

SUMMER TRAINING

At

Delcure Lifesciences Ltd.

REPORT ON

**Market research on scope and acceptance of Diclofenac and
Thiocolchioside injections in trauma/critical care unit**

UNDER THE GUIDANCE

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“No one who achieves success does so without acknowledging the help of others. The wise and confident acknowledge this help with gratitude.”

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1.1 COMPANY PROFILE

DelCure Life Sciences Ltd. Is a complete-scale pharmaceutical business enterprise with a goal to convey differentiated awesome merchandise via international collaboration with innovator companies from the United States, Switzerland and European international locations. High high-quality merchandise is assured from the producing companion of excessive reputation. DLL is one of the fastest growing pharmaceutical businesses in India.

The technology backed innovative medicines ensures the health and well being of people around the country. Every Delcure medicines and service is a testament to its uncompromising quality standards. All products are manufactured in facilities that are approved by the major global regulatory agencies including the USFDA, ISO2009, ANVISA and more. Being a healthcare centric and innovation driven company they valued not only for pharmaceutical product but also for the way to serve patients and healthcare professionals.

The company, founded in 2013 by **Mr.Prashant kumar Pathak** under the leadership of **Mr.Akshay Kumar Mahapatra (CEO)**, Delcure has evolved into a multidivisional company with products ranging from oral solids, oral liquids, topical to injectable.

Robust portfolio, therapy coverage, certified manufacturing partner and an energetic team have been the catalyst for their impressive recognition in pharmaceutical industry.

➤ Divisions

- **WinSpire**

DLL commenced marketing operations inside the discipline from June 2013. The primary divisions changed into launched three hundred members in Paediatrics, ENT, and Chest Specialties. This department has merchandise with differentiated era, “Fast Absol” in all pill

variety and “KuraFast” in all dispersible capsules, for the result in faster onset of action and as a result faster comfort.

The divisions plans to assist Paediatrics, ENT & chest fraternity with progressive advertising and marketing activities like medical information aid in affiliation with Elsevier, era-based totally activities like CME’s and convention participation and many others.

- **Delvoice**

Delvoice is the second department of DLL launched in August 2013. It is multispecialty division with a focus in the direction of Orthopaedics, Gastroenterologists and Consulting Physicians.

It has revenue of \$5.3 million and 56 personnel. DLL primary competitions are Celogen Pharma, Inventia Healthcare and Calyx. The business corporation has entered into strategic long term production collaboration with Akums Drugs & Pharmaceutical Limited, the only prevent destination for pharmaceutical companies and India’s largest Contract Research and Manufacturing (CRAMS) agency chargeable for manufacturing about 11-12 % of all pills consumed inside the country.

DelCure has sturdy distribution channel, accomplice stockiest are gift at each nook across India. Their companion enables us to ensure accessibility of Delcure drugs to needy sufferers on time.

1.2 INTRODUCTION

NSAIDs are the drugs that widely used for the treatment of pain and inflammation. NSAIDs also lie in the wider range of non opioid analgesics which provide the relieve by adding on Prostaglandins. These are usually prescribed by the doctors in less severe cases of pain. NSAIDs display anti inflammatory, analgesics, antipyretic results and additionally inhibit thrombocyte aggregation. They are used regularly to treat irritation, slight to mild ache and fever.

Recently NSAIDs are used all over the world in surgery and many areas of medicines generally to prevent and cure a huge number of conditions related to the pain and inflammation (1). Use of NSAIDs is very common in practice in post operative as well as post traumatic pain therapy which can be administered either in conventional dosage form or in novel dosage form. Diclofenac is one of the most widely used NSAIDs with verified anti-inflammatory, analgesic consequences and antipyretic houses which have been proven to be effective in treating a selection of acute and persistent pain and inflammatory situations (2). As with all NSAIDs, diclofenac exerts its motion through inhibition of prostaglandin synthesis by using inhibiting cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2) with relative equipotency (3) (4). Diclofenac sodium acts thru robust cyclo-oxygenase inhibition, discount of arachidonic acid launch, and enhancement of arachidonic acid uptake. It thereby consequences in a dual inhibitory impact on both the cyclo oxygenase pathways (4). Muscle relaxants are the common treatment for the condition of severe pain such in case of the management of nonspecific low back pain. The term “muscle relaxants” includes wide spectra of drugs having different mechanisms and other effects. These drugs are CNS depressants with side effects such as sedation and drowsiness may cause addiction on long term use (5).

Thiocolchicoside is a semi-artificial by-product of colchicines with affinity for the inhibitory glycine and gamma-amino butyric acid (GABA)-A receptors, which bills for its myorelaxant and analgesic pastime (5). Thiocolchicoside is a powerful and safe inside the remedy of decrease lower back pain. Thiocolchioside is a muscle relaxant. It works on the facilities in the mind and spinal cord to relieve muscle stiffness or spasm and decorate movement of muscle organizations (6). It indicates affinity for the inhibitory glycine and (GABA)-A receptors and therefore the compound are endowed with glycinomimetic interest and are being used in rheumatology and orthopaedic subject for its myorelaxant residences (5). Thiocolchioside produce muscle

relaxation and is prescribed in acute trauma situations and extreme pain whereas diclofenac is used as parenterals preferably in acute pain situations (7). Although those businesses of medicine typically help to lessen spasticity but decreases in muscle tone someplace else, may also cause a lower inside the mobility of the patient (6).

The development of sedation is discovered to be a first-rate limiting factor in the use of muscle relaxants as they could affect each day sports and running capabilities. Hence, these proscribing elements within the use of muscle relaxant without consequences on psychomotor overall performance, free of sedation and higher tolerability.

1.3 BACKGROUND

The purpose of study is to focus at the goal, ensuring the reputation and scope of Thiocolchicoside + Diclofenac injections in the Trauma/crucial care unit. Diclofenac is one of the most extensively used NSAIDs with set up anti inflammatory, analgesic effects and antipyretic effects, which proves to be powerful in treating an expansion of acute and persistent pain and inflammatory situations. As with all NSAIDs, Thiocolchioside and Diclofenac relieve muscle ache. Thiocolchioside is a muscle relaxant. It works on the middle of the thoughts and spinal cord to alleviate muscle stiffness or spasm and decorate motion of muscle tissues. Diclofenac is a (NSAIDs) which matches the use of blockading the discharge of fantastic chemical messengers within the mind that reason ache and inflammation (2).

The general outline of the research indicates the market prospect of Diclofenac+ Thiocolchicoside injections in the Trauma/critical care unit to know the understandings and awareness of the combination injections prescribed amongst the targeted doctors and also recognizing the ground level problems faced when interacting with doctors.

The project has been done through targeting the different cities of Uttarakhand state conducting online survey and come up with the ideas to improve the present scenario of the product.

1.4 LITERATURE REVIEW

Egidio Sproviero et al., 2018: The study focused on efficacy and tolerability of the 4 ml volume diclofenac + thiocolchicoside FDC for IM injection in evaluation with the separate injection of the 2 additives, in patients with moderate excessive acute LBP. The control of severe lower back pain (LBP) is indicated to achieve early and most remedy for the neighborhood and regional ache, and to enhance potency and physical function. Five day treatment with Intra muscular injection of diclofenac + thiocolchioscide in a 4 ml extent was a powerful and well tolerated as the disparate injection of the 2 additives in enhancing ache signs and symptoms with acute slight-extreme lower returned ache. The new diclofenac + thiocolchioscide FDC components allows treating efficaciously acute lower back ache while decreasing the quantity of injections and progressed compliance and reduced risk of nearby unfavorable reactions.

Zeynep Ozturk et al., 2016: This studies turned into performed to analyze the behind schedule effects of thiocolchicoside exposure among pregnant women. It become determined that the survey was followed up inside the girls at some stage in being pregnant and the babies was observed up monthly till 2 years of age. Performed by using the circle of relatives' physicians or pediatricians, no increase or developmental issues have been observed among kids. The youngsters born to moms who used thiocolchicoside in being pregnant had regular scientific opinions during their early years and no symptoms of any genetic disorders.

Irianni et al., 2016: In this look at, the discovery pertains to a stable injectable aqueous solution containing diclofenac and thiocolchicoside which might be use in the remedy of painful and inflammatory rheumatic or traumatic conditions of the joints, muscle tissues, tendons and ligaments. It demonstrates that diclofenac is a substance containing a combination of propylene glycol and polyethylene glycol. While getting ready a liquid composition containing diclofenac and thiocolchicoside, it's been discovered that it's far vital to triumph over some of technological problems, the most essential requirement is to prevent the degradation of one or both of the energetic components when formulated in a single unit dose solution..

Huma Ali et al., 2016: This observe changed into carried out with an objective to decide pharmacological and bioequivalence of diclofenac potassium 50 mg take a look at (F4) pill

components with the product (Caflam). The person dose, randomized, segment go over layout, performed in 12 healthy Pakistani volunteers and deliberate according with FDA tips. The procedure was demonstrated in the variety of fifty - 0.05 µg.ML⁻¹ and utilized in bioequivalence trial of two products. Several blood samples were collected at various time factors (0.Five, 1, 2, 3, 4, five, 6, eight, 10, 12 and 14 hr after treating volunteers with test (F4) and marketed reference logo. Plasma separation and deproteination were accomplished with acetonitrile; samples (20µL) had been injected using the verified HPLC method. Bioequivalence amongst the goods was installed by way of calculating the ninety% CI with log and non log converted records for C_{max}calc, T_{max}calc, AUC_{0-∞}, AUC_{tot} and AUC_{last} the use of way ANOVA and Schirmann's two one sided t- test. No massive distinction was located among log and non-log statistics. The 90% self assurance c programming language values the usage of log converted data for AUC_{0-∞} (zero.997-1.024), AUC_{tot} (1.004-1.031), AUC_{last} (zero.997 - 1.024), C_{max}calc (zero.994-1.007) and T_{max}calc (zero.996-1.013) for the trial and reference merchandise have been determined inside the FDA proper limits of 0.8-1.25. Results showed the bioequivalence of check and reference formulations. Both the products have been nicely tolerated.

Bairy KL et al., 2015: The observation was carried out to evaluate efficacy of different classes of medicine in remedy of low lower back pain. A potential observational examine changed into performed over a period of three hundred and sixty five days in which a complete of three hundred sufferers with low returned ache were apply and divided similarly into three groups, (NSAIDs), (muscle relaxant ± NSAIDs) and (muscle relaxant ± NSAIDs ± neurotropic pills).. Mean percent reduction in incapacity index was maximum in organization 2 (54.66± 9.85), observed through institution 3 (51.33 ± 6.95) and organization 1 46.78 ± 10.12). A significant inter-institution distinction turned into located. NSAIDs with muscle relaxants are more efficacious for low back pain as compared to different combinations.

Giuseppe Carlucci et al., 2002: The observation was carried out to observe that the physicochemical compatibility among thiocolchicoside and various injectable capsules regularly utilized in affiliation. Physicochemical properties of thiocolchicoside mixtures with extraordinary drugs, along with color, pH and drug content have been found or measured before and after (3 h) mixing at required room temperature. Results shows that the affiliation of

Miotens† with certainly one of a type anti inflammatory drugs and nutrients does no longer cause, up to 3 hours from blending, any high-quality variation inside the physicochemical parameters. The outcomes showed that the physicochemical compatibility of thiocolchioside with various anti inflammatory drugs and vitamins.

Von Stetten et al., 1987: The studies become targeted on the aqueous, strong, particularly focused solutions of diclofenac, which comprise a mixture of propylene glycol and polyethylene glycol in described quantitative proportions. The solutions ideally contain a local anesthetic consisting of lidocaine and a lowering agent as stabilizer. Due to the exceedingly large 'first-skip-impact' of the substance and for quicker flooding it's far desirable to use injection answers, in which an quantity of 75 mg ought to be used per injection. For intramuscular injections, but, the volume is to be saved as little as feasible. Due to the notably terrible solubility of diclofenac in water an aqueous injection solution with a reasonable quantity cannot be received. It has been observed that even better dissolution of the diclofenac may be acquired whilst a neighborhood anesthetic, i.e. Lidocaine, is delivered. Due to this a sufficient diploma of solubility is received already at decrease pH values which correspond greater to the physiological cost.

2. RESEARCH METHODOLOGY

2.1 OBJECTIVE AND SCOPE OF THE STUDY

- **Objective:** The main objective is to find out the scope and acceptance of thiocolchioside and diclofenac injections in trauma/critical care.
- **Primary Objectives:**
 - To find out the potential of thiocolchioside and diclofenac injections in Uttarakhand region.
 - To study and understand the concept of market research.

➤ **Scope of the study:**

- The major scope of this study is to know what is the scope and acceptance of thiocolchioside and diclofenac injections in trauma/critical care and then to identify its market strategy to increase its sales and promotional tools.

➤ **Sample Design:**

Descriptive Study

➤ **Sample Size:**

Respondents 200

➤ **Sample Population:**

Orthopaedic doctors and General Physicians

➤ **Sample Area:**

Uttarakhand

➤ **Tools used for data collection:**

Direct Questionnaire Method

➤ **Type of Questionnaire:**

Structured

➤ **Type of Questions:**

Closed and Open-ended

➤ **Tools used for data analysis:**

MS-EXCEL

➤ **Data collection:**

- Primary- Primary data has been collected by the means of questionnaire.
- Secondary- The secondary data involved in this project has been gathered from the medical journals, literature, and internet.

➤ **Study duration:**

2 Months

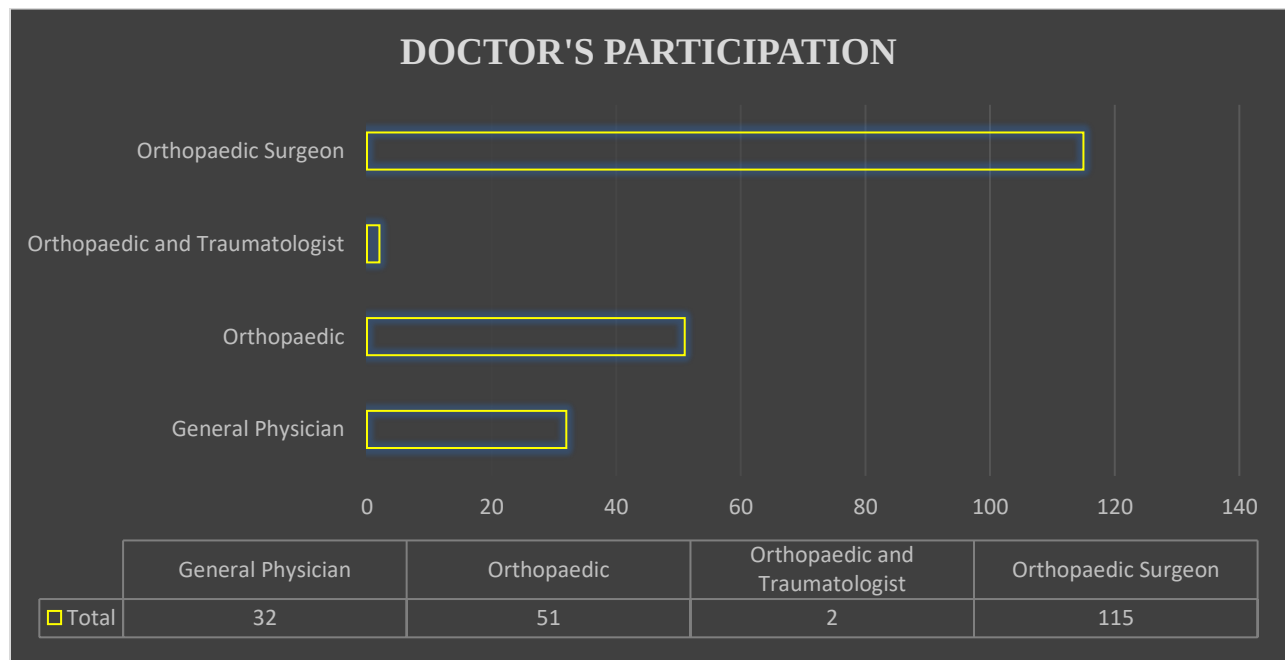
2.2 ETHICAL CONSIDERATION:

The research has been completed with proper research guidelines. Enough time has been given to the respondents for the study so that they can depict their true view on research questions. Consent from the respondents has been taken and appropriate permission was similarly ensured for the usage of their data. The disclosure of respondents' identification has been based on their permission. The usage of secondary data from the source was acknowledged with proper reference.

3. DATA ANALYSIS

3.1 FINDINGS AND INTERPRETATION

1. The number of doctors participated in the survey.



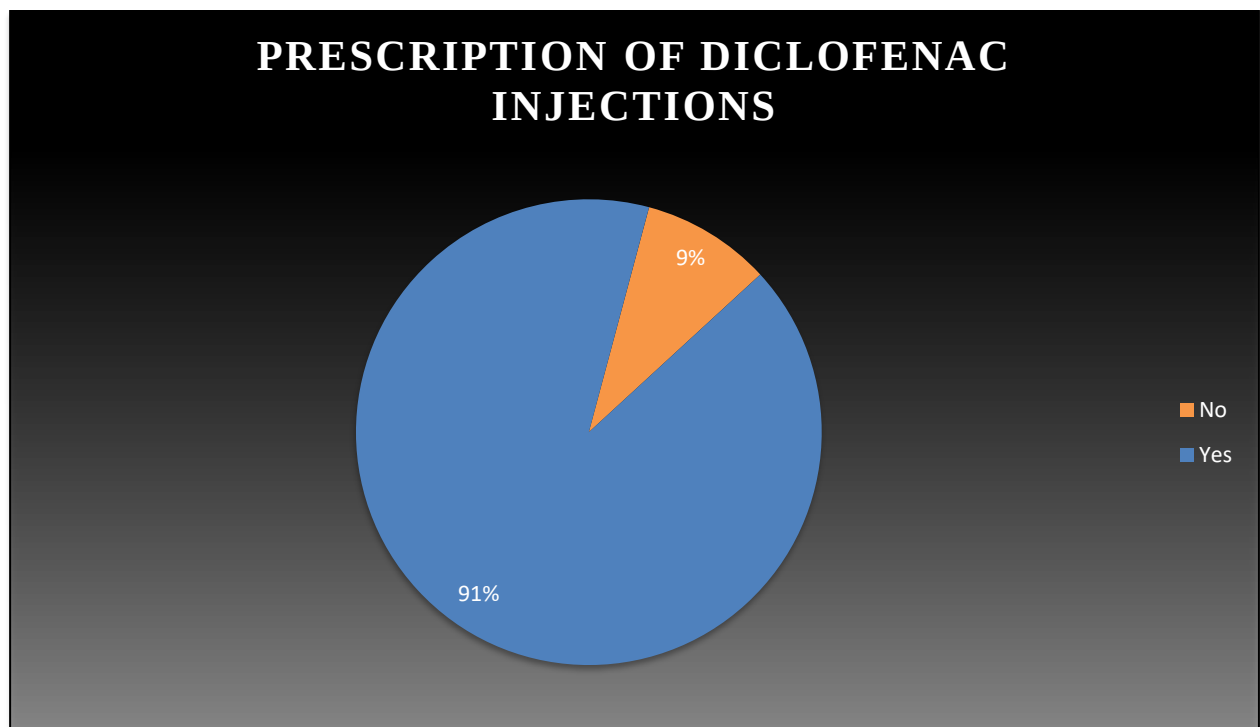
(Figure 1)

1. Interpretation: The above graph represents the number of doctors who responded to survey conducted on the scope and acceptance of thiocolchioscide and diclofenac injections in trauma

and critical care unit. Of the total 115 were Orthopaedic surgeon 51 were Orthopaedic and 32 were General Physician in targeted location (Uttarakhand).

2. Prescription of diclofenac Injections by the Orthopaedic and General Physician.

Do you prescribe Diclofenac Injection?	
Yes	182
No	18
Grand Total	200

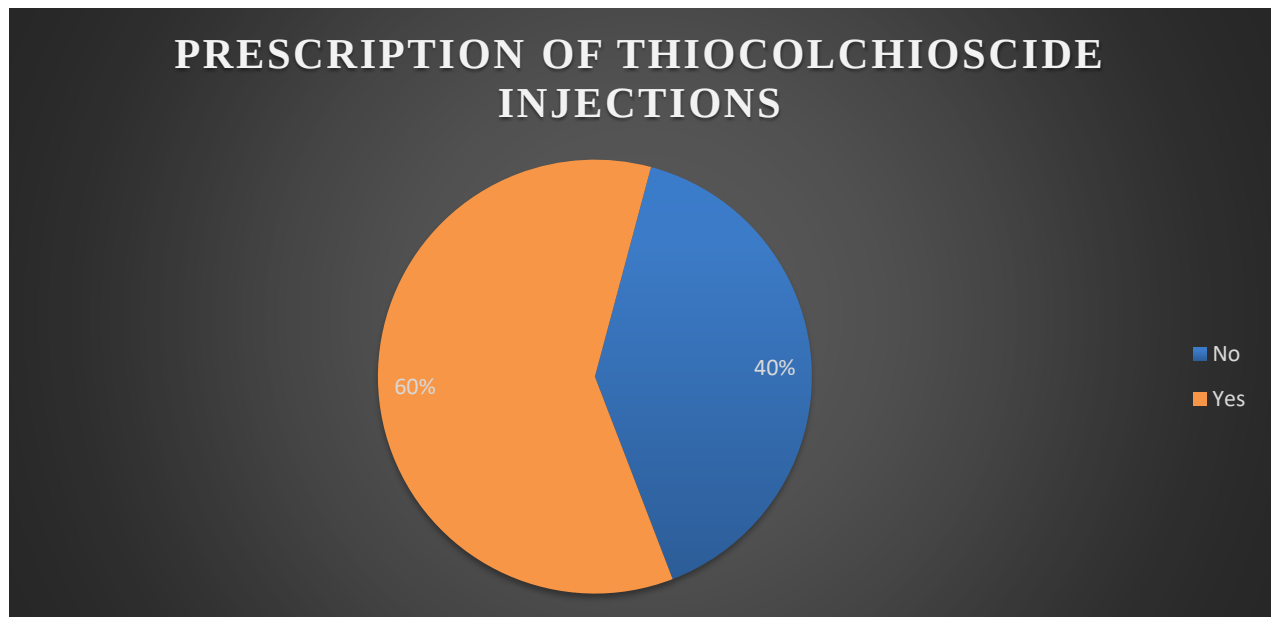


(Figure 2)

2. Interpretation: The graph illustrates the percentage of prescription of diclofenac injection. It was found that 91% of the doctors prescribed the use of the injection while the rest 9% doctors do not, due the side effects like Allergy, GIT rash and drowsiness.

3. Prescription of Thiocolchioside Injections by the Orthopaedic and General Physician.

Do you prescribe Thiocolchioside Injection?	
Yes	120
No	80
Grand Total	200



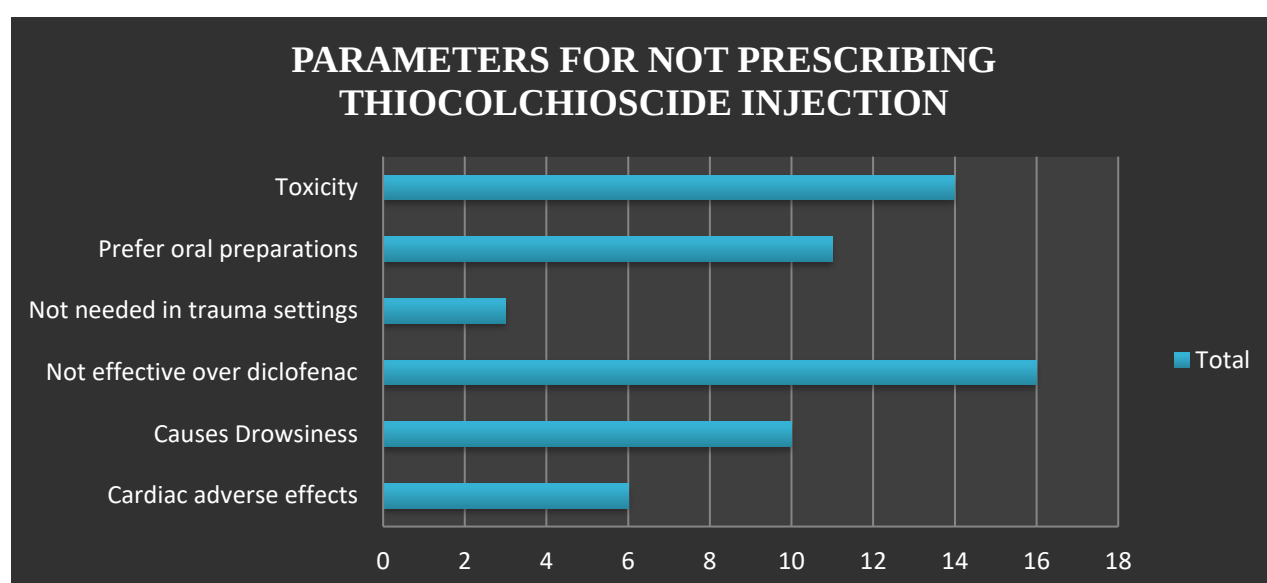
(Figure 3)

3. Interpretation: The chart depicts the prescription of thiocolchioside injections amongst orthopaedic and general physician. 60% of the doctors allowed the use of thiocolchioside in their practice while 40% of the doctors did not.

4. Parameters for not prescribing Thiocolchioside Injection.

If NO then what is the reason (Thiocolchioside)	General Physician	Orthopaedic	Orthopaedic Surgeon	Grand Total
Not needed in trauma	1.7%	3.3%	0.0%	5.0%

settings				
Cardiac adverse effects	1.7%	1.7%	6.7%	10.0%
Causes Drowsiness	0.0%	13.3%	3.3%	16.7%
Prefer oral preparations	1.7%	10.0%	6.7%	18.3%
Toxicity	0.0%	0.0%	23.3%	23.3%
Not effective over diclofenac	8.3%	15.0%	3.3%	26.7%
Grand Total	13.3%	43.3%	43.3%	100.0%



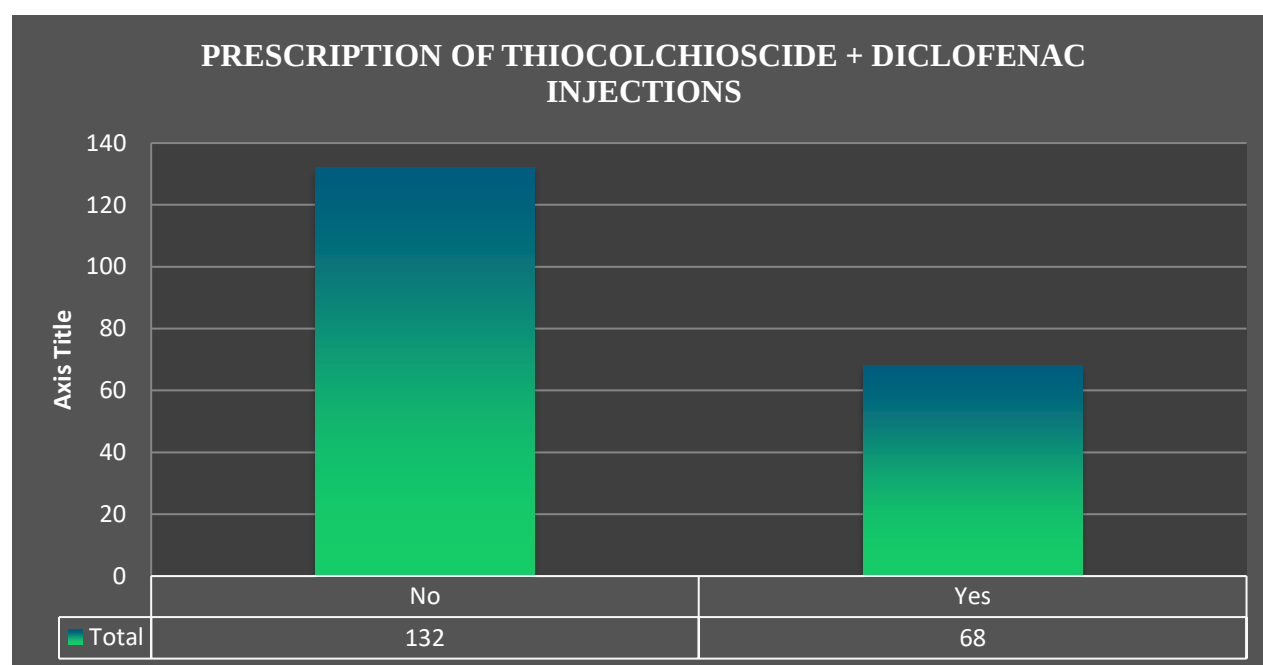
(Figure 4)

4. Interpretation: The chart outlines the various parameters of not prescribing Thiocolchioscide injections wherein according to 26% of the Orthopaedic doctors find it less effective over diclofenac while 23% find it to be toxic and 16% preferred oral preparation.

5. Prescription of Thiocolchioscide and Diclofenac Injection by the Orthopaedic and General Physician.

Do you prescribe Thiocolchioscide + Diclofenac Injections?	No. of doctors responded
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Yes	68	34.%
No	132	66%
Grand Total	200	100.00%



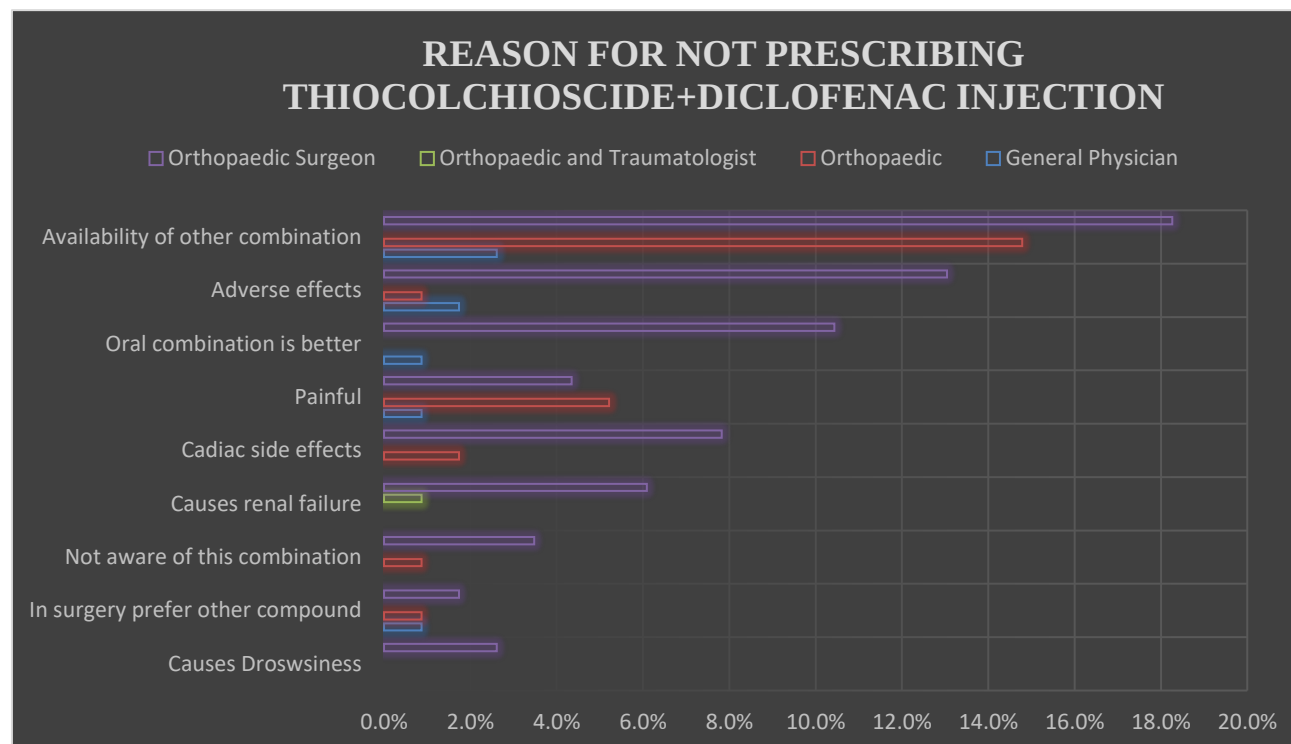
(Figure 5)

5. Interpretation: The above chart is the graphical representation of the prescription of thiocolchioscide + diclofenac injections where it is seen that 34% of the orthopaedic doctors including general physician prescribe the combination while 66% seems to lessen its prescription.

6. Restriction for not using Thiocolchioscide and Diclofenac Injections.

Count of If No then what restricts you to use Thiocolchioscide + Diclofenac Injections?	General Physician	Orthopaedic	Orthopaedic and Traumatologist	Orthopaedic Surgeon	Grand Total
Causes Drowsiness	0.0%	0.0%	0.0%	2.6%	2.6%

In surgery prefer other compound	0.9%	0.9%	0.0%	1.7%	3.5%
Not aware of this combination	0.0%	0.9%	0.0%	3.5%	4.3%
Causes renal failure	0.0%	0.0%	0.9%	6.1%	7.0%
Cardiac side effects	0.0%	1.7%	0.0%	7.8%	9.6%
Painful	0.9%	5.2%	0.0%	4.3%	10.4%
Oral combination is better	0.9%	0.0%	0.0%	10.4%	11.3%
Adverse effects	1.7%	0.9%	0.0%	13.0%	15.7%
Availability of other combination	2.6%	14.8%	0.0%	18.3%	35.7%
Grand Total	7.0%	24.3%	0.9%	67.8%	100.0%

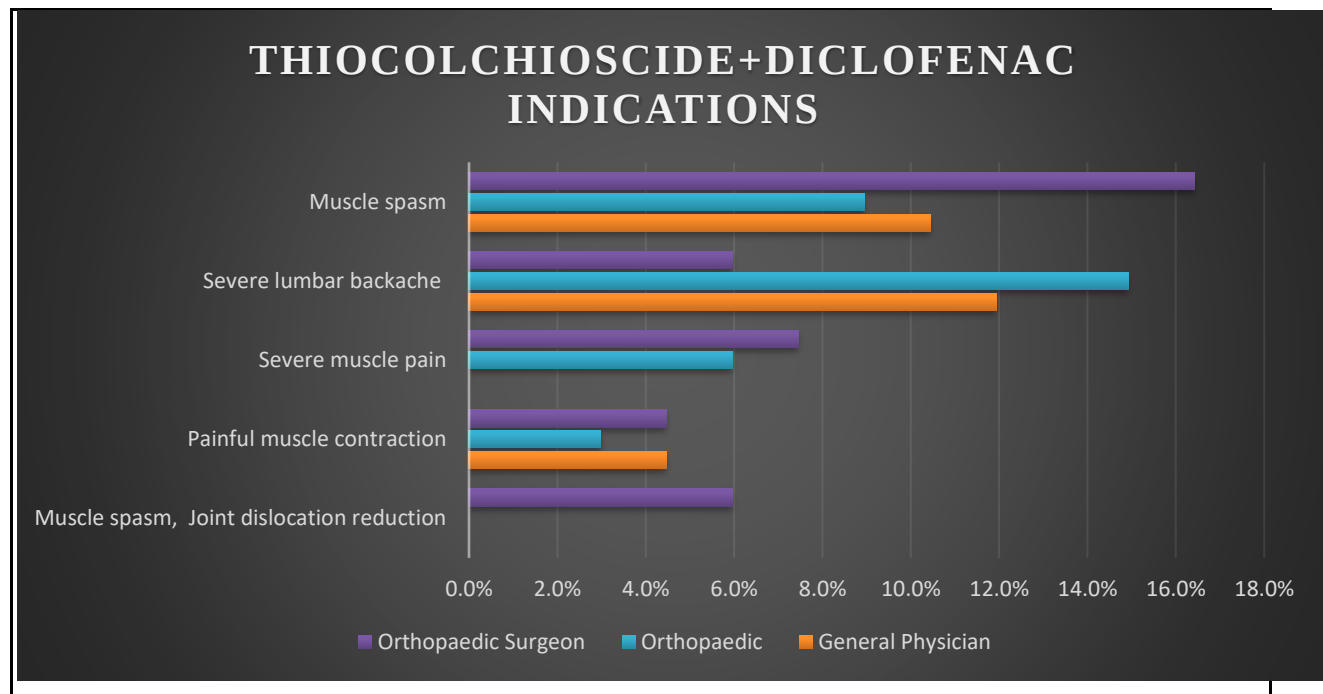


(Figure 6)

6. Interpretation: The above tabulation along with the graph illustrates the reason for restricting the use of thiocolchioside + diclofenac injection. Lack of availability of the combination to the doctors was found to be the major reason for not prescribing it. However, 15% of the doctors find the combination to cause adverse effects and 13% of them prefer giving oral combination to the patients.

7. Major indications in which Thiocolchioside and Diclofenac Injections is prescribed.

Count of What are the major indications in which you prescribe Thiocolchioside + Diclofenac Injection?	General Physician	Orthopaedic	Orthopaedic Surgeon	Grand Total
Muscle spasm, Joint dislocation reduction	0.0%	0.0%	6.0%	6.0%
Painful muscle contraction	4.5%	3.0%	4.5%	11.9%
Severe muscle pain	0.0%	6.0%	7.5%	13.4%
Severe lumbar backache	11.9%	14.9%	6.0%	32.8%
Muscle spasm	10.4%	9.0%	16.4%	35.8%
Grand Total	26.9%	32.8%	40.3%	100.0%

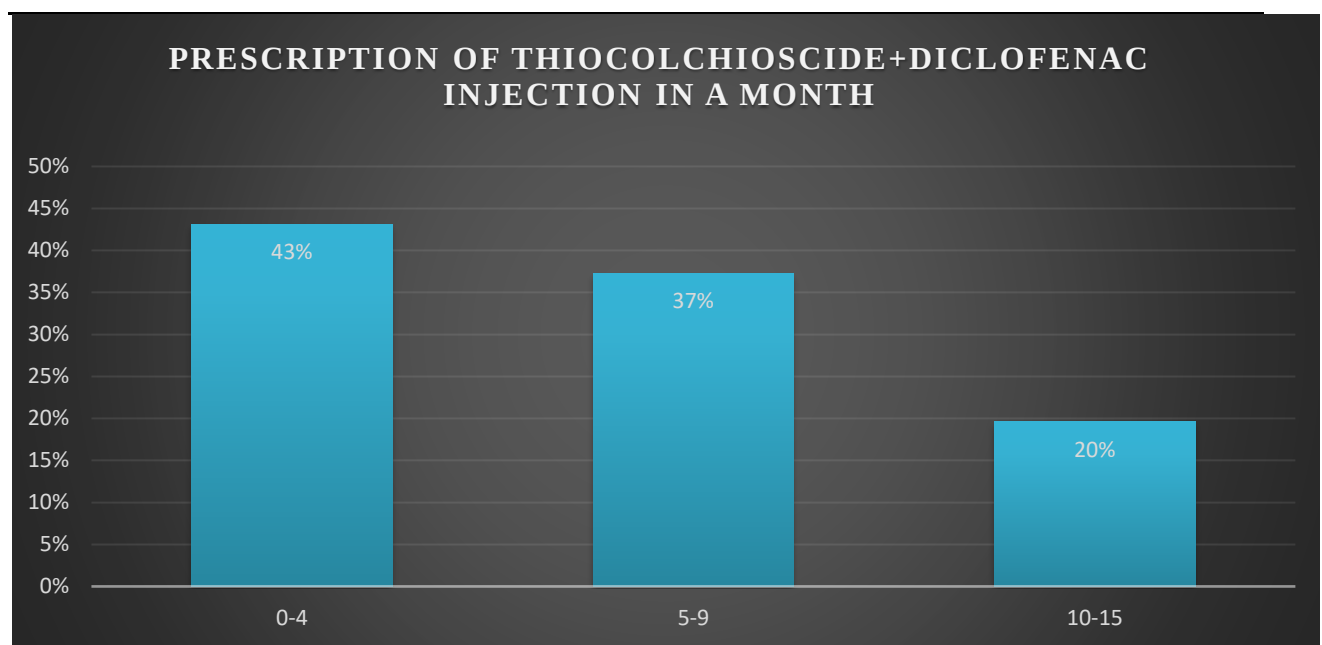


(Figure 7)

7. Interpretation: This graph illustrates the indications in which the thiocolchioside+ diclofenac injections are prescribed by the orthopaedic doctors and general physician. 35% of the doctors prescribed it in muscle spasm , 34% in severe lumbar backache while only 6% of the orthopaedic surgeon prescribe it in muscle spasm, joint dislocation reduction.

8. Prescription of Thiocolchioside and Diclofenac Injections to patients in a month.

No. of patients	How many patients do you prescribe Thiocolchioside + Diclofenac Injection in a month?
0-4	43%
5-9	37%
10-15	20%
Grand Total	100%

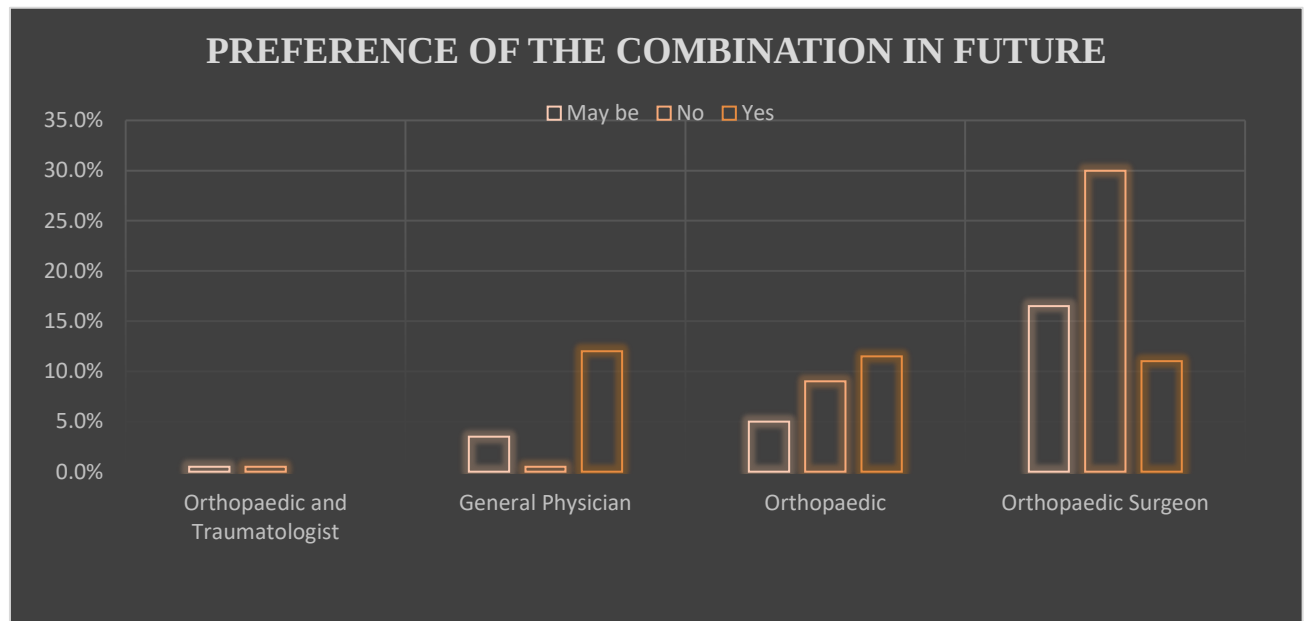


(Figure 8)

8. Interpretation: This graph gives the numeric value of patients to which thiocolchioside + diclofenac injection was prescribed in a month. It was found that 43% of the orthopaedic doctors prescribed it to 0-4 patients while 37% prescribed it to 5-9 patients and 19% prescribed to 10-15 patients in a month.

9. Preference of the combination by the Doctors in future.

Will you prefer combination of thiocolchicoside + diclofenac injection, if in near future a new brand will launch with same combination?	May be	No	Yes	Grand Total
Orthopaedic and Traumatologist	0.5%	0.5%	0.0%	1.0%
General Physician	3.5%	0.5%	12.0%	16.0%
Orthopaedic	5.0%	9.0%	11.5%	25.5%
Orthopaedic Surgeon	16.5%	30.0%	11.0%	57.5%



(Figure:9)

9. **Interpretation:** This graphical representation is of the orthopaedic doctors and general physicians who in near future may prescribe the same combination if launched by some the other brand. 34% of the doctors agreed to use the combination while 40% of the doctors disagreed and 22% of the doctors response was found to be in dilemma.

3.2 CONCLUSION

As the completion of the market research it was found that the combination of thiocolchioside+ diclofenac injections in trauma/ critical care unit prescribed by orthopaedic doctors and general physician were less in number while the use of individual injection was high in preference.

It was also recorded that the doctors including orthopaedic and general physician avoid the usage of the combination in trauma and critical care unit and while prescribing the combination most of the doctors consider patient compliance, side effects and other parameters for ease of patients.

3.3 LIMITATION

- As the project deals with the process of survey conduction thus to interact with the targeted doctors was quite a difficult task as they are bounded with a busy schedule.
- Due to personal attitudes, person values and organizational guidelines, orthopaedic and fashionable physician hold maximum in their assignment mystery.
- The researcher received minimal cooperation from some respondents. Therefore, the availability of records was limited hence limiting the readiness of more information that would have permit elaborate more research.
- Doing survey on the name of students becomes very challenging as the frequently asked question is what benefit you provide if the data is being provided.
- Resources constraints, additionally posed a high-quality dilemma with restricted budget and busy agenda consequently the researcher having restricted time to carry out the research.

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5. ANNEXURE

AIM: To find out the acceptance and scope of Thiocolchioscide & Diclofenac injections in Trauma/Critical Care unit.

Dr Name	Speciality
Qualification	Contact
Place	Date

1. Do you prescribe Diclofenac Injection?

Yes ☐

No ☐

If No what is the reason?

2. Do you prescribe Thiocolchicoside Injection?

Yes ☐

No ☐

If NO what is the reason?

3. Do you prescribe Thiocolchicoside + Diclofenac Injection?

Yes ☐

No ☐

[If NO question no.(4 & 8) If YES question no.5]

3. If No then what restricts you to use Thiocolchicoside + Diclofenac injection?

.....

5. What are the major indications in which you prescribe Thiocolchicoside + Diclofenac Injection?

.....

6. How many patients do you prescribe Thiocolchioscide+ Diclofenac Injections in a month?

.....

7. Will you prefer combination of thiocolchicoside + diclofenac injection, if in near future a new brand will launch with same combination?

.....

8. Any other comments/suggestions:

.....

Thank you for the participation!!