

Exploratory Study on Calcium Supplementation (Calcium Citrate)

By

Vishalakchi

*Dissertation submitted for the partial fulfillment of the
MBA Pharmaceutical Management*

Academic year, 2018-2020



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At last but not the least most importantly I am thankful to God who is the creator and director of all the initial and final modes to reach the destiny.

Vishalakshi
MBA. Pharmaceutical Management
(10th Batch)

DECLARATION

I hereby declare that this Internship project in Pharmed Limited, Bengaluru, submitted to IIHMR University, Jaipur, in the partial fulfilment of requirement for the award of degree of MBA Pharmaceutical management is a Bonafide and the study carried out by me under the guidance of **Dr Ashok Peepliwal**, Associate Professor, IIHMR University, Jaipur. The extent of information gathered in the study & discussed in this project report, is original and confidential.

VISHALAKCHI

EXECUTIVE SUMMARY

This Study (Market Surveillance) has been accomplished at Pharmed Limited. The purpose was exploratory study on Calcium Supplementation (Calcium Citrate) conducted in Bangalore, in various location ensuring about the collection of Data complemented with feedback from Doctors(Gynaecology,Orthopaedic) under market research.

In the initial stage detailed study of calcium was done under the BPT Training, multiple sessions had been attended. Gaining the information and competency then the study was proceeded through Questionnaire preparation under the guidance of PMT team. Data Analysis was performed by considering different aspect of the study. Findings were made through data collected and prevalence of different pregnancy induced disorders were found and line of treatment and utility of calcium was discussed with KOL.

INTRODUCTION:

CALCIUM

1. Most abundant and important mineral in the body.
2. Essential body electrolyte.
3. Plays an important role in body homeostasis.
4. Disturbance in Ca^{++} metabolism can cause derangements of various cellular functions.
5. Body contains 1200gm of calcium.
6. 99% is present in the skeleton.
7. Exists in the form of a complex salt containing calcium, phosphate, and carbonate (Hydroxyapatite crystals).

FUNCTIONS OF CALCIUM:

1. Chief mineral in the bone, responsible for hardness of the bone.
2. Required for Nerve transmission.
3. Required for maintenance of homeostatic balance.
4. Regulates hormonal secretion e.g. PTH (Parathyroid hormone) and Calcitonin.
5. Calcium ions participate in many enzymatic reactions such as :
 - Muscular Contraction
 - Blood Coagulation
 - Activates Digestive enzymes (e.g. Trypsin, Amylase etc.)

CALCIUM REQUIREMENT:

Normal serum calcium level ranges from 8.5 to 10.5mg/Dl

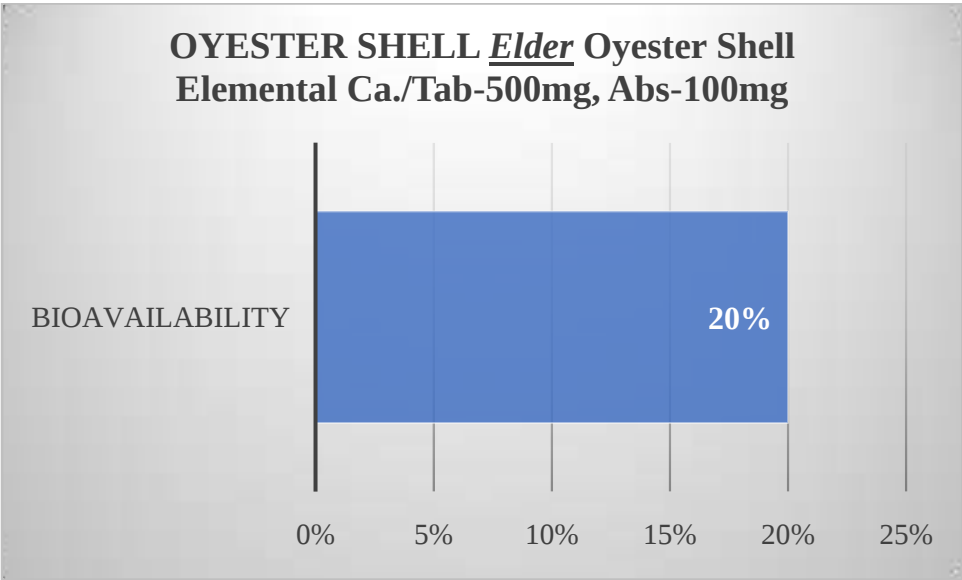
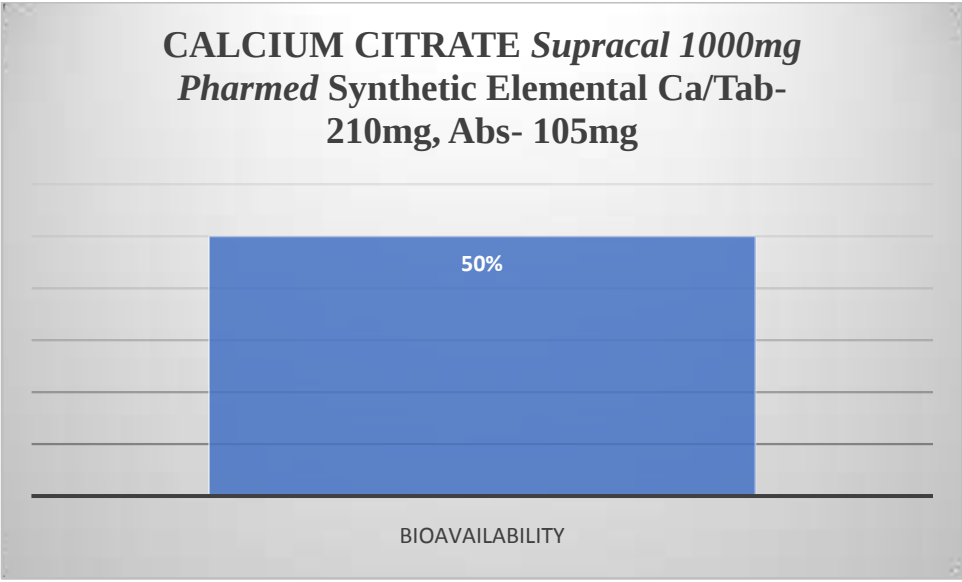
<i>AGE</i>	<i>CALCIUM (mg/day)</i>
0-6 months	210
7-12 months	270
1-3 years	500
4-8 years	800
9-18 years	1300
19-50 years	1000
51+ years	1200

- Current RDA is 800mg(elemental calcium)/day for both men and women.
- Pre-menopausal women need 1000mg(elemental calcium)/day.
- Post-menopausal women need 1500mg(elemental calcium)/day.

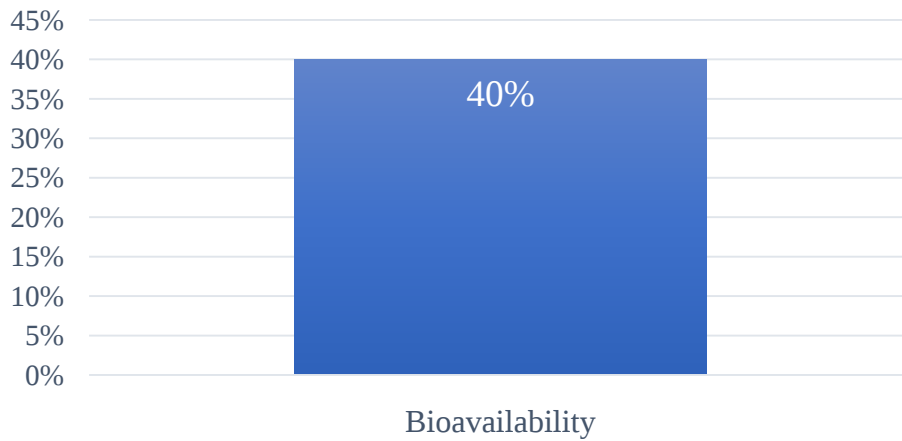
ELEMENTAL CALCIUM:

The amount of mineral calcium present in a salt of calcium is called elemental calcium.

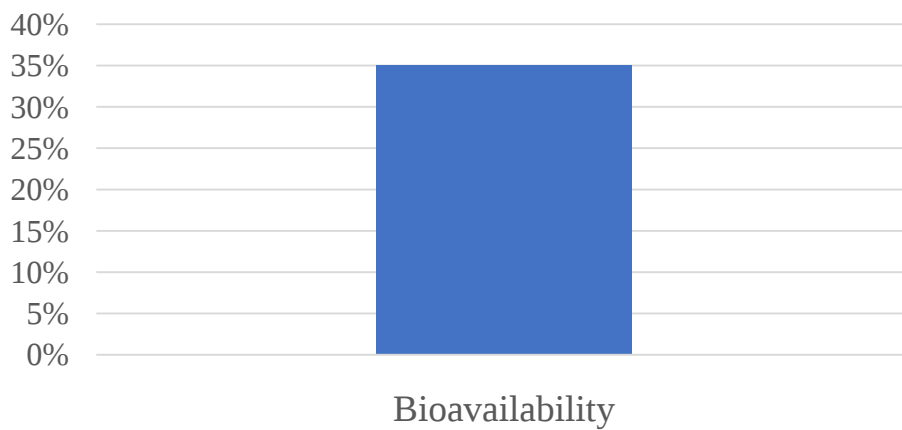
COMPETITIVE ANALYSIS OF CALCIUM:



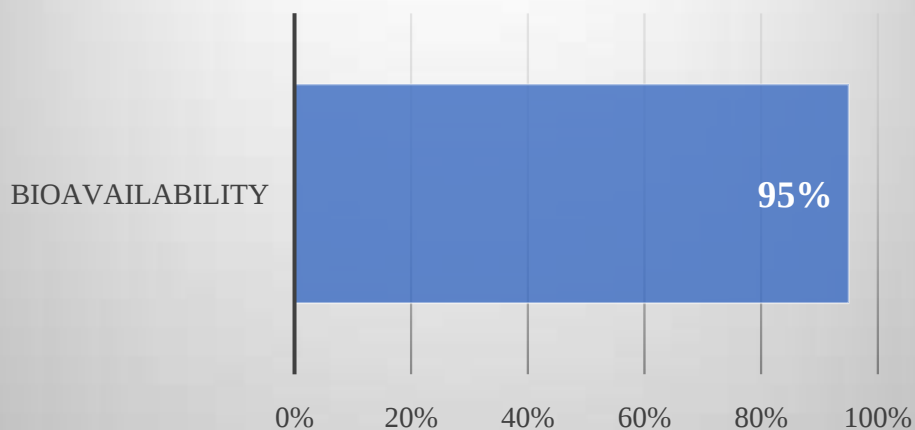
ALGAE TREATED CALCIUM FORTE Triple A USV
Algae Treated.Elemental Ca./Tab-150mg, Abs-60mg

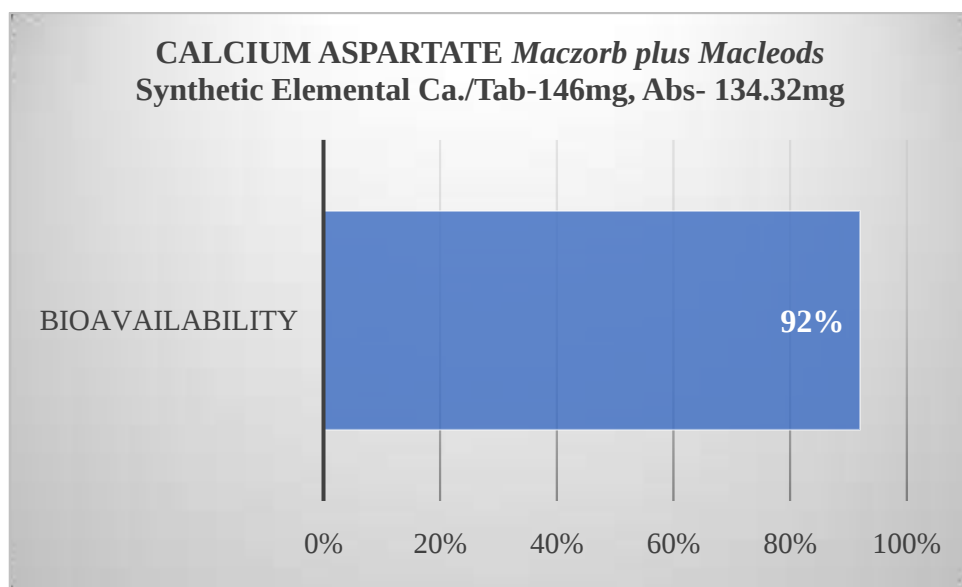
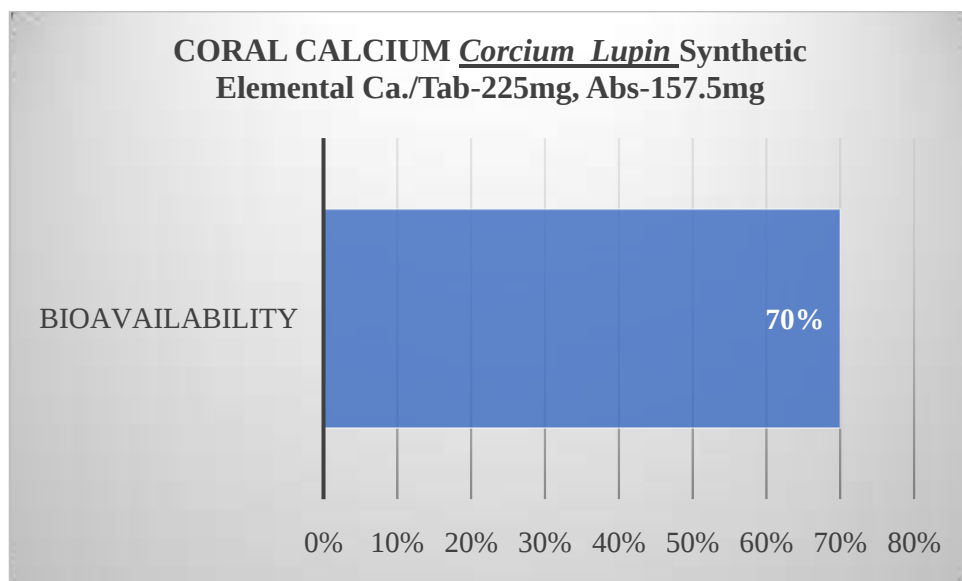


CALCIUM CITRATE MALEATE CCM Glaxo
Synthetic Elemental Ca./Tab-250mg, Abs-87.5mg



CALCIUM OROTATE Cdence Wanbury Synthetic
Elemental Ca./Tab-74mg, Abs-70.3mg





CALCIUM CITRATE PROPERTIES:

- It Offers 21% elemental calcium with 50% absorption.
- 2.5 times more bioavailable calcium
- Does not interfere with iron absorption.
- Does not interfere with Phosphorous absorption
- Does not require gastric acid for absorption.
- Less Incidences of GI side effects.
- Less risk of kidney stone formation.
- Pure and safe.
- Any time calcium meaning can be taken with or without meals.
- Ultra- micronized meaning very small size leading to a faster and superior absorption.
- Undergoes both intracellular and paracellular absorption (Intracellular-through cell, Paracellular-between the cell)

CONDITIONS IN WHICH CALCIUM IS REQUIRED WITH THE COMBINATION OF VITAMIN D3:

GYNAECOLOGY	ORTHOPAEDIC
Pregnancy induced Hypertension, Preeclampsia, IUGR, Elderly Primigravida.	Musculo-skeletal disease like osteoarthritis , Arthritis .

RATIONALE:

Exploratory study on calcium supplementation is based on the affordability, accessibility, availability, adaptability and acceptability. Market research has been done on the properties of both Calcium Carbonate and Calcium Citrate, with the motive of how calcium citrate is better than calcium carbonate.

Sr.No.	Parameter	Calcium carbonate	Calcium Citrate
1	Salt	Inorganic	Organic
2	Solubility	Only acid media	Acid and alkaline media
3	Elemental	40%	21%
4	Bioavailability	Interfere with iron abs.	Do not interfere with iron abs.
5	Absorption	Only transcellular	Both Transcellular and Paracellular
6	Stone Formation	Yes	No renal Calculi
7		Before meal	Any time Calcium

Looking into the above information, Market Intelligence Department has prepared the Questionnaire, which follows the

doctors perception and acceptance of calcium citrate molecule.

OBJECTIVES:

- To determine acceptance of calcium citrate over calcium carbonate.
- To identify Adverse event of calcium citrate through Doctors feedback.
- To determine Pregnant women compliance level with the extended products. (Of Calcium Citrate).
- To identify additional and non-additional attributing factors of prescription.
- To find out whether doctors use calcium citrate or not with it's appropriate reason and attributing factors.

RESEARCH METHODOLOGY:

Research Design

Study Area- Bangalore

Type of Study – Descriptive (Additive and Non-additive information)

Data Collection Technique- Survey(Market Research)
Primary and secondary.

Data Collection Tool- Researcher Administered Structured Questionnaire .

Sample Design:

Target Population- Gynaecologist

Sampling Method- Non-Probability Convenience Sampling

Sample size- 122 Gynaecologist (At 95% Confidence Interval)

ETHICAL CONSIDERATION:

The Research was completed with appropriate research guidelines. Enough Time was given to respondent of the study so that they can depict their true view on research questions. Consent from the respondents was taken and appropriate permission was also ensured for the usage of their given data. The disclosure of respondent identity was based on their permission where if they are not willing to disclose identity , their identity was exhibited.

DATA ANALYSIS:

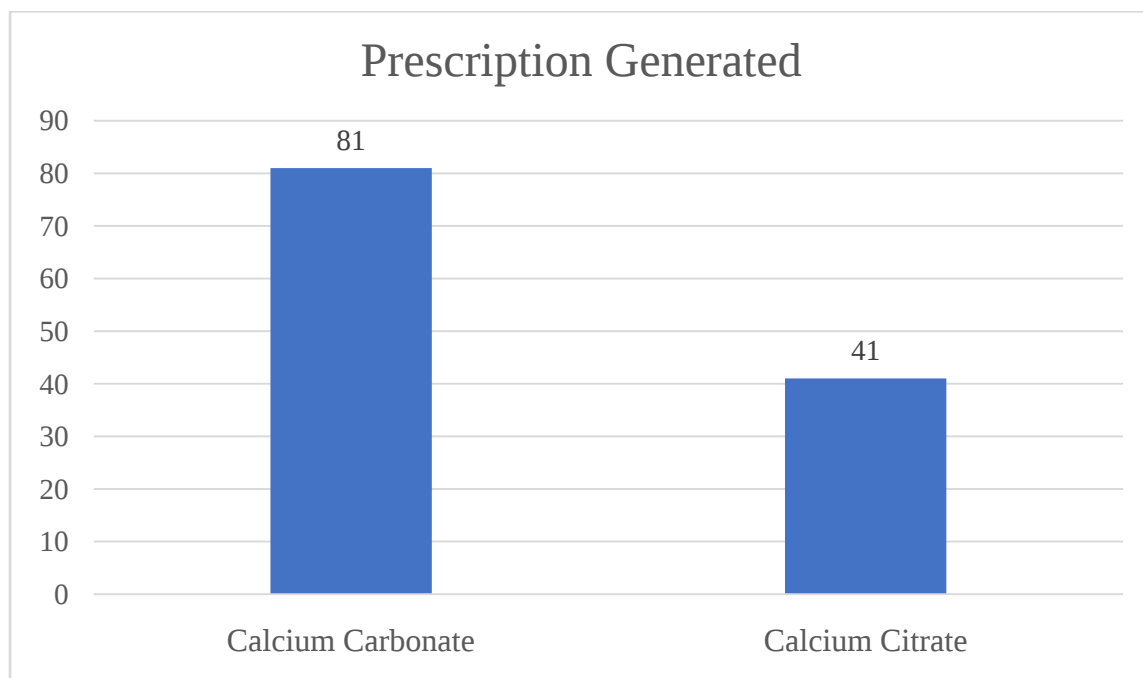


Fig.1.-Comparison between prescriptions of Calcium Carbonate vs Calcium Citrate.

Interpretation- As in the figure, we can see that number of prescriptions generated is being configured which significantly show that the gynaecologist are much more inclined towards prescribing calcium carbonate as compared to calcium citrate.

Targeted Doctors—Gynaecologist.

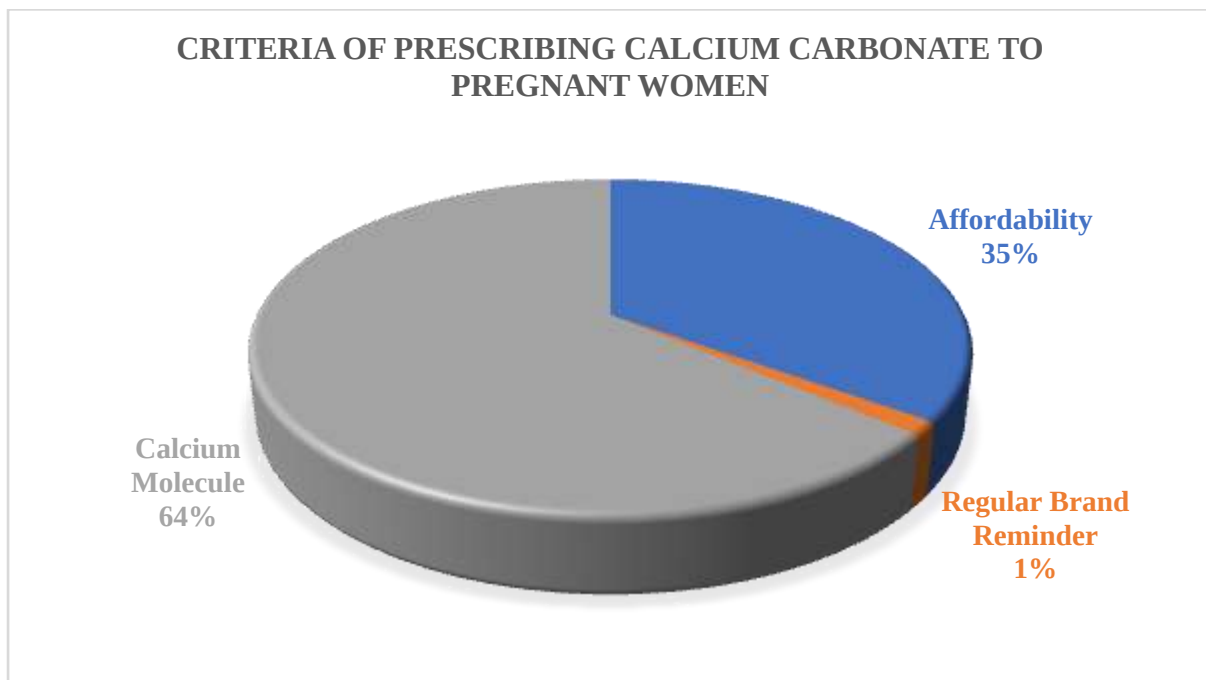


Fig.2.Criteria of prescribing calcium carbonate to Pregnant women.

Interpretation- According to the above chart gynaecologist criteria of prescribing calcium carbonate is much more based upon the calcium molecule that is 64% apart from this the respondents are also concerned about affordability factor complemented with accessibility that is 35% and Prescribing pattern of 1% is dependent upon regular brand reminder.

Few important administrative steps of calcium carbonate which is being used are :

- 1.They are administered with the lime juice so as that it can not interfere with the iron absorption.
- 2.Also the acidic factor is nullified, as it starts possessing the properties of calcium citrate.
- 3.Patient compliance is increased in affordable price.

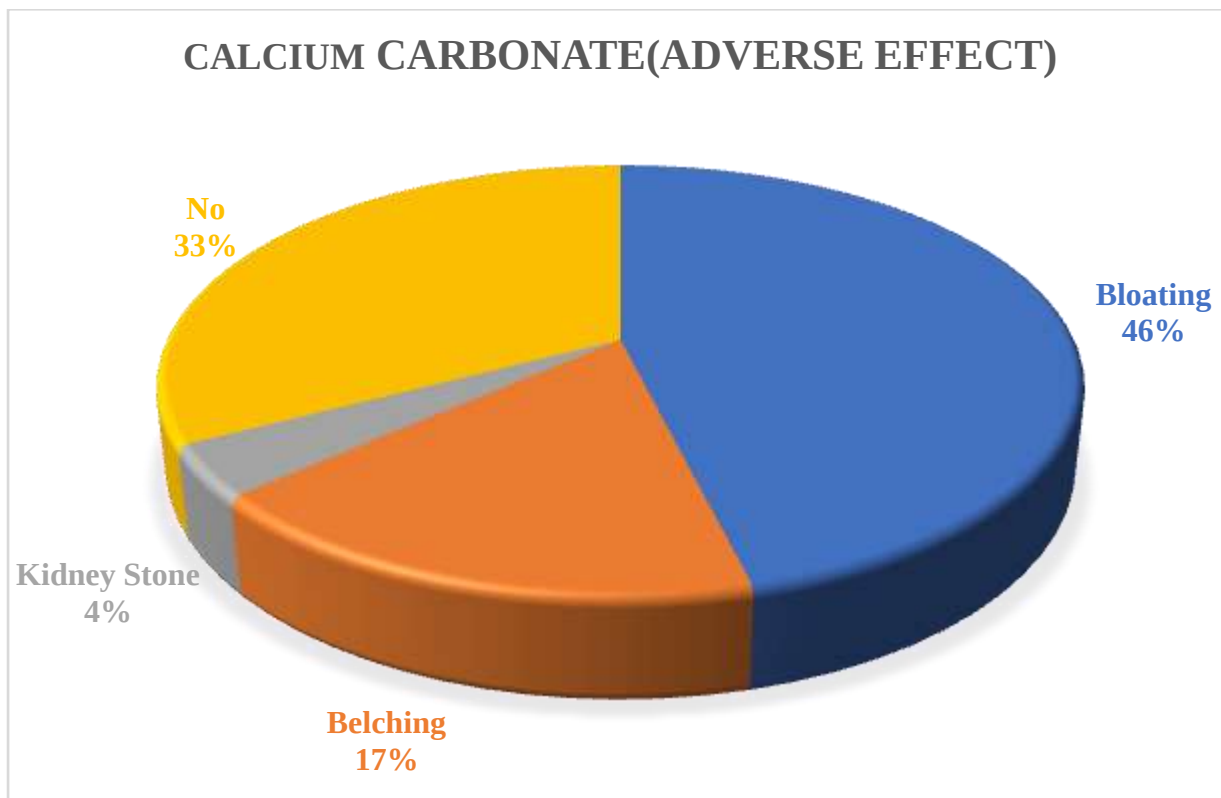


Fig.3. Calcium carbonate Adverse effect.

Interpretation-According to above chart patient are coming to KOL's with the above complications or adverse effect that is Bloating, belching, kidney stone and few are not having any complication. Bloating and belching is due to acidic reaction. Kidney stone is being found in the patient due to long term usage of calcium carbonate so it must be avoided. The reason doctors are shifting from carbonate to Citrate.

The above data shows 46% of patient are suffering from bloating, 17% are suffering from belching, 4% of patient are suffering from Kidney stone due to the administration of Calcium carbonate.

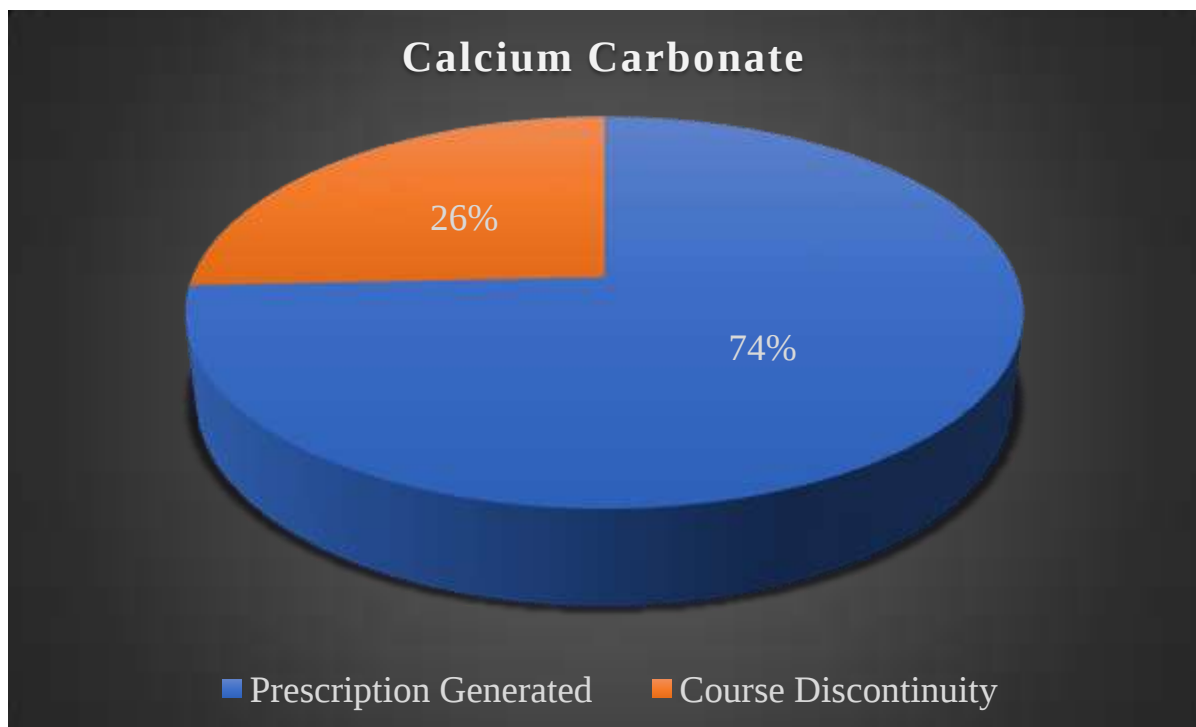


Fig.4. Course discontinuity due to calcium carbonate

Interpretation- According to the above chart the respondents were much more significant towards course discontinuity which arises due to the usage of calcium carbonate.

Biggest reason is not being any time calcium which limits the usage of calcium carbonate and bone problems persist thus the out of pocket expenditure is increased as the patient is facing the problems of course discontinuity which is meant to be administered before meal.

Above data shows that 74% of 26% is facing the problems of course discontinuity which is followed due to not

administering calcium carbonate.(Calcium carbonate is not any time calcium)

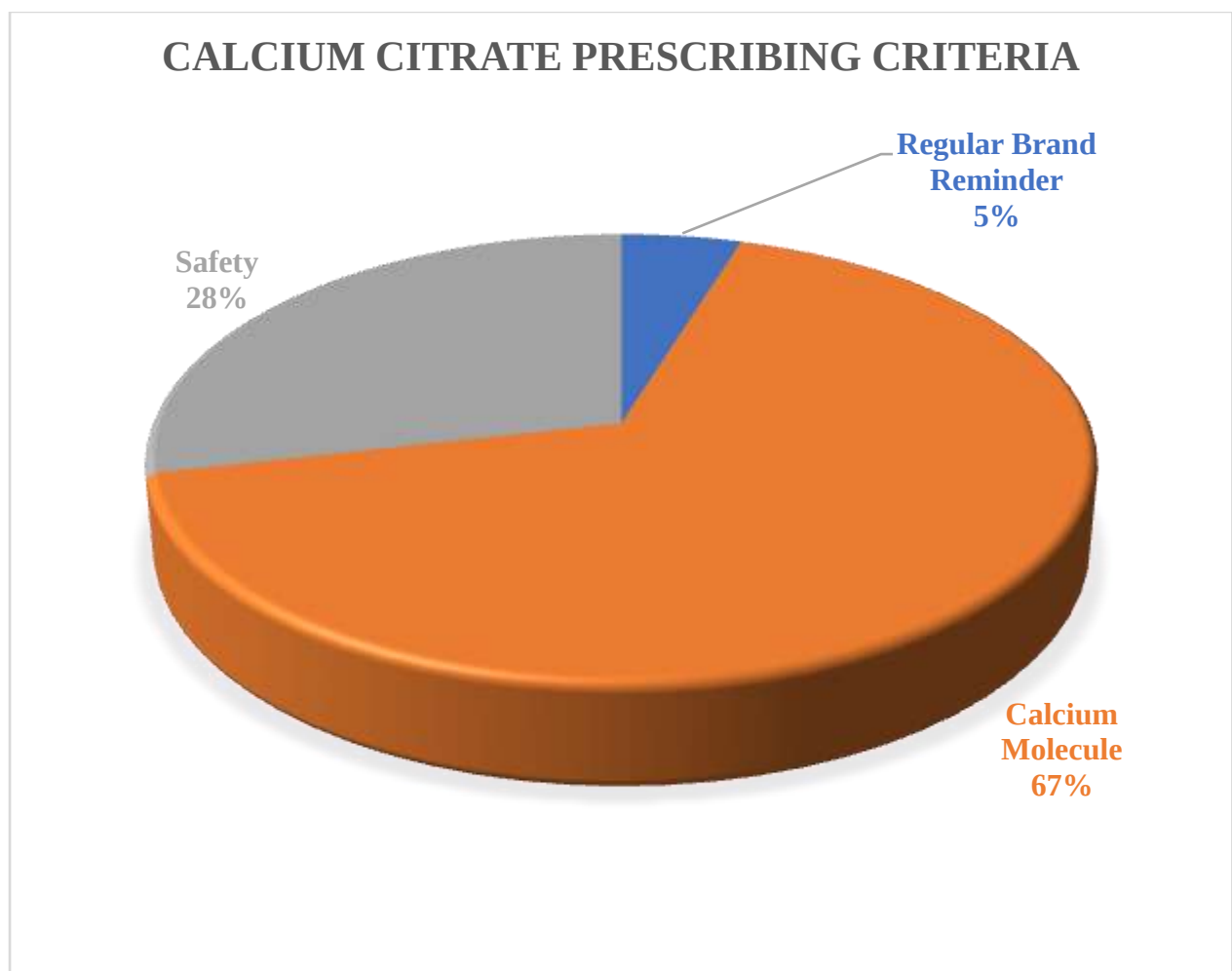


Fig.5.Calcium Citrate Prescribing Criteria.

Interpretation- According to above chart criteria of prescribing Calcium Citrate is based upon three attributing factors those are Safety , Calcium Molecule and Regular brand reminder by company. Major KOL's were concerned about the safety of the drug rather that affordability, In the present scenario respondents are shifting towards calcium citrate due to it's therapeutic effect, safety, Non interference

with the iron absorption, Being any time calcium so that the situation of course discontinuity does not arises . From the above data it's significant that 67% Of respondents said calcium molecule(Means calcium citrate) 28% Of respondents were

more concerned about safety and rest 5% were influenced due to regular brand reminder.

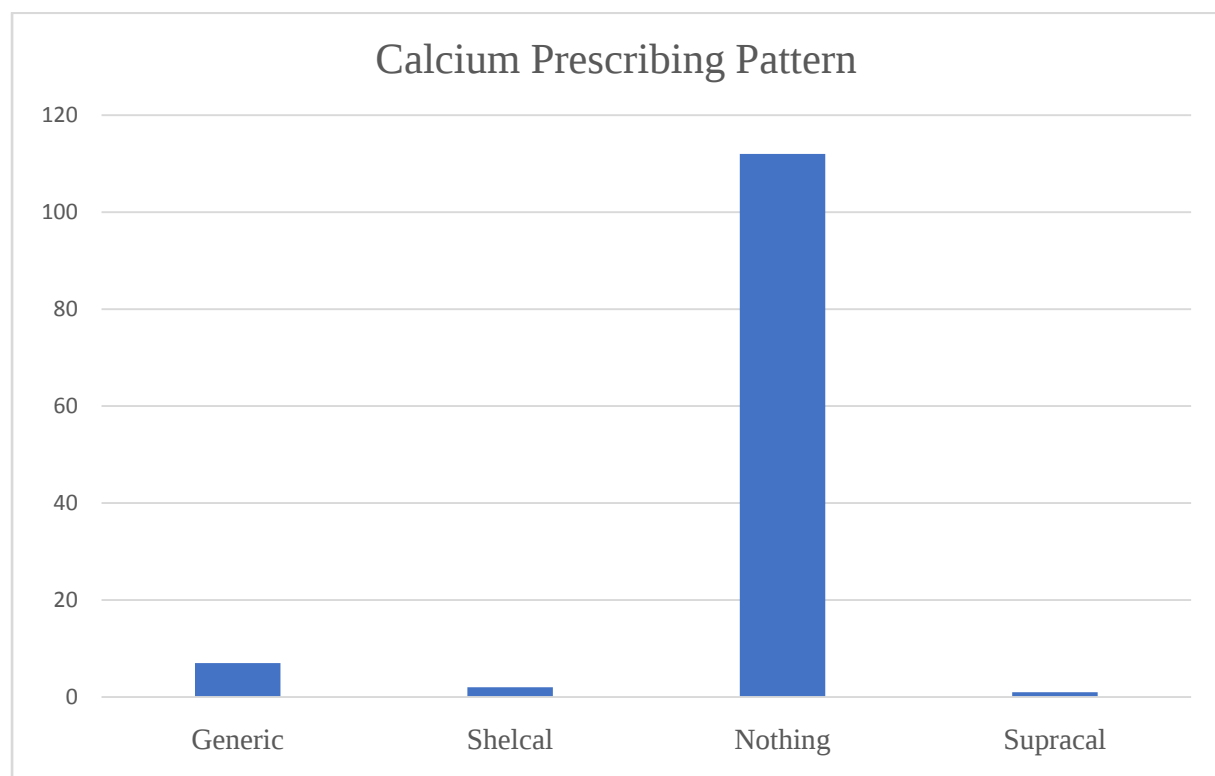


Fig.6.Calcium Supplementation Competitive Analysis

Interpretation- According to above chart competitive analysis has been done on the sample size collected, with due consent the information were collected thus the data is like this which signifies that Generic medicine is the most preferred one due to the affordability , accessibility and

adaptability esp.in Trust hospitals. Shelcal and supracal has been also noted as a prescribing product.

CONCLUSION:

So, from the above discussion and statistics , we can easily understand that calcium carbonate is common and highly used calcium molecule among Doctors as compared to calcium citrate. But looking into the few factors which tends to be negative such as bloating , belching, kidney stone on the usage of calcium carbonate put it into the concerned matter which is directly being resolved by replacing it by Calcium Citrate one of the safest calcium molecule with having patient compliance such as, Calcium citrate is any time calcium which means could be taken anytime as the absorption is both in acidic as well as basic medium apart from this calcium citrate is not having any adverse effect thus, no course discontinuity. On the other hand viability of course discontinuity is seen in administration of calcium carbonate. Looking into the above information it is suggested that calcium citrate usage should be more and more as compared to calcium carbonate.

RECOMMENDATION:

Looking into the criteria of prescribing calcium molecule differing both for carbonate and citrate , also adverse effect reported on the usage of calcium carbonate it's been suggested to Doctors focusing more on prescribing calcium citrate.

Kano model has been used for the study implying on attributing factors , in which awareness about the products price and therapeutic effect has been informed Because affordability plays a very important role due which in many hospitals it has been observed that Calcium Carbonate with lime juice is being prescribed to enhance the property or can say mimic the property of calcium citrate.

But when the calculation were made it was found that calcium citrate price with high therapeutic properties is being delivered same as the calcium carbonate with adverse effects. It has been recommended by the team and now the awareness campaign would be made and the usage of citrate over carbonate would be promoted.

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ANNEXURE:

QUESTIONNAIRE

(For Gynaecologist)

Q.1. What is important criteria for you while prescribing calcium to pregnant women?

- Calcium Molecule
- Brand Name
- Safety
- Affordability
- Regular brand reminders
- Others

Q.2.Which calcium molecule you prefer and why?

Q.3.Which are the common adverse effect in calcium citrate if any?

Q.4.Which are the common adverse effect of calcium carbonate?

Q.5.Could you please recall any calcium brands?