

***“TO UNDERSTAND THE PRESCRIPTION BEHAVIOUR OF EPA AND
DHA AMONG ORTHOPAEDIC AND CONSULTING PHYSICIAN”***

SUMMER TRAINING REPORT

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TO WHOMSOEVER MAY CONCERN

This is to certify that Ankita Dixit, student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training at **Delcure lifescience** from **April 1, 2020 to May 31, 2020**

The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific, and analytical.

The Internship is in fulfillment of the course requirements.

Dean, Academics and Student Affairs
The IIHMR University, Jaipur

Professor
The IIHMR University, Jaipur

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the Summer Internship titled ***To understand the prescription behaviour of EPA and DHA among Orthopaedics and Consulting Physicians*** and put together by Ankita Dixit, Enrollment No. IIHMR-U/02/2019-21/170 under the supervision of **Dr. Sandeep Narula** for grant of MBA in Pharmaceutical Management completed during the period from April 1, 2020 to May 31, 2020 encapsulates my unique work and has not shaped the reason for the honour of any degree, recognition partner transport, cooperation, titles in this or some other foundation or other comparable organization of higher learning.

Signature

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ANKITA DIXIT

PM11 (170)

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INTRODUCTION-

The project aims at the paradigm shift from the conventional marketing strategies to the new digital model. The company which provided with the project was DelCure Lifescience and the product which was worked with was Omega3 fatty acid. Before starting with the project, it was very much necessary to know about the Company and the Product and the next sub-topics will be relating the same.

Organization Profile:

DelCure Life Sciences Ltd. (DLL) is a complete drug company with an aim to bring various differentiated high-quality product through international collaboration with ground breaker corporations from the USA, Switzerland, and European countries. prime quality product square measure assured from our producing partner of high repute.

Vision:

“To become a most respected uniquely positioned leading pharmaceutical company in the Chosen Areas or Specialty verticals in India and abroad with distinct value-based characters”.

Product Overview:

- A prescription form of omega-3 fatty acids has been approved by u. s. Food and Drug Administration as an adjunct to diet for the treatment of very high lipid levels. The active ingredients of omega-3 fatty acids are omega-3 (EPA) and omega-3 (DHA), which are answerable for the acylglycerol lowering.
- The prescription product contains a complete of 0.84 g of those 2 active ingredients in each capsule of omega-3 fatty acids. the whole EPA and DHA dose suggested for triglyceride-lowering is just about 2–4 g/day fish oil product containing EPA and DHA square measure on the market without a prescription, however, the Yankee Heart Association advises that therapy with independent agency and DHA to lower terribly high acylglycerol levels ought to be used solely below a physician's care.
- In patients with acylglycerol levels on top of five hundred mg/dl, just about four g/day of DHA reduces acylglycerol levels forty fifth and extremely and extremely cholesteric levels by over five hundredths.
- Low-density conjugated protein cholesteric levels might increase counting on the baseline acylglycerol level, however the cyber web result of independent agency and DHA medical aid may be a reduction in non–high-density conjugated protein cholesteric level.

- Alternatively, patients might receive one among the fibrates (gemfibrozil or fenofibrate) or B complex for acylglycerol lowering if their acylglycerol levels square measure beyond five hundred mg/dl. In controlled trials, prescription omega-3 fatty acids were well tolerated, with an occasional rate of each adverse events and treatment-associated discontinuations.

The availableness of prescription omega-3 fatty acids, that ensures consistent quality and purity, ought to influence be valuable for the medical management of hypertriglyceridemia.

EPA:

Body uses EPA to produce signalling molecules called eicosanoids which plays numerous physiological roles and reduce inflammation.

It is found mainly in sea food e.g., Eel, Shrimp, Salmon etc.

DHA:

DHA is an important structural component of our skin and the retinas of our eyes.

Boost heart health by reducing triglycerides and possibly LDL (bad) cholesterol

Uses: Omega-3 fatty acids area unit thought to assist cut back the danger of cardiovascular disease and additionally to push healthy skin. they're additionally used at the side of diet and exercise to assist lower levels of definite blood fat (triglyceride) and to lift levels of "good" steroid alcohol (HDL). This product may be accustomed to facilitate treat high Blood pressure and arthritis .

Omega 3 market in India

Indian market for omega-3 polyunsaturated fatty acid(PUFAs) fixings is in the development phase of its lifecycle. Omega-3 unsaturated fats have been utilized in food stronghold and dietary enhancements from an extensive stretch in India. Customer attention to omega-3 medical advantages and rising extra cash, particularly in urban zones of the nation, will lead the market development later on. It is evaluated that the market will develop by a sound pace of 11.4% CAGR from 2013 through 2020 as far as volume, though regarding esteem it is anticipated to contact US\$29.4 million by 2020 developing at a CAGR of 13%. Dietary enhancements area is the biggest purchaser of omega-3 fixings as far as volume and worth, trailed by food and refreshment stronghold segment. Fish oil sourced omega-3 fixings rule the dietary enhancements area, while algal DHA oils are driving in food and drink stronghold industry. Opposite end-use application businesses for omega-3 fixings incorporate new born child nourishment with a critical utilization and pet sustenance with least utilization regarding volume. Pharma and clinical wholesome applications are yet to be created in the Indian omega-3 market.

India is considered as the second biggest market represented a portion of 25.3% in the omega-3 market in 2018, as far as worth, in the Asia Pacific district. Dietary enhancements have seen a steady ascent sought after because of the expanding wellbeing awareness among the expanding grown-up populace in India. As indicated by Nutra fixings Asia 2016, India's high omega-3 inadequacy has become a genuine motivation of medical problems and the ascent in Chronic infections among grown-up populace in India. The investigation

additionally specifies that the ascent in untimely births in the nation as of late is because of Omega-3 lack. This has urged the organizations to progressively concentrate on putting resources into the baby recipe section to take into account the wellbeing prerequisites of rashly conceived new born children in the nation.

The organizations are significantly putting resources into expanding customer mindfulness on omega-3 based medical advantages. At present, the accessibility of omega-3 based practical food and refreshments is altogether low in the nation. As indicated by the National Institute of Health (NIH) 2018, there has been a flood in the dry eye illness cases among the Indian Women because of the low omega-3 utilization. This has likewise urged buyers to expend omega-3 dietary enhancements in the nation.

The general market is grouped into Dietary Supplements and Functional Food and Beverages, with the previous evaluated to involve the bigger lump of around 65% in 2015. Utilitarian food and refreshments are required to develop with a higher development rate. This is because of the expanding perceivability of such items in present day retail designs and limited time exercises through TV commercials.

In 2015, the Indian dietary enhancements advertise was esteemed at US\$ 1.8 Billion. Notwithstanding, with developing mindfulness, number of individuals deciding on dietary enhancements all alone has likewise expanded. Higher buying power has incited Indians to be more wellbeing cognizant and receive a sound eating routine finished with utilization of wholesome enhancements, said **Mr. D S Rawat, Secretary General ASSOCHAM.**

The interest for the nutrient and mineral enhancements may increment later on because of the undesirable dietary patterns and worry in day by day way of life. Individuals may profit by the additional supplements found in these enhancements. A multivitamin and mineral enhancement will help in shielding against occasional supplement setbacks in the eating routine. Because of these reasons the nutrient and mineral market in India is foreseen to develop in the coming years and arrive at an estimation of US\$ 2.1 Billion by 2022, includes the examination.

According to current market division, nutrients and minerals represent a lot of around 40 percent in Indian dietary enhancements showcase followed by natural enhancements (30 percent), probiotic (10 percent), omega-3 unsaturated fats (five percent) and proteins, amino acids and other basic components together record for the rest of the portion of 15 percent.

Dietary enhancements (for the most part nutrients and minerals) are principally delivered by pharmaceutical organizations and are dominatingly medicine based, suggested by doctors, nutritionists, rec center educators and other people who go about as significant influencers.

Higher buying power has made individuals more wellbeing cognizant and incited them to embrace a sound eating routine finished with utilization of healthful enhancements.

Attractive Opportunities in the Omega-3 Market



SWOT ANALYSIS:

STRENGTH: Extensive reach across India Fastest growing brand in the country Strong brand image Higher efficacy Low cost higher quantity Dynamic field force Has anti-inflammatory properties and improves immunity Reduces the risk of heart diseases	WEAKNESS: Already existing competition Lack of brand loyalty and retention of mid-level customers Lack presence on the social media.
OPPORTUNITY: New customers Increased number of patients Utilization and optimization of existing corporate hospital entries To increase presence on the social media.	THREATS: Lack of brand awareness Pricing policies and restrictions Increase in the new entrants. Changing policies of the government. Environmental factors.

BACKGROUND

From ten years, several Americans have turned to polyunsaturated fatty acid animal oil supplements, that have advantages for healthy individuals, and conjointly those with cardiopathy. Omega-3 animal oil contains omega-3 (DHA) and omega-3 (EPA). Polyunsaturated fatty acid are essential nutrients that are necessary for preventing and managing cardiopathy.

Findings show omega-3 fatty acids may help to:

- Lower pressure level
- Reduce triglycerides level
- Slows down the event of plaque within the arteries
- Reduce the prospect of abnormal rhythm
- Reduce the chance of heart failure and stroke
- Lessen the prospect of sharp internal organ death in folks with cardiovascular disease. (Simopoulos, 1991) [1]

DHA (Docosahexaenoic acid) DHA is principally set in cell membranes, wherever it makes the membranes and gaps between cells additional fluid. DHA makes it easier for nerve cells to send and receive electrical signals.

Therefore, adequate levels of DHA and EPA (Eicosapentaenoic acid) appear to create it easier, quicker, for your nerve cells to communicate. Having low levels in your brain or eyes could reduce the signals between cells, leading to poor visual sense or altered brain performance. It's found within the flesh of cold-water fish, together with mackerel, herring, tuna, halibut, salmon, cod liver, whale blubber, or seal blubber. (Kidd, 2007)[2]

A prescription form of omega-3 fatty acids has been approved by the United States Food and Drug Administration as an adjunct to diet for the treatment of very high triglyceride levels. The active ingredients of omega-3 fatty acids are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), these are responsible for lowering the level of triglyceride. The prescribed product contains a total of 0.84 g of these two active ingredients in every 1-g capsule of omega-3 fatty acid. The total EPA and DHA dose recommended for lowering triglyceride level is approximately 2–4 g/day. In patient having triglyceride levels more than 500 mg/dl, approximately 4 g/day of EPA and DHA reduces triglyceride levels 45% and very low-density lipoprotein cholesterol levels by more than 50%. Low-density lipoprotein cholesterol levels may increase depending on the baseline triglyceride level, but the net effect of EPA and DHA therapy is a reduction in non–high-density lipoprotein cholesterol level. The availability of prescription omega-3 fatty acids, which ensures consistent quality and purity, should prove to be valuable for the medical management of hypertriglyceridemia.[3]

LITERATURE REVIEW-

Among the fatty acids, it's the omega-3 fatty acid unsaturated fatty acids (PUFA) that possess the foremost potent immunomodulatory activities, and among the omega-3 fatty acid PUFA, those from fish oil—eicosapentaenoic acid (EPA) and omega-3 fatty acid Docosahexaenoic acid (DHA)—are biologically more potent than -linolenic acid (ALA). The experiment on animals and with clinical intervention study shows that omega-three fatty acids have medicinal properties, so it'd be utilized in inflammatory and Autoimmune problems. omega three supplementations to the healthy volunteers suppress the capability of monocytes to synthesize interleukin-1 (IL-1) and TNF (tumour necrosis factor). omega-3 fatty acid fatty acids suppress IL-1 RNA [40,41]. These observations lead to the studies in patients with an autoimmune disease and inflammatory. there is a minimum of thirteen clinical trials that shows the beneficial effect through the fish oil supplements in Arthritis. (Simopoulos, 2002)[4]

Through randomized controlled trials (RCTs), are reportable regarding the useful effects of omega-3 fatty acid (or n-3) fatty acids on the disorder (CVD) in patients with pre-existent CVD issues and likewise as in a healthy people. omega-three fatty acids appear to have low dose dependant, hypotensive impact, the extent of that appears to be reliant on the degree of High blood pressure. ingest 5.6 g/d of omega-3 fatty acid fatty reduces the pressure level of -3.4/-2.0 mmHg in studies. (Kris-Etherton et al., 2002) [5]

Omega three fatty acid shows its impact on the supermolecule (lipid) profile and AHA recommends 2-4 g daily of EPA and DHA to the patients with a high tri-glyceride level. omega-three fatty acids conjointly also help to slow down the hypoglycemic agent resistance. after three-five years of a trial period the relative risk of death from CVD has been slowed down by 45% among the patients receiving treatment of omega-3 fatty acid.(Kris-Etherton et al., 2002)(Lee et al., 2009) [6]

Omega three fatty acid formulation contains EPA and DHA in a very magnitude ratio i.e about 4.01:1 to 5:1.EPA and DHA within the formulation either within the type of tri-glyceride or esterified fatty acid. Capsules usually contain the ethyl ester form of EPA and DHA.it helps to treat various types of CVD issues and also helpful in rheumatoid arthritis and used to reduce joint inflammation ,pain and various problems .omega three fatty acids ought to be administered orally within the type of pills, tablets or gel capsule.(Feuerstein et al., 2010)[7]

OBJECTIVE-

- To understand the prescription behaviour of EPA and DHA among Orthopaedics and consulting physician.
- Find out at which indication Dr. prescribes Omega 3 capsule?
- Do they prescribe omega 3 capsules in case of Arthritis?
- If yes, then as a Monotherapy or co-therapy?

RESEARCH METHODOLOGY-

Sample design- Descriptive study

Sampling- Nonprobability convenience sampling

Data collection- primary data will be collected through the questionnaire and meeting with respondents.

Secondary data will be collected through published journals and literatures.

Sample size- 200 doctors

Sample area- Lucknow

Duration- 60 Days

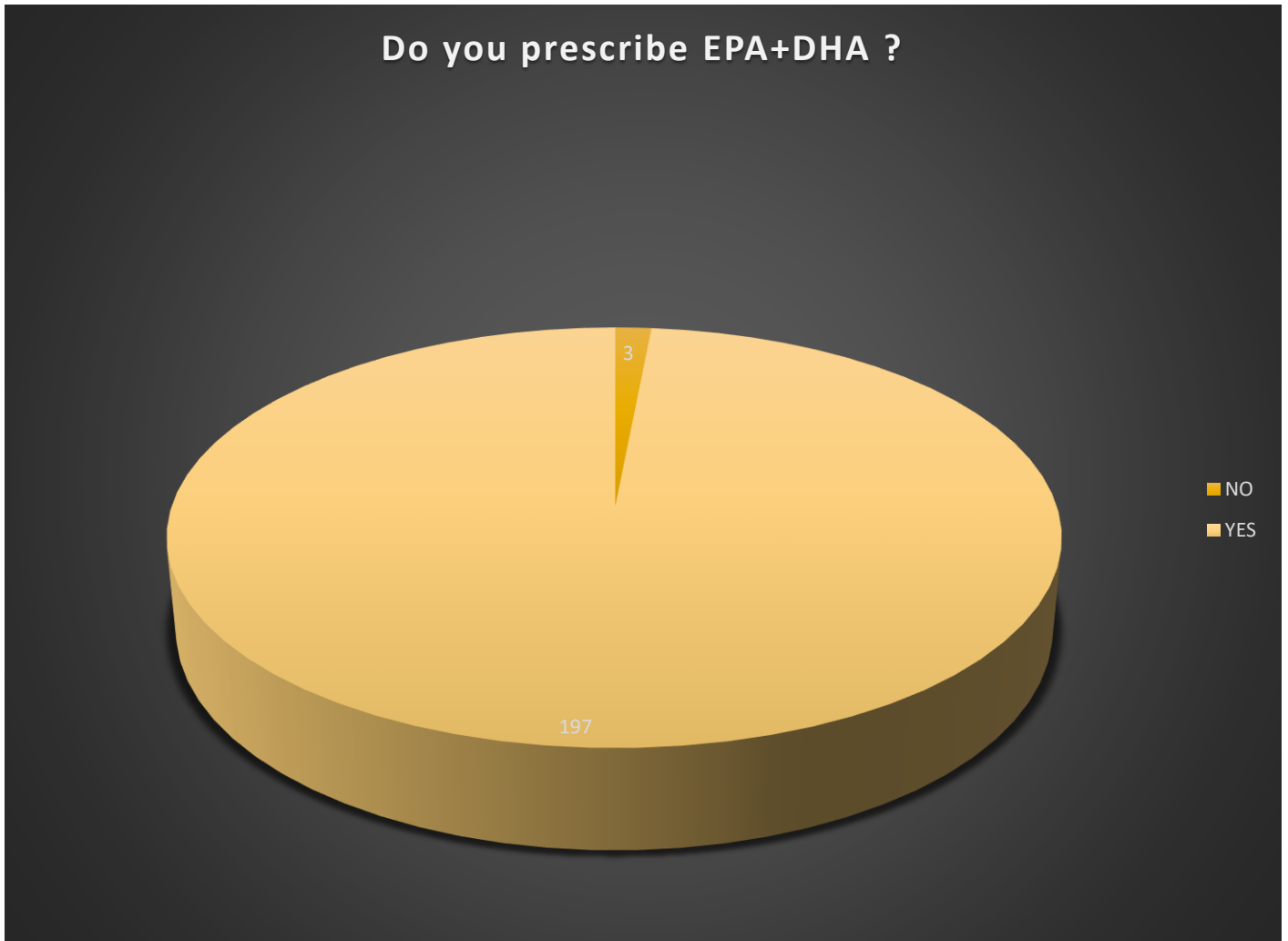
Inclusion criteria- Orthopaedics and General physicians.

Tools- Questionnaire to collect primary data

Microsoft Excel for analysis

DATA ANALYSIS

Answer of Q1:-



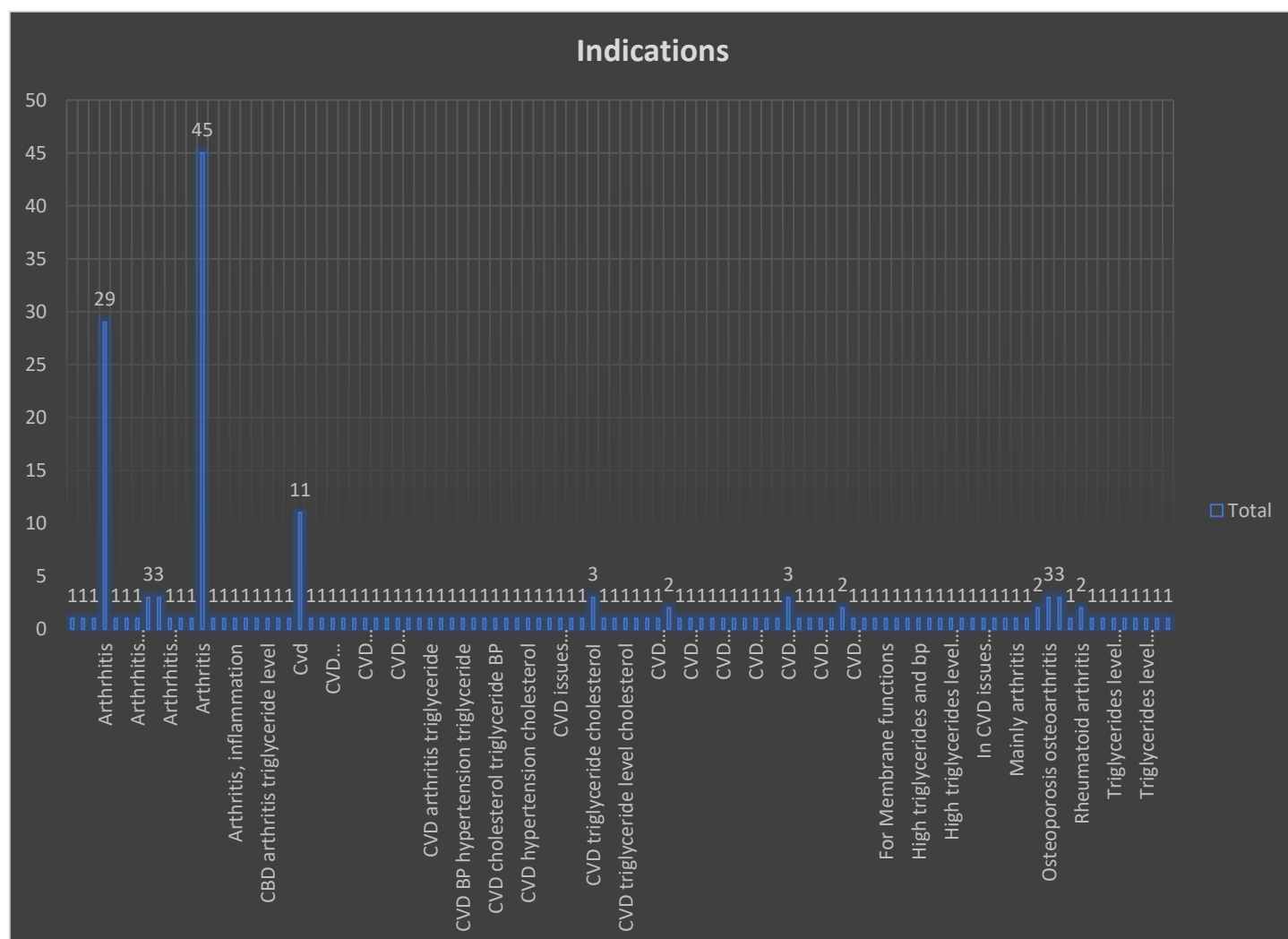
(fig 1)

Through this above pie-chart I have tried to show that maximum of the Doctors whether the Orthopaedic or the consulting physician they use to prescribe EPA +DHA to their patients.

Answer of Q2:-

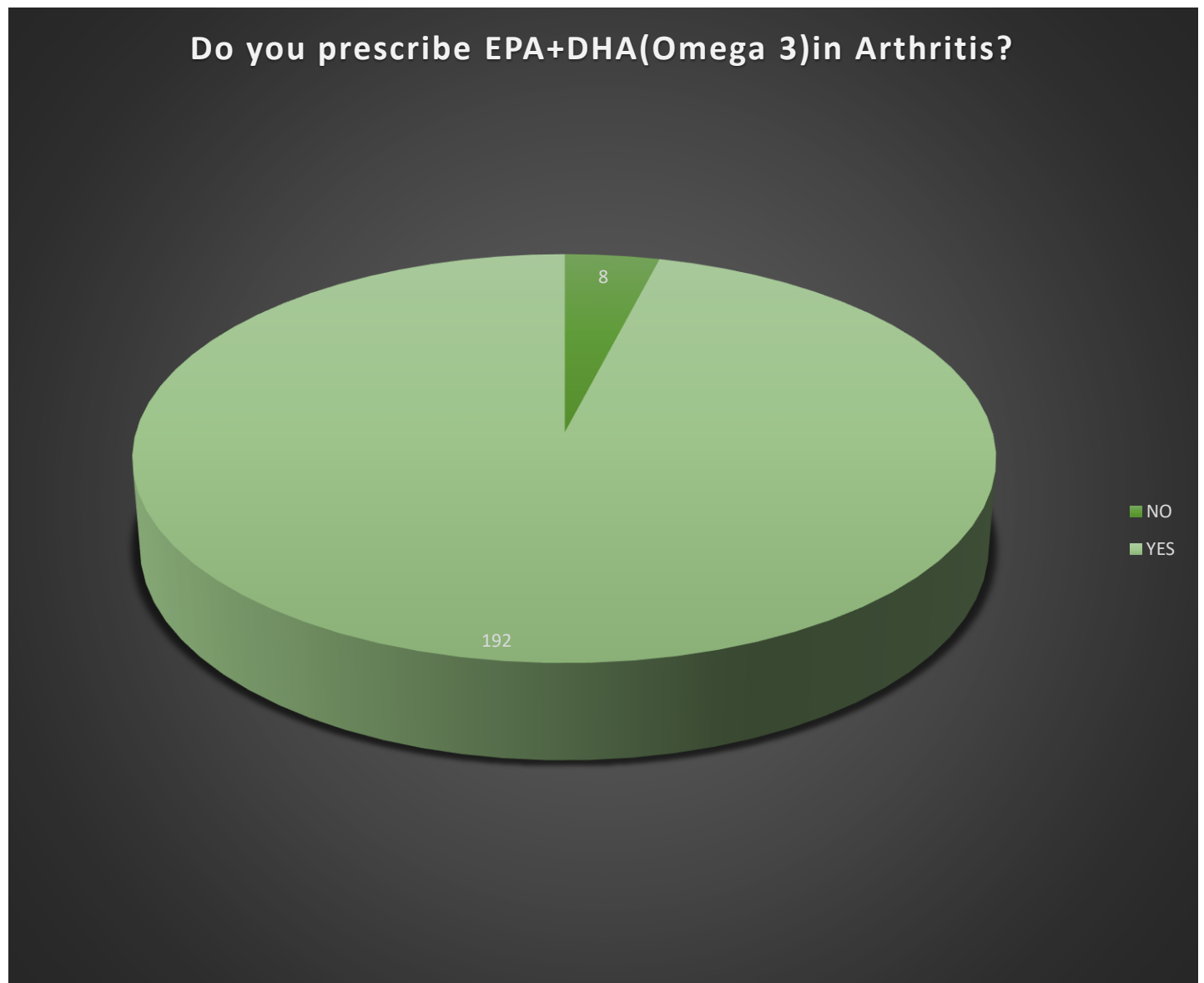
This question was an open ended and maximum number of the Doctor's said that they use to prescribe Omega 3 in the Indication are:

- ARTHRITIS
- CVD PROBLEMS i.e. heart attack, stroke, Arrhythmia, Angina etc
- BLOOD PRESSURE
- HIGH TRIGLYCIRIDE
- HDL, LDL
- CHOLESTEROL
- JOINT INFFLAMATION
- Etc



(fig2)

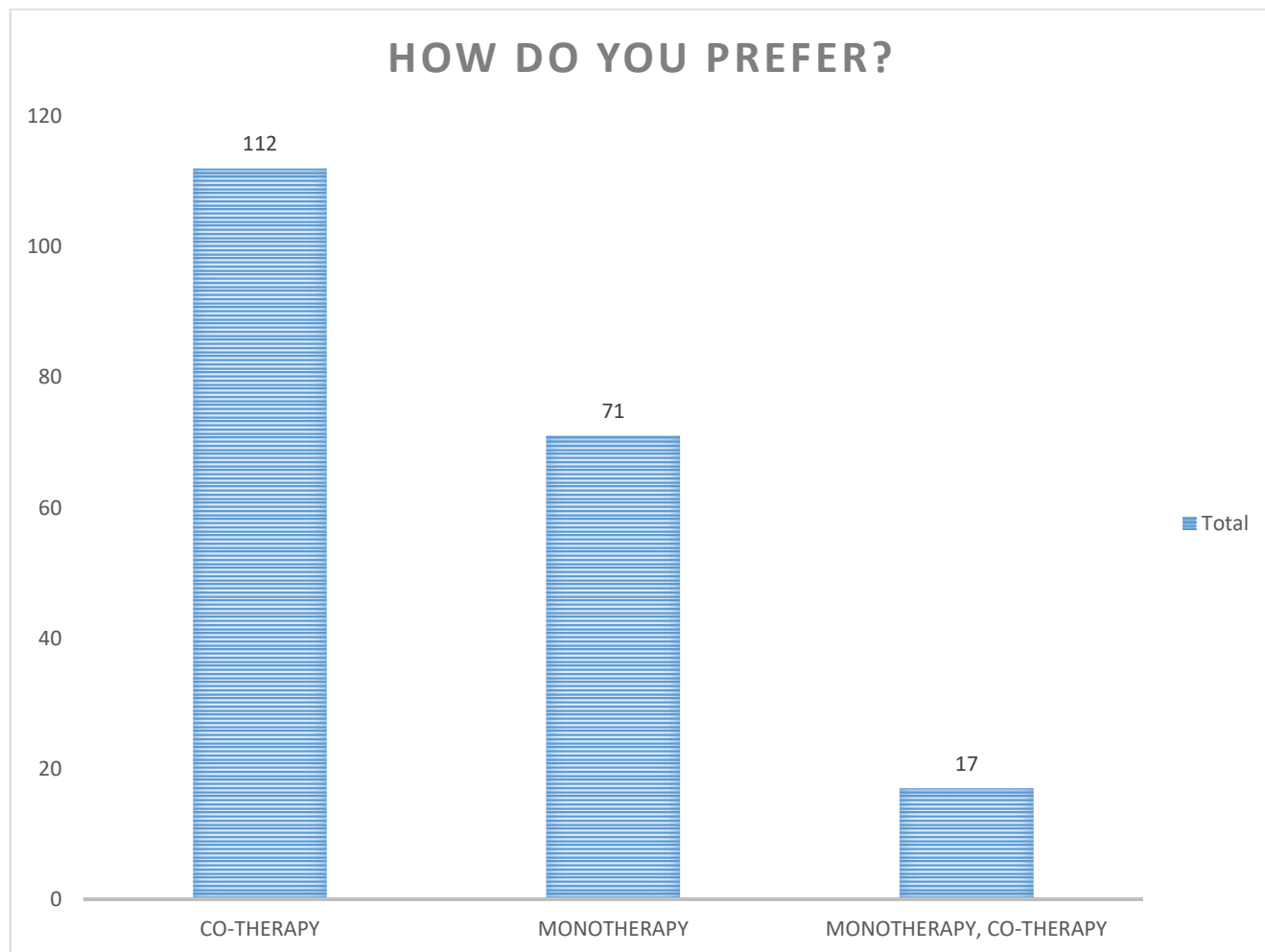
Answer of Q3:-



(fig 3)

Through the above pie-chart, its clearly showing that omega 3 is usually prescribed by the Doctor's to their arthritis patients about 96% of the doctors use to prescribe.

Answer of Q4:-

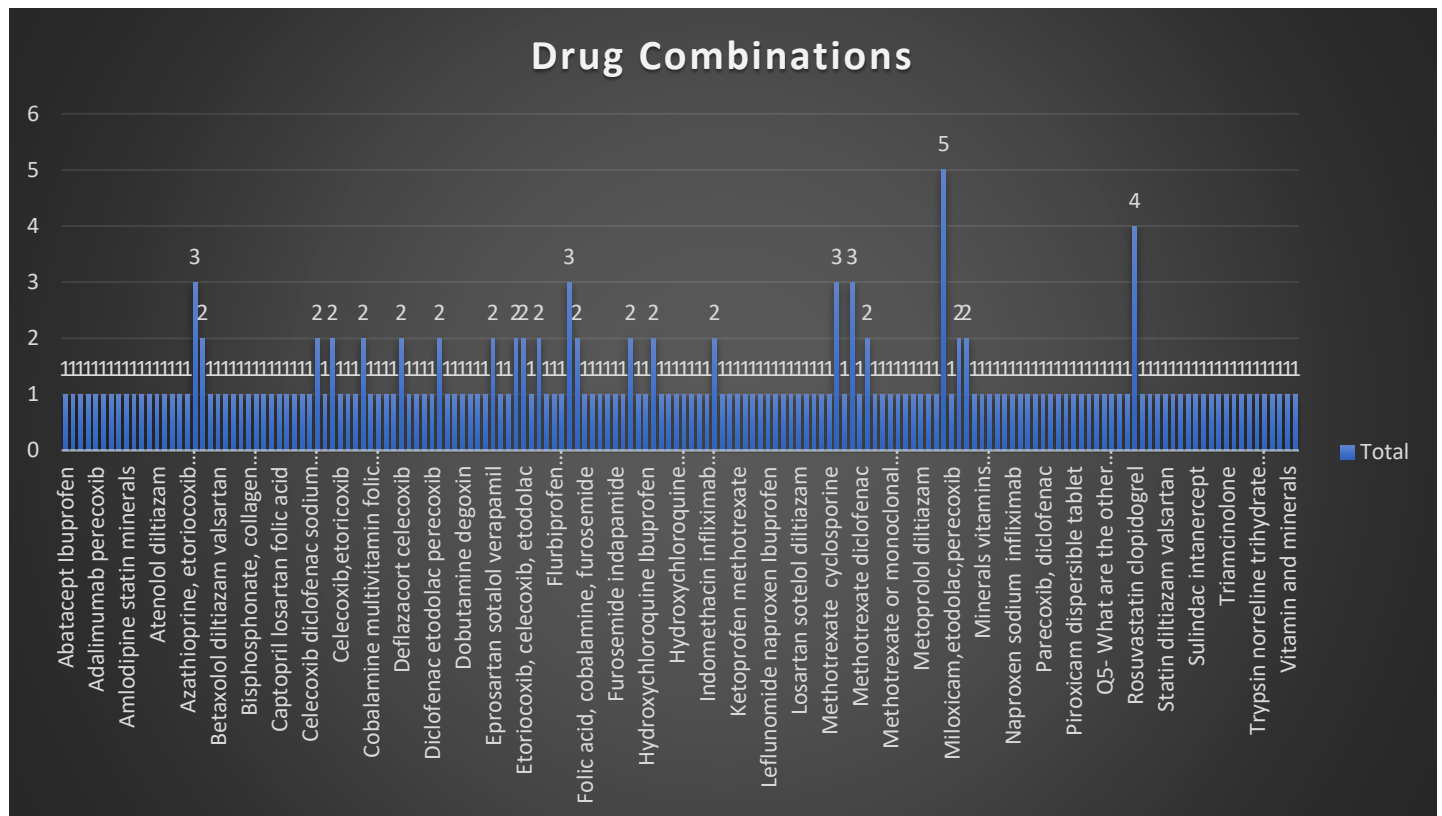


(fig 4)

Trough the above pie chart, Most of the Doctors use to prefer CO-THERAPY i.e. about 56% of the Doctor’s and about 35% of them use to prefer Monotherapy.

Answer of Q5:-

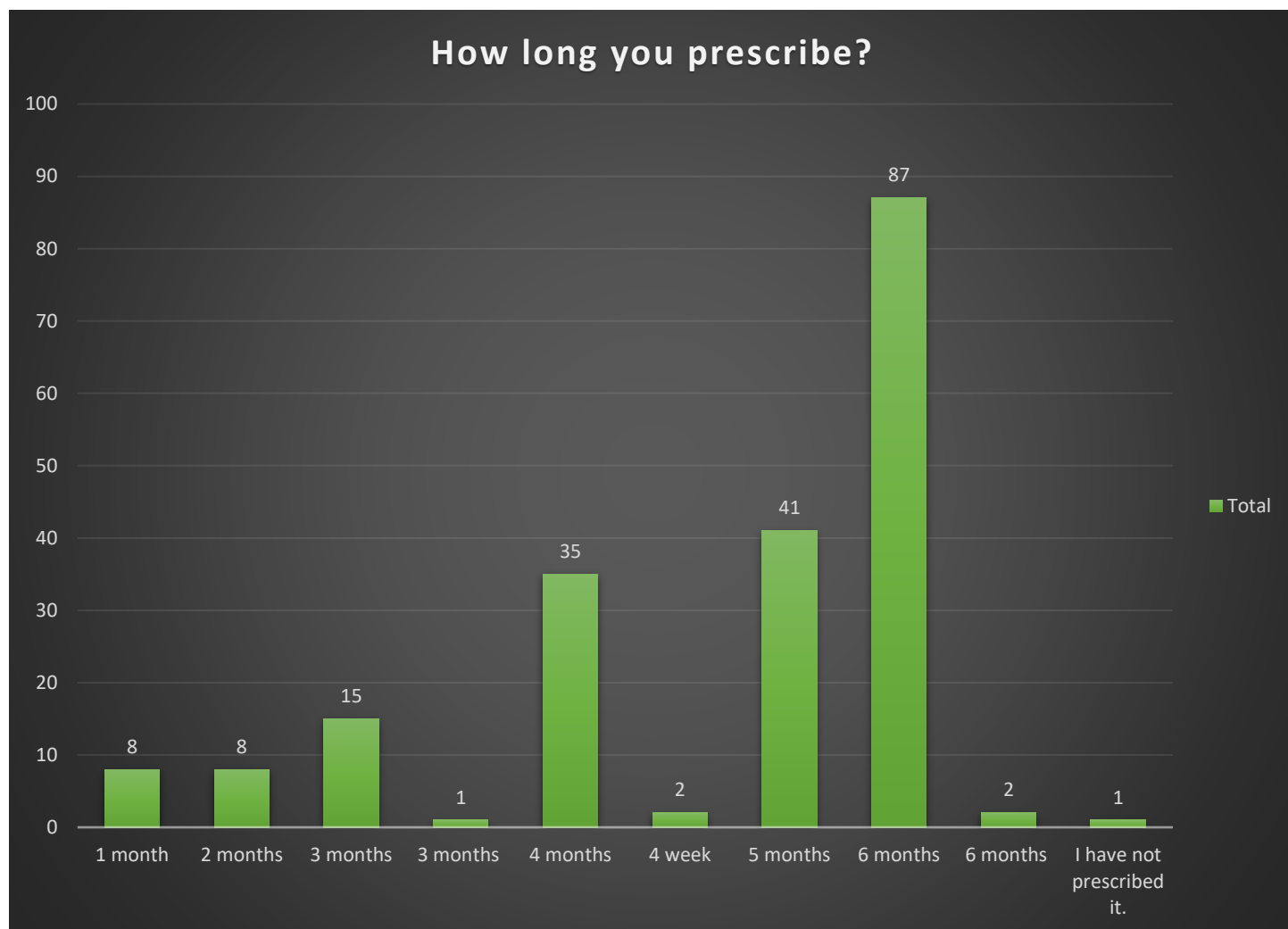
Each and every DOCTOR'S use their Different combinations but most of the drugs they use to prescribe with omega 3 are-



(fig 5)

Trypsin norrelne trihydrate, Diclofenac sodium
 Glucosamine sulphate potassium chloride
 Celecoxib parecoxib, etoricoxib
 Sulfasalazine, chloroquine, Celecoxib
 Metoprolol succinate telmisartan
 Clinidipine metoprolol succinate
 Rosuvastatin clopidogrel
 Metoprolol succinate telmisartan cilnidipine
 Vincort azitocort
 Ritoxomab abatacept
 Hydroxychloroquine ketorolac
 Rituxan diclofenac prednisolone
 Hydroxychloroquine ketorolac celecoxib
 Methotrexate celecoxib etodolac
 Deflazacort ibuprofen
 Hydroxychloroquine ketorolac
 Benazepril ramipril valsartan

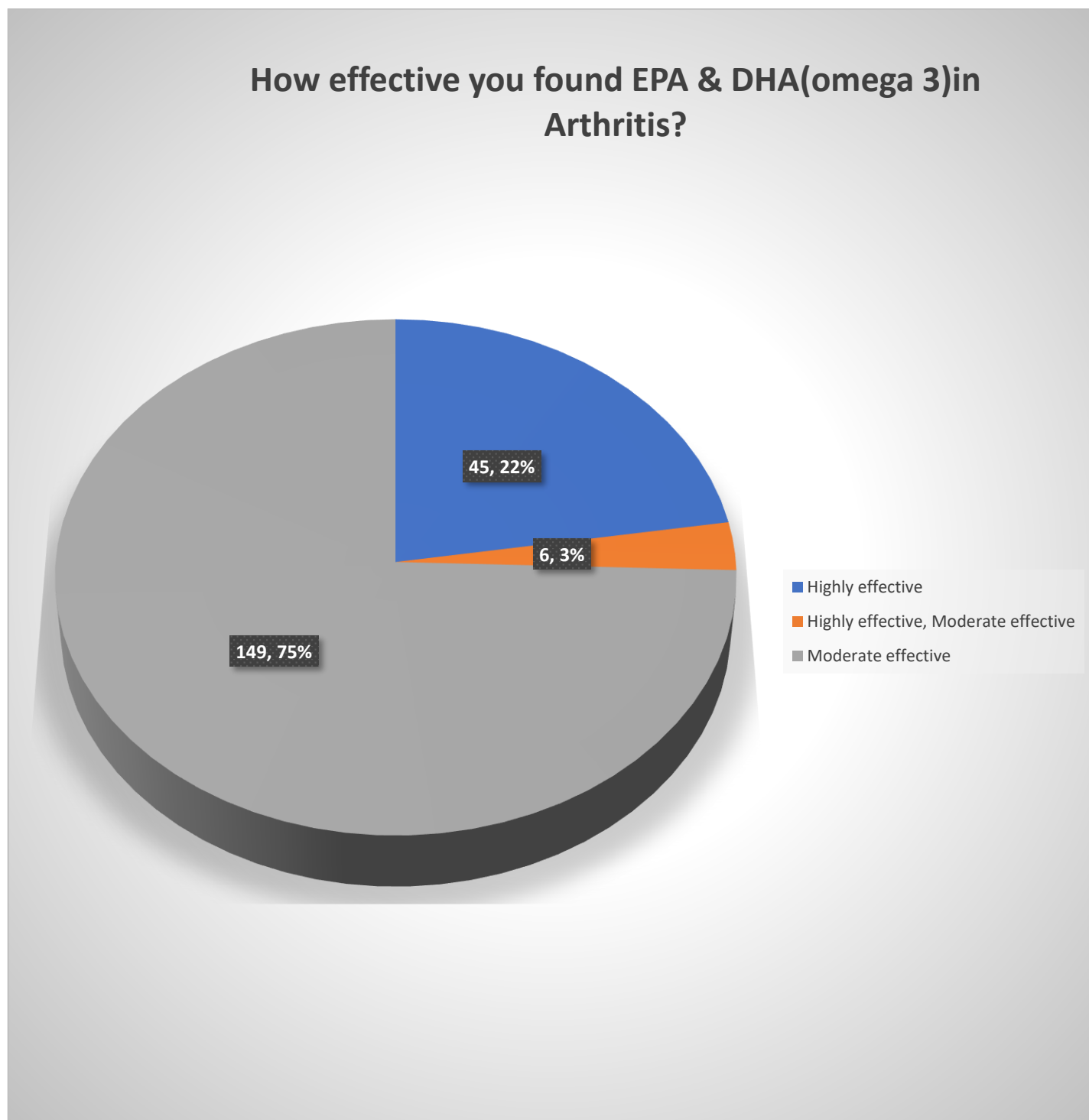
Answer of Q6:-



(fig 6)

From the above graph we came to know that maximum Doctor's use to prescribe omega 3 for upto 6 months.

Answer of Q7:-



(fig 7)

Through above pie-chart, Most of the Doctors i.e. about 75% said that they found Omega 3 is MODERATE EFFECTIVE in the Arthritis. And about 22% of them found HIGHLY EFFECTIVE in Arthritis.

RESULT: -

The present study has provided an information about the prescription behaviour of EPA and DHA among Orthopaedics and consulting physician. As we can see from the above Graph that maximum Doctor's use to prescribe Omega 3 fatty acid i.e. about 98% .they mainly use to prescribe on – arthritis ,CVD problems - Heart-Attack, Stroke ,Angina ,Blood pressure ,to the patient with high cholesterol level ,triglyceride level ,HDL ,LDL ,Hypertension ,Anxiety ,skin related problem ,joint inflammation, etc. it is clear from the above graph (fig 3) that omega3 are mainly prescribed by the doctor's in arthritis patient i.e about 96%.and if we talk about How do they prefer then most of the Doctor's use CO-THERAPY i.e about 56% ,MONOTHERAPY is about 35%,and who use to prefer both i.e co-therapy and monotherapy is about 8.5%.

And if we talk about the combination which they use to prefer then every Doctors have their different combinations but they use to give an arthritis drug with NSAIDS with anti-inflammatory drug with the Omega 3 its totally depend on the patient problems. Some of the drug they used are – Methotrexate,Hydroxychloroquine,diclofenac,celecoxib,etadolac,parecoxib,deflazacort,salfasalazine,rituximab ,abatacept,ibuprofen,naproxen,piroxicam,ketorolac,meloxicam,prednisolone,cortisone,betamethasone ,etc these drugs used in arthritis patient.

Captopril,benazepril,ramipril,fosinopril,losartan,valsartan,telmisartan,Olmesartan,atenolol,metoprolol,bisoprolol,carvedilol,amlodipine,diltiazem,nifedipine,statin,furosemide,isosorbide dinitrate, minoxidil ,etc these drugs are mainly used in cvd, hypertension ,cholesterol, blood pressure etc.(fig 5)

Now if we talk about the duration of Omega 3 fatty acids used to prescribe by the Doctor's to their patients then its totally depend on their problems and the requirements, most of the doctor's said that they mainly used it about 3-6 months.(fig 6)

And if we see that omega 3 is how much effective in arthritis then 75% of Doctors said that it is moderate effective and 22% of them said is highly effective. (fig 7)

So, these are the outcomes which I have received from the survey.

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QUESTIONNAIRE: -

Dr Name.....Speciality.....
Qualification..... Contact.....
Place.....Date.....

Questions:

1. Do you prescribe EPA + DHA? Yes ☐ No ☐
If yes – Question 2
2. In which indication do you prescribe?
.....
.....
.....
.....
3. Do you prescribe EPA+DHA (Omega 3) in arthritis? Yes ☐ No ☐
If yes – Question 4, If no - Why?
4. How do you prefer? Monotherapy ☐ Co-therapy ☐
If Combination- Question 5.
5. What are the other molecules you prescribe in combination with EPA+DHA (Omega3)?
.....
.....
.....
.....
6. How long you prescribe EPA+DHA (Omega 3) in arthritis (Therapy duration)?
.....
.....
7. How effective you found EPA&DHA (Omega 3) in Arthritis?
Highly effective ☐ Moderate effective ☐ Not effective ☐
8. Any Suggestion?
.....
.....

