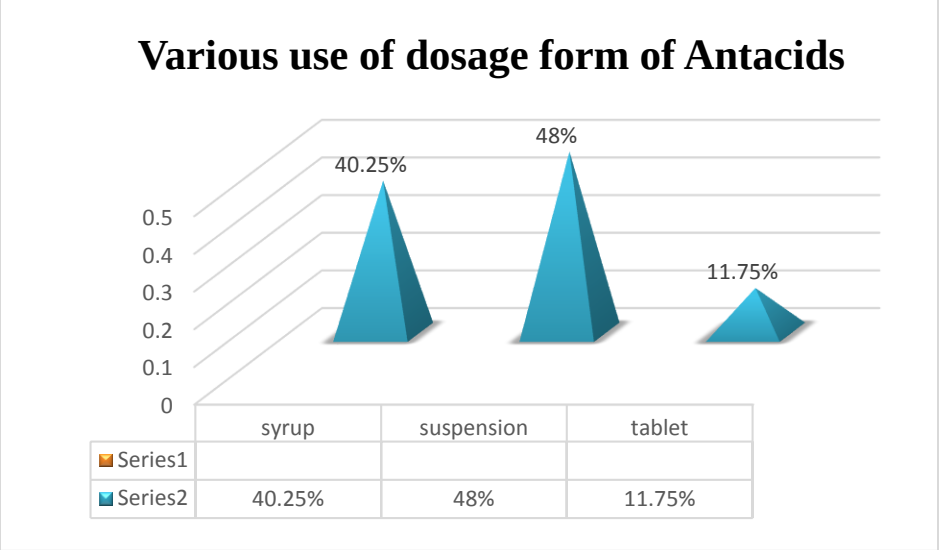

Figure 4.22: Graphical Representation of people various use of dosage form of Antacids.

4.23 Side effects profile of Antacids either hallucination, constipation, kidney disorder in Antacid users.

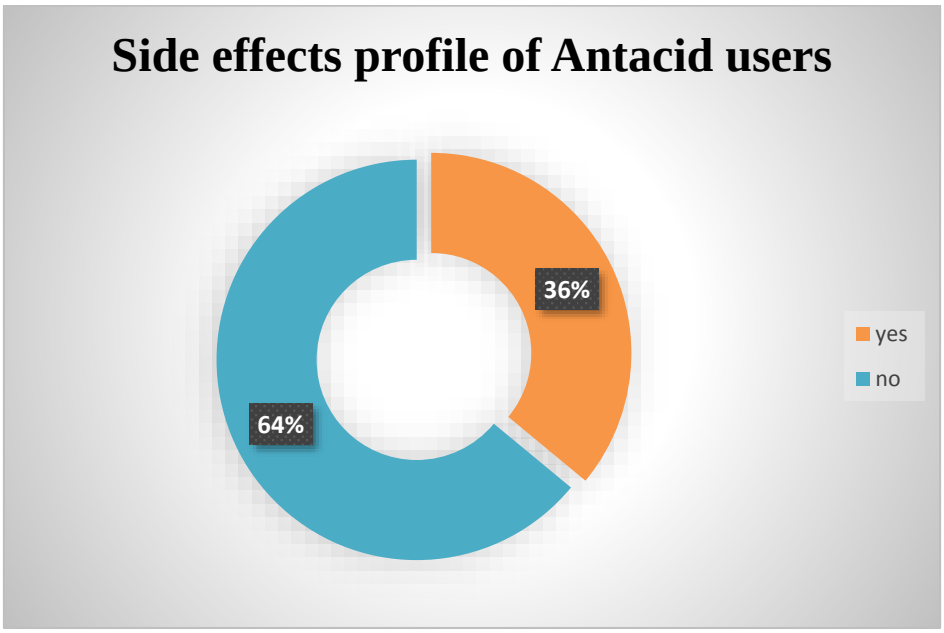

Figure 4.23: Graphical Representation of people side effects profile of Antacids users.

4.24 Percentage of people use Magaldrate.

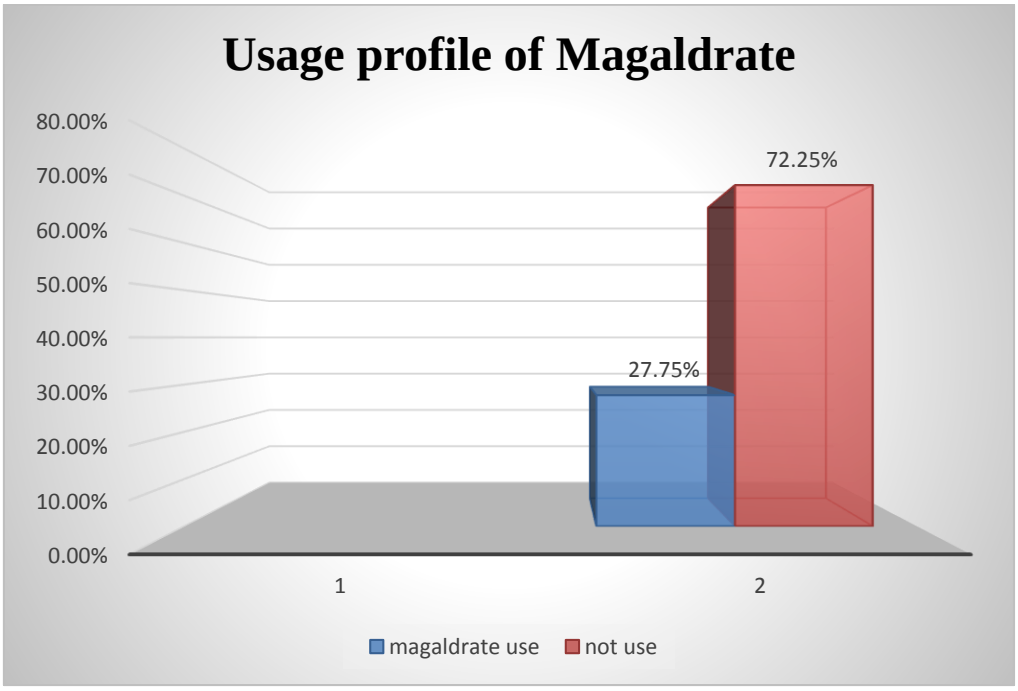

Figure 4.24: Graphical Representation of people percentage of people use Magaldrate.

4.25 Hallucination in Magaldrate users.

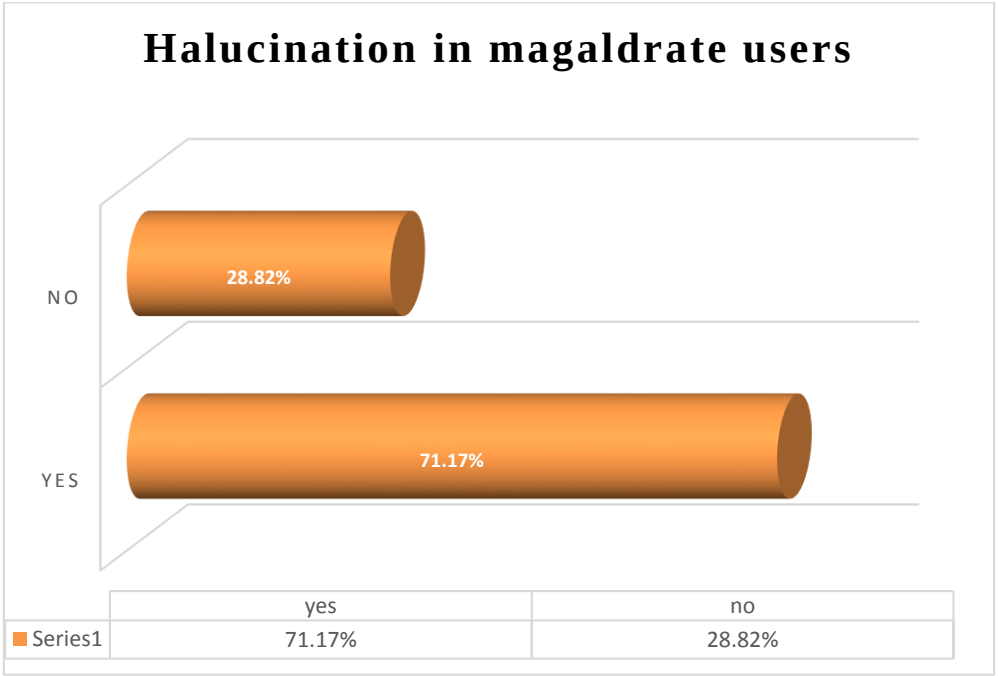

Figure 4.25: Graphical Representation of people faced hallucination in Magaldrate users.

4.26 Side effects (diarrhea) due to Cimetidine.

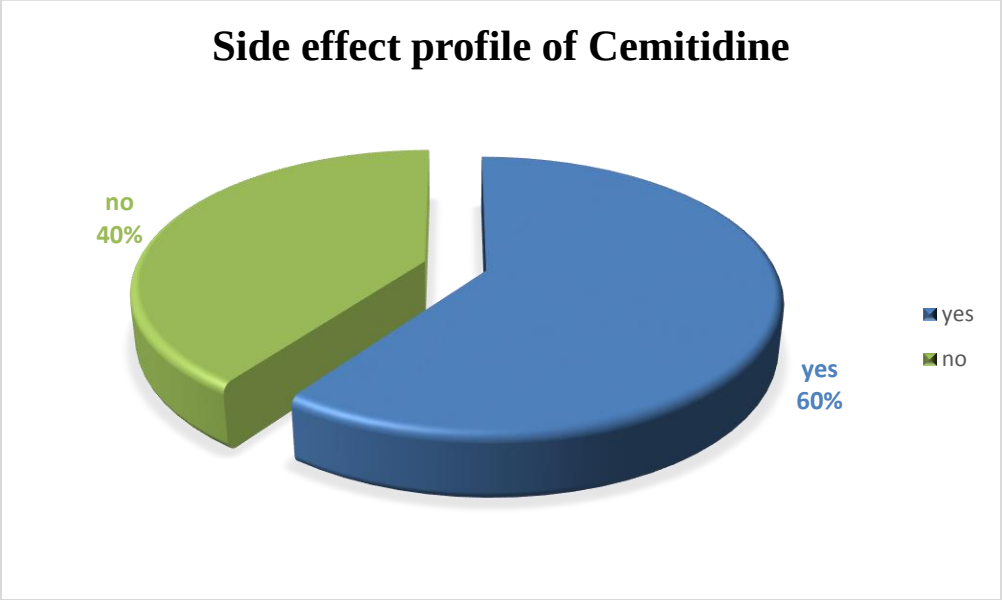

Figure 4.26: Graphical Representation of people side effects (diarrhea) due to Cimetidine.

4.27 What are the people doing when they miss the dose (Cimetidine).

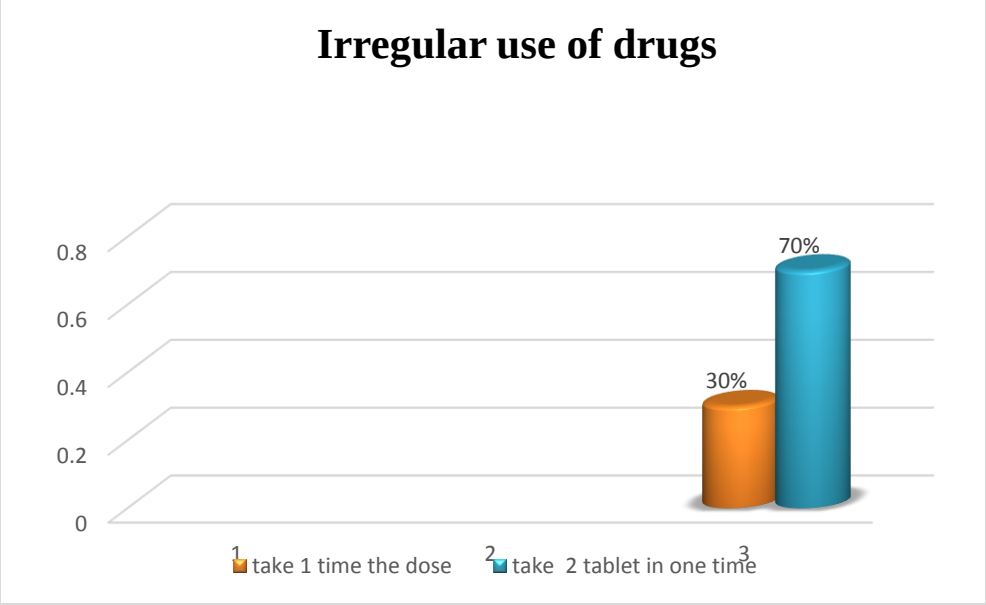

Figure 4.27: Graphical Representation of people irregular use of drugs.

4.28 Smoking profile of the observed people.

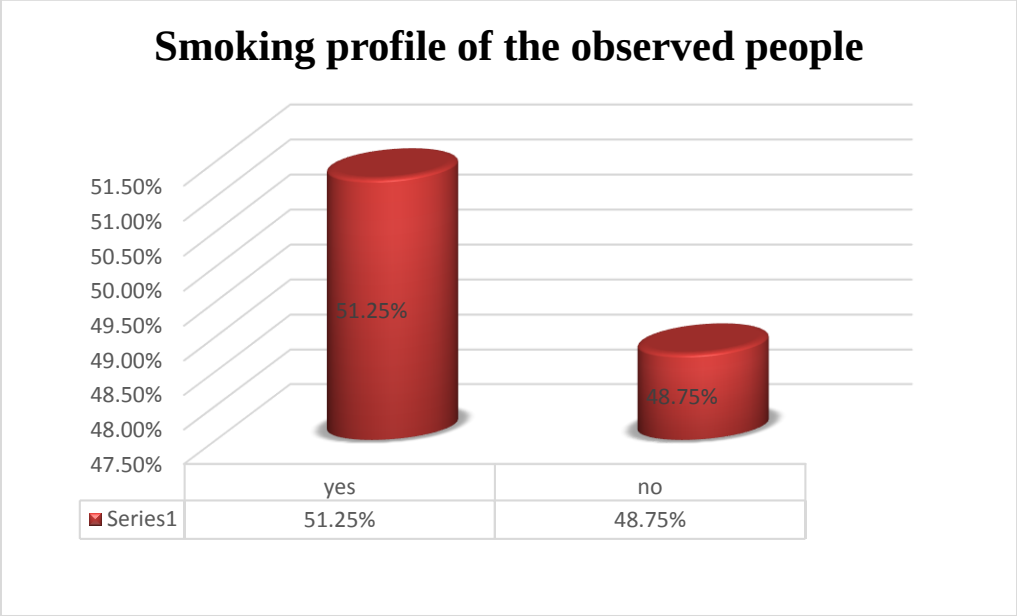

Figure 4.28: Graphical Representation of people Smoking profile of the observed people.

4.29 After using these GIT drugs (without prescription) which are the common side effects and there Percentage.

Side effects	Percentage
Nausea	69.5%
Vomiting	64.75%
Fever	49.5%
Abdominal pain	55.25%
Problem of vision	14%
Kidney disease	7.25%
Dry ness of mouth	28%

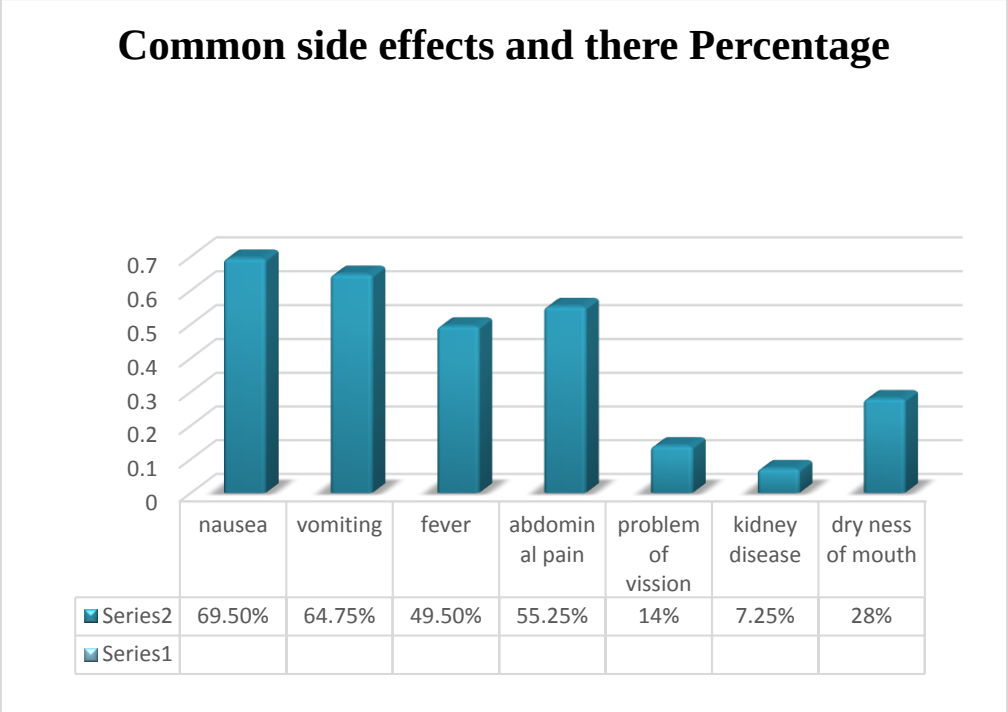

Figure 4.29: Graphical Representation of people common side effects and there Percentage.

Chapter 5

Discussion

5.1 Discussion

Gastrointestinal tract (GIT) disease is an important problem in lower class people in Bangladesh. Because of the unhealthy food and unhealthy environment of the lower class people in Bangladesh.

The objective of this study is to get a picture of overall condition of the GIT disease, the drug's side effects profile which are using for GIT disease without prescription. And thereby get more accurate measures to minimize the occurrence. The result are obtained in this study are correlated with each other and by establishing a relationship among these give a better picture to make a suitable decision with lower class people in Bangladesh. The results are:

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people about 29.50% people were female and 70.50% people were male. And all the people are earn less than 10000 in a month.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 7.75% were within (10-20) years, 30.5% were within (20-30) years, 37.75% were within (30-40) years, 16.5% were (40-50) years, and 8% were (50-60) years old.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 35.25% were rishkaw puller, 18% were sweeper, 24.75% were worker, 10% were hoker, and 12 were other types of occupation.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 4.5% were go to the doctor and 95.5% people were go to pharmacy shop for the treatment.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 6.8% were get drugs or treatment with prescription and other 93.2% people were get drugs or treatment without prescription.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people, they were using Omeprazole and 24.25% people were take 2 times, 13.25% people were take 3 times, 66.5% were facing take Omeprazole at 1 time in a day. There were 66.5% were facing severe pain in stomach and 33.5% were not facing the pain in Omeprazole users.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 48% people were using Clozapine. In the clozapine users 69.27% faced constipation and 29.68% did not face constipation. And 43.22% people were giving positive answer for weight gain in clozapine users.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people, they used NSAIDs in various conditions. The percentage of using Paracetamol and aspirin is respectively 38% and 17.75%. The most important information about NSAIDs is just 1.75% were know about NSAIDs and 98.25% did not know about NSAIDs. In the NSAIDs users 13.25% were facing problem like ulcers.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 80% were used Ciprofloxacin and 20% did not used Ciprofloxacin, among that 43.43% used newfloxin. The important information is 11.25% people completed the dose and 88.75% did not complete the dose of ciprofloxacin.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people used various brands of Metronidazole. 51.25% used Felmate, 43% used Flazile and 5.75% used Amodise. A very important information is in Metronidazole users, 83.25% people faced constipation, 31.75% faced liver disease and 23% people have anemia.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people used various brands of Antacids, 36% were facing constipation, kidney disease in antacids users.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people about 27.75% used Magaldrate for constipation, 71.17% were face various problem like hallucination.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people used Cimetidine or Ranitidine and 60% faced diarrhea and 70% people were not maintain the accurate frequency of the dosage form.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people 51.25% were smoker and 48.75% were not smoker.

From the present study among the 400 lower class people in Bangladesh it was seen that among 400 people, they faced many common side effects due to use drugs without prescription which is treated for various GIT disease or problems. 69.5% faced nausea, 64.75% faced vomiting, 49.5% faced fever, 55.25% faced abdominal pain, 28% faced dryness of mouth, 14% faced problem of vision, and 7.75% faced kidney disease.

Chapter 6

Conclusion

6.1 Conclusion:

The result of this study confirm that, the prevalence of using GIT drugs without prescription in lower class people in Bangladesh is a frequent problem. From this study it also reveals that, the inadequate knowledge of people about the side effects of drugs, and the result of using drugs without prescription. The results of using drugs without prescription and without consulting with doctor are very dangerous to health. Because of the low earning, it's very difficult to consulting doctor for lower class people in Bangladesh. And also the retailers are serving drugs to the people without prescription which is a very important problem in Bangladesh. Adequate health education to stop this unsavory practice needs to be mounted while efforts should be made to make qualitative health care readily available. Heath care providers should educate people on the dangers of self-medication or using drugs without prescription. Such messages should be extended to the community at large periodically by government health care.

Chapter 7

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