

Awareness among Patients Regarding Adverse Drug Reaction upon taking Analgesics

A dissertation submitted to Department of Pharmacy, East West University, in Partial
fulfillment of the requirements for the Degree of Bachelor of Pharmacy

Submitted by

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June, 2017



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Declaration by the Research Candidate

I, **Sadia Afroz**, ID: 2013-3-70-021, hereby declare that the dissertation entitled — “**Awareness among Patients Regarding Adverse Drug Reaction upon taking Analgesics**” submitted by me to the Department of Pharmacy, East West University and in the partial fulfillment of the requirement for the degree Bachelor of Pharmacy, under the supervision and guidance **Ms. Farah Shahjin**, Senior Lecturer, Department of Pharmacy, East West University, Dhaka.

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Acknowledgement

At first, I would like to thank the almighty —ALLAH! the most gracious and merciful for enabling me to successfully complete my research work soundly and orderly.

I would like to express my deepest gratitude to my research supervisor, **Ms. Farah Shahjin**, Senior Lecturer, Department of Pharmacy, East West University, who has always been optimistic and full of passion and ideas. Her generous advice, constant supervision, intense support, enthusiastic encouragements and reminders during the research work not only helped shape this study but also moulded me into being a better researcher. Her in-depth thinking, motivation, timely advice and encouragement have made it possible for me to complete this research.

I put forward my most sincere regards and profound gratitude to **Chairperson Dr. Shamsun Nahar Khan**, Associate Professor, Department of Pharmacy, East West University, for his inspiration in my study. She also paid attention for the purpose of my research work and extending the facilities to work.

I want to give special thanks to **Md. Shakilur Rahman, Md. Delowar Hossain, Tahrina Haque, Mst. Sharmin Sultana** and my all friends, who gave me support for my research work and for their extended cooperation for my study.

I express my sincere thankfulness to my family for guiding me all through my life, including that for my research project.

During the course of this research work, a lot of experiences I have received in which is of inestimable value for my life.

DEDICATION

This research work is dedicated to my parents, husband, honorable
faculties and loving friends.

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List of Abbreviation

| Abbreviation | Full form |
|---------------------|--------------------------------------|
| NSAID | Non-steroidal anti-inflammatory drug |
| ADR | Adverse drug reaction |
| COX | Cyclooxygenase |
| PG | Prostaglandin |
| FDA | Food and Drug Administration |

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Abstract

Analgesics are used by people very frequently. Analgesics are mostly used as pain killer. Doctors suggest various type of analgesics. The objective of this study was to determine the knowledge and awareness of patients regarding adverse drug reaction with analgesics. The present study was designed and conducted to establish a basic understanding on the level of gap of knowledge and awareness of the patients about the adverse drug reaction and side effect of analgesics. 145 were included in this study. Men and women both were participated in this study. The age of the respondents were between thirty and sixty and above. No patient has any medical or health science related background. They were interviewed with a questionnaire from this study we see that most of the people are unaware and have very poor knowledge about the adverse drug reaction and side effect of the drug. There were also self-medication tendency among some of the patients. Even most of the doctors discuss about the possible side effects and other indication of the drug but the patient most of the time do not follow them properly. It is very important to raise awareness among the people regarding adverse drug reaction and side effect of the medication. According to the Bangladesh perspective majority of the population do not know about the ADR and side effects. We need to take adequate steps to raise awareness among the population about adverse drug reaction and their management.

CHAPTER ONE
INTRODUCTION

Introduction:

1.1 Overview:

Non-steroidal anti-inflammatory drugs (NSAIDs) are used by millions of people worldwide to neutralize pain, fever and inflammation. The easy access to NSAIDs and the universality of utilization amongst people worldwide brings about the notion that NSAIDs are without adverse effects. Due to this universality of thinking, diagnosing and treating the patient displaying acute or chronic complications after NSAID employment has become a serious problem in today's medicine. One of most common side effects of NSAID overconsumption is gastrointestinal tract injury. This is signaled by abdominal pain, heartburn, nausea, as well as dyspepsia, and results in gastroduodenal lesions, bleeding, and gastroduodenal mucosa damage .Beyond this, NSAID misuse can lead to very serious hematological complications such as aplastic and hemolytic anemia, or thrombocytopenia. It should, as well, be noted that systemic side effects can be expressed. Among these are headaches and dizziness, insomnia, shortness of breath and palpitations .Hence, patients experiencing the complications caused by NSAIDs frequently require costly and prolonged treatment.

1.2 Adverse Drug Reaction:

Adverse drug reactions can be considered a form of toxicity; however, toxicity is most commonly applied to effects of over ingestion (accidental or intentional) or to elevated blood levels or enhanced drug effects that occur during appropriate use (e.g., when drug metabolism is temporarily inhibited by a disorder or another drug). Because all drugs have the potential for adverse drug reactions, risk-benefit analysis (analyzing the likelihood of benefit vs risk of ADRs) is necessary whenever a drug is prescribed.

Side effect is an imprecise term often used to refer to a drug's unintended effects that occur within the therapeutic range. (MSD Manual Professional Edition, 2017)

Incidence and severity of adverse drug reactions vary by patient characteristics (e.g., age, sex, ethnicity, coexisting disorders, genetic or geographic factors) and by drug factors (e.g., type of drug, administration route, treatment duration, dosage, and bioavailability). Incidence is higher with advanced age and polypharmacy. ADRs are more severe among the elderly although age per se may not be the primary cause. The contribution of prescribing and adherence errors to the incidence of ADRs is unclear.

1.2.1 Classification of ADRs:

1.2.2 Type A (Augmented):

These are predictable, common and pharmacological action of drug.

- Toxicity of overdose (e.g.: hepatic failure with high dose of paracetamol),
- Side Effects (e.g.: sedation with Antihistamines),
- Secondary effects (e.g.: development of diarrhea with antibiotic therapy due to altered gastrointestinal bacterial flora)
- Drug Interaction (e.g.: Theophylline toxicity in the presence of erythromycin therapy).

1.2.3 Type B (Bizarre Effects):

These are unpredictable, uncommon, usually not related to the pharmacological action of the drug.

- Intolerance (e.g.: tinnitus with use of aspirin)
- Hypersensitivity: immunological reaction (e.g.: anaphylaxis with penicillin administration)
- Pseudoallergic: non-immunological reaction (e.g.: radio contrast dye reaction)

- Idiosyncratic Reaction (e.g.: development of Anemia with the use of antioxidant drugs in the presence of glucose 6-phosphate dehydrogenase deficiency).

1.2.4 Type C (Chronic):

These reactions are associated with long term drug therapy (eg: Benzodiazepine dependence and analgesic neuropathy).

1.2.5 Type D (Delayed):

These reactions refer to carcinogenic and teratogenic effects. These reactions are delayed on onset and is time related (e.g.: diethylstilbesterol taken by women can cause vaginal and other reproductive organ damage in female offspring).

1.2.6 Type E (Ending of Use):

This occurs when a drug was suddenly stopped a long term used drug, the patient suffers from a withdrawal reaction (e.g.: rebound hypertension following sudden cessation of clonidine).

1.2.7 Type F (Failure of treatment):

It is a common dose related and often results from ineffective treatment of drug.

1.2.8 Type G (Genotoxicity):

Many drugs can produce genetic damage in humans. Notably some are potential carcinogenic and genotoxic.

1.2.9 Type H (Hypersensitivity reaction):

These reactions are side effects caused by allergy or hypersensitivity, they are probably the most common adverse reaction after type A. They are not pharmacologically predictable and dose dependent. Accordingly dose reduction does not leads to amelioration of symptoms, so the drug must be stopped.

1.2.10 type U (Unclassified):

Some ADRs have a mechanism that's not understood and these must remain unclassified until more is known about them.

1.2.11 ADRS ARE ALSO CLASSIFIED IN TERMS OF SEVERITY, CAUSALITY AND PREVENTABILITY

| Severity | Definitions |
|----------|---|
| Minor | No antidote, therapy or prolongation of hospital required. |
| Moderate | Change in drug therapy, specific treatment or an increase in hospitalization by at least one day. |
| Severe | Potentially life threatening cause permanent damage or require intensive care. |
| Lethal | Directly or indirectly contributed to death of patient. |

(ljpsr.com, 2017)

1.3 Sign and Symptoms

Adverse drug reactions are usually classified as mild, moderate, severe, or lethal. Severe or lethal ADRs may be specifically mentioned in black box warnings in the physician prescribing information provided by the manufacturer.

Symptoms and signs may manifest soon after the first dose or only after chronic use. They may obviously result from drug use or be too subtle to identify as drug-related. In the elderly, subtle ADRs can cause functional deterioration, changes in mental status, failure to thrive, loss of appetite, confusion, and depression.

1.4 Treatment

- Modification of dosage
- Discontinuation of drug if necessary
- Switching to a different drug

For dose-related adverse drug reactions, modifying the dose or eliminating or reducing precipitating factors may suffice. Increasing the rate of drug elimination is rarely necessary. For allergic and idiosyncratic ADRs, the drug usually should be discontinued and not tried again. Switching to a different drug class is often required for allergic ADRs and sometimes required for dose-related ADRs.

1.5 Prevention

Prevention of adverse drug reactions requires familiarity with the drug and potential reactions to it. Computer-based analysis should be used to check for potential drug interactions; analysis should be repeated whenever drugs are changed or added. Drugs and initial dosage must be carefully selected for the elderly. If patients develop nonspecific symptoms, ADRs should always be considered before beginning symptomatic treatment.

1.6 Analgesics:

Analgesics, also known as painkillers, are a class of drugs that are generally used to reduce or relieve pain, an unlikable emotional and sensory experience in a human body linked with potential or actual tissue damage, or expressed in terms of such damage. The term "Analgesic" is derived from two Greek words – (1) an ("without") and (2) algos ("pain").

In other words, an analgesic is a medicinal agent, which relieves or reduces pain by heightening the threshold level in a body, without hampering consciousness or varying other sensory modalities. In short, therapeutic substances that diminish or reduce pain are termed as analgesics.

1.6.1 Classification of Analgesics

Drugs that are included in analgesics work in diverse ways to diminish or relieve pain. They act mainly on the central and peripheral nervous system. There are two classes of oral analgesics in general: Non-opioid and opioid analgesics. Non-opioid analgesics include paracetamol and non-steroid anti-inflammatory drugs (NSAIDs).

a) Narcotic / Opioid Analgesics:

The narcotic analgesics are the agents that cause sleep or loss of consciousness (narcosis) in conjunction with their analgesic effect. In other words, drugs that directly act on central nervous system (CNS) to relieve pain are termed as narcotic analgesics. In addition, the term narcotic becomes associated with the addictive properties of opioids and other CNS depressant agents. The opiates and the derivatives of opiates (i.e. opioids) are the most frequently used narcotic analgesics. For this reason, in United States, these analgesics are also known as opioid analgesics (e.g. morphine, codeine, pathedine, etc).

Opioid analgesics act on the body's peripheral and central nervous systems to block or decrease sensitivity to pain. Most of the opioid analgesics are prescription-only medicines and are suitable for moderate to severe pain, particularly of visceral origin. They can be further classified into two categories: mild and potent opioids. Mild opioid analgesics include codeine and tramadol. Strong opioid analgesics such as morphine and methadone are mainly used to treat cancer pain. Repeated administration of opioid analgesics may cause dependence, which means that when you stop taking them you may feel unwell due to withdrawal of the drug.

b) Non-narcotic analgesics / Non- Opioid Analgesics:

Non-opioid analgesics include paracetamol and non-steroid anti-inflammatory drugs (NSAIDs). Paracetamol is an over-the-counter medicine, whereas most of the NSAIDs are prescription-only medicines and should be used strictly under doctor's instruction and recommendation. Non-opioid analgesics are the first choice analgesics for treating mild to moderate pain and are also used in moderate to severe pain to potentiate the effects of opioids. There would be no dependence and tolerance with these drugs. The non-narcotic analgesics act peripherally on the nervous system to reduce pain. Excluding the analgesic effect, the non-narcotic analgesics usually have two other properties (antipyretic and anti-inflammatory effects). Unlike narcotic analgesics, drugs of this class do not cause physical dependencies and narcosis. However, most of the drugs in this class are gastric irritant. For this reason, physicians generally recommend an antacid or anti-ulcerent when prescribing these drugs.

c) Paracetamol: It relieves pain only and unlike NSAIDs, it does not have any anti-inflammatory actions. It works by blocking the production of the chemicals called prostaglandins, making the body less aware of the pain or injury. Paracetamol has relatively fewer side effects and is less irritable to the stomach. However, overdose may lead to liver damage.

The non-narcotic analgesics act peripherally on the nervous system to reduce pain. Excluding the analgesic effect, the non-narcotic analgesics usually have two other properties (antipyretic and anti-inflammatory effects). Unlike narcotic analgesics, drugs of this class do not cause physical dependencies and narcosis. However, most of the drugs in this class are gastric irritant. For this reason, physicians generally recommend an antacid or anti-ulcerent when prescribing these drugs. (Drugoffice.gov.hk, 2017)

1.7 NON-STEROIDAL ANTIINFLAMMATORY DRUGS (NSAIDS):

The non-steroidal antiinflammatory drugs (NSAIDs) are widely used for the treatment of minor pain and for the management of edema and tissue damage resulting from inflammatory joint disease (arthritis). A number of these drugs possess antipyretic activity in addition to having analgesic and antiinflammatory actions, and thus have utility in the treatment of fever. Most of these drugs express their therapeutic actions by inhibition of prostaglandin.

1.7.1 Most commonly used NSAIDs:

1. Aceclofenac
2. Naproxen
3. Indomethacin
4. Ketorolac
5. Ibuprofen
6. Sulindac
7. Eterocoxib

1.7.2 NSAID Mechanism of Action:

The major mechanism by which the NSAIDs elicit their therapeutic effects (antipyretic, analgesic, and anti-inflammatory activities) is inhibition of prostaglandin (PG) synthesis. Specifically NSAIDs competitively (for the most part) inhibit cyclooxygenases (COXs), the enzymes that catalyze the synthesis of cyclic endoperoxides from arachidonic acid to form prostaglandins (see Prostaglandin Chapter). Two COX isoenzymes have been identified: COX-1 and COX-2. COX-1, expressed constitutively, is synthesized

continuously and is present in all tissues and cell types, most notably in platelets, endothelial cells, the GI tract, renal microvasculature, glomerulus, and Jack DeRuiter, Principles of Drug Action 2, Fall 2002 2 collecting ducts. Thus COX-1 is important for the production of prostaglandins of homeostatic maintenance, such as platelet aggregation, the regulation of blood flow in the kidney and stomach, and the regulation of gastric acid secretion. Inhibition of COX-1 activity is considered a major contributor to NSAID GI toxicity. COX-2 is considered an inducible isoenzyme, although there is some constitutive expression in the kidney, brain, bone, female reproductive system, neoplasias, and GI tract. The COX-2 isoenzyme plays an important role in pain and inflammatory processes.

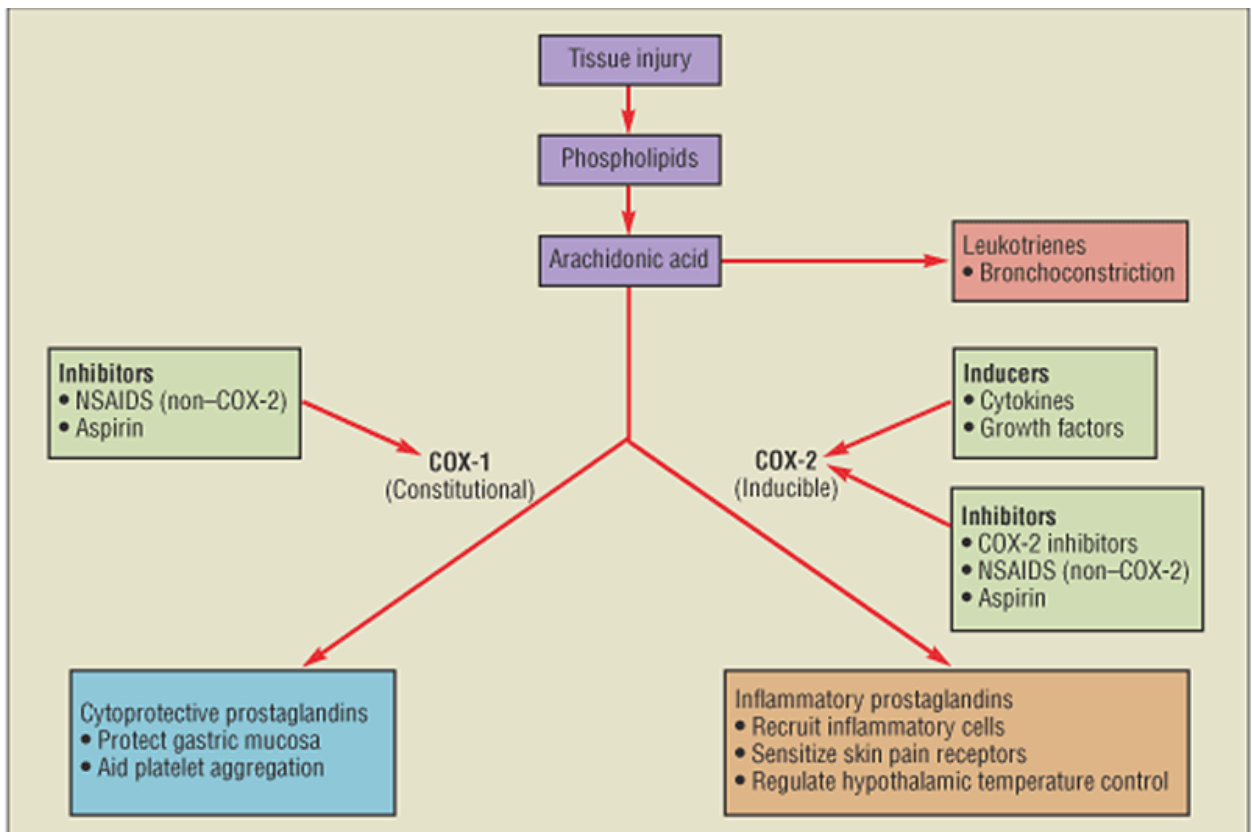


Figure: Mechanism of action of NSAID.

Generally, the NSAIDs inhibit both COX-1 and COX-2. Most NSAIDs are mainly COX-1 selective (eg, aspirin, ketoprofen, indomethacin, piroxicam, sulindac). Others are considered slightly selective for COX-1 (eg, ibuprofen, naproxen, diclofenac) and others may be considered slightly selective for COX-2 (eg, etodolac, nabumetone, and meloxicam). The mechanism of action of celecoxib and rofecoxib is primarily selective inhibition of COX-2; at therapeutic concentrations, the COX-1 isoenzyme is not inhibited thus GI toxicity may be decreased. Other mechanisms that may contribute to NSAID anti-inflammatory activity include the reduction of superoxide radicals, induction of apoptosis, inhibition of adhesion molecule expression, decrease of nitric oxide synthase, decrease of proinflammatory cytokine levels (tumor necrosis factor- α , interleukin-1), modification of lymphocyte activity, and alteration of cellular membrane functions. Central analgesic activity has been demonstrated in animal pain models by some NSAIDs such as diclofenac, ibuprofen, indomethacin, and ketoprofen. This may be because of the interference of prostaglandin (PGE₁, F₂ and F_{2a}) mediated pain formation or with transmitters or modulators in the nociceptive system. Other proposals include the central action mediated by opioid peptides, inhibition of serotonin release, or inhibition of excitatory amino acids or N-methyl-D-aspartate receptors. NSAIDs are mainly effective against the type of pain in which PGs sensitize pain receptors (inflammation and tissues) including the pain of arthritis, bursitis, pain of muscular and vascula origin and dysmenorrhea. The effectiveness of these agents against headache may result from their ability to inhibit PG-mediated cerebral vascular vasodilation. Antipyretic activity of NSAIDs results from inhibition of prostaglandin E₂ (PGE₂) synthesis in Arachidonic Acid NSAID COX circumventricular organs in and near the preoptic hypothalamic area. Infections, tissue damage, inflammation, graft rejection, malignancies, and other disease states enhance the formation of cytokines that increase

PGE2 production. PGE2 triggers the hypothalamus to promote increases in heat generation and decreases in heat loss.

1.7.3 Other Actions of the NSAIDs:

The NSAIDs also express a variety of other actions in addition to their antiinflammatory, analgesic and antipyretic activities as outlined below

: • GI Tract (N/V, ulceration and hemorrhage). In the gastric mucosa, prostaglandins play a cytoprotective role inhibiting the proton pump and thereby decreasing gastric acid synthesis, stimulating the production of glutathione that scavenges superoxides, promoting the generation of a protective barrier of mucous and bicarbonate, and promoting adequate blood flow to the gastric muscosal cells. Since NSAIDs block PG biosynthesis in the GI tract, they block these cytoprotective processes. The primary toxicity seen with the NSAIDs is GI irritation which may lead to the production of ulcers when used in large doses over a long period of time. This occurs quite frequently in patients with RA and it may become so severe that the drug must be discontinued. There have been a number of attempts to eliminate this side effect and some success has been achieved but since most of the compounds suppress the production of PGs involved in limiting the secretion of gastric acid and since this a consequence of their mechanism of action it has been difficult to completely eliminate this side effect. In addition to inhibition of PG biosynthesis, NSAID gastric irritation may also be due to a direct irritation of the gut by these acidic compounds

- CNS: High NSAID doses cause CNS stimulation (confusion, dizziness, etc), tinnitus, etc. PGE2 may also cause fever via interactions within the hypothalamus

- Respiratory: Direct and indirect (increased CO₂ production) stimulation of respiratory centers, stimulation of O₂ consumption in muscle (increased CO₂); respiratory alkalosis. Also PGI₂ and the PGEs cause bronchodilation while PGF_{2a}, PGGs, PGH₂, PGD₂ and TxA₂ are bronchoconstrictors (asthma)
- Acid-Base: Initial respiratory alkalosis. This is generally somewhat unique to the salicylates and is only seen with large doses.
- Cardiovascular: PGH₂ and PGH₂ cause transient vasoconstriction, but these intermediates are converted to PGI₂ and other PGS (PGD₂ PGF_{2a}) which are vasoconstrictors. At high doses NSAIDs cause vasodilation and depression of the vasomotor center.
- Uterus: PGF_{2a} and PGE₂ (in low concentrations) promote uterine contraction while PGI₂ and PGE₂ in high concentrations promote uterine relaxation. NSAIDs decrease contractility and prolong gestation
- Blood clotting: PGS I₂ (vascular endothelium), E₂ and D₂ inhibit platelet aggregation while TXA₂ (platelets) promotes aggregation. NSAIDs may significantly increase clotting times and can be used for prophylaxis of thromboembolism and MI. However, patients with liver damage, vitamin K deficiency, hypoprothrombinemia or hemophilia should avoid aspirin Jack DeRuiter, Principles of Drug Action 2, Fall 2002 4 therapy
- Renal: The inhibition of PGE₂ and PGI₂ both of which produce vasodilation in the kidney results in a decrease blood flow to the kidneys due to constriction of afferent arterioles which is mediated by norepinephrine and Angiotensin II. NSAIDs may decrease sodium and fluid elimination resulting in edema

- **Reye's syndrome:** This is seen in children who take an NSAID such as aspirin while recovering from mild viral infection. Although it occurs rarely there is a 20-30% mortality seen with this type of side effect.

1.7.4 Uses of NSAIDs:

Some of the primary indications for NSAID therapy include:

- **Rheumatoid Arthritis (RA):** No one NSAID has demonstrated a clear advantage for the treatment of RA. Individual patients have demonstrated variability in response to certain NSAIDs. Anti-inflammatory activity is shown by reduced joint swelling, reduced pain, reduced duration of morning stiffness and disease activity, increased mobility, and by enhanced functional capacity (demonstrated by an increase in grip strength, delay in time-to-onset of fatigue, and a decrease in time to walk 50 feet).
- **Osteoarthritis (OA):** Improvement is demonstrated by increased range of motion and a reduction in the following: Tenderness with pressure, pain in motion and at rest, night pain, stiffness and swelling, overall disease activity, and by increased range of motion. There are no data to suggest superiority of one NSAID over another as therapy for OA in terms of efficacy and toxicity. NSAIDs for OA are to be used intermittently if possible during painful episodes and prescribed at the minimum effective dose to reduce the potential of renal and GI toxicity. Indomethacin should not be used chronically because of its greater toxicity profile and its potential for accelerating progression of OA.
- **Acute gouty arthritis, ankylosing spondylitis:** Relief of pain; reduced fever, swelling, redness and tenderness; and increased range of motion have occurred with treatment of NSAIDs.

- **Dysmenorrhea:** Excess prostaglandins may produce uterine hyperactivity. These agents reduce elevated prostaglandin levels in menstrual fluid and reduce resting and active intrauterine pressure, as well as frequency of uterine contractions. Probable mechanism of action is to inhibit prostaglandin synthesis rather than provide analgesia:
 - high temperature or fever
 - inflammation
 - back ache- particularly long-term pain in the lower back
 - cold or flu
 - headaches
 - joint or bone injuries, sprains, and strains
 - muscle or joint complaints
 - toothache

1.7.5 Side effects and adverse drug events:

The most common side effects are:

- vomiting,
- nausea,
- constipation,
- diarrhea,
- reduced appetite,
- headache,
- dizziness,
- rash, and
- Drowsiness.

The adverse events are:

- NSAIDs also may cause swelling of the arms and legs due to the retention of fluid from their renal effects.
- The most serious side effects are ulcers, bleeding, kidney failure, and, rarely, liver failure.
- Individuals allergic to NSAIDs may experience shortness of breath after taking an NSAID and may experience a similar reaction when other NSAIDs are taken.
- People with asthma are at higher risk for experiencing serious allergic reactions to NSAIDs.
- Administering aspirin to children or teenagers with chickenpox or influenza has been associated with Reye's syndrome, a serious and potentially fatal disease of the liver. Therefore, aspirin and salicylates for example, salsalate (Disalcid), should not be used in children and teenagers with suspected or confirmed chickenpox or influenza.

NSAIDs (except aspirin) may increase the risk of heart attacks, stroke, and related conditions, which can be fatal. This risk may increase with duration of use and in patients who have underlying risk factors for disease of the heart and blood vessels. NSAIDs should not be used for the treatment of pain resulting from coronary artery bypass graft (CABG) surgery.

- NSAIDs, particularly non-selective NSAIDs, cause an increased risk of serious, even fatal, stomach and intestinal adverse reactions such as 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 types of reaction.

- Low doses of aspirin, less than 325 mg/day, taken for preventing heart attacks and strokes, also are associated with stomach and intestinal adverse reactions; however, the heart attack and stroke preventing actions of the low doses may compensate for the increased risk of these adverse reactions.

1.8 Patient awareness regarding NSAIDs and their side effects:

Adverse drug reactions as a significant cause of hospital admissions, with aspirin and non-steroidal anti-inflammatory drugs (NSAID) being among the commonest culprits. Upper gastrointestinal (GI) bleeding and perforation are well known common side effects of NSAID. About a third of ulcer bleeding and perforation in elderly patients has been shown to be NSAID related. Wynne and Long showed that many admitted with upper GI bleeding do not know this to be a NSAID side effect, and continue taking the NSAID when bleeding starts. NSAID are widely used in Rheumatology outpatients.

Education of patients about prescribed drugs is becoming an increasingly important aspect of public health care system throughout the world. In a country like India where quacks outnumber the qualified physicians, patients suffer due to lack of knowledge about drugs prescribed to them. There is often a discrepancy between what the patient has been advised and how the patient complies with the given instructions. During recent years lot of attention has been paid to rational use of medicine, but still there are lacunae in educating patients about the prescribed drugs. Non-compliance rates of 30-80% are consistently reported in the literature even in developed countries. One of the important cause of non-compliance is failure of communication between the health care provider and the patient. Scenario gets worse due to poor doctor-patient ratio and towering illiteracy rate.

The patient is supposed to attain the information regarding the prescribed drugs at various levels like at the time of consultation with the doctor, when the patient visits the pharmacist to get the medicine and even after the patient has actually started taking drug.

At the first level i.e., at the time of patient's interaction with the doctor, patient should be informed about the disease, progression of the disease, the drugs patient is supposed to take, lag period required for the benefits of prescribed drug to appear, possible side effects, how to recognize those side effects, how serious these are and what measures should be taken by the patient regarding the disease and side effects. At the second level comes the interaction of the patient with the pharmacist. Here again, patient should be re-enforced about the dosage regimen prescribed by the doctor and if possible, pharmacist should fit it into the patient's daily routine so that the compliance can be improved. In addition, the patient should be informed about the proper storage method of the drug. The third and the last stage is when patient starts taking the medication, where the patient actually needs the practical application of the above information. At this point of time, patient may not be able to recall many things. Here the written information, if given, by the doctor/pharmacist can be of great help. A lot of information to the patient at this stage can be attained by the Patient Package Insert (PPI) or by searching the internet.(Singh et al., 2017)

1.9 Preventable Harm Associated with NSAID Therapy

Optimization of current pain management strategies is necessary in order to reduce medication risks. Promoting patient and healthcare provider education on pain and pain medications is an essential step in reducing inadequate prescribing behaviors and

adverse events. In an effort to raise awareness on medication safety, the FDA has launched the Safe Use Initiative program.

1.9.1 Medication error:

Medication use can result in unwanted adverse reactions that can cause injury and even death. It was documented in 2001 that over 4 million people experienced medication adverse events, which was about 1.5 times the rate observed in 1995. The Institute of Medicine has estimated that 1.5 million preventable adverse events occur every year and up to 50% could have been prevented by the modification of prescribing methods. Certain risks cannot be avoided, and these include unknown risks that do not manifest during the medication development program and unpreventable known side effect risks, which result even if drug administration is executed optimally, that factor in the risk-benefit evaluation during the regulatory review process of innovative medications. Though these risks are of great concern, proper precaution and prescribing methods cannot circumvent or minimize them. FDA's Safe Use Initiative (SUI) focuses on preventable risks that are significant and amenable to implementable interventions that have potential impact and measurable outcomes.

Identifying, describing, and understanding the root cause of significant preventable risks are essential for reducing harm from medications. FDA's SUI describes four main categories of preventable risks: medication errors, unintended/accidental exposure, intentional misuse/abuse, and drug quality defects. Medication errors can also be broken into subcategories: informational errors in prescribing or by patients/consumers, and procedure and process type errors. Procedure type errors are frequent, especially in hospital settings. It was reported that in the ICU individual patients experienced 1.7 medication errors per day. A review of the literature focusing on hospital practices

identified that most medication errors occurred during administration (53%), but they also occurred during prescription (17%), preparation (14%), and transcription (11%). Though the procedural and process type errors are of concern, the major focus of FDA's SUI is informational errors.

1.9.2 Information Errors

Informational errors occur during the different stages of the prescribing process and can be a result of the healthcare worker or patient's limited access to the available knowledge on a particular medication. Examples of such events occur when a physician prescribes an NSAID to a patient with known cardiovascular risk factors; patients "overdose" or intake greater than the recommended dosage because approved therapeutic doses did not relieve the symptoms, or when proper professional monitoring of the patient while on medication is either not feasible or not part of the treatment protocol. More attention to education and awareness among patients, caregivers, and healthcare professionals could reduce or eliminate these errors, and methods to promote education will be discussed later.

Since the launch of the SUI in November of 2009, the FDA met with stakeholders and has held workshops in order to identify areas of preventable harm and discuss how to improve current practices to reduce informational errors. One group of experts convened to address preventable harm associated with pain medication in older adults and identified the prescribing practices of NSAIDs as a therapy where medication errors potentially occur. Treating pain in elderly patients is a complex task, requiring a tailored and patient focused approach to prescribing. Because a "one-size-fits-all" approach is neither beneficial nor safe for this population, physicians need to be properly informed about the factors that increase the odds of harm from this class of medications, risk

profiles of the different NSAIDs, available prescribing guidelines, and available pain management options. Areas of concern related to NSAID use in the elderly are discussed in order to promote awareness of where changes in the current practice might have an impact:

1.9.3 Complexity of the Elderly in Pain Management

The elderly population is normally classified as being greater than 65 years of age. The information provided by the Administration of Aging estimates that by 2030 there will be 72.1 million people over the age of 65 in the United States, which is approximately double what the population was in 2000. Better lifestyles through proper dieting/exercise and more efficient disease management therapies (e.g., surgical/pharmaceutical technology) have contributed to this population rise. Prescribing pain medications within the elderly population requires the skill of a very knowledgeable physician to navigate through the numerous variables (e.g., physiologic changes, comorbid conditions, multiple medications) that make the elderly population a heterogeneous and complex population to treat; Additionally, the lack of evidence-based practices, training, awareness, and thorough understanding of these variables increase the risk of pain medication safety events in an already complex patient.

An initial task during one of the workshops was to identify factors impacting the safe use of pain medications in the elderly. The pathophysiologic profile of older adults significantly changes with age. Decline in organ function, particularly the renal and hepatic functions, which are critical in the clearance of ingested substances, dictates the pharmacokinetic properties of many drugs. In addition, aging patients can experience changes in body fat and water composition. These changes alter the tissue and plasma distributions of many lipophilic and hydrophilic drugs in ways that predispose patients to adverse effects. Decline in the cognitive function is also an area of concern with aging

adults. Impairment of cognitive function can lower medication literacy, which has been associated with a decrease in the likelihood of reading prescription leaflets or additional medication information; a reduction in medication reconciliation (agreement between physicians and patients on what medications are currently being used), patients misinterpreting dosage directions on drug labels, and failure to adhere to verbal counseling by physicians. Physiologic changes that occur with aging increase the incidence and prevalence of many diseases which directly increases the risk of developing a drug-related disease interaction. In 2009, the Administration of Aging reported that almost all of Medicare beneficiaries had at least one morbid condition while approximately 24% had greater than 4 morbid conditions. Common conditions among the elderly population include diagnosed arthritis, hypertension, heart disease, cancer, diabetes, and sinusitis. Comorbidity is associated with polypharmacy, a phenomena where a single person may be prescribed multiple medications from different doctors or by self-prescribing over-the-counter medications (OTCs) for each medical condition present. A general list of medications that many elderly may be on include cardiovascular drugs (thiazide diuretics, (ACE) inhibitors, beta-blockers); antidiabetic drugs (sulfonylureas, thiazolidinediones, and metformin); fluticasone/salmeterol, tiotropium, albuterol, bronchodilators and steroid inhaler, non-sedating antihistamines, and steroid nasal sprays . Depending on the definition of polypharmacy or type of study conducted, anywhere from 13 to 92% of the geriatric population is on more than one drug. Other studies indicate 80% of patients over the age of 65 years have at least one chronic condition while 50% have more than one; this same group uses between 2 to 6 prescribed medications and 1 to 3.4 nonprescription medications on a regular basis . As the number of medications that are taken increases, the risk of adverse drug reactions increases. Patients taking two drugs concurrently have a 13% risk of adverse drug interactions, those taking four drugs have a risk of 38%, and those taking seven or more

drugs have a risk of up to 82%. Another issue that arises from polypharmacy is that it becomes difficult for multiple physicians, pharmacists, and even the patients themselves to keep track of all the medications, thus increasing the odds of drug-drug interactions. Understanding, preventing, monitoring, and treating adverse events in the elderly are difficult tasks. Whether it is just aging in itself and/or the physiologic changes associated with aging, the elderly population is at increased risk of experiencing more adverse events. In the 2011 DAWN report, it was estimated that in 2008 more than 31% of people 65 and older were hospitalized due to a medication adverse event and that patients older than 50 represented 51.5% of all hospitalizations related to adverse events. The challenge is that often it is difficult to discern between the aging process itself, associated comorbidities, and an adverse event that is secondary to drug therapies. Some symptoms such as lethargy, confusion, lightheadedness, falls, constipation, and depression that are observed as side effects of a number of medications are often experienced in elderly patients not on any particular drug. In the dominant climate of evidence-based medicine, there is a general unease regarding how medications affect the elderly population. Even though enrollment of older adults in clinical trials has been occurring since the 1980s, the representation of the “complex” elderly population is limited, rendering optimal evaluation of the benefits and risks of any medication to be a challenging task. Complex elderly people are typically aged 75 and older, have multiple concomitant illnesses, take multiple medications, and have some level of functional decline, cognitive impairment, and limited social support. In addition to homogenous selection process among the elderly for the clinical trials, most clinical trials also require “homogenous” treatment plans. Therefore, it is also hard to evaluate adverse events associated with drug-drug interactions.

1.9.4 Physician Barriers in NSAID Pain Management

The non-steroidal anti-inflammatory drugs have been a mainstay option for chronic pain management for many years. Adverse side effects associated with NSAIDs including gastrointestinal, cardiovascular, renal, and hematological, have been known for a long time. However, introduction of new drugs into the marketplace and the continuous stream of new research data have recently called into question the use and prescribing guidelines of NSAIDs in the elderly, especially “complex” elderly patients

The workshop assembled by FDA’s SUI wanted to determine areas in the prescribing process of NSAIDs that may lead to medication errors and potential injury. Optimal pain management and an increased risk of harm may occur due to “physician barriers”, factors that may hinder or prevent a physician from adequately and safely treating a patient. Prescribing NSAIDs to any patient, especially the elderly, requires knowledge of individual patient risk factors, the ability to assess the benefits and risks of the NSAID, and the responsibility for educating patients and monitoring for effectiveness and side effects of the prescribed NSAID. A recent report demonstrated that more than 50% of patients were not properly informed by a physician or pharmacist on the side effects associated with Rx or OTC NSAIDs. Recent data show that the majority of physicians studied are unaware of potential complications associated with cardiovascular and gastrointestinal systems. NSAID guidelines have been established to increase physician awareness of the complications associated with NSAID use; however, some physicians either do not recognize or do not adhere to such guidelines. A recent survey of physicians identified six major barriers that affected their use of established NSAID guideline. The barriers mentioned were as follows: lack of familiarity with the guidelines, perceived limited validity of the guidelines, and limited applicability of the guidelines to specific patient populations, clinical inertia, anecdotal experiences, and clinical heuristics. The lack of familiarity was attributed to the overwhelming number of published

medical guidelines and difficulties in keeping up to date with new recommendations. In support of this, a search of the literature identified more than 20 different guidelines that mention NSAIDs and the elderly in addition to other highly acclaimed medication risk factor guidelines or tools. In addition to education on NSAIDs, prevention and monitoring mechanisms should also be followed or adhered to appropriately in order to provide additional levels of protection for the patients. For example, in a survey of 615 elderly patients in an outpatient or old age/nursing home setting for the co-administration of an NSAID with a prophylactic product to protect against gastrointestinal side effects, 65.3%, 76.2%, and 42.6% failed to receive necessary prophylaxis in the outpatient, old age, and nursing home settings, respectively, even though treatment for such side effects are documented in well-established guidelines put forth by the American Geriatric Society.

1.9.5 Patient Barriers in NSAID Pain Management

There are also “patient barriers” that might limit the effectiveness of pain treatment or predispose to greater risk of adverse effects. Before taking any type of medication, patients should be fully aware of the risks involved; however, data suggest that current patient education on NSAIDs, in particular side effects and how to manage them, is not adequate. Another study that analyzed 807 NSAID users reported that 54% did not know the side effects associated with NSAIDs; additionally, it reported that 33% believed prescription NSAIDs were safer, 32% believed OTC NSAIDs were safer, 20% believed there was no difference, and 15% did not know. Sixty percent and 29% of exclusive OTC NSAID users were neither aware or did not believe they were at risk of side effects from NSAIDs, respectively.

In addition to being ill-informed on the side effects of taking a single NSAID, patients are also unaware of the consequences of taking multiple NSAIDs or taking NSAIDs for long periods of time. A recent report analyzed responses from rheumatologic pain patients on their knowledge of prescribed NSAID and OTC NSAID risks. Forty-nine percent knew

that taking multiple NSAIDs increased the risks of side effects, 41% were uncertain, and 10% did not believe the claim. Some of the reasons for taking multiple doses of NSAIDs include seeking more or faster relief, experiencing no relief with the recommended dose, or a result of doctor's suggestion. In addition, patients are sometimes unaware of or misinformed by practitioners about other medications that contain NSAIDs, like cold or flu OTC medicines. (Taylor et al. 2017)

Aim of the study

The aim of this study is-

1. To investigate the basic knowledge of patient about the medications,
2. To investigate the awareness of the patients regarding the adverse drug reaction of NSAIDs,
3. To understand self-medication tendencies with NSAIDs among the patients.

CHAPTER TWO
LITERATURE REVIEW

2 Literature review:

2.1 Patient's Knowledge and Perception Towards the use of Non-steroidal Anti-Inflammatory Drugs in Rheumatology Clinic Northern Malaysia

Sulaiman, Seung and Ismailet al, 2017

In Rheumatology, non-steroidal anti-inflammatory drugs (NSAIDs) has been widely prescribed and used. However, despite their clinical benefits in the management of inflammatory and degenerative joint disease, NSAIDs have considerable side effects, mostly affecting the upper gastrointestinal system, which therefore, limit their use. This study was conducted to determine the patients' knowledge and perception regarding the use of NSAIDS. A total of 120 patients who attended the rheumatology clinic Hospital, Raja PermaisuriBainun, Malaysia, and received NSAIDs more than 3 months were interviewed irrespective of their rheumatological conditions. Patient's knowledge and perception on the side effects of NSAIDs were recorded. Fifty-four percent of the patients obtained information regarding the side effect of NSAIDs either from the rheumatologist, rheumatology staff nurse or other medical staffs (75.4%). The remaining 45.8% were naive of such knowledge. Fifteen percent obtained the information by surfing the internet and 9.2% from printed media. This study shows that half of the patients who attended the rheumatology clinic were unaware of the side effect of NSAIDs. Available data showed that most of the knowledgeable patients are more conscience and self-educated. This study also reveals the important roles of clinicians, trained staff nurses as well as the pharmacist in providing the guidance and knowledge of any medication taken by patients.

2.2 A QUESTIONNAIRE BASED SURVEY STUDY FOR THE EVALUATION OF KNOWLEDGE OF PAKISTANI UNIVERSITY TEACHERS REGARDING THEIR AWARENESS ABOUT IBUPROFEN AS AN OVER THE COUNTER ANALGESIC

(Chen J et al, 2017)

In recent time, due to convenient availability of number of over the counter (OTC) drugs, patients are able to treat minor ailments by themselves. The self-medicated regimen has lead to certain health problems in all age groups irrespective of their professions. People are usually unaware about the safe use of NSAIDs (non-steroidal anti-inflammatory drugs) and currently there is no study carried out in COMSATS Institute of Information Technology (CIIT), Abbottabad, regarding the choice of faculty members for NSAIDs to relieve pain and their knowledge about its safety and use. A questionnaire based survey was carried out to collect data about the choice of CIIT faculty for a specific NSAID and their cognition related to ibuprofen. Two hundred fifty faculty members (comprising of 53 pharmacy faculty members and 197 faculty members who belonged to other departments) of which 87 were females, took part in this study. Average age of participants was 34.86 ± 9.02 years. Ibuprofen was the drug of choice NSAID among the participants. It is concluded that a majority of the faculty members (61%) were lacking basic information about the OTC drugs and also they consider ibuprofen as the safest drug having no potential side effects. Thus, there is a need that such people should take health lectures, so that they gain useful information regarding the possible reactions of drugs with food and other drugs, side effects on health and the risk factors.

2.3 Patient awareness of the adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs)

(WYNNE and LONG, 2017)

The study was conducted to determine the extent to which two groups of patients reported having been informed about the adverse effects of NSAIDs. These consisted of 50 patients who had suffered an acute gastrointestinal bleed while taking a NSAID. Only 33% of all patient remembered receiving information about side effects of NSAID. It has been known that many patient feel that not enough information has given about medication and their side effects by the doctors and the pharmacist.67% of the patient was not given any information about the adverse side effect of the drug by the physician or by the pharmacists.

2.4 A survey of patients' knowledge of gastrointestinal side-effects of NSAIDs in a rheumatology clinic

(Gibson et al, 2017)

Non-steroidal anti-inflammatory drugs (NSAIDs) are a common cause of adverse drug reactions (ADRs). For example, a Spanish study showed that NSAIDs were responsible for 8.8% of all ADRs reported, second only to antibiotics.¹ ADRs are also a significant cause of hospital admissions, with aspirin and NSAIDs being among the most common ulprits.^{2,3} Upper gastrointestinal (GI) bleeding and perforation are well-known common side-effects of NSAIDs. In addition to patient morbidity and mortality from ADRs, there is considerable financial burden to the NHS.³ NSAIDs are widely used in rheumatology outpatients and primary care. The prescription cost analysis data for England showed that 24.4 million prescriptions were dispensed in the community for section 10.1 (containing NSAID) of the British National Formulary (BNF) during 2004.⁷ This survey assessed the knowledge of GI side-effects of

NSAIDs in rheumatology outpatients. In total 32 males and 63 females were included. Ages ranged from 20 to 91 years (mean 52.6). The commonest NSAID was diclofenac (38; 40%), followed by ibuprofen (17; 18%). Nine were on an NSAID for 0 to 6 months, 11 from 6 months to 1 year, 29 from 1 to 5 years, 19 for more than 5 years, five for many years (not specified) and 22 not recorded. Seven also took misoprostol, five omeprazole, one lansoprazole, one Rennie's, five ranitidine, one cimetidine and five prednisolone. Seventy-seven were on no other significant medication.

Sixty-one (64.2%) knew the possibility of 'abdominal discomfort', but 34 (35.8%) did not. Thirty-three (34.7%) knew 'vomiting blood' to be a side-effect, 62 (65.3%) did not. Thirty-two (33.7%) knew the side effect of 'black motions', 62 (65.3%) did not, and one (1%) did not comment. Sixty-two (65.3%) would stop if these side-effects occurred, 25 (26.3%) said they would not, and eight (8.4%) did not comment. Eighty-five (89.5%) knew the importance of taking NSAIDs with meals, nine (9.5%) did not, and one (1%) did not comment. Patients also reported a wide variety of information sources. For example, many learnt information from a leaflet enclosed with the medication or from the prescribing doctors.

2.5 Adverse drug reactions of no steroidal anti-inflammatory drugs in orthopedic patients

Gor and Saksena, 2017

The objective was to identify the ADRs due to NSAIDs and to know how to monitor the drug's effect. A descriptive study was undertaken in the Orthopedic Outpatients Department of a tertiary care teaching hospital. Hundred patients were enrolled in this study to observe the risk of adverse drug reactions (ADRs) due to NSAIDs. All the ADRs were further analyzed in relation to age and sex, type of drug and its pattern. Probability scale was used for the causality assessment of the ADRs. 26% of

the 100 patients developed ADR due to NSAIDs. There was not much of a difference in the number of the ADRs in relation to the gender. Diclofenac was the highest prescribed drug (65 patients), followed by paracetamol (12), nimesulide (10), ibuprofen (6), piroxicam (5) and Etoricoxib (2). Diclofenac accounted for the maximum number (73%) of ADRs, followed by nimesulide (16%), paracetamol (7%), and Etoricoxib (4%). Pharmacovigilance improves recognition of ADRs by the medical students. It allows the treating physician to identify the ADR associated with drugs, in particular, with the ones considered relatively safe and with those commonly prescribed by the medical and non-health professionals.

CHAPTER THREE
METHODOLOGY

Methodology

3.1 Type of Study:

It was a questionnaire based survey study.

3.2 Study Area:

The study was conducted in different hospitals in Dhaka city.

3.3 Study Population:

A Total of 120 patient were included in this study and interviewed as per the question.

3.4 Study Period:

The duration of study was January-April 2017.

3.5 Statistical Analysis:

Data will be organized, tabulated and aggregated using Microsoft excel. The result was shown in bar, pie, column and other chart.

Questionnaire (Intentionally kept incomplete)**Demographic Information**

1. Age: _____ 2. Gender: Male Female
3. Education level: Illiterate Primary school certification High school certification /College Graduate or Post graduate
4. Have medical/health science background in education: Yes No

Medical Information

5. Medical condition that requires an analgesic(s): _____
6. Name of the analgesic (s): Brand name _____ Generic name: _____

Knowledge and Awareness information:

9. When prescribed an analgesic, did the doctor discuss the possible side effects?
Yes No
10. Do you read the Patient Information Leaflet (PIL) prior to medicine administration? Yes No
11. Do you self-medicate with analgesics for the medical condition? Yes No
12. What other medication do you take along with the analgesic(s)?

CHAPTER FOUR
RESULTS

4.1 Age Distribution of the respondents:

Table 4.1: Age Distribution

| Age Limit | Total Number | Percentage % |
|------------|--------------|--------------|
| 20-40 | 24 | 16% |
| 40-60 | 78 | 54% |
| 60 & Above | 43 | 30% |

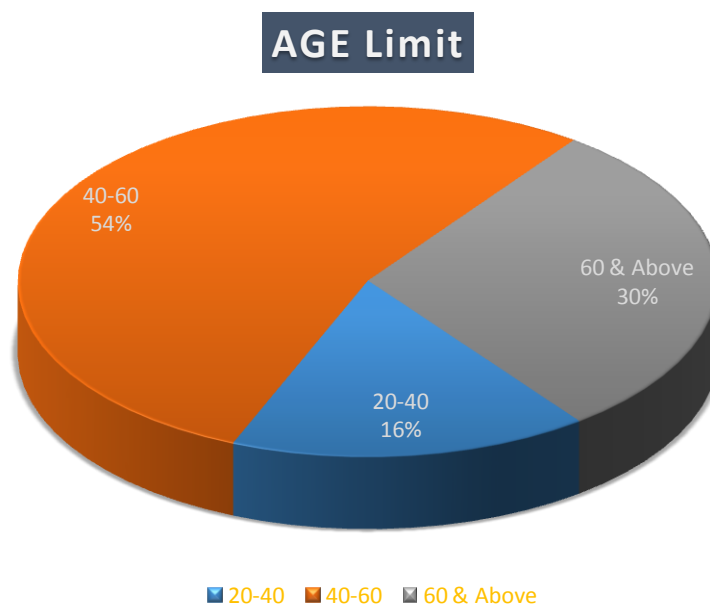


Figure 4.1: Age Limit

Majority of the patients' age is between 40-60 years and patient of 60 years and above.

4.2 Gender Distribution of the respondent.

Table 4.2: Gender Distribution

| Sex | No. of Respondents | Percentage % |
|--------|--------------------|--------------|
| Male | 60 | 41% |
| Female | 85 | 59% |

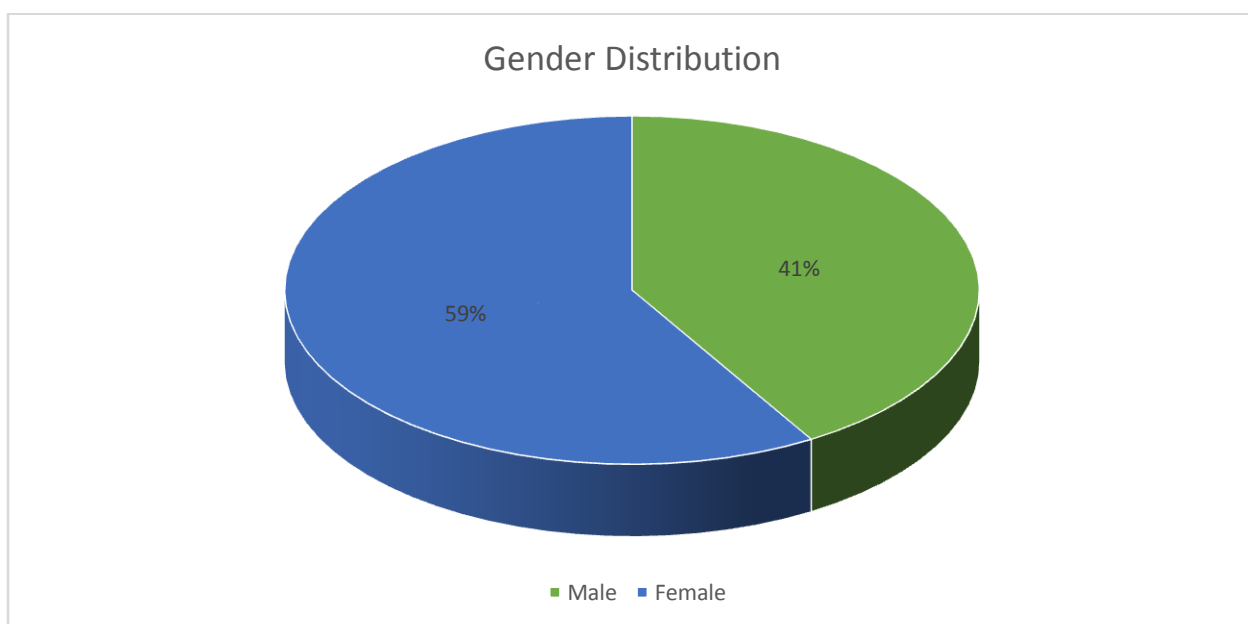


Figure 4.2: Gender Distribution

Majority of the patients are female and the rest male.

4.3 Educational Level of the respondents.

Table4.3: Educational Level

| Level | Total Number | Percentage % |
|------------------------------------|--------------|--------------|
| Illiterate | 5 | 3% |
| Primary School Certificate | 34 | 23% |
| High School Certificate or College | 76 | 52% |
| Graduate or Post Graduate | 30 | 21% |
| Total | 145 | 100% |

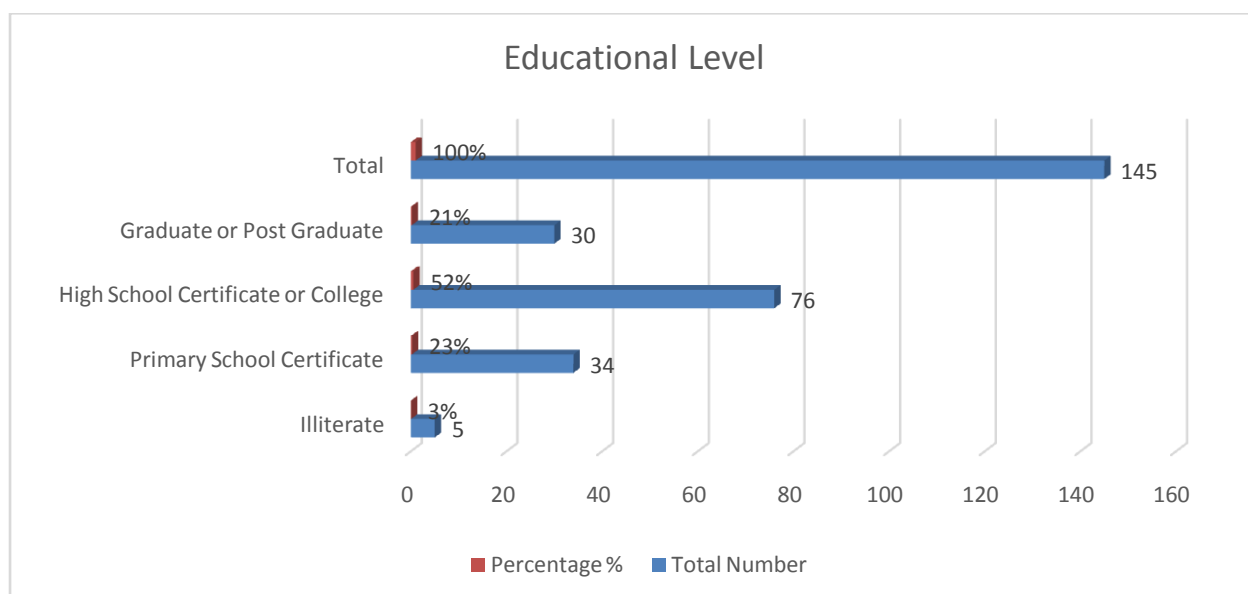


Figure 4.3: Educational Level

Majority of patients have passed high school certificate or college. Graduate or post graduate are less and the rest of them are primary school certificate passed. Very few are illiterate.

4.4 Medical or Health Science Background of the patients.

Table 4.4: Medical or Health Science Background

| Medical or Health Science Background in Education | Number | Percentage % |
|--|--------|-----------------|
| Yes | 0 | 0% |
| No | 145 | 100% |
| TOTAL | 145 | 100% |

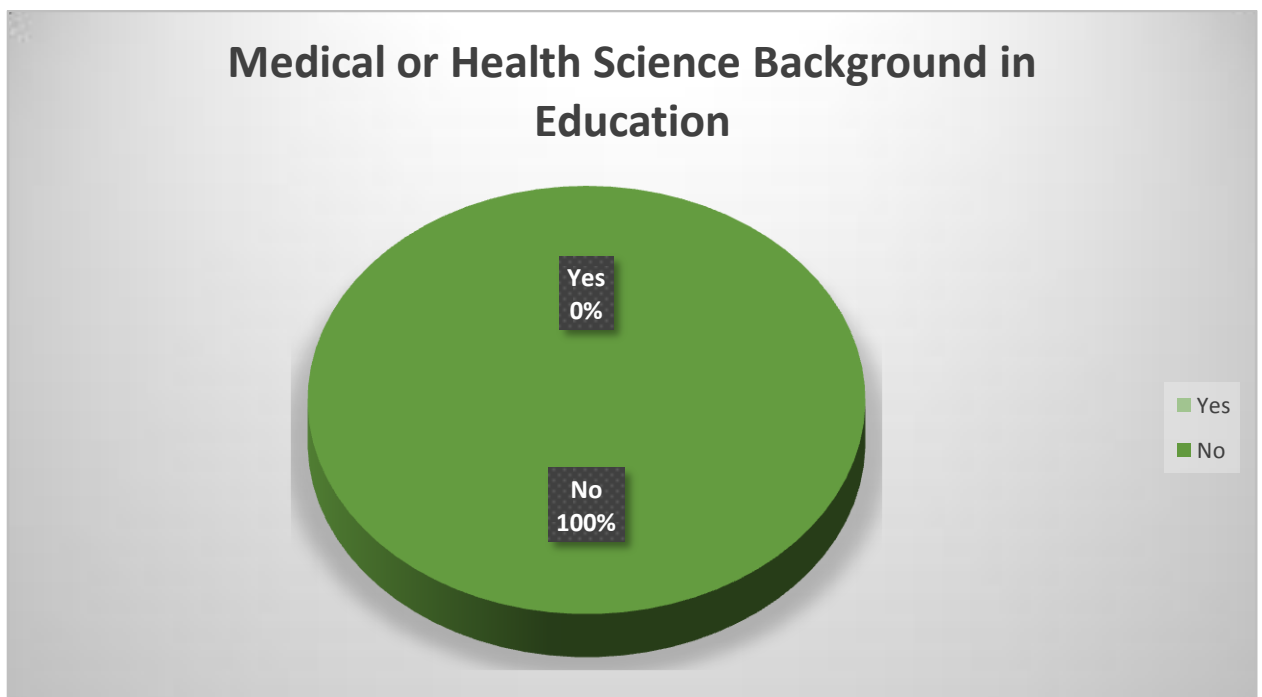


Figure 4.4: Medical or Health Science Background

No Patient has medical or health science background.

4.5 Medical Condition that requires analgesic(s)

Table 4.5: Medical Condition that requires analgesic(s)

| Sl No | Type of Disease | No. of Patient | Percentage % |
|-------|---------------------------------|----------------|--------------|
| 1 | Gout, Arthritis, Osteoarthritis | 27 | 19% |
| 2 | Spondylitis, Strain | 29 | 20% |
| 3 | Pain Management | 26 | 18% |
| 4 | Injury | 15 | 10% |
| 5 | Swelling & Inflammation | 14 | 9.60% |
| 6 | Post Operative | 18 | 12.40% |
| 7 | Frozen Shoulder | 9 | 6% |
| 8 | Disc Herniation & Others | 7 | 5% |
| Total | | 145 | 100% |

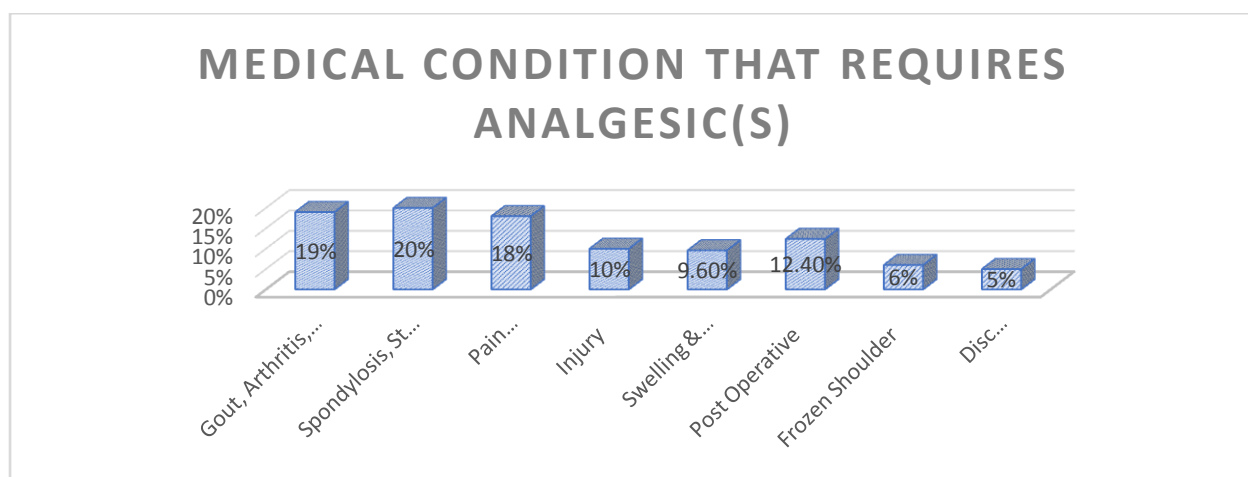


Figure 4.5: Medical Condition that requires analgesic(s)

Most of the patients require analgesic for treating gout, arthritis, spondylitis, strain and pain management.

4.6 List of Analgesics Prescribed by Doctors

Table 4.6: List of Analgesics Prescribed by Doctors

| SI No. | Name of Analgesics | No. | Percentage % |
|--------|--------------------|-----|--------------|
| 1 | Aceclofenac | 24 | 16.00% |
| 2 | Naproxen | 52 | 36% |
| 3 | Indomethacin | 24 | 16.00% |
| 4 | Keterolac | 27 | 19% |
| 5 | Ibuprofen | 9 | 6% |
| 6 | Sulindac | 4 | 3% |
| 7 | Eterocoxib | 5 | 4% |
| Total | | 145 | 100% |

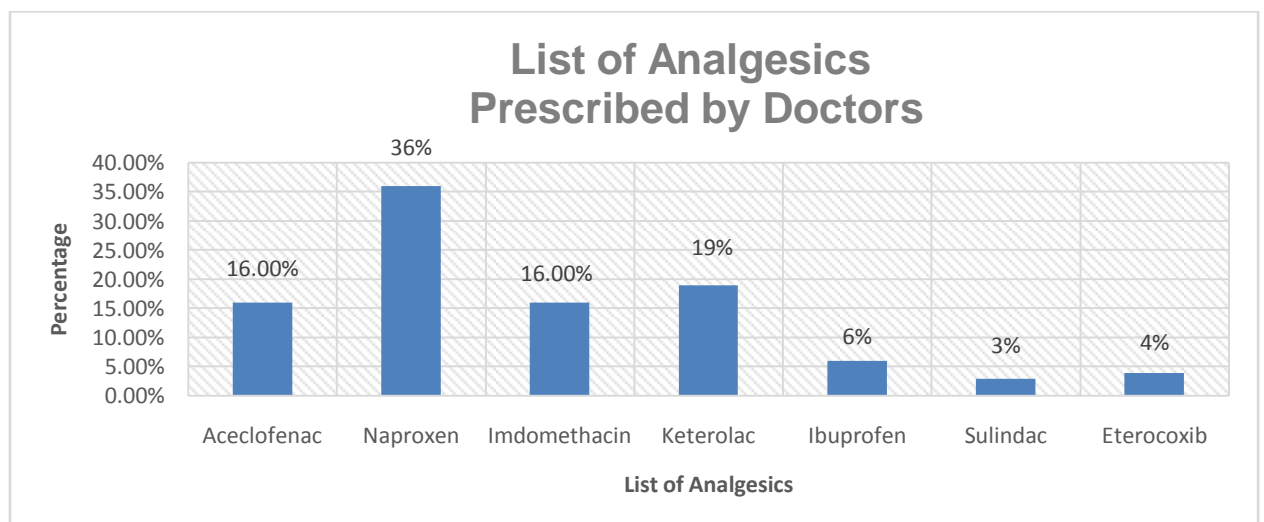


Figure 4.6: List of Analgesics Prescribed by Doctors

Among all the analgesics naproxen is highly prescribed.

4.7 Type of User

Table 4.7: Type of User

| Sl No | Type of User | No | Percentage % |
|-------|--------------|-----|--------------|
| 1 | Acute | 82 | 57% |
| 2 | Chronic | 63 | 43% |
| Total | | 145 | 100% |

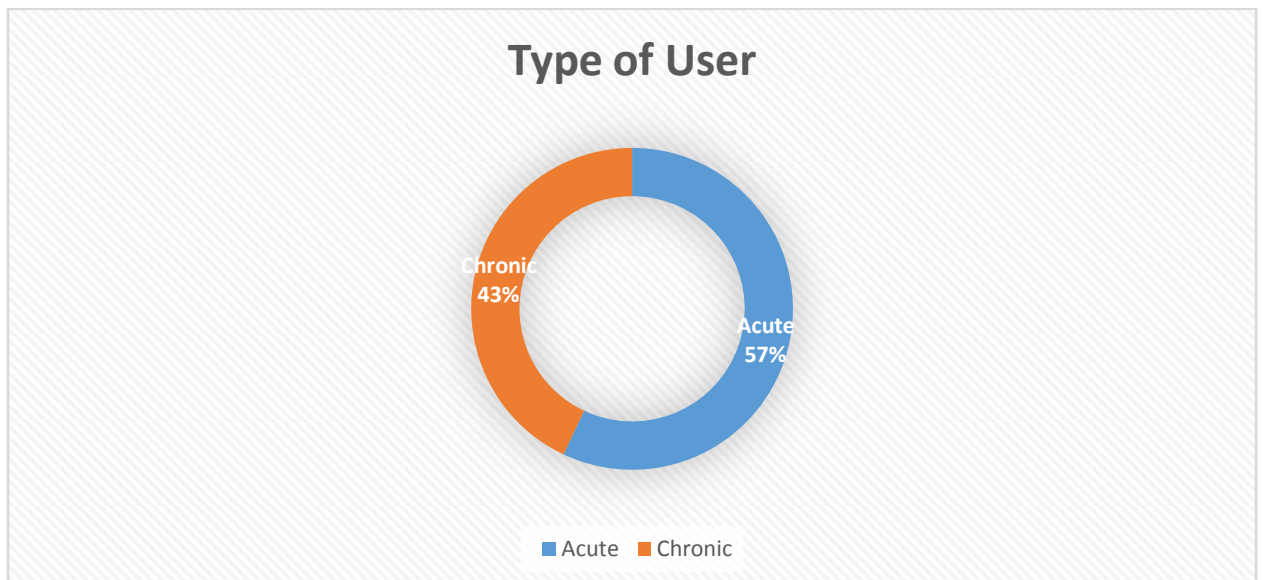


Figure 4.7: Type of NSAID(s) User

Majority of the patients are acute user.

4.8 Discussion of the Side Effects with Patients by Doctor

Table 4.8: Discussion of the Side Effects with Patients By Doctor

| SI NO | Discussion of the Side Effects with Patients By Doctor | No | Percentage% |
|-------|--|-----|-------------|
| 1 | Yes | 78 | 54% |
| 2 | NO | 67 | 46% |
| Total | | 145 | 100% |

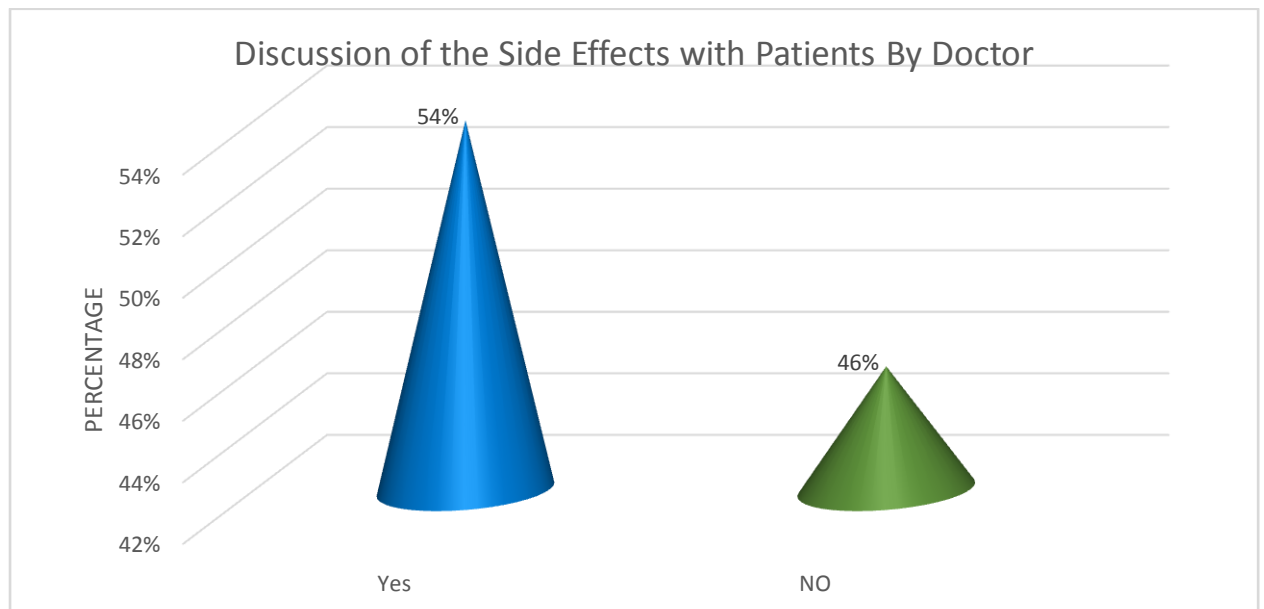


Figure 4.8: Discussion of the Side Effects with Patients By Doctor

Most of the doctors discuss the possible side effects with the patients.

4.9 Patient Information Leaflet (PIL) Reading Status of the Patients

Table 4.9: Patient Information Leaflet (PIL) Reading Status of the Patients

| SI NO | PIL Reading Status | Number | Percentage% |
|-------|--------------------|--------|-------------|
| 1 | Yes | 22 | 15% |
| 2 | NO | 123 | 85% |
| Total | | 145 | 100% |

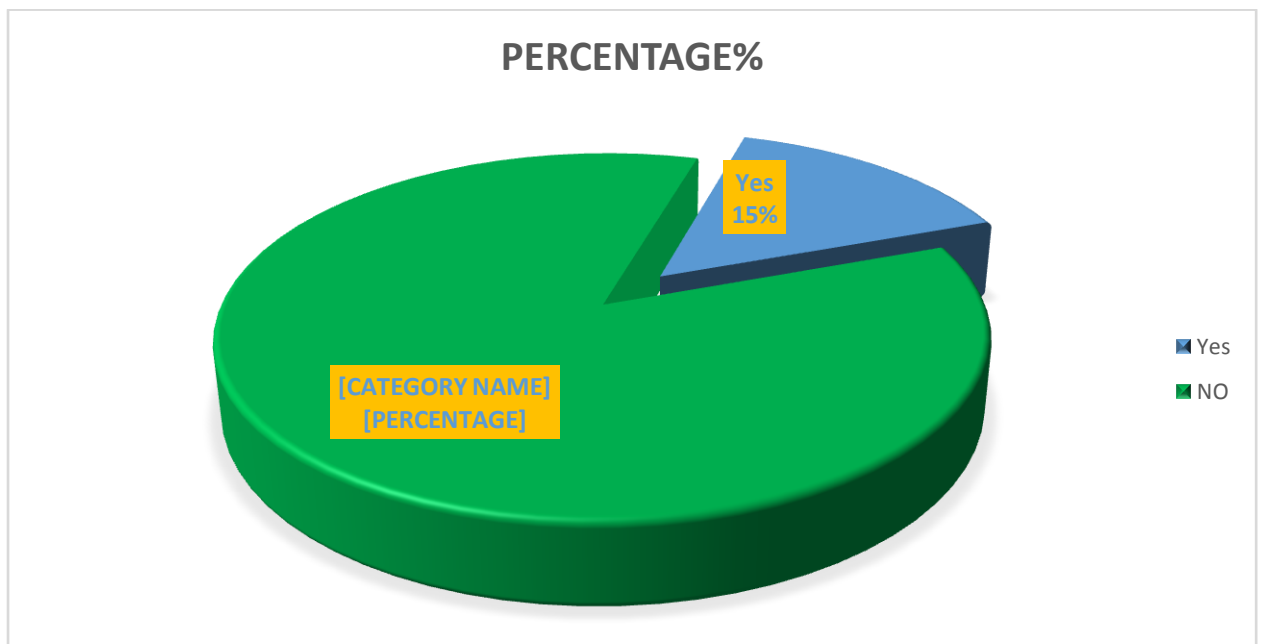


Figure 4.9: Patient Information Leaflet (PIL) Reading Status of the Patients

According to the data we can say that, Most of the patients do not read the patient information leaflet.

4.10 Self Medication Tendency of the Patients

Table 4.10: Self Medication Tendency of the Patients

| SI No | Tendency | Nos | Percentage % |
|-------|----------|-----|--------------|
| 1 | Yes | 60 | 41% |
| 2 | No | 85 | 59% |
| Total | | 145 | 100% |

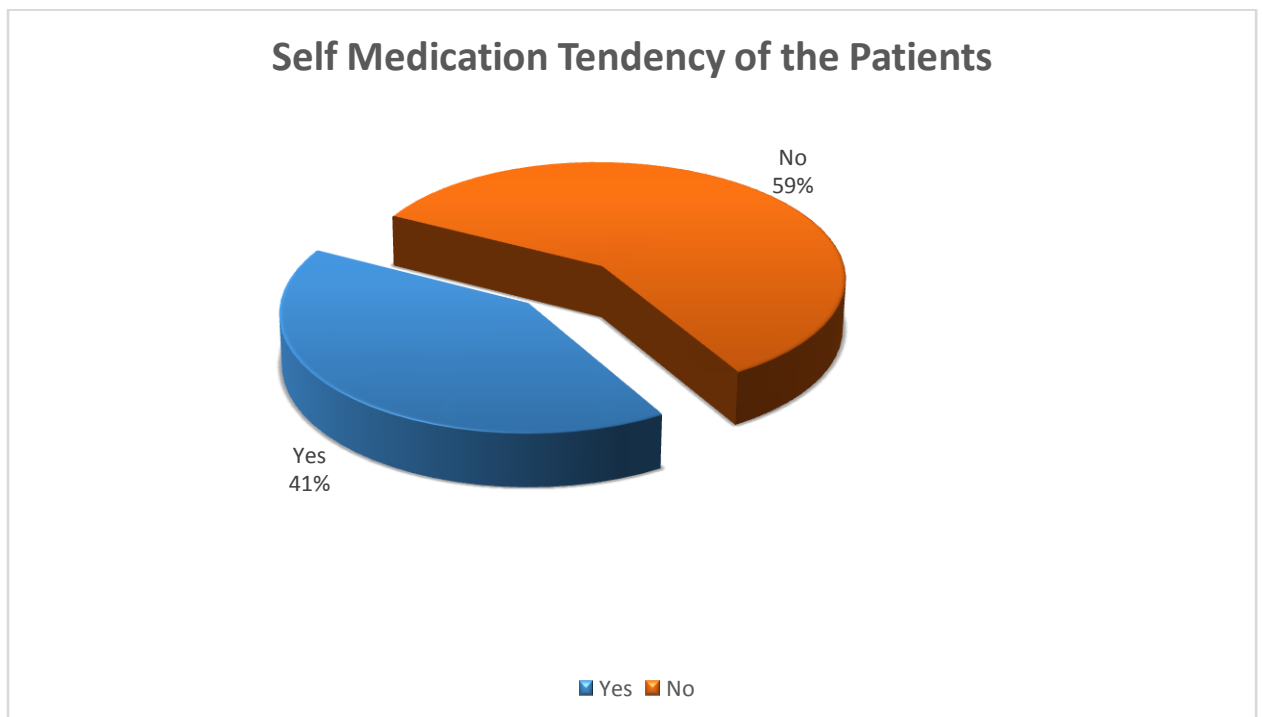


Figure 4.10: Self Medication Tendency of the Patients

Majority of the patients do not self-medicate with analgesics.

4.11 Special Instructions Given By the Doctor While Taking Analgesics

Table 4.11: Special Instructions Given By the Doctor While Taking Analgesics

| SI No | Instruction Given | Nos | Percentage % |
|-------|-------------------|-----|--------------|
| 1 | Yes | 94 | 65% |
| 2 | No | 51 | 35% |
| Total | | 145 | 100% |

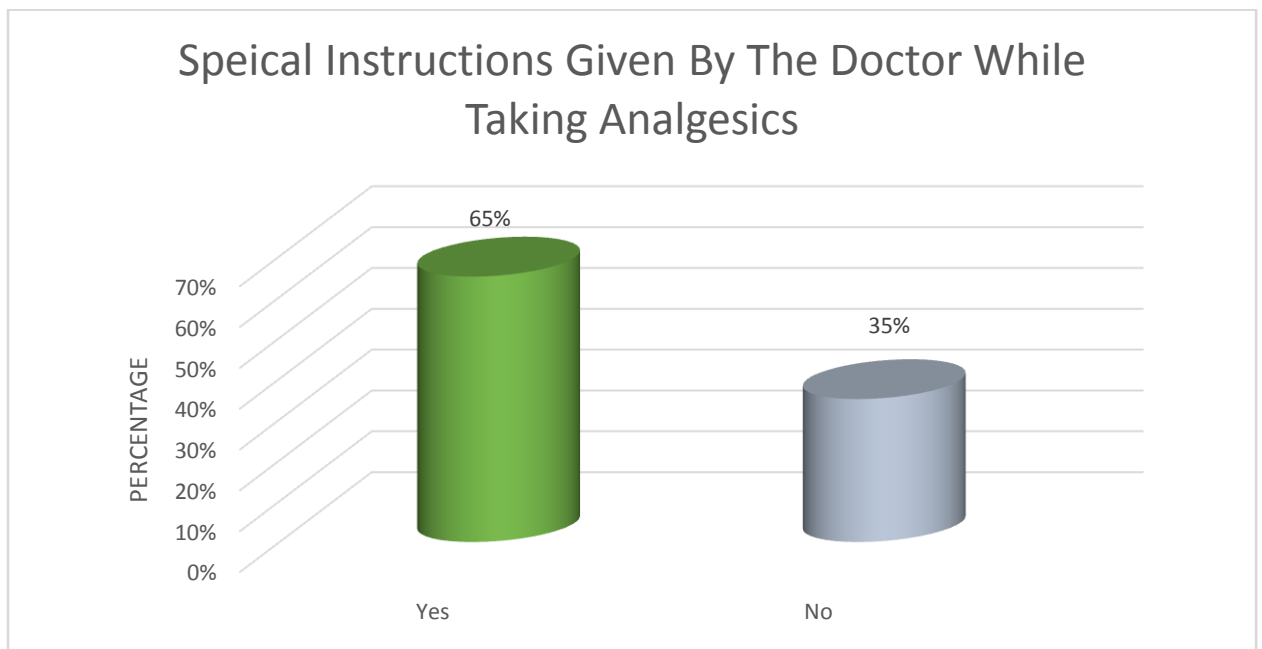


Figure 4.11: Special Instructions Given By the Doctor While Taking Analgesics

Majority of the doctors give especial instructions to the patients.

4.12.1 Patient Awareness: Medications that must avoid while taking analgesics

Table 4.12: Medications that must avoid while taking analgesics

| SI No | Patient's Response | Percentage % |
|-------|--------------------|--------------|
| 1 | Correctly Answered | 7.5% |
| 2 | Wrong Answer | 4% |
| 3 | Didn't Answer | 88.5% |
| Total | | 100% |

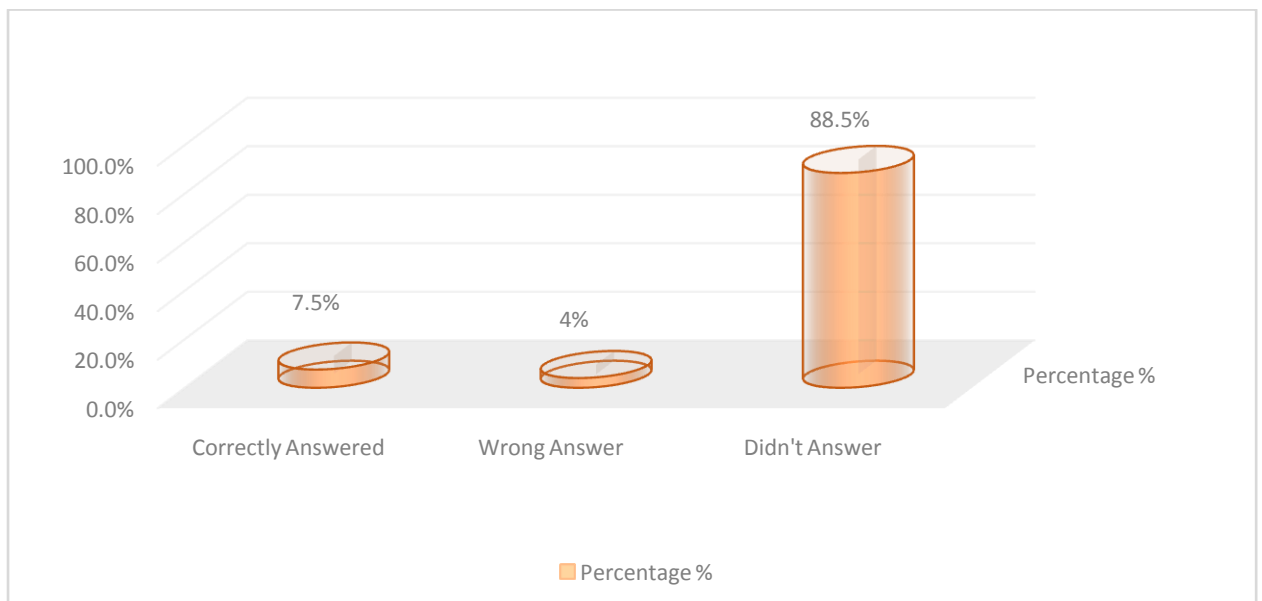


Figure 4.12.1: Medications that must avoid while taking analgesics

Majority of the patients did not know about the medications that must be avoid while taking analgesics.

4.12.2 Patient Awareness: Food or Beverage that must avoid while taking analgesics

Table 4.12.1: Food or Beverage that must avoid while taking analgesics

| Sl No | Patient's Response | Nos | Percentage % |
|-------|--------------------|-----|--------------|
| 1 | Correctly Answered | 17 | 12.0% |
| 2 | Wrong Answer | 33 | 23% |
| 3 | Didn't Answer | 95 | 65.0% |
| Total | | 145 | 100% |

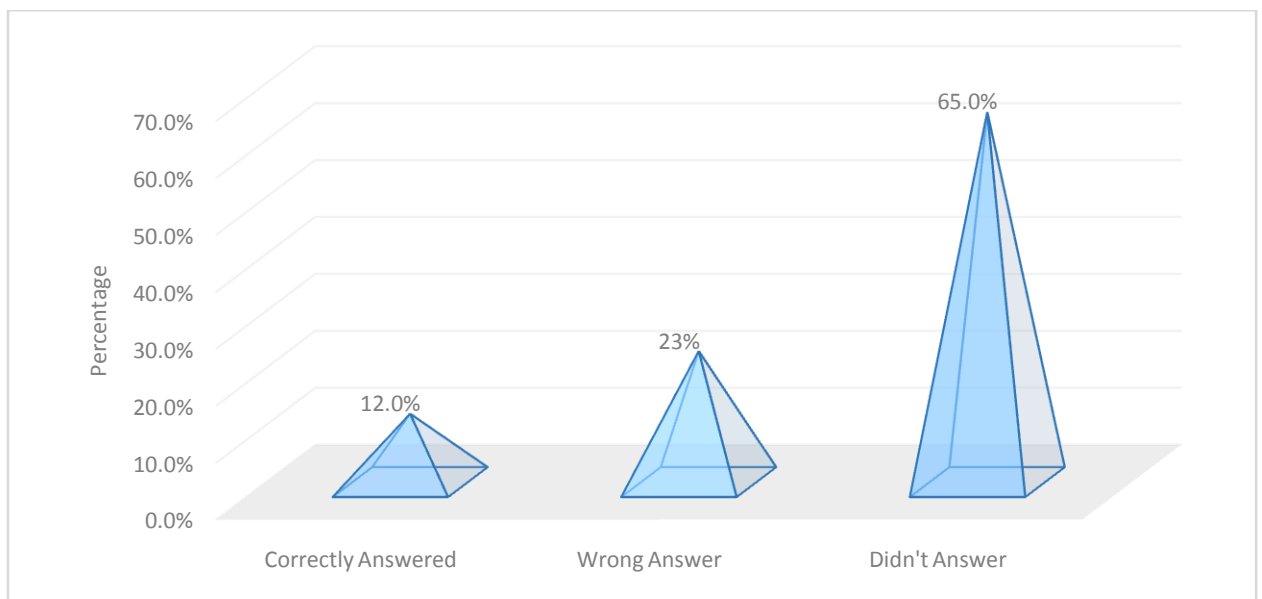


Figure 4.12.2: Food or Beverage that must avoid while taking analgesics

Most of the patients did not know about the food or beverage must be avoid while taking analgesics.

4.12.3 Patient Awareness: Side Effects of analgesics

Table 4.12.3: Side Effects of analgesics

| Sl No | Patient's Response | Nos | Percentage % |
|-------|--------------------|-----|--------------|
| 1 | Correctly Answered | 55 | 38.0% |
| 2 | Wrong Answer | 29 | 20% |
| 3 | Didn't Answer | 61 | 42.0% |
| Total | | 145 | 100% |

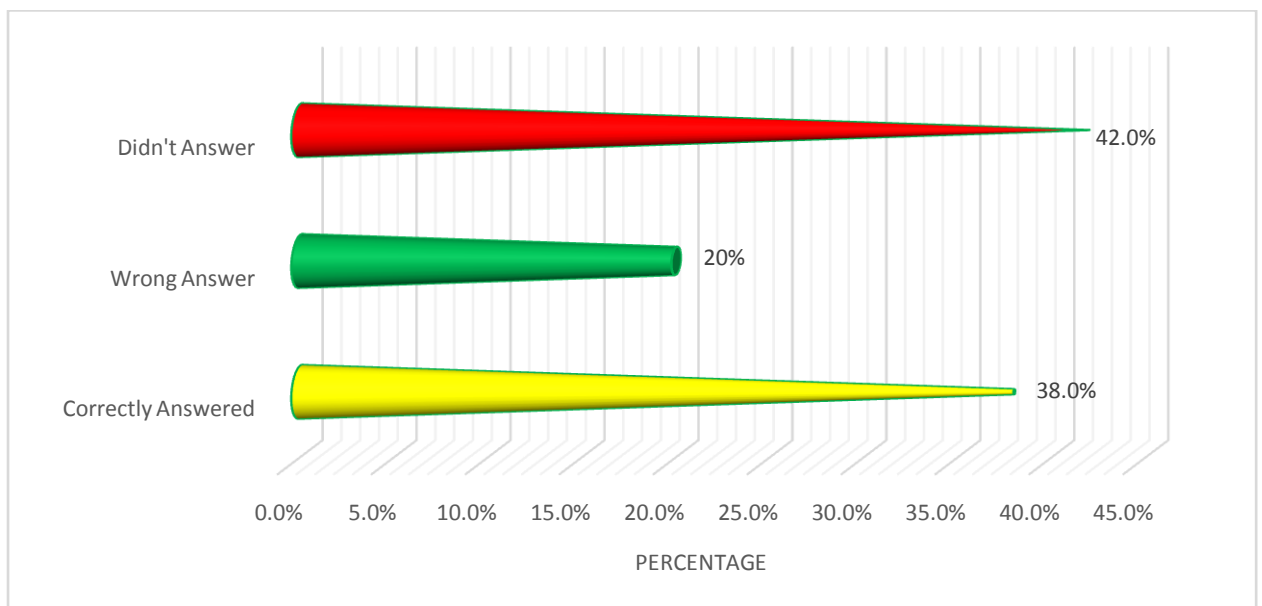


Figure 4.12.3: Side Effects of analgesics

Majority of the patients did not know about the side effects of analgesics.

4.12.4 Patient Awareness: Cautionary Approaches to Avoid Adverse Drug Events

Table 4.12.4: Cautionary Approaches to Avoid Adverse Drug Events

| Sl No | Patient's Response | Nos | Percentage % |
|-------|--------------------|-----|--------------|
| 1 | Correctly Answered | 18 | 12.0% |
| 2 | Wrong Answer | 35 | 24% |
| 3 | Didn't Answer | 92 | 64.0% |
| Total | | 145 | 100% |

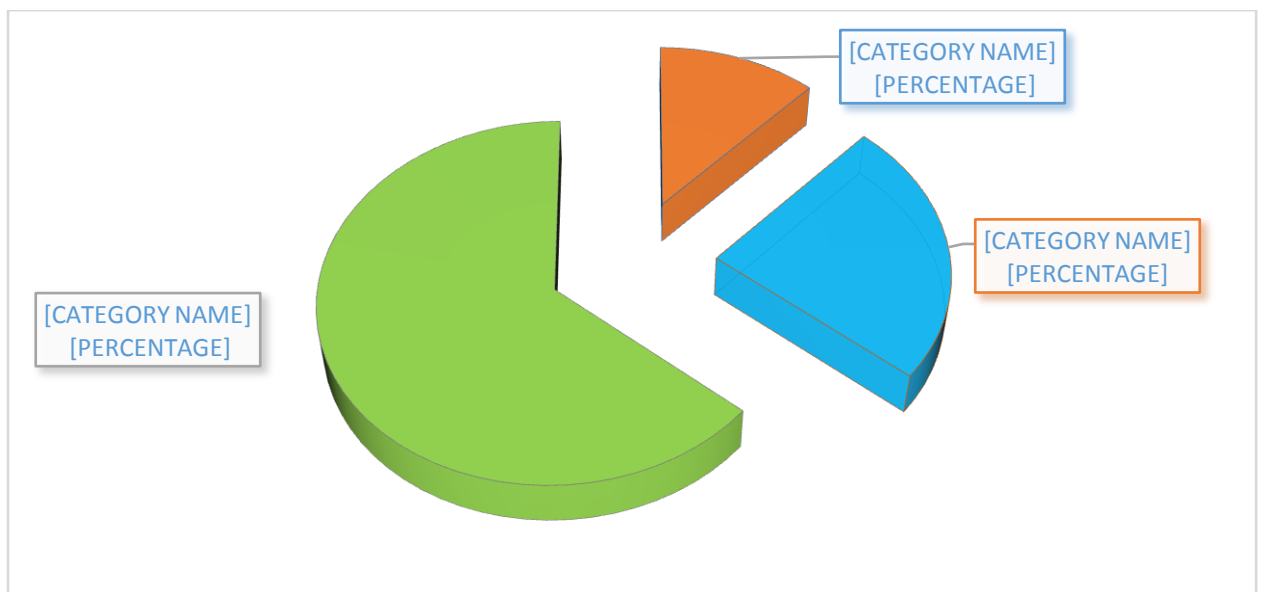


Figure 4.12.4: Cautionary Approaches to Avoid Adverse Drug Events

Majority of the patients did not know about the cautionary approaches to avoid adverse drug event.

4.12.5 Patient Awareness: What to do Upon Appearance of any Side Effects

Table 4.12.5: What to do Upon Appearance of any Side Effects

| SI No. | Patient's Response | No | Percentage % |
|--------|--------------------|-----|--------------|
| 1 | Correctly Answered | 18 | 12.0% |
| 2 | Wrong Answer | 34 | 24% |
| 3 | Didn't Answer | 93 | 64.0% |
| Total | | 145 | 100% |

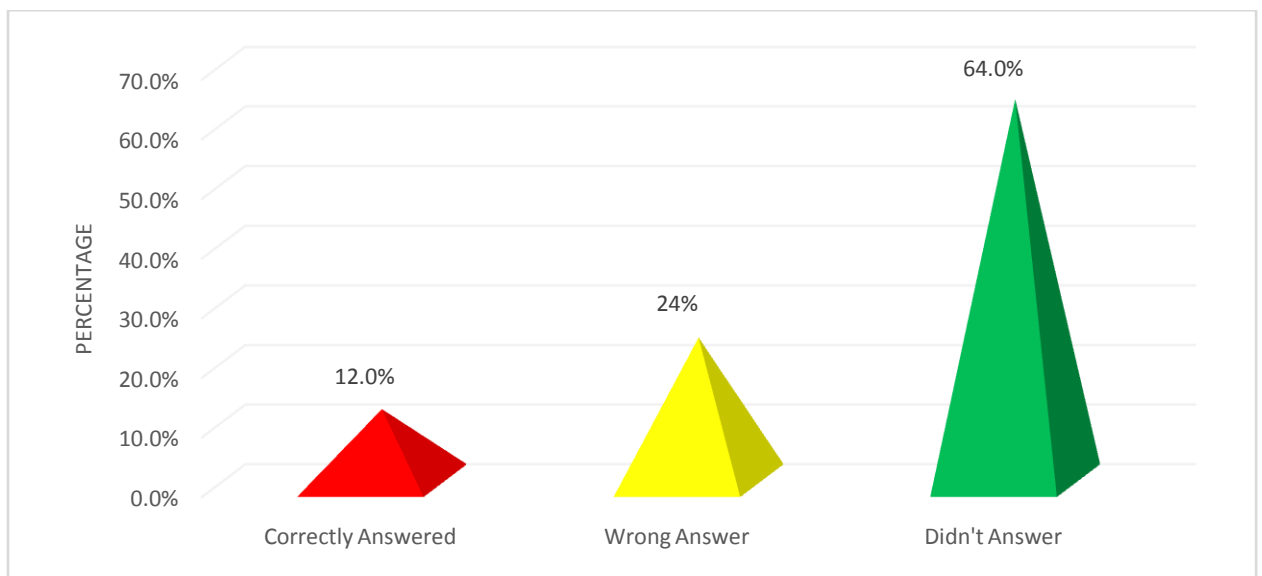


Figure 4.12.5: What to do upon Appearance of any Side Effects

Most of patients did not know what to do upon appearance of any side effects.

CHAPTER FIVE
DISCUSSION

Discussion

The major objective of this study was awareness of patients regarding ADR of NSAID. The survey was done among 100 and 45 people. Among the respondents 59% were female and 41% were male. Most of the patients, about 52% have passed the high school certificate or college and 21% were graduate and post graduate. Among the rest 23% have passed primary school certificate and 3% were illiterate. No patient has medical or health science background.

Gout, arthritis, oosteoarthritis, spondylitis, strain, pain management, injury, swelling and inflammation, post-operative, frozen shoulders were the common disease for which NSAID were prescribed and naproxen were the highly prescribed drug.

Majority of the patients of the acute users but there were also chronic users. The patients were asked that if the doctor has discussed about the possible side effects, adverse drug events, about the PIL, their knowledge about the side effects and ADR of the medications and what should they do upon any appearances of any adverse drug event.

The patients were also asked if they were given any special instructions for taking the medications.

Majority of the patients did not know proper answers, many patients give wrong answers and a few people can answers the questions correctly. The possible side effects were discussed by many of the doctors and they have also given special instructions for taking the medications.

From this study we can see group of patients that tended to be better informed about the side effects and adverse effect were patient with more education. They also read the PIL carefully and they were aware about the adverse effects of the medications.

Whereas the people with less education was not aware about the adverse effects and they have many wrong information or idea.

So according to the Bangladesh perspective majority of the populations. Do not know about the side effects and adverse events, adverse drug events of NSAID. They also lack proper knowledge about adverse drug effects and their managements.

CHAPTER SIX
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