A

Summer Internship Project Report

On

TO ANALYZE THE PRESCRIBING TREND & SAFETY ISSUES IN ANALGESICS FOR PAIN MANAGEMENT

In partial fulfillment for award of

Masters of Business Administration- Pharmaceutical Management

Submitted By

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MBA-Pharmaceutical Management

2014-2016

Under the guidance of

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INSTITUTE OF HEALTH
MANAGEMENT RESEARCH
(WHO Collaborating Centre for District Health System Based on Primary Health Care)

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that **Mr. Shubham Chaudhary**, a student of Master's in Business Administration Pharmaceutical Management 6th Batch, IIHMR University, Jaipur, has successfully completed his summer training for the period from April 1st to June 5th , 2015 at Zydus Cadila Ltd, Ahmadabad under my guidance.

During this period he has completed a Project Entitled "**To Analyze The Prescribing Trend & Safety Issues In Analgesics for Pain Management"** as a part of his Summer Internship Project .

The Project was field work and was carried out by him with a sincere, scientific and analytical approach under my supervision and guidance.

I wish him all the best and good luck in his future endeavours.

Col. (Dr.) Ashok Kaushik (Retd.)

Dean (Academic and Student Affairs)

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ACKNOWLEDGEMENT

It gives me immense pleasure to acknowledge My MentorMr. Maulesh Patel (product Manager), at Zydus Cadila pharmaceuticals, Ahmedabad, for their guidance throughout my Internship; it is the constant encouragement that has enriched my growth as an intern.

I place on record, my sincere gratitude to Mr. Dhawal Jaspara (Area Manager) for being so supportive and his wonderful team.

I owe a debt of gratitude to My Mentor Dr.Nirmal Gurbani, Professor, at Institute of Health Management Research, Jaipur; India, all my teachers for grooming me and my classmates for the inspiration needed to work with dedication and motivation throughout as an Intern at Zydus pharmaceuticals ltd, Ahmedabad.

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards the industry in coming future.

Contents

EXECUTIVE SUMMARY

In today' s competitive world where cut-throat competition exists, everyone wants to know their position, their strength and weakness, so it is very essential to know opportunity to target the potential market, capture the market, evaluate from the marketing strategies.

The objective of the project was **'To understand the prescription pattern of Analgesics & safety issues in Pain Management".**

The project was undertaken in Ahmedabad city with respect to the survey with orthopedic surgeons/ physicians.

The project was started on April after knowing all the relevant information regarding the project, under the guidance of Mr. Maulesh Patel (Product manager in Zydus Cadila Pharmaceuticals ltd.). The first part of project was to study the history of analgesics, current market scenario in terms of latest molecules as well as market value, and various pitfalls regarding FDA warning issues. For this I used Internet as a primary source of information for study. More focus was on Antifungal drugs in IFIs.

The next part of project was to develop the questionnaire for orthopedic physicians/ surgeons. Then the data was collected from the survey which was done by visiting doctors.Close ended as well as open ended questionnaire was made and statically analysis was carried to draw conclusion. The project was completed on June 5

During the study it was found that Diclofenac & paracetamol are majorly prescribed painkillers in acute as well as chronic painful conditions. While, pantoprazole is the most preferred PPI to overcome GI risk associated with pain killers.

INTRODUCTON

An **analgesic**, or **painkiller**, is any member of the group of drugs used to achieve analgesia — relief from pain..

Analgesic drugs act in various ways on the peripheral and central nervous systems. They are distinct from anesthetics, which reversibly eliminate sensation.

Analgesics include paracetamol(known in the US as acetaminophen or simply APAP), the non-steroidal anti-inflammatory drugs (NSAIDs) such as the salicylates, and opioid drugs such as morphine and oxycodone.

In choosing analgesics, the severity and response to other medication determines the choice of agent; the World Health Organization (WHO) pain ladder specifies mild analgesics as its first step.

Paracetamol and NSAIDs:

The exact mechanism of action of paracetamol/acetaminophen is uncertain but appears to act centrally in the brain rather than peripherally in nerve endings. Aspirin and the other non-steroidal anti-inflammatory drugs (NSAIDs) inhibit cyclooxygenases, leading to a decrease in prostaglandin production. In contrast to paracetamol and the opioids, this reduces not only pain but inflammation as well.

Paracetamol has few side-effects and is regarded as generally safe in low and infrequent doses as prescribed or per manufacturer's instructions, otherwise use can lead to potentially life-threatening liver damage and occasionally kidney damage.

Side effects include Bloody or black, tarry stools, bloody or cloudy urine, fever with or without chills (not present before treatment and not caused by the condition being treated), pain in the lower back and/or side (severe and/or sharp), pinpoint red spots on the skin, skin rash, hives, or itching, sore throat .

While paracetamol is usually taken orally or rectally, an intravenous preparation introduced in 2002 has been shown to improve pain relief and reduce opioid consumption in the perioperative setting.The use of aspirin in children under 16 suffering from viral illness has been linked to Reye's syndrome, a rare but severe liver disorder.

COX-2 inhibitors:

These drugs have been derived from NSAIDs.

The cyclooxygenase enzyme inhibited by NSAIDs was discovered to have at least 2 different versions: COX1 and COX2. Research suggested most of the adverse effects of NSAIDs to be mediated by blocking the COX1 (constitutive) enzyme, with the analgesic effects being mediated by the COX2 (inducible) enzyme.

Thus, the COX2 inhibitors were developed to inhibit only the COX2 enzyme (traditional NSAIDs block both versions in general). These drugs (such as rofecoxib,celecoxib, and etoricoxib) are equally effective analgesics when compared with NSAIDs, but cause less gastrointestinal hemorrhage in particular.

After widespread adoption of the COX-2 inhibitors, it was discovered that most of the drugs in this class increase the risk of cardiovascular events by 40% on average.

This led to the withdrawal of rofecoxib and valdecoxib, and warnings on others. Etoricoxib seems relatively safe, with the risk of thrombotic events similar to that of non-coxib NSAID diclofenac.

Opioids:

Morphine, the archetypal opioid, and various other substances (e.g., codeine, oxycodone, hydrocodone, dihydromorphine, pethidine) all exert a similar influence on the cerebralopioid receptor system. Buprenorphine is thought to be a partial agonist of the opioid receptor, and tramadol is an opiate agonist with SNRI properties

.

Tramadol is structurally closer to venlafaxine than to codeine and delivers analgesia by not only delivering "opiate-like" effects (through mild agonism of the mu receptor) but also by acting as a weak but fast-acting serotonin releasing agent and norepinephrine reuptake inhibitor.

The effects of serotonin andnorepinephrine on pain, while not completely understood, have had causal links established and drugs in the SNRI class are commonly used in conjunction with opioids (especially tapentadol and tramadol) with greater success in pain relief.

When used appropriately, opioids and similar narcotic analgesics are otherwise safe and effective, however risks such as addiction and the body's becoming used to the drug (tolerance) can occur. The effect of tolerance means that frequent use of the drug may result in its diminished effect so, when safe to do so, the dosage may need to be increased to maintain effectiveness. This may be of particular concern regarding patients suffering with chronic pain.

Flupirtine:

Flupirtine is a centrally acting K+ channel opener with weak NMDA antagonist properties. It is used in Europe for moderate to strong pain and migraine and its muscle-relaxant properties. It has no anticholinergic properties and is believed to be devoid of any activity on dopamine, serotonin, or histamine receptors. It is not addictive, and tolerance usually does not develop.However, tolerance may develop in single cases.

Specific agents

In patients with chronic or neuropathic pain, various other substances may have analgesic properties. Tricyclic antidepressants, especially amitriptyline, have been shown to improve pain in what appears to be a central manner.Nefopam is used in Europe for pain relief with concurrent opioids. The exact mechanism of carbamazepine,gabapentin, and pregabalin is similarly unclear, but these anticonvulsants are used to treat neuropathic pain with differing degrees of success. Anticonvulsants are most commonly used for neuropathic pain as their mechanism of action tends to inhibit pain sensation.

Combinations:

Analgesics are frequently used in combination, such as the paracetamol and codeine preparations found in many non-prescription pain relievers. They can also be found in combination with vasoconstrictor drugs such as pseudoephedrine for sinus-related preparations, or with antihistamine drugs for allergy sufferers.

While the use of paracetamol, aspirin, ibuprofen, naproxen, and other NSAIDS concurrently with weak to mid-range opiates (up to about the hydrocodone level) has been said to show beneficial synergistic effects by combatting pain at multiple sites of action,several combination analgesic products have been shown to have few efficacy benefits when compared to similar doses of their individual components.

Topical or systemic:

Topical analgesia is generally recommended to avoid systemic side-effects. Painful joints, for example, may be treated with an ibuprofen- or diclofenac-containing gel (The labeling for topical diclofenac has been updated to warn about drug-induced hepatotoxicity.

Capsaicin also is used topically. Lidocaine, an anesthetic, and steroids may be injected into painful joints for longer-term pain relief.

Atypical, adjuvant analgesics & potentiators:

Drugs that have been introduced for uses other than analgesics are also used in pain management. Both first-generation (such as amitriptyline) and newer anti-depressants (such as duloxetine) are used alongside NSAIDs and opioids for pain involving nerve damage and similar problems. Other agents directly potentiate the effects of analgesics, such as using hydroxyzine, promethazine, carisoprodol, or tripelennamine to increase the pain-killing ability of a given dose of opioid analgesic.

COMPANY PROFILE:

Cadila pharmaceuticals ltd. is one of the largest privately held pharmaceutical companies in India, headquartered at Ahmedabad, in the state of Gujrat.

Over the last six decades, the company has been developing and manufacturing pharmaceutical products in India and selling and distributing these in over eighty –five other countries around the world. Focused strongly on innovation and research, the company is present in more than 45 therapeutic areas spread across 12 specialties, including cardiovascular, gastrointestinal, analgesics, hematinic, anti-infective and antibiotics, respiratory agents, anti-diabetics and immunological.

At, Cadilapharmaceuticals, research and development is at the core of all itsinitiatives, be it biotechnology, API'S, Formulations, Plant tissue culture of Phytochemistry. More than 300 scientist in its various research and development steps reinforce the competitiveness of research in the therapeutic areas which have high unmet medical needs. Cadila pharmaceuticals excellence in manufacturing facilities is central to Cadila pharmaceuticals.

The company formulation manufacturing plant at dholka near Ahmedabad, Gujrat is spread over hundred acres of land. This state of the art facility is not only impressive in size but also USFDA approved.

The second manufacturing facility is located at samba in Jammu and Kashmir. The facility meets most of the stringent quality standards across the globe to produce tablets, capsules, soft and hard gelatin capsules, liquid and orals.

API MANUFACTURING PLANTS:

Two Active Pharmaceutical Ingredient (API) manufacturing units at Ankleshwar, Gujrat manufacture a wide range of API'S and intermediates including many USFDA products. This company has foothold in African continent through its formulation manufacturing at Addis Ababa in Ethiopia

The company makes active pharmaceutical ingredients at three sites in India:

Ankleshwar plants – Zydus Cadila's plant complex at Ankleshwar in Bharuch District of Gujarat, has been producing drug material since 1972. There are around 12 plants in the complex, which is ISO 9002 and ISO 14001 certified approved by the U.S. Food and Drug Administration (FDA). Total plant capacity at Ankleshwar is around 180 million tons.

Vadodara plant – Zydus Cadila's plant at Dhabhasa, in Vadodara District's Padra taluka (in the eastern part of the district) in Gujarat, was commissioned in 1997 by a company called Banyan Chemicals, and acquired by Zydus Cadila in 2002. The plant has a 90 million ton capacity. It is approved by the U.S. FDA and is also approved to World Health Organization (WHO) good manufacturing practice (GMP) guidelines.

Patalganga plant – Zydus Cadila acquired an API plant at Patalganga in Maharashtra state, 70 km from Mumbai, about 859 km from Nagpur, in the 2001 German Remedies deal. This plant operates to WHO GMP standards

Zydus Research Centre (ZRC) (Changodar) – Zydus's NCE, NME, and MBE research facility is the largest of its kind in Indian, with more than 500 post graduate scientists it is working towards the prosperous future of the company and Indian Pharmaceutical Industry.

Corporate Social Responsibility:

CSR ACTIVITIES:

1. ZYDUS SCHOOL FOR EXCELLENCE

The purpose of such an institution was to create a fountainhead where children had an opportunity to broaden the knowledge and the freedom to explore their creative impulses.

2. HEALTH CAMPS:

Zydus Cadila organizes annual healthcare camps at Moraiya, a village adjacent to its plant premises. So far, general diagnostic, dental healthcare, vaccination, pediatric, eye care, hypertension and blood sugar detection camps have been organized.The response to these camps is so overwhelming that villagers from nearby villages throng the village school premises where the camps are held. The earthquake, which struck Gujarat in January 2001, left a trail of death and destruction in its wake. Zydus Cadila set up a 24 hour helpline at its headquarters responding to calls for medicines and first aid. Through this helpline, the group distributed medicines worth Rs.1 crore as relief tons the victims of the earthquake.

3. ZYDUS CADILA AND RED CROSS FELICITATE 500 BLOOD DONORS:

Zydus Cadila which has been actively promoting blood donation drive having held one recently for its employees earlier this year, honored 500 people who have donated their blood for over 25, 50, 75, 100 times.

The awardees received the Zydus Red Cross Blood Donation awards from His Excellency, Governor of Gujarat at a function held at the Tagore Hall Paldi. The function was jointly organized by Zydus Cadila in association with Ahmedabad Red Cross Program.

NEED FOR STUDY

The study helps to determine the current scenario of Analgesics in pain management and overall market potential of the analgesics.The study helps to determine current prescribing trend of doctors for analgesics.It gives idea of current market coverage of competitorbrands.

It can help a pharmaceutical company to understand the need of the customer (doctor) prior launching any new molecule. It can help a pharmaceutical company to make strategies and make a foothold through creative marketing so as to acquire a good market share for their product.

RESEARCH QUESTION:

What is the prescription trend & safety issues of Analgesics in pain Management (Ahmedabad)?

OBJECTIVE:

- ✓ To analyse the market scenario of analgesics in terms of safety issues.
- ✓ To identify the choice of Analgesics by physicians/surgeons in acute as well as chronic painful conditions.

METHODOLOGY:

STUDY- DESIGN:

The research conducted was semi- **Exploratory**

Population

In this study samples included:

Orthopedic Surgeons/ Physicians/ Consulting physicians .

Sample size

During the studydata from 66 physicians wwere obtained through questionnaire.

Sampling method

Non-Probability (Convenience) sampling

SAMPLE-AREA:

Ahmedabad (Gujarat)

Data collection:

Primary and secondary data:

Primary data- The primary data for this project was gathered through a research using questionnaire, face to face interview.

Secondary data- The main source of secondary data for this study was the information from various information media such as-

Reference books.

Tools & Techniques:

- ✓ Questionnaire to collect primary data.
- ✓ Microsoft Excel to carry out analysis.

Study duration

2 months (1st April to 5th June)

DATA ANALYSIS:

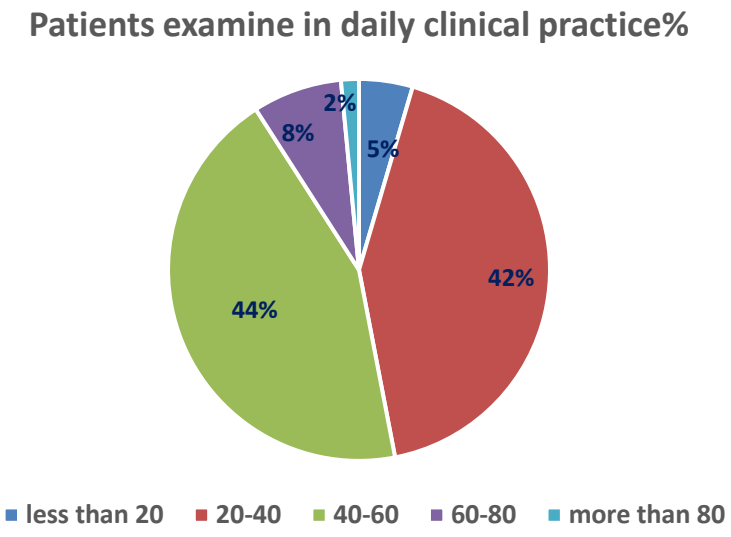
Findings and Interpretation:

Objective 1:

To identify the choice of Analgesics by physicians/surgeons in acute as well as chronic painful conditions

1. **Total no of patient's examined :**

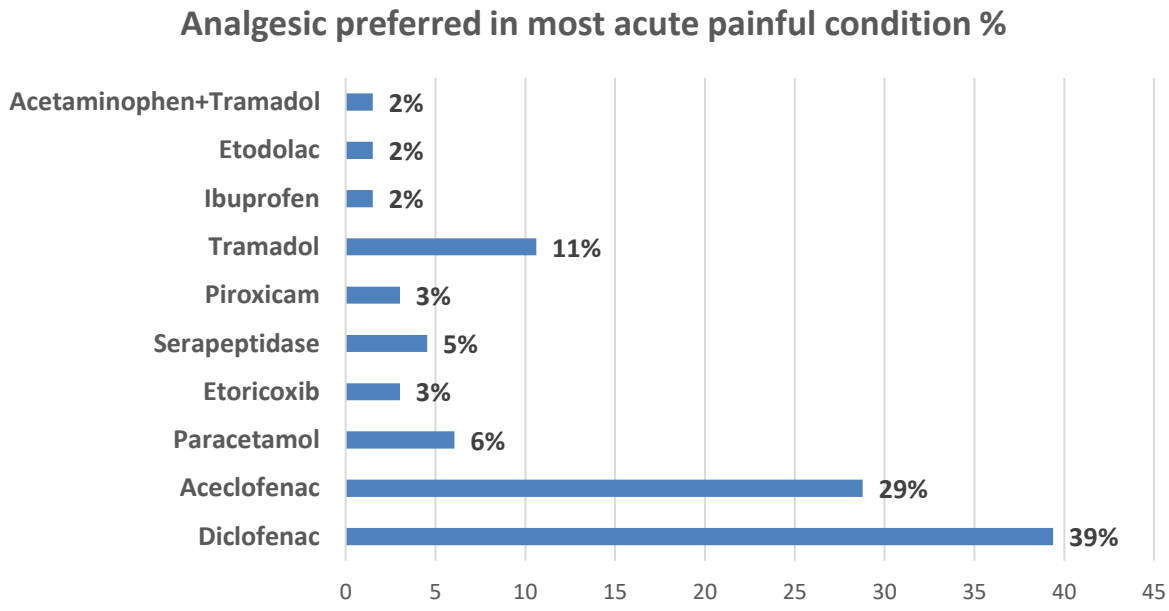
Options	Responses	%Responses
less than 20	3	4.545455
20-40	28	42.42424
40-60	29	43.93939
60-80	5	7.575758
more than 80	1	1.515152



Inference: It was found that data taken from most of doctors have strong prescribing base with 40-60 patients/ day

2. **Analgesic's prefered in acute painful conditions.**

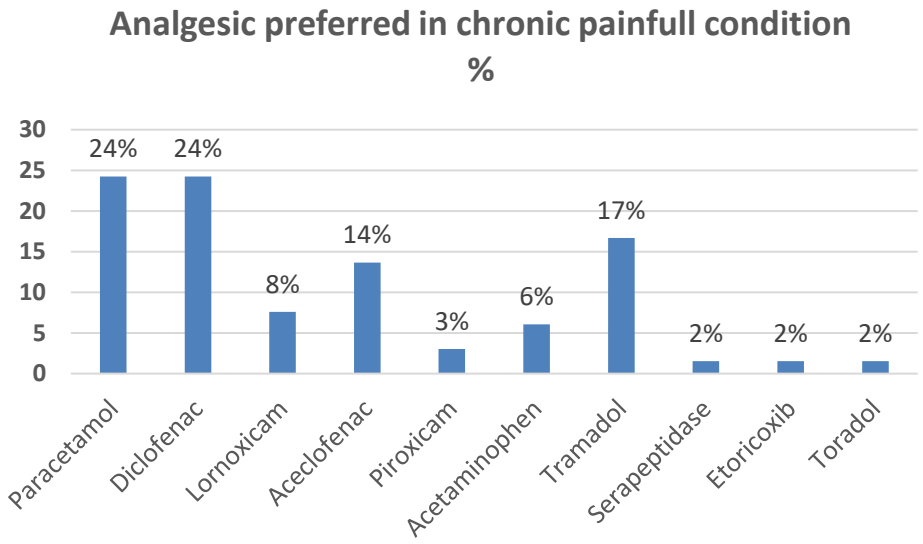
Options	Response	%Response
Diclofenac	26	39.39394
Aceclofenac	19	28.78788
Paracetamol	4	6.060606
Etoricoxib	2	3.030303
Serapeptidase	3	4.545455
Piroxicam	2	3.030303
Tramadol	7	10.60606
Ibuprofen	1	1.515152
Etodolac	1	1.515152
Acetaminophen+Tramadol	1	1.515152



Inference: It was found that most of the doctors prefer Diclofenac in acute pain conditions followed by Aceclofenac.

3. Analgesic prefered in chronic painful condition.

Options	Responses	%Response
Paracetamol	16	24.24242
Diclofenac	16	24.24242
Lornoxicam	5	7.575758
Aceclofenac	9	13.63636
Piroxicam	2	3.030303
Acetaminophen	4	6.060606
Tramadol	11	16.66667
Serapeptidase	1	1.515152
Etoricoxib	1	1.515152
Toradol	1	1.515152



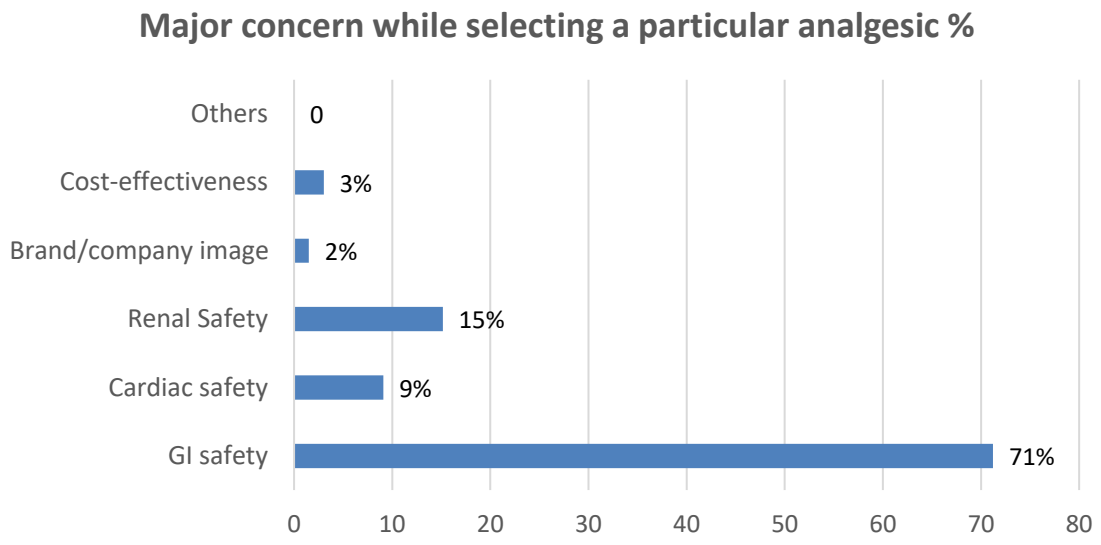
Inference: It was found that 24% doctors prefer paracetamol& diclofenac most in chronic pain conditions followed by Tramadol.

Objective 2:

✓ To analyse the market scenario of analgesics in terms of safety issues.

4. Major concern while selecting a particular Analgesic for your patient.

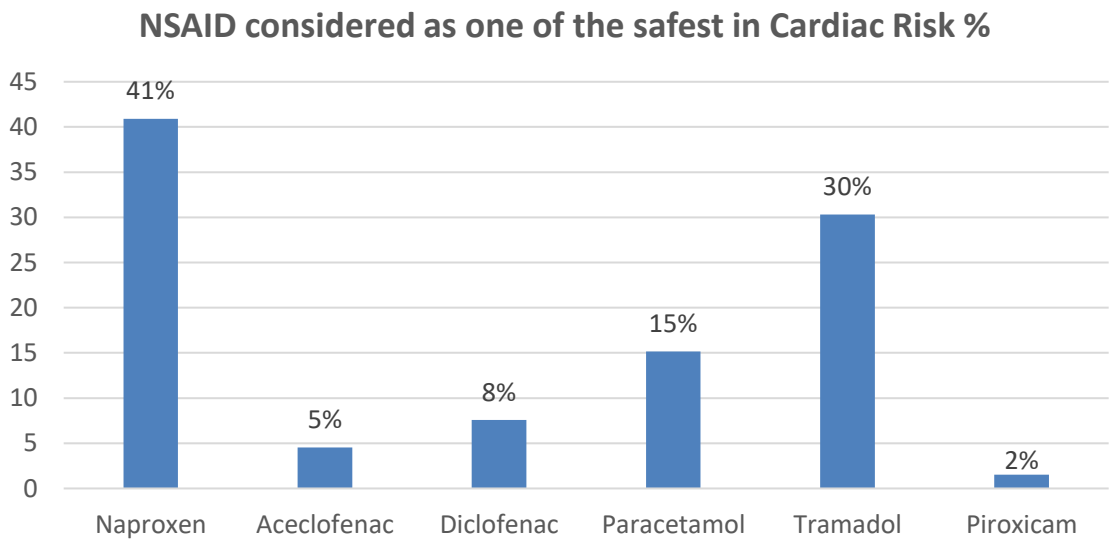
Options	Responses	%Response
GI safety	47	71.21212
Cardiac safety	6	9.090909
Renal Safety	10	15.15152
Brand/company image	1	1.515152
Cost-effectiveness	2	3.030303
Others	0	0



Inference: It was found that 71% of doctors were concerned for GI safety followed by RENAL SAFETY .

5. NSAID considered safest in terms of CARDIAC RISK.

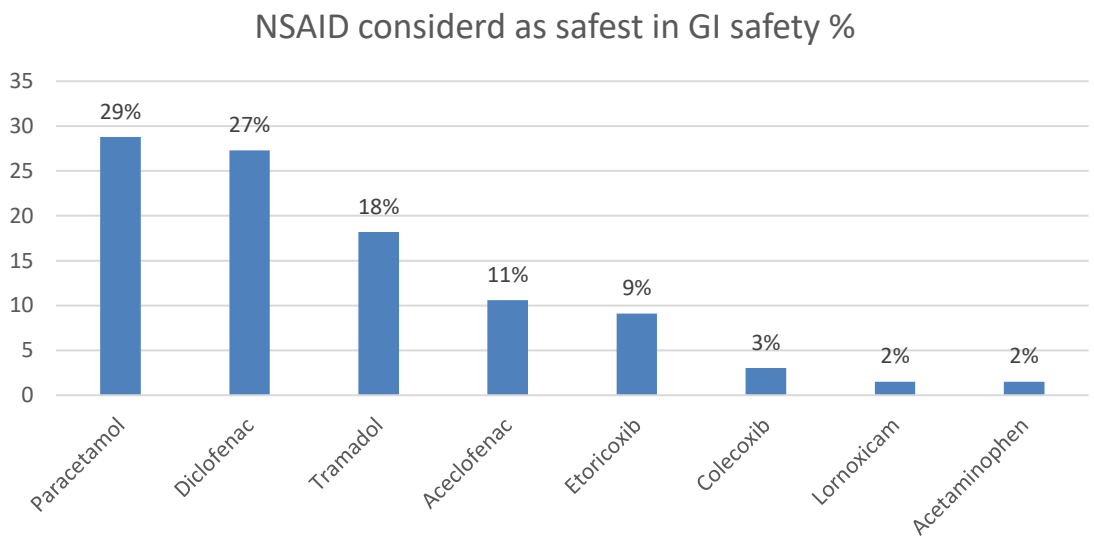
options	Responses	%Responses
Naproxen	27	40.90909
Aceclofenac	3	4.545455
Diclofenac	5	7.575758
Paracetamol	10	15.15152
Tramadol	20	30.30303
Piroxicam	1	1.515152



Inference: It was found during study that 41% doctors consider Naproxen safest in Cardiac risk followed by 31% preference to Tramadol.

6. NSAID you consider safest in terms of GI safety?

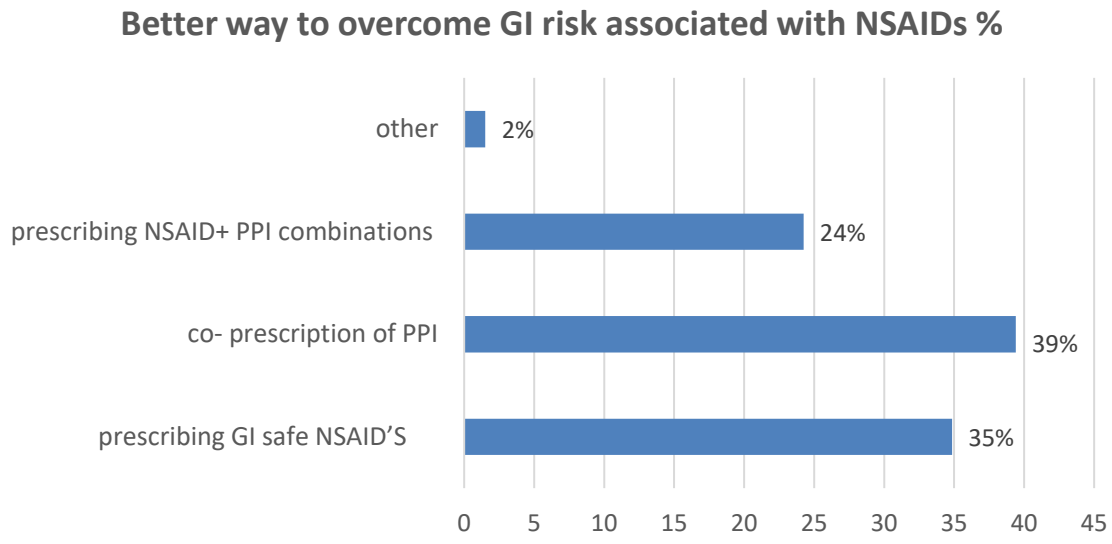
Options	Response	% Responses
Paracetamol	19	28.78788
Diclofenac	18	27.27273
Tramadol	12	18.18182
Aceclofenac	7	10.60606
Etoricoxib	6	9.090909
Colecoxib	2	3.030303
Lornoxicam	1	1.515152
Acetaminophen	1	1.515152



Inference: It was found that 29% doctors consider paracetamol safest in GI risk followed by 27% preference to Diclofenac.

7. **Better way to overcome GI risk associated with NSAID'S.**

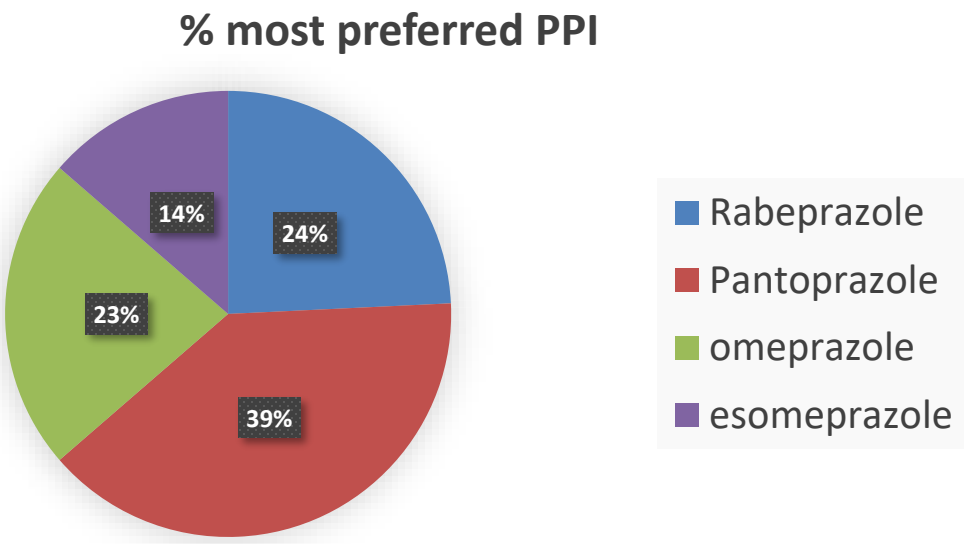
Options	Response	% Response
prescribing GI safe NSAID'S	23	34.84848485
co- prescription of PPI	26	39.39393939
prescribing NSAID+ PPI combinations	16	24.24242424
other	1	1.515151515



Inference: It was found that 39% of the doctors prefer co- prescription of PPI with NSAID while 35% doctors prefer prescribing GI safe NSAIDs.

8. PPI mostly prefered for GI complications in daily clinical practice.

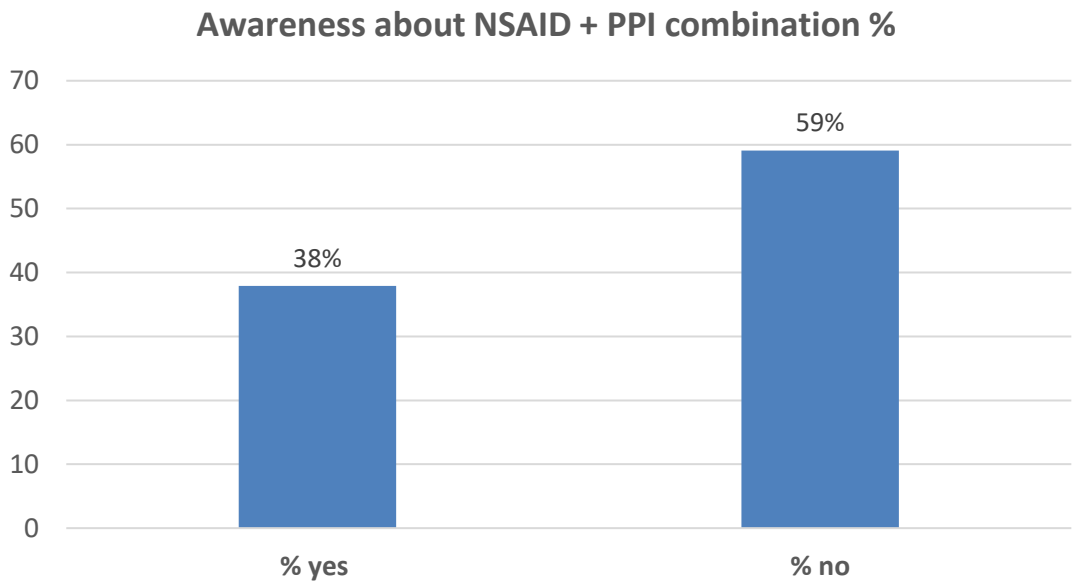
Options	Response	% Response
Rabeprazole	16	24.24242424
Pantoprazole	26	39.39393939
omeprazole	15	22.72727273
esomeprazole	9	13.63636364



Inference: It was found that 39% doctors prefer pantoprazole for GI complications followed by Omeprazole.(23%).

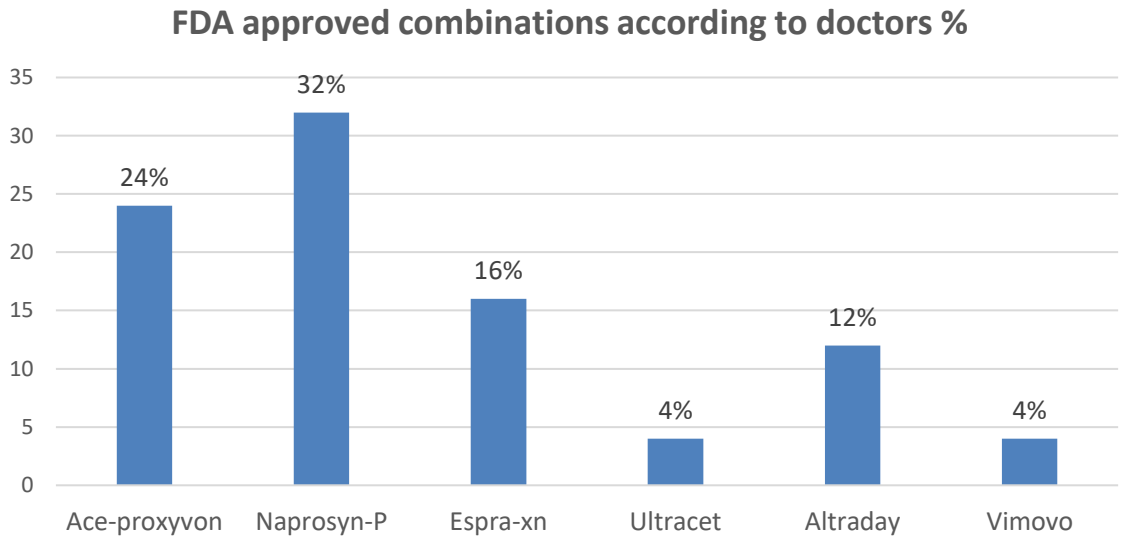
9. Awareness of any NSAID + PPI combination approved by USFDA.

options		% Response	
yes	**no**	**% yes**	**% no**
25	39	37.87879	59.09091



FDA approved combination

Options	Response	% Response
Ace-proxyvon	6	24
Naprosyn-P	8	32
Espra-xn	4	16
Ultracet	1	4
Altraday	3	12
Vimovo	1	4



Inference: It was found that most of the doctors were not aware of any Nsaid+PPi combination approved by USFDA.

While, 40% doctors were mostly aware of. Naprosyn –p followed by ACE-proxyvon.

After meeting the orthopaedic physicians/ surgeons, following findings were observed:

OTHER -FINDINGS:

- ✓ Doctor's prefer diclofenac & aceclofenac mostly in acute pain conditions while they prefer paracetamol & diclofenac most in chronic pain.

- ✓ GI & RENAL safety are their major concerns while selecting any pain killer for their patients and besides that patient's medical history and other etiology were also considered.

- ✓ Doctor's consider Naproxen as safest in terms of cardiac risk but they prefer paracetamol as they don't like to prescribe any NSAID which has even a minimum cardiac risk to their patients.

- ✓ Paracetamol is also considered as GI safe by majority of doctors followed by diclofenac and tramadol.

- ✓ Doctor's used to prefer monotherapy over the combinations by co prescribing antacids or PPIs with NSAIDs.

- ✓ Awareness as well as usage of Naprosyn-p is the most, which clearly shows that naproxen+ esomeprazole have good market opportunity.

Doctors suggest to combine paracetamol with PPI or non-NSAID with PPI.

Doctor's have also suggested the following:

a. Pre dose profiles
b. Low dose combinations

c. Sustained release combinations
d. Company should focus on treating rote cause rather than symptom
e. Paracetamol+tramadol is the best combination
f. Cardiac and GI safe combination with better safety profile
g. Product with Local application is better than oral route.
h. Palatable in size
i. dosing frequency should be minimal
j. Should be given with antacids.
k. NSAID is a culprit for patient with co-morbid conditions

DOSAGE PREFERED BY DOTORS IN ACUTE / CHRONIC PAIN CONDITIONS:

A. Diclofenac: 50mg (TID)/50MG (BD) (ACUTE)

B. Diclofenac SR:100mg (OD)/ Diclofenac: 50mg/day (CHRONIC)

C. Aceclofenac: 50-100mg/day… (ACUTE)

D. Aceclofenac: 200mg/OD... (CHRONIC)

E. Naproxen: 750mg/day

F. Paracetamol: 325mg/day

G. Tramadol: 50mg (BD)... (ACUTE)

H.Tramadol SR: 50mg (OD)... (CHRONIC)

I. Tramadol + Diclofenac: 500mg (OD)... (ACUTE)

J. Tramadol +diclofenac 250 mg (BD)... (CHRONIC)

K. Tramadol+paracetamol: 50mg/day... (CHRONIC)

I. Tramadol+paracetamol (<100mg/d) + (<1.5g/d)(CHRONIC)

M. Tramadol+paracetamol: (<150mg/d+ (<2.0g/d)(ACUTE)

RECOMMENDATIONS:

1) Awareness of brand ESPRA-XN need to be effectively promoted to doctors by medical reps through clinical evidence.

   Awareness of new molecule/combination therapy through literature/research findings among doctors by company's representative is needed for product's acceptance.

2) Availability of the product must be assured by sales force through prompt feedback and by visiting hospitals and retailers more often.

3) Language is a major constraint. For awareness of a particular product among Doctors, company's representatives should know the local language (i.e. Gujarati). So that they feel connectivity & tended to know more about product & research findings.

LIMITATIONS:

1) Sample unit are limited for survey, it affect the accuracy of outcomes.

2) Survey was carried out in one region only (Ahmedabad).

3) Time duration of the survey did not allow collecting more data.

4) The respondents were very busy and could not afford more time to answer.

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ANNEXURE:

Sr. No _____ DATE _____

NAME _____ LOCATION _____

Q.1 How many patients do you examine in your daily clinical practice?

1.Less than 20

2. 20-40
3. 40-60
4. 60-80
5. More than 80

Q.2 WhichAnalgesic you prefer most in acute painfulconditions?

_____

Q.3 which Analgesic you prefer in chronic painfulconditions?

_____

Q.4 What according to you is the ideal dosage for your preferredmolecule?

Acute _____

Chronic_____

Q.5 what is your major concern while selecting a particular Analgesic for your patient?

1. GI safety.
2. Cardiac safety.
3. Renal safety.
4. Brand/ company image
5. Cost effectiveness
6. OTHERS ……..

Q.6 which NSAID you consider as one of the safest in terms of CARDIAC RISK?

……..

Q.7 Which NSAID you consider safest in terms of GI safety?

_____

Q.8 According to you what is a better way to overcome GI risk associated with NSAID'S?

1. Prescribing GI safe NSAID'S.
2. co- prescription of pip's.
3. Prescribing NSAID+ PPI combinations.
4. Others…….

Q.9 Which PPI you mostly prefer for GI complications in your daily clinical practice?

Q.10 Do you know any nsaid+ ppi combination approved by USFDA?

YES NO

IF YES _____

Q.11 what suggestions would you like to offer in current NSAID therapy's to ensure better cardiac n GI safety?

