STUDY ON DRY EYE SYNDROME

AVAILABLE TREATMENT & NEW THERAPY

A SUMMER TRAINING PROJECT REPORT SUBMITTED IN

PARTIAL FULFILLMENT FOR THE AWARD

OF

POST GRADUATE DIPLOMA IN PHARMACEUTICAL MANAGEMENT

SUBMITTED BY

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UNDER THE GUIDANCE OF

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AKUMENTIS HEALTHCARE Ltd.

MUMBAI

INDIAN INSTITUTE OF HEALTH MANAGEMENT & RESEARCH

JAIPUR, RAJASTHAN

JUNE 2015

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 VIVEK N. MAHODAYA has undergone his summer training from 1st April to 8th June 2015. This candidate himself carried out all the studies and assignments related to his summer training on "STUDY ON DRY EYE SYNDROME-AVAILABLE TREATMENT & NEW THERAPY"

His approach to the study has been scientific and analytical.

The summer training is in partial fulfilment of the course requirement recommended for the award of Master in business administration-Pharmaceutical Management. I wish him success in all his future endeavours.

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Dean (Academic and Student Affairs)
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Date: June 25, 2015.

To Whom So Ever It May Concern

This is to certify that Mr.Vivek Mahodaya a student of MBA from The IIHRM University, Jaipur, has successfully completed the assigned market research project with Akumentis Healthcare Ltd.

He was found to be punctual, honest & hardworking during the project period from April 1st, 2015 to June8th ,2015.

We are pleased to the hard work put in by Mr.Vivek Mahodaya during the project & wish him luck in all future endeavours.

For Akumentis Healthcare Ltd.

Mr.Milind Bhalekar

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ACKNOWLEDGMENT

It gives me immense pleasure to acknowledge My Mentors Mr. Praduman Purey, Executive Vice President, at Akumentis Healthcare Ltd., Mumbai and Mr. Swapnil Wachkawde, DGM, at Akumentis Healthcare Ltd.Mumbai.They have always been an inspiration and will continue to be.

I place on record, my sincere gratitude to all my teammates for being such a supportive and a wonderful team, it was pleasure working with them.

I owe a debt of gratitude to My Mentor Mr. Rahul Sharma, Assistant Professor, at Institute of Health Management Research, Jaipur; Our Alumni Ms. Smita Kadam; all my teachers for grooming me and my friends for the inspiration needed to work with dedication and motivation throughout as an Intern Akumentis Healthcare Ltd.

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.

ABSTRACT

Dry eye syndrome is a multifactorial disorder of tears and ocular surface due to tear deficiency, excessive tear evaporation and instability of tears. Present treatment for dry eye syndrome mainly focuses on symptomatic relief which can is done by lubricants, anti-inflammatory therapy and corticosteroids. The treatment does not treat the root cause of the problem which is mucin production. Hence the goblet cell proliferation and mucin secretion remains unexplored area in the management of dry eye. [1 (M. A. Lemp C. B.)]

Market survey was done to assess the doctor's perception on the current available treatment and new therapy. The objective of the study was to identify the potential market for new molecule for treatment of dry syndrome.

INTRODUCTION

Dry eye syndrome (DES) present available treatment are lubricants which provide temporary layer acting as a tear film.

Anti-inflammatory therapy acts on intermediate factors like IL-1, TNF-alpha, MMP's and thus prevent apoptosis of goblet cells eventually preventing mucin loss. [(Sweeney DF, 2013)]

Corticosteroid therapy decreases inflammation on ocular surface by inhibiting cytokines and mmp pathway. [(Tanaka H, 2013)]

The dry eye syndrome in which the eyes do not produce enough tears is also known as "Sjogren's syndrome [(N. Delaleu, 2005)]

Rebamipide increases the expression of MUC1, MUC4 which is membrane associated mucin and MUC5 which is secreted mucin. It decreases tear hyperosmolarity, stabilizes tear film, decreases ocular surface inflammation by acting on MMP's, cytokines. [(Shimazaki-Den S, 2013)]

Rebamipide also proliferates goblet cells which are responsible for mucin production eventually helping in stabilizing the tear film.[(Koh S, 2013)]

RESEARCH METHODOLOGY

STUDY DESIGN: DESCRIPTIVE STUDY

SAMPLING : NON PROBABLITY SAMPLING

SAMPLE AREA : MUMBAI

SAMPLE POPULATION: OPHTHALMOLOGIST

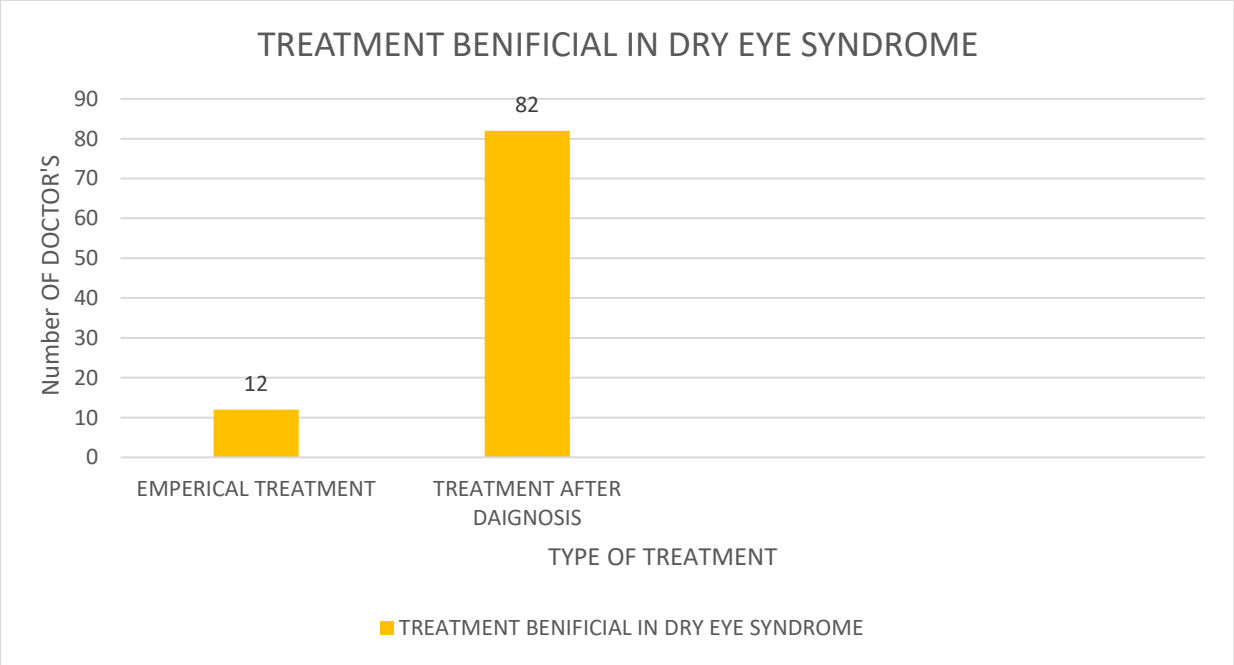
SAMPLE SIZE : 93

TOOL : QUESTIONNAIRE

TECHNIQUE : SURVEY

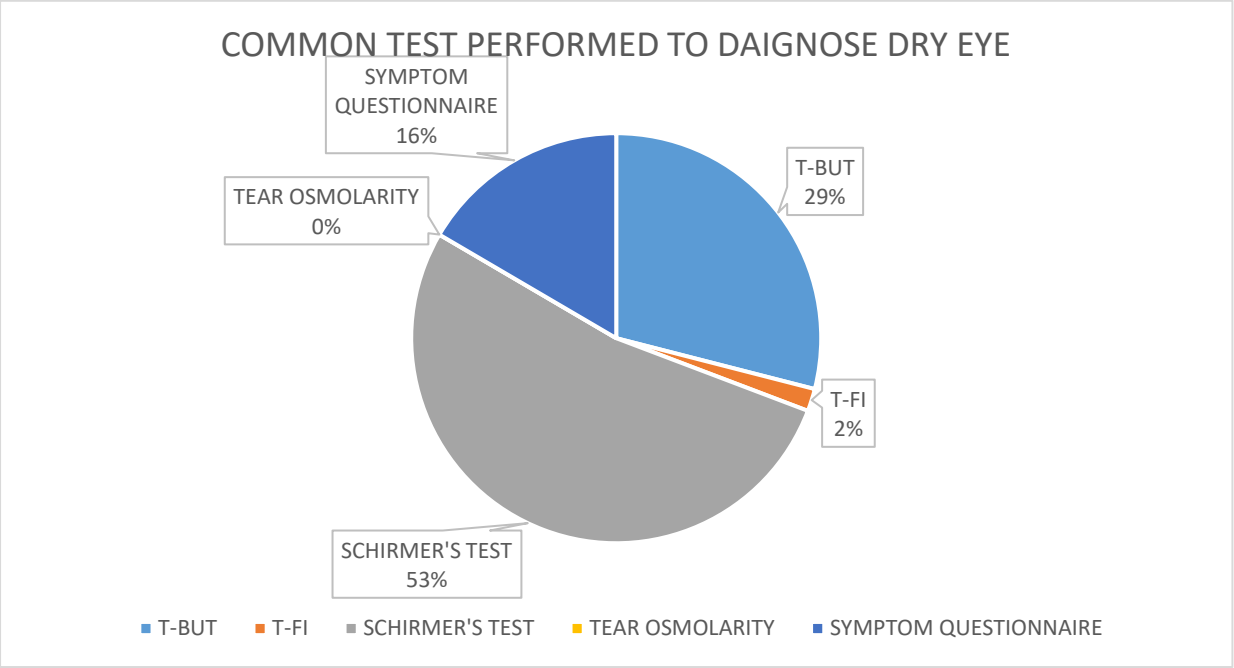
RESULT & FINDINGS

1. **According to you what kind of treatment would be beneficial in dry eye syndrome?**



It is important to detect the cause of dry eye as it can be of Evaporative deficient or Aqueous deficient and accordingly the therapy will differ for both condition. So treatment after diagnosis is preferred by doctors.

2. What are the common test you perform to diagnose dry eye?

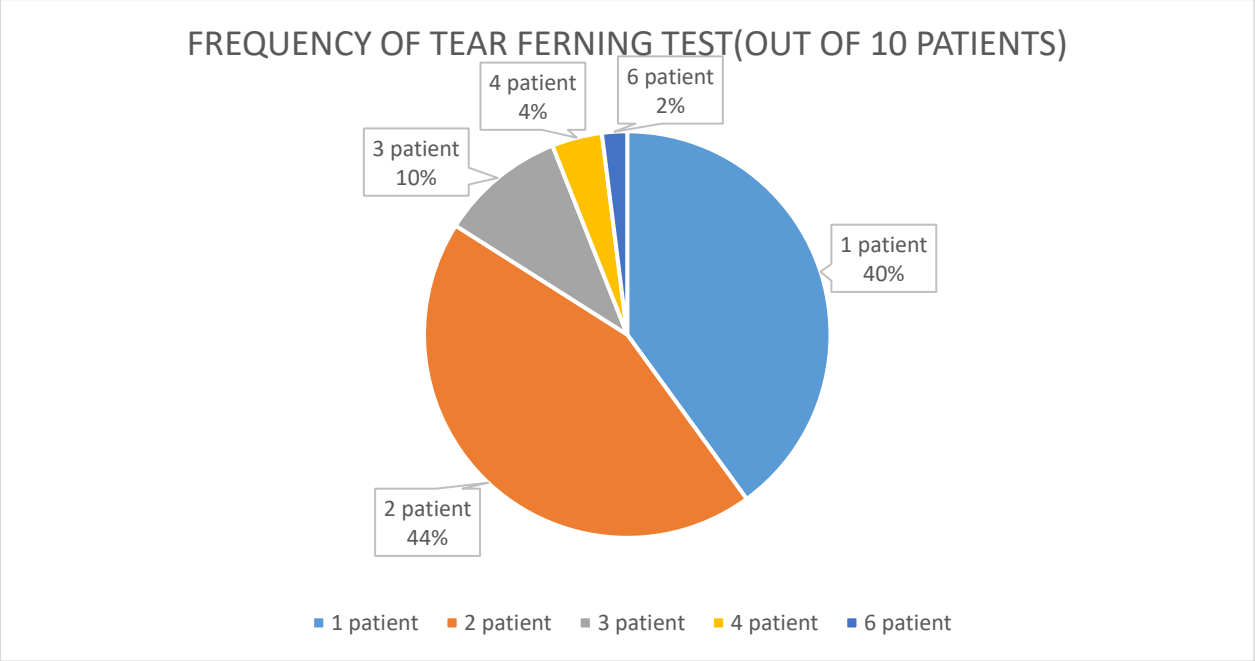


Quantitative methods are more conclusive in diagnosis of dry eye so T-BUT & Schirmer's is preferred.

Schirmer's test measures basic tearing function & reflex tearing function of eyes. Also T-BUT & Schirmer's test are less time consuming than others.

Symptom questionnaire was mainly preferred by hospital ophthalmologist.

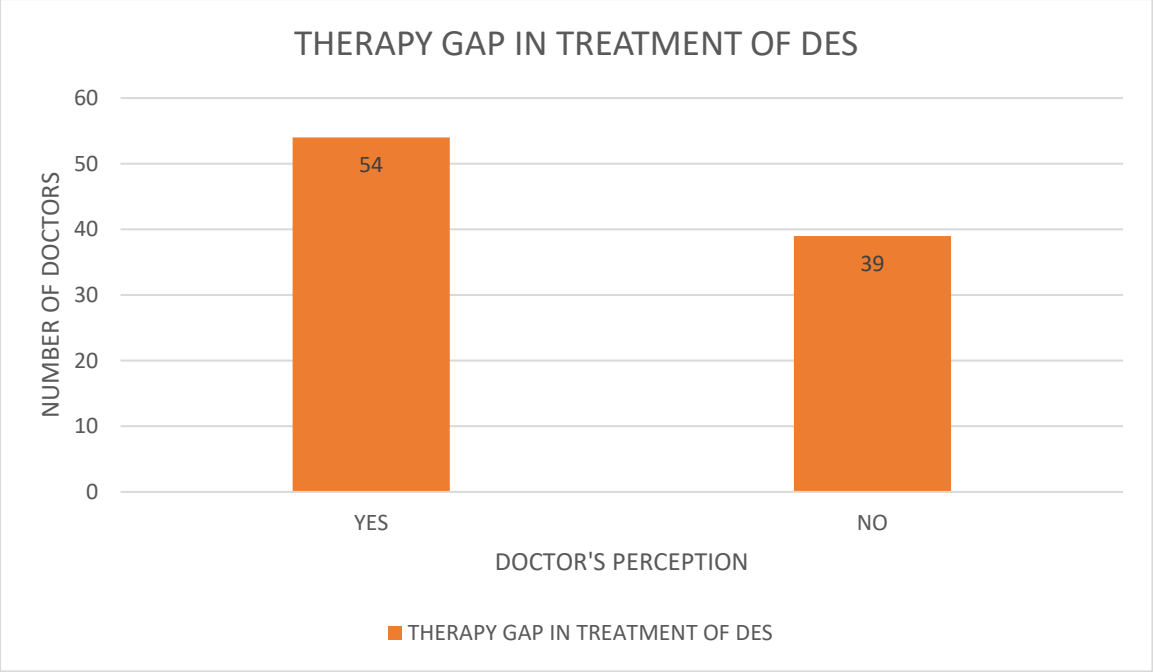
3. How often do you do tear ferning test?



As T-FT is a laboratory test its relevance with ophthalmologist is less.

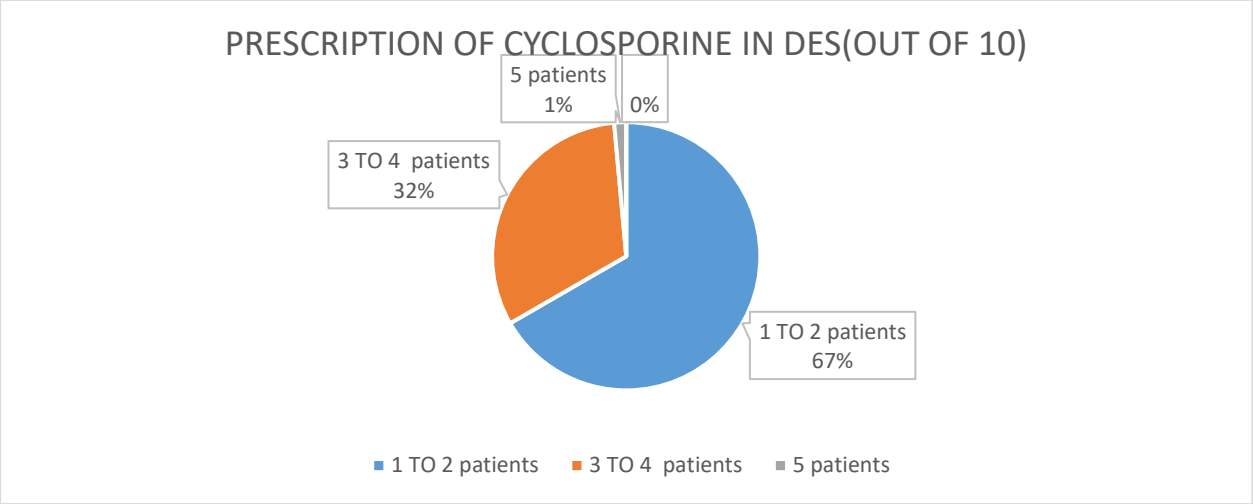
T-FT is qualitative test so they are performed only in sensitive cases.

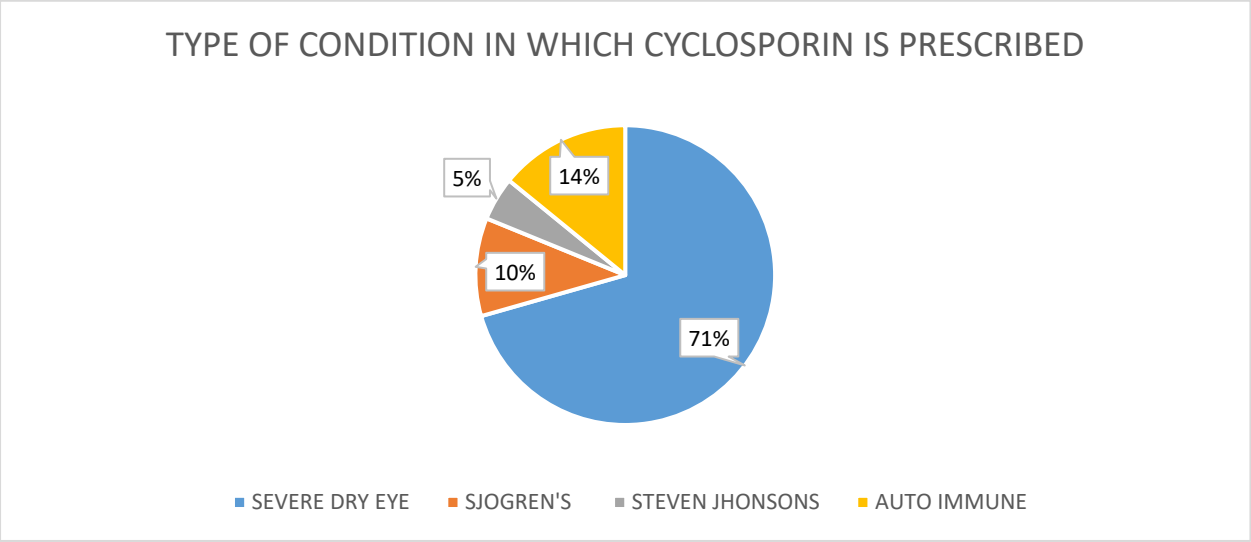
4. Is there any therapy gap you still face while treating dry eyes?



58% of ophthalmologist agreed that they are facing therapy gap in treatment of dry eye.

5. How often you do tear ferning test (T-FT)?

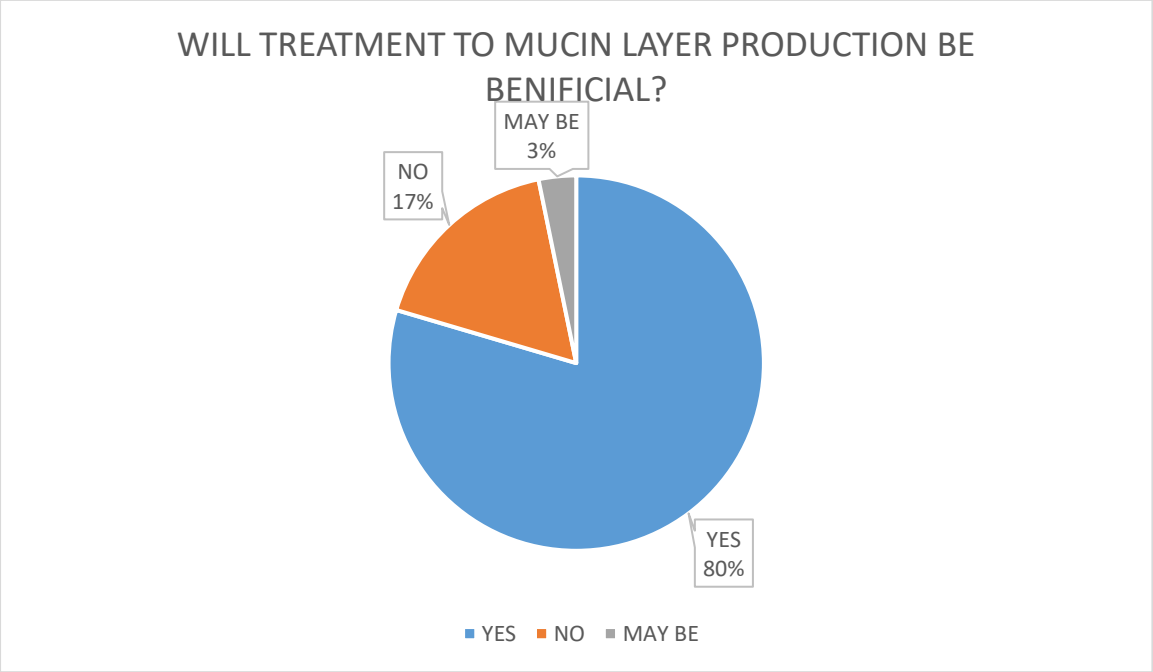




It is clear that cyclosporine is prescribed mainly in severe dry eye & to some extent in auto-immune disorder and Sjogren's syndrome.

So rebamipide can be easily targeted to these patient population as it decreases inflammatory mediators like MAPK, IL-1 & MMP's.

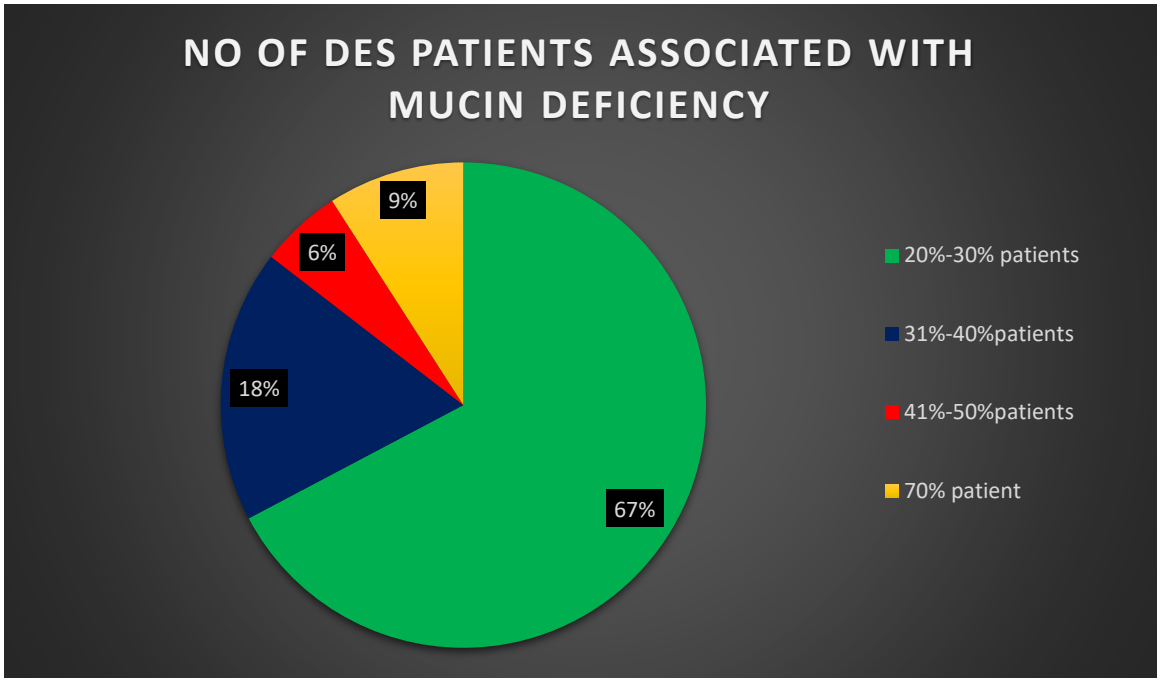
6. Current treatment addresses mebomian gland dysfunction lubricants. Will the treatment of mucin is going to benefit your dry eye patient?



Majority of doctors agreed that mucin layer production will be beneficial to their DES patient.

There is no molecule which focuses on natural mucin production.

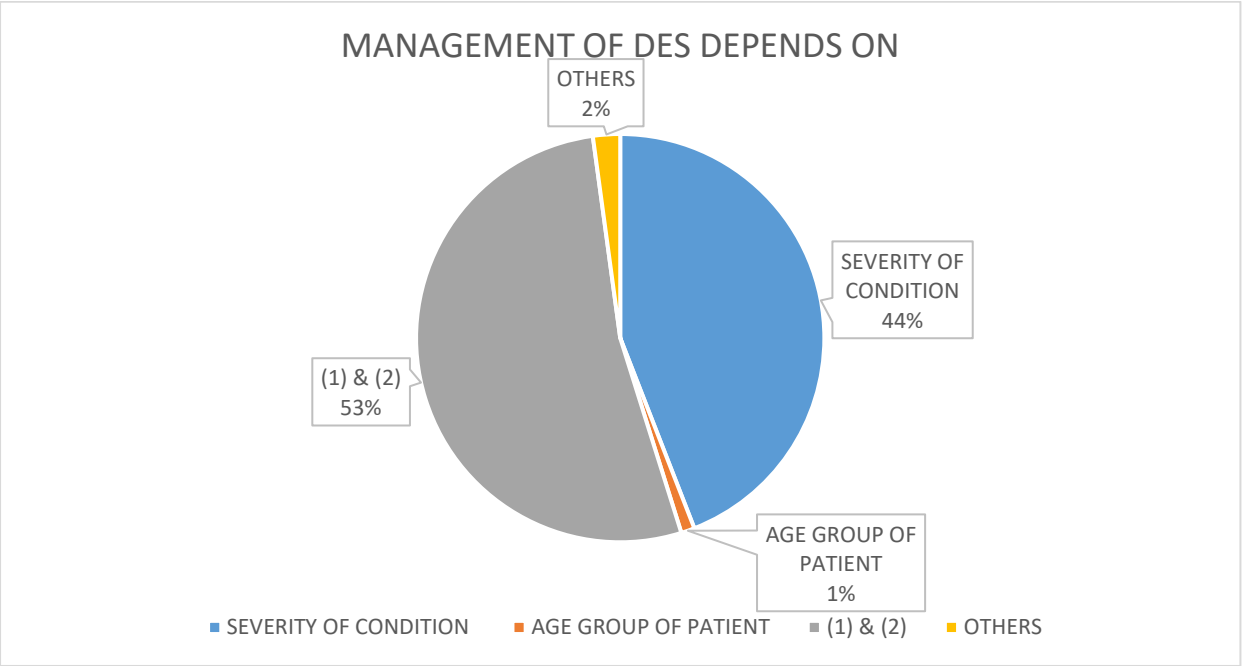
7. What is the percentage of patient you see dry eye associated with mucin deficiency?



67% sample population says there are 20%-30% cases of mucin deficiency.

Doctors encounter more of evaporative dry eye cases.

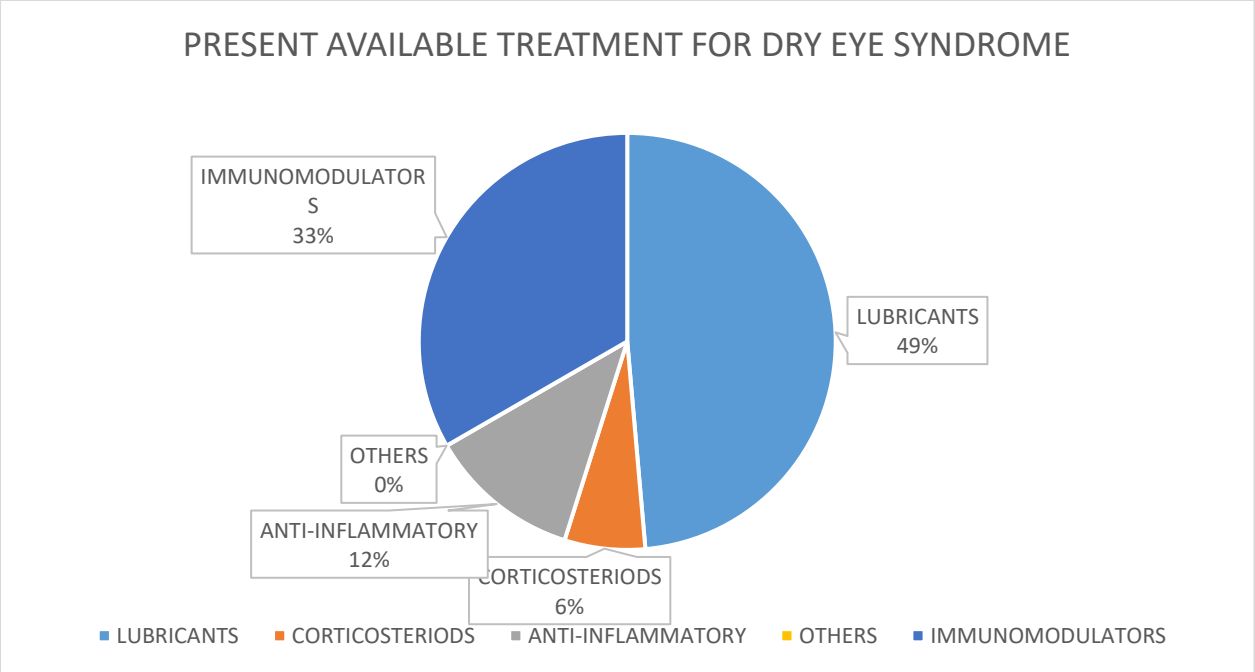
8. Management of dry eye syndrome depends on

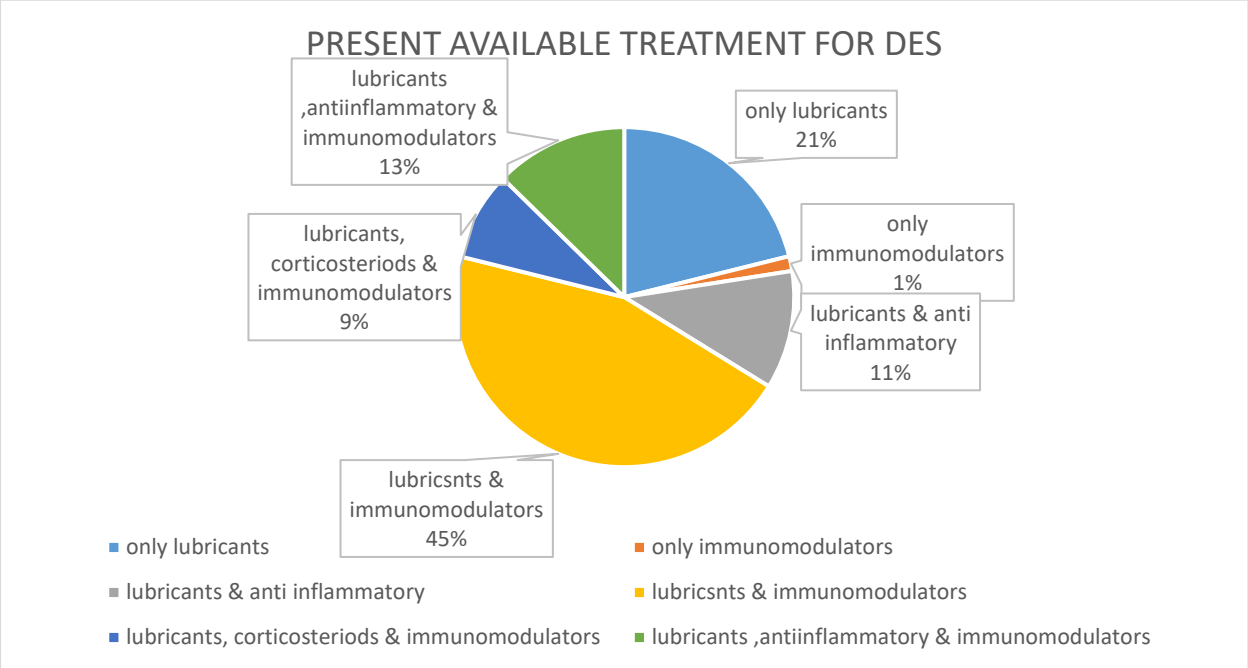


Severity of condition and age group of patient both are important criteria in treatment of Dry Eye Syndrome.

Treatment varies for different conditions of the patient like aqueous deficient, evaporative dry eye, dry eye due to auto immune condition.

9. What is the current available treatment for dry eye syndrome?

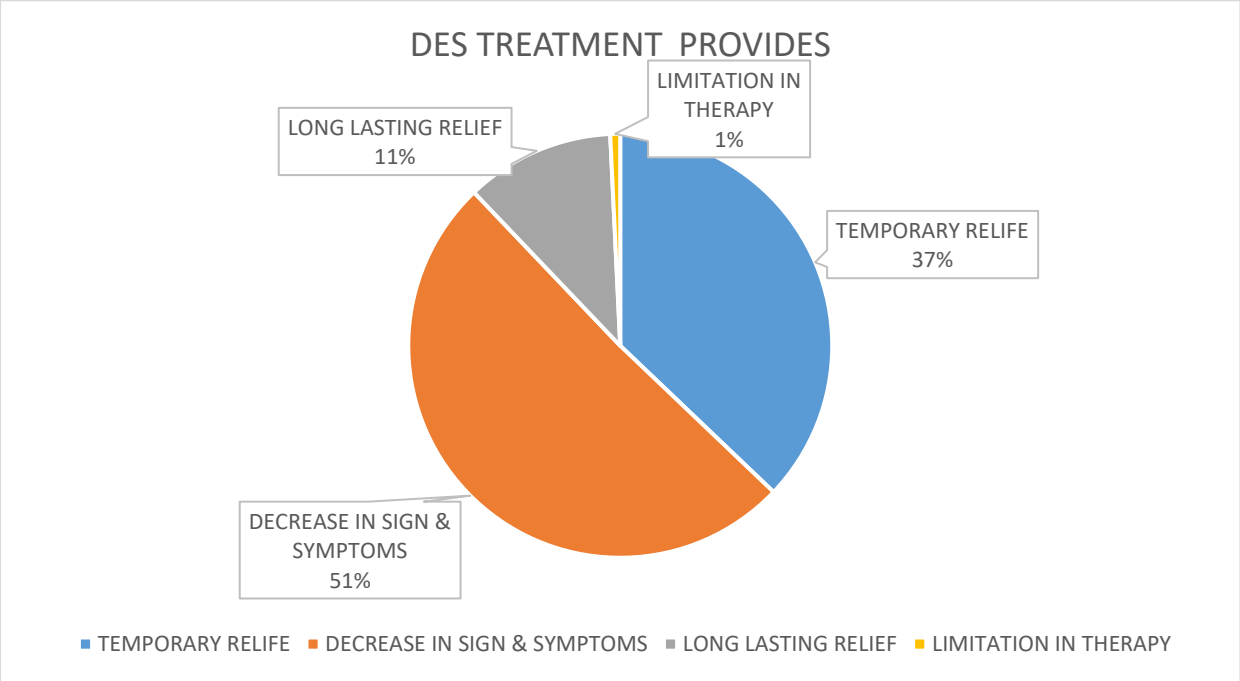


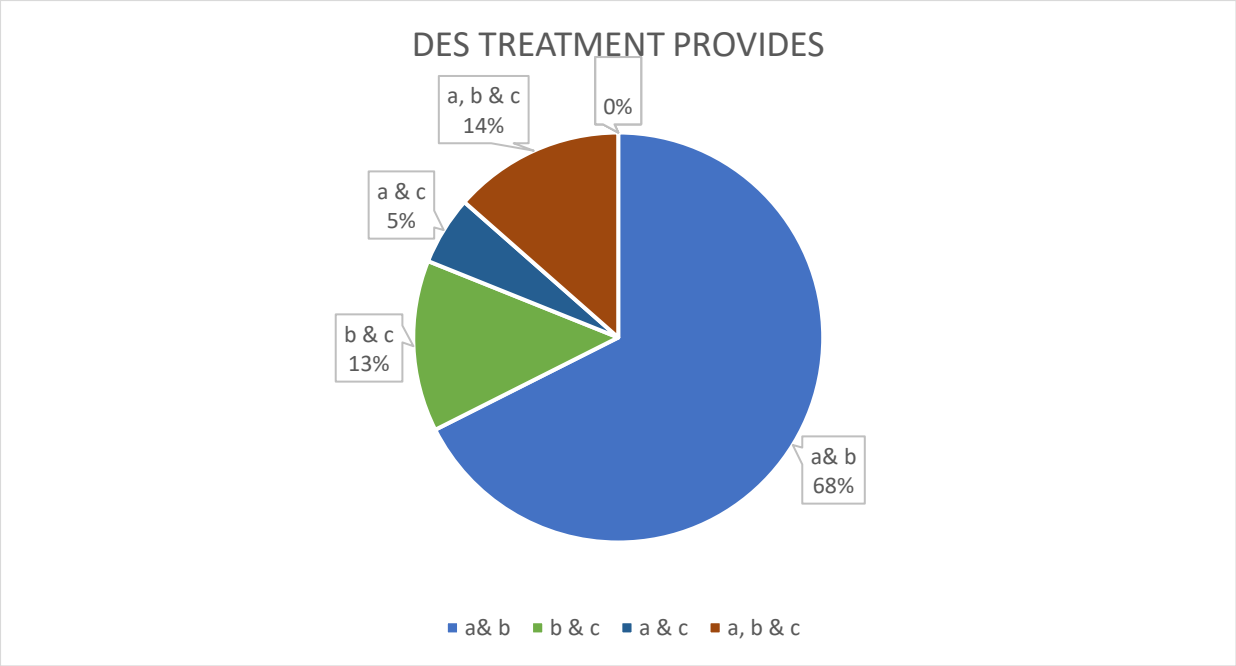


Doctors find combination of lubricants and immuno-modulators more effective than using lubricants & immuno-modulators singly.

Also Lubricants+Immune-modulators combination is preferred than Lubricants+anti-inflammatory agents for management of DES.

10.current available treatment of des provides

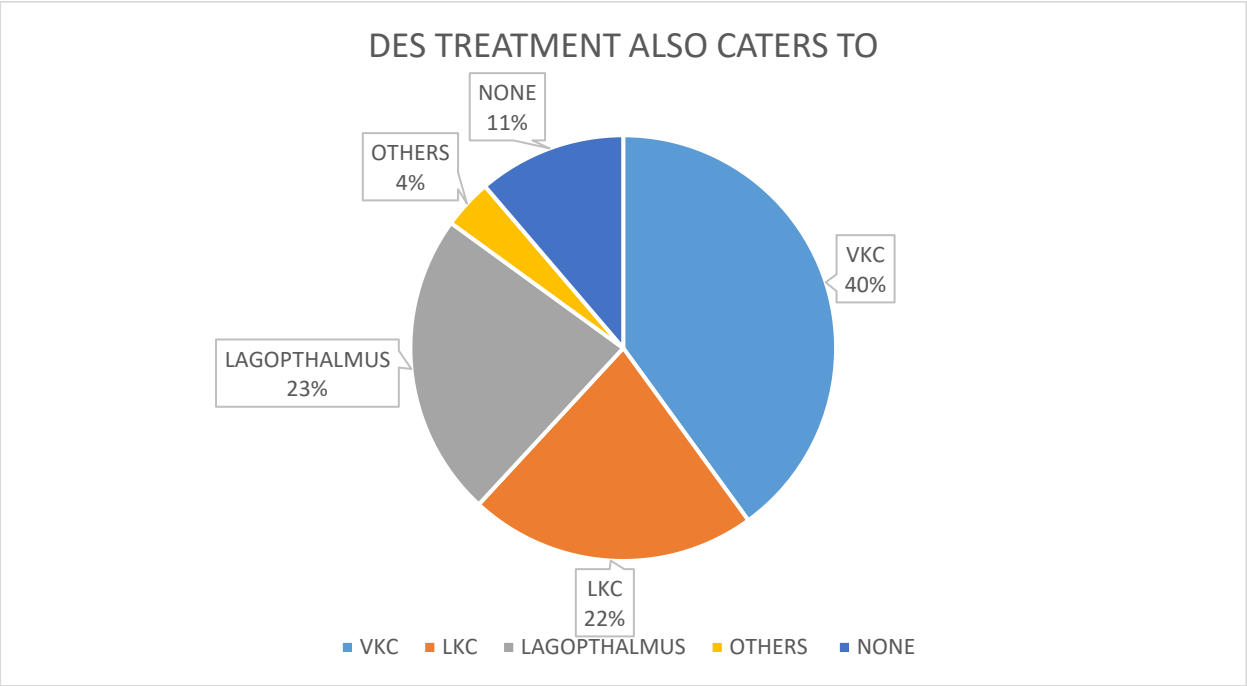


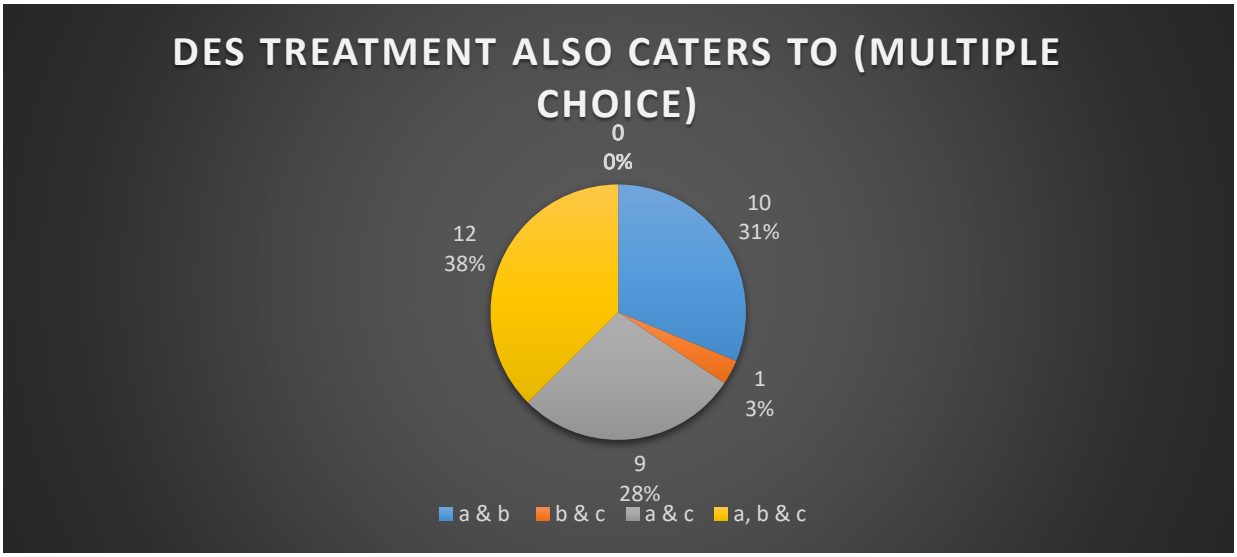


66% of doctors say current available treatment provides temporary relief and decrease in signs and symptoms of DES.

No doctors says that available treatment treats the root cause of the condition which is mucin production.

11.does available treatment also caters to

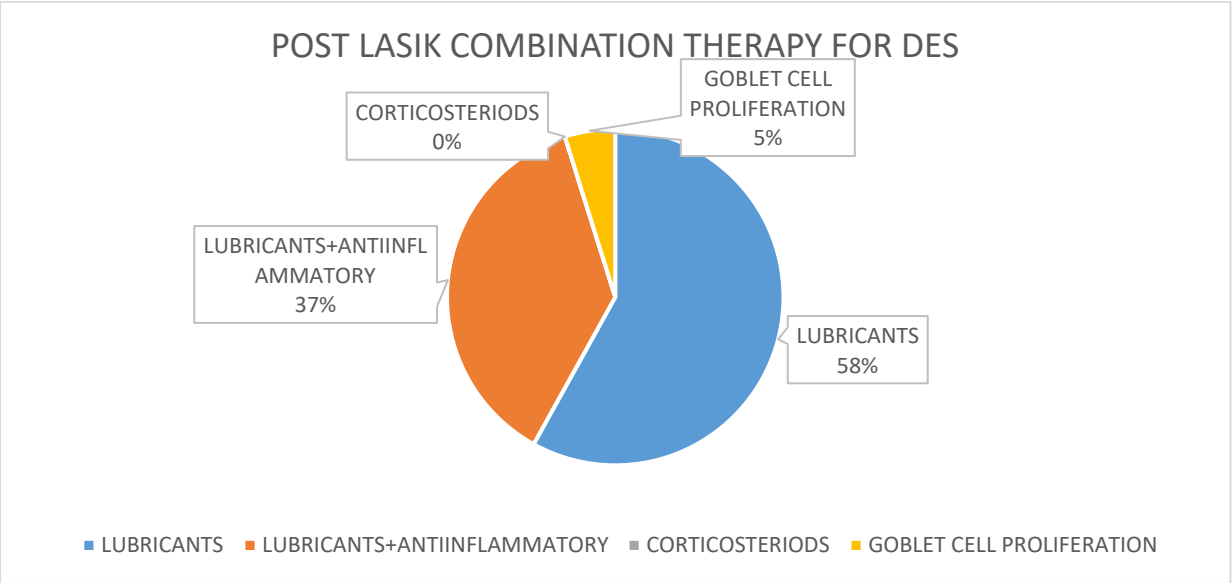


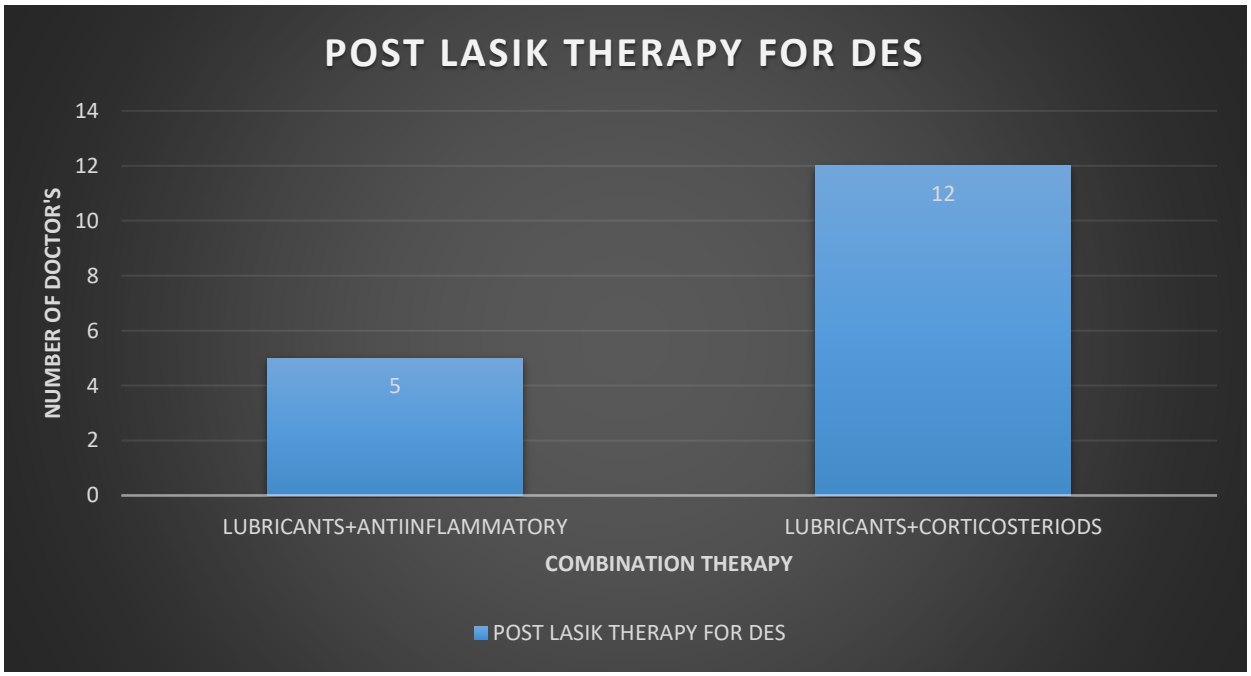


40% doctors says available treatment treats vkc/akc.11% says available treatment doesn't manage any condition like vkc, lkc, and lagopthalmus.

No one agreed to manage vkc, lkc, and lagopthalmus by a single molecule. For treatment of these conditions combination therapy is essential. And doctors said there is less patience compliance in combination therapy.

12.What is the best post lasik management for DES

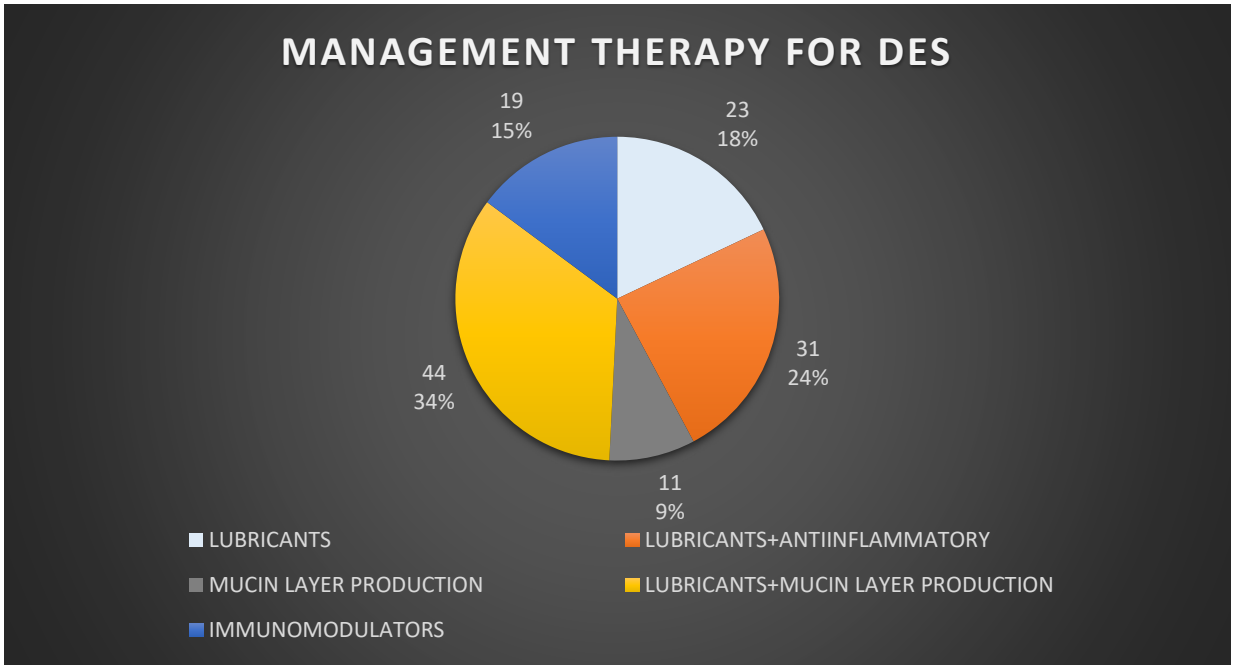


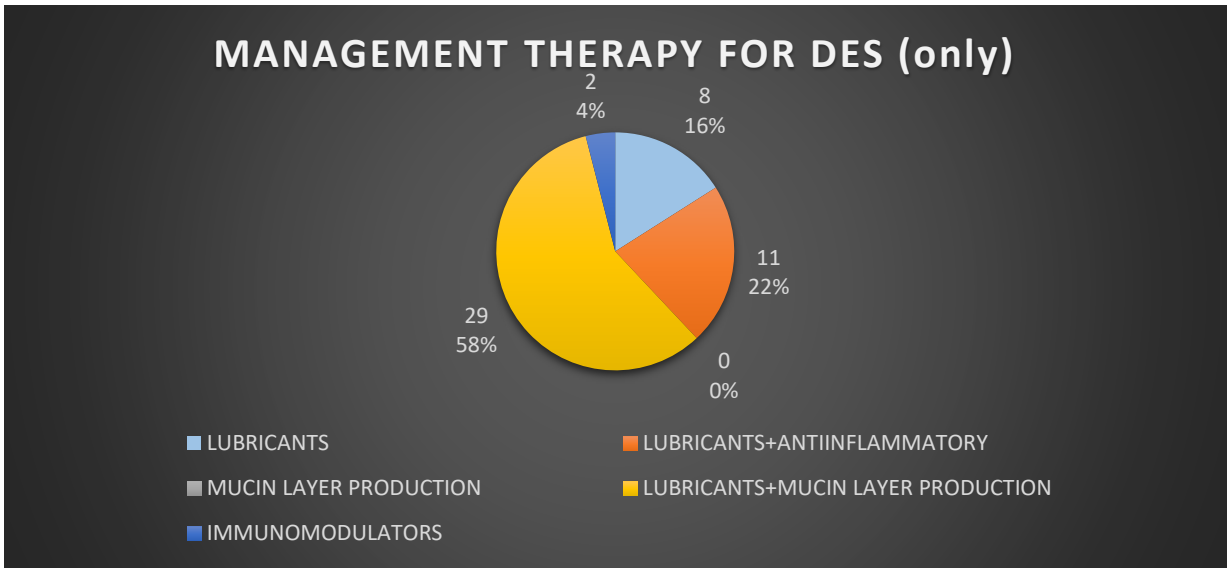


In combination therapy doctors prefer lubricants either with corticosteroids or with anti-inflammatory according to the patient etiology.

As there is no molecule available which can give management of anti-inflammatory & corticosteroid solely doctors have to prescribe 2 eye drops to manage one condition. There was no availability of goblet cell proliferation so doctors can't prescribe it.

13.What kind of management therapy best for dry eye syndrome?



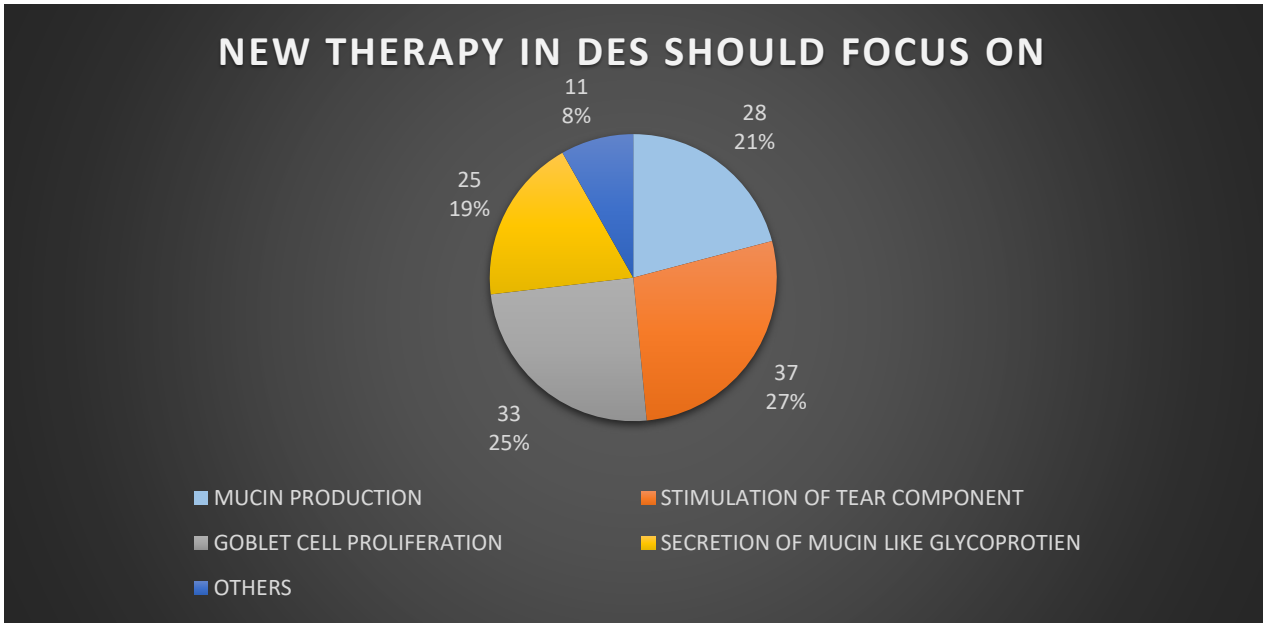


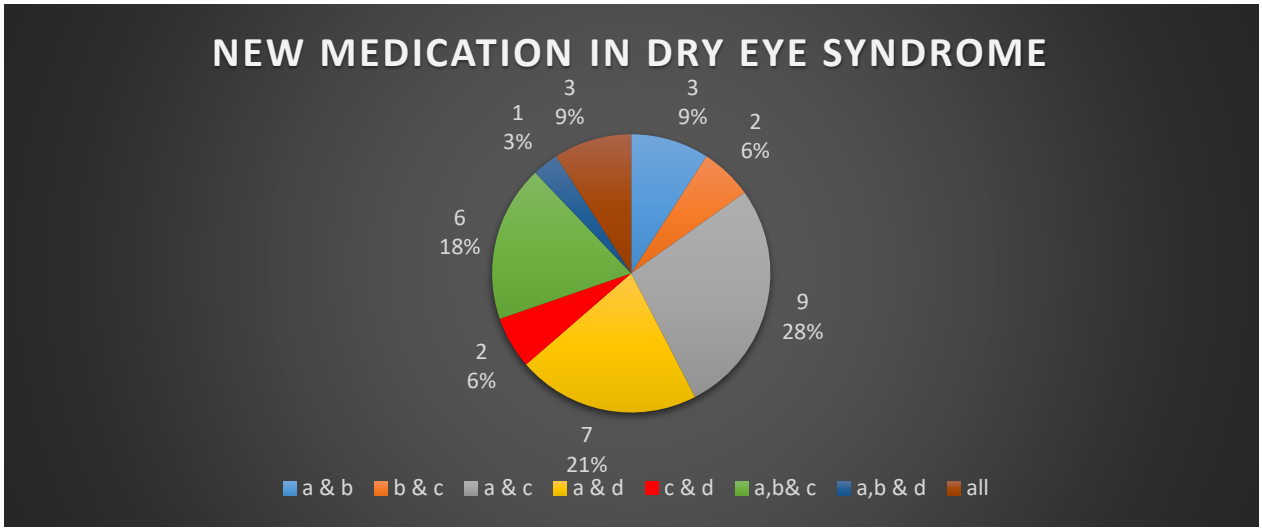
According to analysis 58% of doctors perceive only lubricant+mucin layer production is best for DES management in comparison to 22% preferring lubricant+anti-inflammatory.

Even in totality lubricant+mucin layer production is more than lubricants+anti-inflammatory.

Other combinations in options varies according to the etiology of the patient.

14. According to you new medication on DES should focus on?



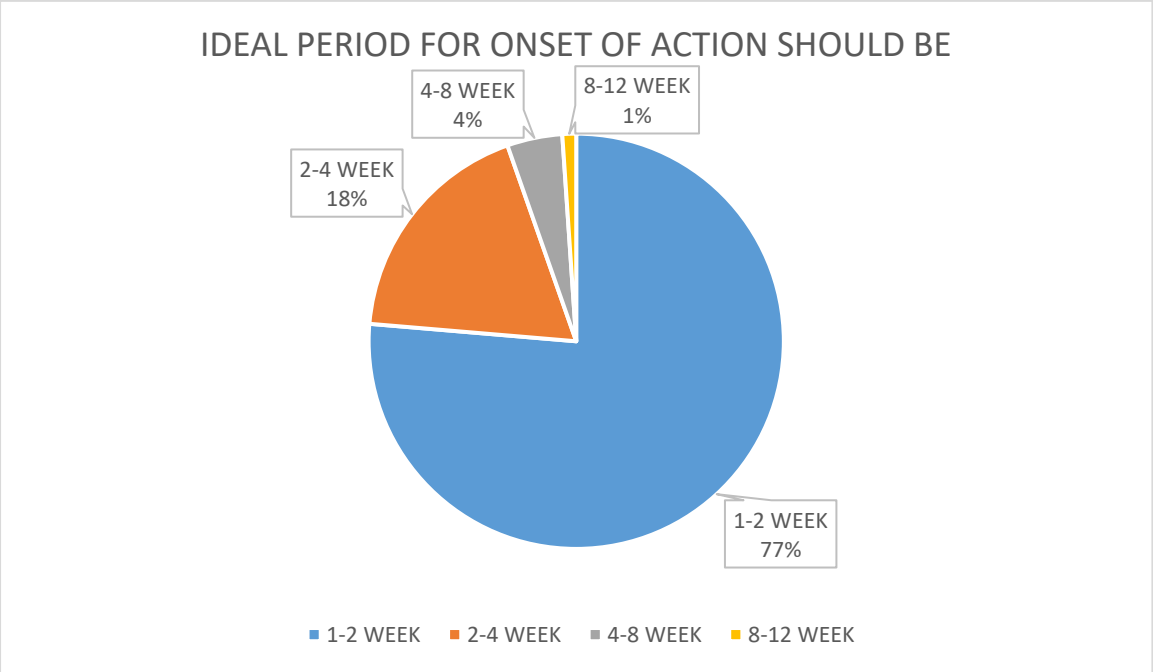


According to doctors new medications in DES management should focus on mucin production, stimulation of tear component & goblet cell proliferation.

Mucin production & goblet cell proliferation is achieved by Rebamipide and this kind of focus is demanded by 46% of the doctors.

Even in combination (a) & (c) was more in comparison to (a) & (b) and (b) & (d).

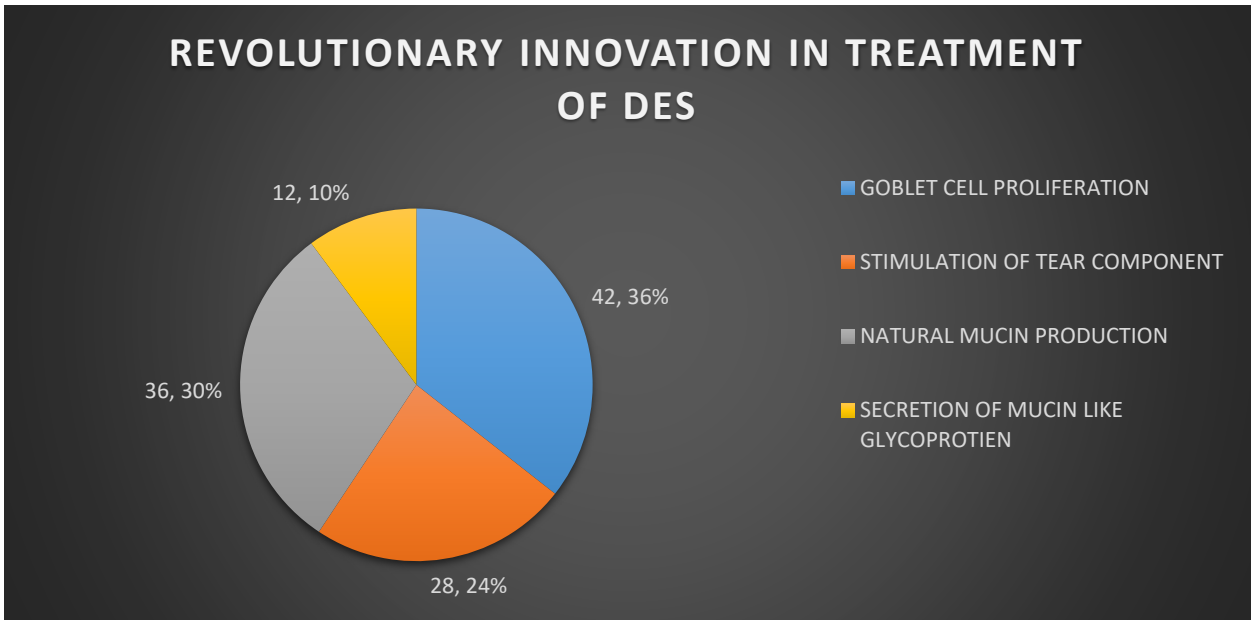
15.what should be the ideal period for onset of action of treatment?

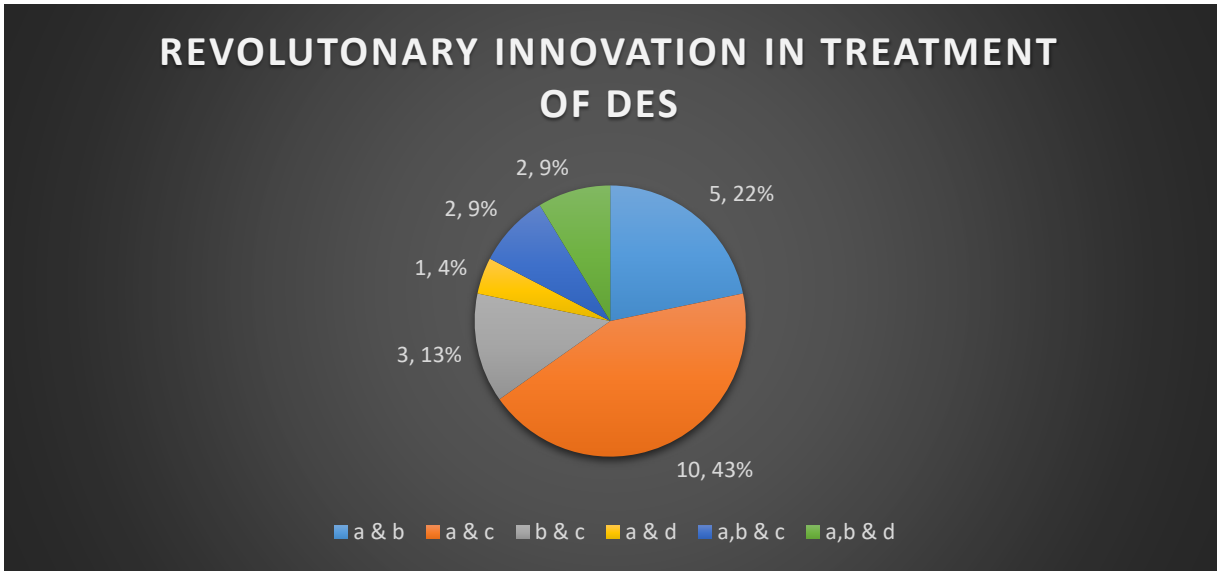


Most of the doctors want quick onset of action i.e. (1 to 2 week) in management of DES.

Rebamipide provides 1 to 2 week onset of action in DES management and no other present market molecule gives this kind of action.

16. What could be the revolutionary innovation in treatment of dry eye syndrome?





According to the survey revolutionary innovation in DES management should be on goblet cell proliferation & natural mucin production.

66% of sample population agreed to natural mucin production & goblet cell proliferation.

This is achieved by Rebamipide.

FINDINGS FROM MARKET SURVEY:

- New treatment should be patient complaint because current treatment which is lubricants with combination of anti-inflammatory or corticosteroid or immuno-modulators has to be instilled for about 3 to 4 times in a day and patient tend to forget one or two dose.
- Doctors demand quick onset of action and recovery from dry eye for their patient because patient report itchiness in eye for several weeks even after management has started.
- New treatment should treat the root cause rather than focusing on symptomatic relief.
- Doctors say that there should be a medication which acts on mucin layer to manage dry eye syndrome.
- Old age patients require more attention for management of DES as body function and mucin secretion is at slower rate as compared to adult patients. So age group of patient & severity of condition is important criteria in management of DES.
- 16% of doctors says only lubricants is the available treatment for dry eye syndrome.
- 34% of sample population says lubricant+immuno-modulators is effective combination in treatment of dry eye.
- 18% of doctors says current available treatment for DES gives temporary relief from dry eye.
- 34% of doctors say available treatment decreases signs and symptoms of DES.
- 39% of doctors say only lubricants is the best therapy for post LASIK management of DES.
- 25% of doctors say lubricants+anti-inflammatory is the appropriate therapy for post LASIK DES management.

- 9% of population says only lubricants is the best management therapy for DES. While 31% of doctors say lubricant+mucinlayer production should be the management therapy.
- 12% doctors feel lubricants+mucin layer production should be the management for DES.
- 28% of sample population says new medication should focus on mucin production in comparison to 16% agreeing to stimulation of tear component.
- 76% of doctors say ideal time for onset of action should be 1-2 weeks as patient demand less irritation as therapy starts.
- 46% of doctors say revolutionary innovation in treatment of dry eye could be natural mucin producing medication which can trigger goblet cell proliferation.

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