Awareness of The Use of Zinc in The Treatment of Pediatric Diarrhoea

By

Preet Jarry

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2017-2019

The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Sanganer, Airport
Jaipur 302029, Rajasthan
Ph: 0141 3924700, Fax: 3924738
Website: **www.iihmr.edu.in**

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Ph: 0141 3924700, Fax: 3924738
Website: **www.iihmr.edu.in**

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This is to certify that **Preet Jarry** student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training at Brandcare,Mumbai from **12th Feb 2019 to 12th May 2019.**

The Candidate has successfully carried out the study assigned 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.

I wish her all success in all her future endeavors.

Dr Sandeep Narula
Dean, School of Pharmaceutical Management
The IIHMR University, Jaipur

Dr. Saurabh Banerjee
Guide, Associate Professor
The IIHMR University, Jaipur

1, Prabhu Dayal Marg, Near Sanganer Airport, Jaipur- 302029, Rajasthan, India.
Ph.: 0141- 3924700, 2791431- 32, Fax: 0141 3924738, E-mail: iihmr@iihmr.edu.in, Web.: www.iihmr.edu.in

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"To study the usage practices of Zinc during Diarrhoea in children among Pediatricians of Thane"

Date: 12/02/2019 to 9/05/2019

Organization: Brandcare

He/ She comes across as a committed, sincere & diligent person who has a strong drive and zeal for learning

We wish him/her all the best for future endeavors

Group Head

Manager – Human Resources

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This is to certify that the dissertation titled **To study the usage practices of Zinc during diarrhoea in children among Pediatricians of Thane** and submitted by **Preet Jarry, 109** under the supervision of Dr. Saurabh Banerjee for award of MBA in Pharmaceutical Management at University carried out during the period from 12th February,2019 to 9th May,2019 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

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ABSTRACT

RESEARCH PROBLEM:

Zinc is not prescribed by the Pediatricians even after being in the guidelines of WHO and UNICEF.

METHODOLOGY:

Objective- To study the usage practices of Zinc during diarrhoea in children among Pediatricians of Thane.

Research Design

Study Type- Descriptive

Study Population- Chemists and Pediatricians

Data Type- Primary and Secondary

Duration- 3 months

Sampling Area- Thane

Sampling Tool- Questionnaire

Sample Size- Pediatricians=40

Sampling Technique- Non Probabilistic Purposive Sampling

KEY RESULTS:

- ORS is the first treatment which is prescribed by Pediatricians to its patients during pediatric diarrhoea.
- There is no updation in the treatment of pediatric diarrhoea. The prescription is based on the traditional benefits of ORS for the treatment.
- Knowing the benefits of zinc, only few doctors prescribe Zinc in the treatment of pediatric diarrhoea.
- Zinc has been prescribed by the doctors in case of Viral diarrhoea.

- Increased immunity and faster relief are the common benefits which the pediatricians are aware about the Zinc.

CONCLUSION:

- There is a set guideline by the WHO & UNICEF for the treatment of diarrhoea which includes ORS+Zinc, inspite of which there is a lesser knowledge and lesser usage of zinc as a treatment in diarrhoea. Only 25% of Pediatricians prescribe Zinc with ORS.
- 35% of Pediatricians do no prescribe Zinc in their treatment.
- 45% of Zinc is prescribed during Viral diarrhoea..
- There is a need for awareness of benefits of zinc among the patients as well as the prescribers i.e. the pediatricians. The benefits of zinc and ORS combined together must be presented so that there is acquaintance with the fact that by adding zinc, ORS proves to give a faster recovery.
- The traditional use of only ORS as a treatment in diarrhoea has become a barrier in knowing more about the different benefits of zinc for treating diarrhoea thus, less number of prescribers were inclined towards prescribing zinc for pediatric diarrhoea.

INTRODUCTION

Diarrhoea

Diarrhoea is the passage of frequent passing of watery or loos stools in a full 24 hour day period which deviates a child from his normal pattern. The symptoms accompanying diarrhoea are vomiting, loss of appetite, rise in body temperature, abdominal pain.

In case of prolonged diarrhoea, dehydration is the most likely symptom. A failure to gain weight can be the result of chronic diarrhoea

Diarrhoea is a very common pediatric concern and causes about 1.5 million deaths/year worldwide.

Diarrhoea is the third most common cause of death in under-five children, responsible for 13% deaths in this age-group, killing an estimated 300,000 children in India each year.

Diarrhoea in children:

An estimated number of 2.5 billion cases of diarrhoea happen among children, most likely under the age of five years. There is an overall incidence which has remained stable over the past two decades.

Vulnerability of children

The most susceptible children are those who have poor hygiene conditions. Those at greater risk of life threating diarrhoea are younger children. Poor sanitation, unhygienic living conditions serve to be important risk factors for diarrhoea. The different sources of water supply, the transportation mode of water at different levels, the management of waste disposal accounts for the factors causing diarrhoea.

SYMPTOMS:

The most likely symptom of diarrhoea is Dehydration which can be mild or severe dehydration causing chronic or acute episodes of diarrhoea.

Severe dehydration

- Loss of consciousness
- Sunken eyes
- Unable to drink or drink poorly
- Decrease in blood pressure
- Severe muscle contraction in the arms, legs
- Bloating of stomach

Early or mild dehydration includes:

- Flushed face
- Extreme thirst, more than normal or unable to drink
- Dryness in skin
- Cannot pass urine or reduced amounts, dark, yellow
- Weakness
- Irritability
- Sunken eyes
- Thirsty, drinks eagerly

The other symptoms of diarrhoea in children include:

- Bloody stools
- Chills
- Fever
- Loss of control of bowel movements
- Nausea or vomiting
- Abdominal pain

TYPES OF DIARRHOEA:

The different types of clinical diarrhoea are:

Acute watery diarrhoea

Persistent diarrhoea

Dysentery

Diasrrhoea with severe malnutrition

- **Acute diarrhoea**: If an episode of diarrhoea lasts less than 14 days, it is acute diarrhoea. Acute watery diarrhea causes dehydration and contributes to malnutrition.
- **Acute bloody diarrhoea/Dysentery**: The main dangers are intestinal damage, sepsis and malnutrition; other complications, including dehydration, may also occur.
- **Persistent diarrhoea:** Persistent diarrhoea is an episode of diarrhoea, with or without blood that lasts at least 14 days. Up to 20% of episodes of diarrhoea become persistent. Persistent diarrhoea often causes nutritional problems, creating the risk of malnutrition and serious non-intestinal infection.
- **Diarrhoea with severe malnutrition:** The main dangers are severe systemic infection, dehydration, heart failure and vitamin and mineral deficiency.

PREVENTION OF DIARRHOEA:

Reducing childhood diarrhoea requires interventions to make children healthier and less likely to develop infections that lead to diarrhoea; clean environments that are less likely to transmit disease; and the support of communities and caregivers in consistently reinforcing healthy behaviours and practices over time.

Water, sanitation and hygiene:

Improvements in access to safe water and adequate sanitation, along with the promotion of good hygiene practices (particularly handwashing with soap), can help prevent childhood diarrhoea. In fact, an estimated 88 per cent of diarrhoeal deaths worldwide are attributable to unsafe water, inadequate sanitation and poor hygiene.

Washing one's hands with soap is another important barrier to transmission, and has been cited as one of the most cost-effective public health interventions.

Accessible and plentiful water has also been shown to encourage better hygiene, handwashing in particular, although the extent to which access to improved water sources reduces diarrhoea rates often depends on the type of water source available (such as public taps or standpipes, protected dug wells or boreholes).

Key measures to prevent diarrhoea in children include:

- Access to safe drinking-water;
- Use of improved sanitation;
- Hand washing with soap;
- Exclusive breastfeeding for the first six months of life;
- Good personal and food hygiene;
- Health education about how infections spread; and
- Rotavirus vaccination

ADEQUATE NUTRITION

Undernourished children are more prone to acquire diarrhoeal symptoms. Therefore adequate nutrition can provide prevention to diarrhoea.

BREASTFEEDING

Breastfeeding can contribute in preventing diarrhoea. Only 37 per cent of infants in developing countries are exclusively breastfed for the first six months of life.

MICRONUTRIENT SUPPLEMENTATION

The deficiency of Vitamin A and zinc can cause diarrhoea. The supplementation of these micronutrients can help prevent diarrhoea.

TREATMENT:

Diarrhoea affecting infants and children is an important primary-care problem. According to the WHO and UNICEF, the treatment package and prevention package for diarrhoea includes

REHYDRATION:-

Oral Rehydration Solution

Oral Rehydration Therapy (ORT) is the cheap, simple and effective way to treat dehydration caused by diarrhoea. An effective solution can be made using ingredients found in almost every household. The ORS drink contains the main elements that are lost from the body during diarrhoea. It is effective in treating dehydration resulting from all types of acute diarrhoeal diseases. One of these drinks should be given to the child every time a watery stool is passed. During or after treatment of dehydration, whatever is causing the diarrhoea, vomiting, or other symptoms should also be treated. The glucose contained in ORS solution enables the intestine to absorb the fluid and the salts more efficiently. ORT alone is an effective treatment for 90-95% of patients suffering from acute watery diarrhoea, regardless of cause.

ORS (oral rehydration salts) is a special combination of dry salts that is mixed with safe water. It can help replace the fluids lost due to diarrhoea.
In addition, for 10–14 days, give children over 6 months of age 20 milligrams of zinc per day (tablet or syrup); give children under 6 months of age 10 milligrams per day (tablet or syrup).

ZINC SUPPLEMENTATION

Zinc is usually given as zinc sulphate, zinc acetate, or zinc gluconate, which are all water-soluble compounds. Zinc restores mucosal barrier integrity and enterocyte brush-border enzyme activity, it promotes the production of antibodies and circulating lymphocytes against intestinal pathogens It has a direct effect on ion channels, acting as a potassium channel blocker of adenosine 3-5-cyclic monophosphate-mediated chlorine secretion.

With increased fluids and continued feeding, all children with diarrhoea should be given zinc supplementation at 20 mg for 10–14 days; infants < 6 months should receive 10 mg.

PAST

- In 2004, WHO/UNICEF issued a joint statement recommending New osmolarity ORS and Zinc supplementation in the treatment of Diarrhoea.
- In spite of the recommendations, there is little progress in Prescriptions and availability of Zinc.
- The first brand of Zinc launched in India is Zinconia followed by Z&D.
- In the recent past, Indian govt has included Zinc in the National programme for treatment of Diarrhea.
- IAP along with NRHM has organized awareness on diarrhea through an activity called IDCF.

PRESENT

- In spite of the recommendations, only 1 % of Zinc is prescribed in India.
- Very few brands of Zinc is launched till date (20 brands) with limited market size of 30 cr and 23% Gr.
- Only 2 brands introduced in the last one year.
- No new clinical references in recent past.

IMPORTANCE OF ZINC IN MANAGING DIARRHOEA

Zinc can benefit in the following ways:

- It can increase cellular immunity and enhances immune response.
- Zinc can reduce overall diarrhoea prevalence by 25%.
- It reduces re-occurrences within 2-3 months by 35%.
- Zinc supplement has been found to reduce severity of diarrhoeal episodes.
- Zinc maintains gut mucosal integrity to reduce or prevent fluid loss.
- Zinc favours intestinal transport of water and electrolytes
- It allows better clearance of pathogens It plays a central role in cellular growth
- A deficiency of zinc will affect mucosal functions, reduce brush border enzymes.
- Elemental zinc is used orally, as an adjunct to ORT in acute diarrhea, in infants (under six months): 10 mg daily for 10 – 14 days; and in children (six months - five years): 20 mg daily for 10 - 14 days.
- Zinc appears to increase ORS uptake and reduces inappropriate drug use with antibiotics and anti-diarrhoeal medications. Clinical studies have shown that a 10- to 14-day treatment course with zinc effectively reduces the duration and severity of both persistent and acute diarrhoea. Zinc has been associated with a 25 per cent reduction in the duration of acute diarrhoea, as well as a 40 percent decrease in severity of both persistent and acute diarrhoea.

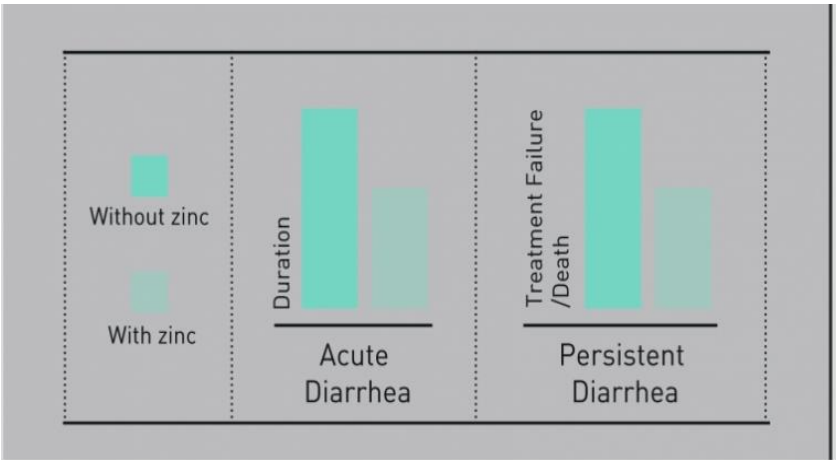
TREATMENT PACKAGE

The treatment package focuses on two main elements, as laid out in the UNICEF and WHO 2004 joint statement:

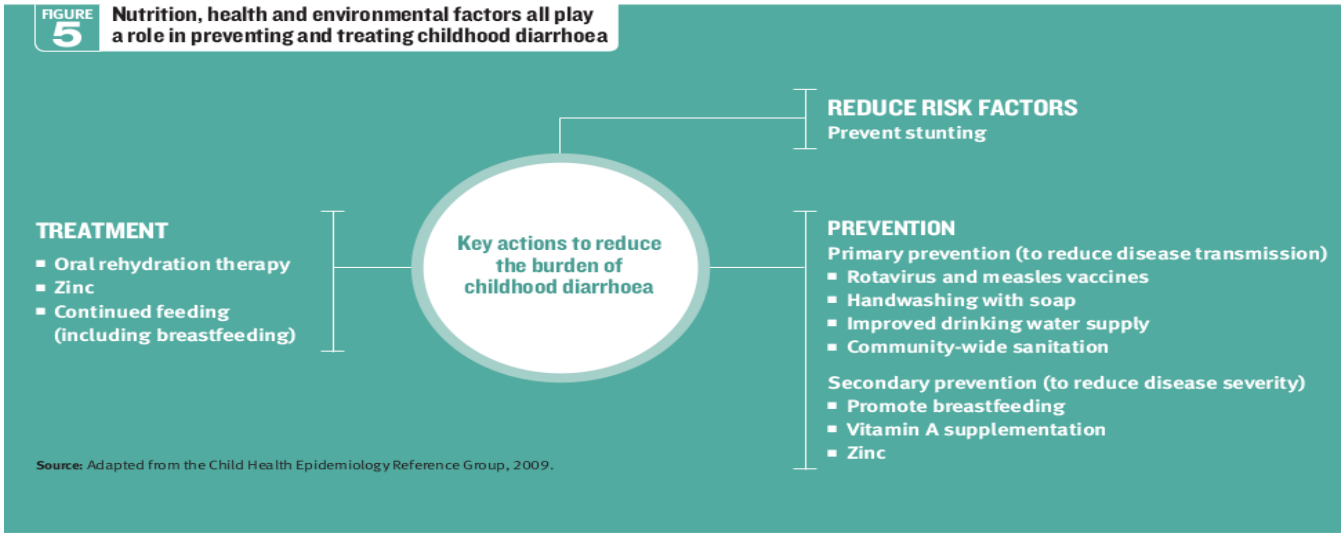
1. Fluid replacement to prevent dehydration
2. Zinc treatment.

This together is known as the Oral Rehydration Therapy.

> Oral rehydration therapy is the cornerstone of fluid replacement. New elements of this approach include low-osmolarity ORS, which are more effective at replacing fluids than the previous ORS formulation, and zinc treatment, which decreases diarrhoea severity and duration. Important additional components of the package are continued feeding, including breastfeeding, during the diarrhoea episode and use of appropriate fluids available in the home if ORS are not available.



Studies have shown that zinc treatment results in a 25 per-cent reduction in duration of acute diarrhea and a 40 percent reduction in treatment failure or death in persistent diarrhea.



PREVENTION PACKAGE

The prevention package focuses on five main elements to reduce diarrhoea in the medium to long term:

- Rotavirus and measles vaccinations
- Promotion of early and exclusive breastfeeding
- vitamin A supplementation
- Promotion of handwashing with soap
- Improved water supply quantity and quality, including treatment and safe storage of household water
- Community-wide sanitation promotion.

New aspects of this approach include rotavirus vaccination, which was recently recommended for global introduction**.** It is important that implementation of the prevention package is approached in a concerted way, since single interventions alone are likely to result in lesser overall impact.

- In acute diarrhoea, zinc supplements have a successful effect on course of acute diarrhoea. zinc supplements reduced stool output and frequency.

- Zinc-supplemented children with persistent diarrhoea had a 24% lower probability of continuing diarrhoea. In children with signs of malnutrition the effect appears greater, reducing the duration of diarrhoea by around a day.

THE BLOOM PROCESS

- **CUSTOMERS**: The customers of the process are the pediatricians of Thane. A survey was done among the pediatricians. The survey was about the treatment prescribed by the doctors to the children suffering from diarrhoea. The questionnaire contained 5 questions which focused on noting what type of treatment is being prescribed by the doctors.

- **MARKETS** : The Markets for zinc medications consist of the following brands in different dosage forms:

1. Z & D
2. ZINCONIA
3. ZN20
4. ZN20
5. ZINCOLIFE
6. ZIORAL
7. ZIFRA

PATIENT: The children suffering from diarrhoea are the patients but the concerns of the mothers during diarrhoea in their children were recorded. We did a focused group discussion among the mothers and noted the different concerns when their child suffers from diarrhoea. The concerns were as follows:

- Stomach ache
- Loss of appetite
- Low energy
- Child cannot communicate about the pain
- Swollen anus which is painful
- Rashes/irritation on the skin
- Dehydration
- The mother has to be always available for the child
- Maintaining the cleanliness

- The child does not take medicines during treatment

CHANNEL MEMBERS: The Channel members of the medicines are the Retailers of Thane. We did a survey among the chemists of Thane to know the available medicines, in which they were asked about the brands which are available with them in the indication of Pediatric diarrhoea. The brands which were present in the area of Thane were:

S.NO	BRAND NAME	FORMULATION	COMPANY NAME
1	Zinconia	Syrup	Zuventus
2	Rinifol	Dry Syrup	Elan Pharma
3	Rinifol-Z	Dry Syrup	Elan Pharma
4	Zincogut	Oral Solution	Centaur
5	Zincolife	Syrup	Mankind
6	Weltone Z	Drops	Delcure Lifesciences Limited

LITERATURE REVIEW

1) Topic- Role of Zinc in childhood diarrhoea management: a case of Nepal

Diarrhea is one of the leading causes of death among children less than five years of age around the world accounting for about two million child deaths annually. One of the recent strategies made to minimize the diarrhea associated mortality in children involves the use of oral zinc in diarrhea management. The inadequacy of dietary zinc uptake is exacerbated by the net loss of zinc during diarrhea. Zinc is enlisted in WHO essential drug list under medicine for diarrhea where it is indicated in acute diarrhea as an adjunct to oral rehydration salts. Zinc is usually well tolerated. It is necessary to explore public health applications, using zinc either as a preventive measure in children or therapeutically for diarrhea.

2) Topic- Zinc supplementation in young children: A review of the literature focusing on diarrhoea prevention and treatment

It is estimated that zinc deficiency is responsible for 4.4% of childhood deaths in Africa, Asia, and Latin America. This review examines the impact of zinc supplementation, administered prophylactically or therapeutically, on diarrhoea. A total of 38 studies were included in this review, 29 studies examined the effect of prophylactic zinc and nine studies examined the effects of therapeutic use of zinc for treatment of diarrhoea in children under five years. The conclusion made was that, Prophylactic zinc has been shown to be effective in decreasing both prevalence and incidence of diarrhoea, reducing respiratory infections and improving growth in children with impaired nutritional status. There is less conclusive evidence of reduction in diarrhoea duration or diarrhoea severity. While prophylactic zinc decreases mortality due to diarrhoea and pneumonia, it has not been shown to affect overall mortality. Therapeutic use of zinc for the treatment of diarrhoea in children has been shown to reduce diarrhoea incidence, stool frequency and diarrhoea duration as well as respiratory infections in zinc deficient children. Specific definitions of diarrhoea severity, respiratory infection in further studies as well as examination of prophylactic zinc effectiveness in diarrhoea duration and severity effectiveness of therapeutic zinc in reducing mortality due to diarrhoea and respiratory infections are warranted.

Objective: - To study the usage practices of Zinc solutions in diarrhoea in kids with pediatricians of Thane Region

Problem Statement: - Zinc is not prescribed by the pediatricians after being in the guidelines of WHO and UNICEF.

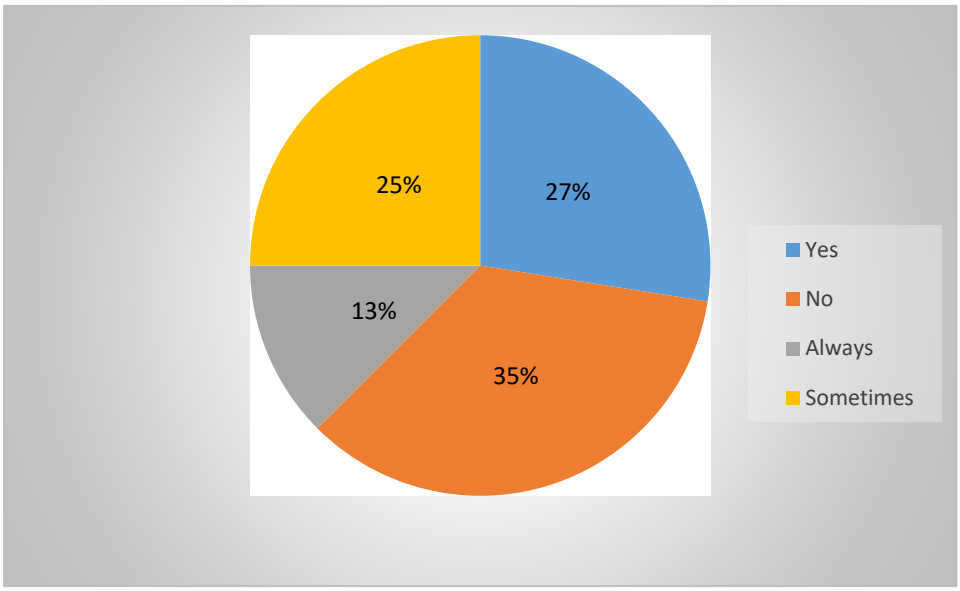
Research Design

- **Study Type:** Descriptive
- **Study Population:** Chemists and Pediatricians
- **Data Type:** Primary and Secondary
- **Duration:** 3 months
- **Sampling Area:** Thane
- **Sampling Tool:** Questionnaire
- **Sample Size:** Pediatricians =40
- **Sampling Technique:** Non Probabilistic Purposive Sampling

FINDINGS & INTERPRETATIONS

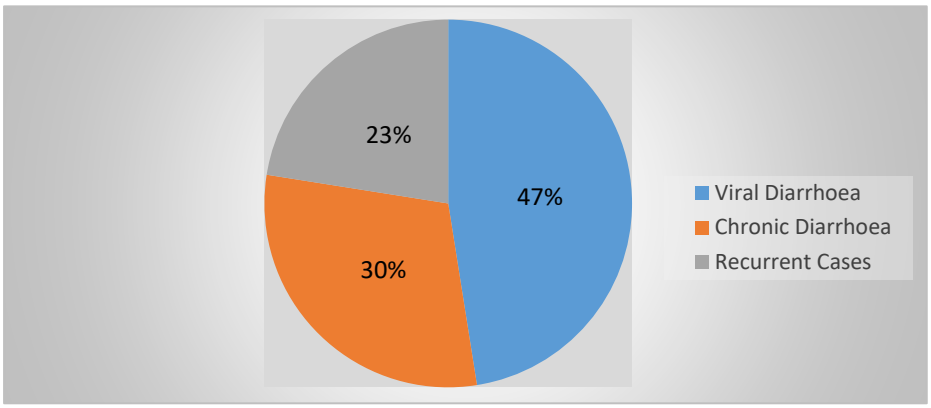
On the basis of the survey done with the pediatricians, the following are the findings of the survey and the interpretations drawn from these findings:-

Q1) What is the treatment you prescribe for a child suffering from diarrhoea?



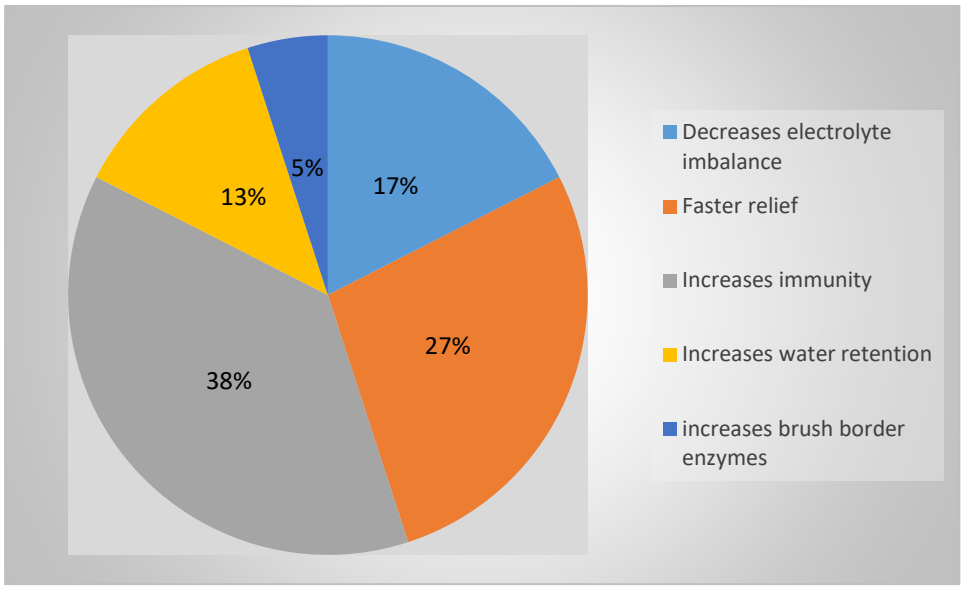
INTERPRETATION: The most common preference of medication among the pediatricians of Thane was of ORS followed by ORS combined with Probiotics. There was not much inclination of the doctors to prescribe zinc for pediatric diarrhoea.

Q2) Have you ever prescribed zinc in your treatment?



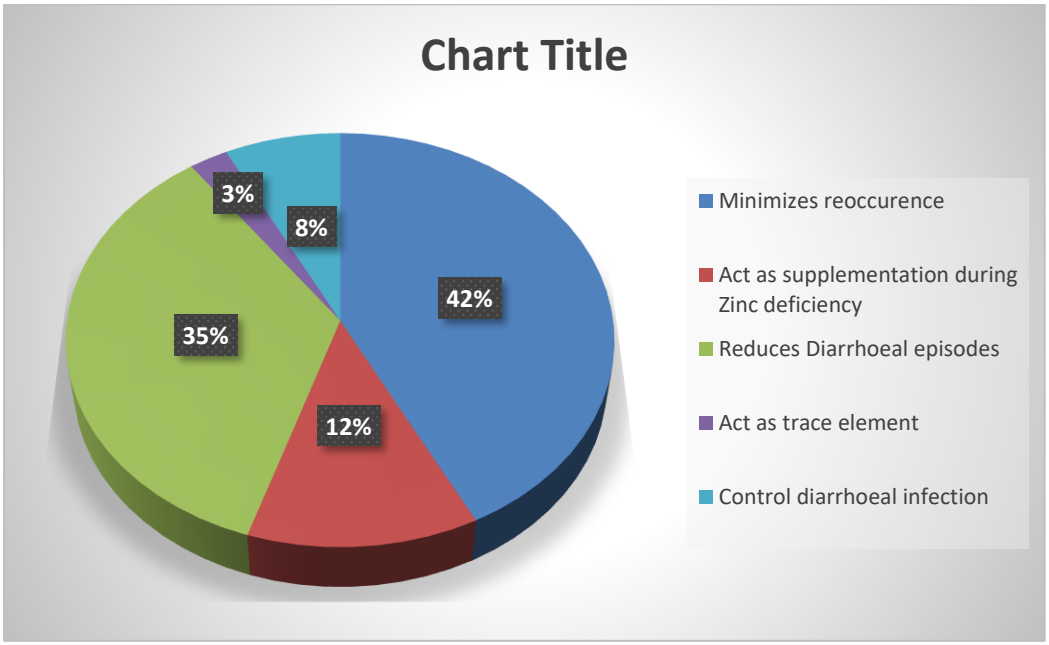
INTERPRETATION: There was a maximum account of the pediatricians not prescribing zinc in the case of pediatric diarrhoea. The percentage of doctors prescribing zinc in diarrhoea was only 27.5%. This graph shows that zinc has not been added in the treatment regime of pediatric diarrhoea by the doctors.

Q3) When do you prescribe zinc?



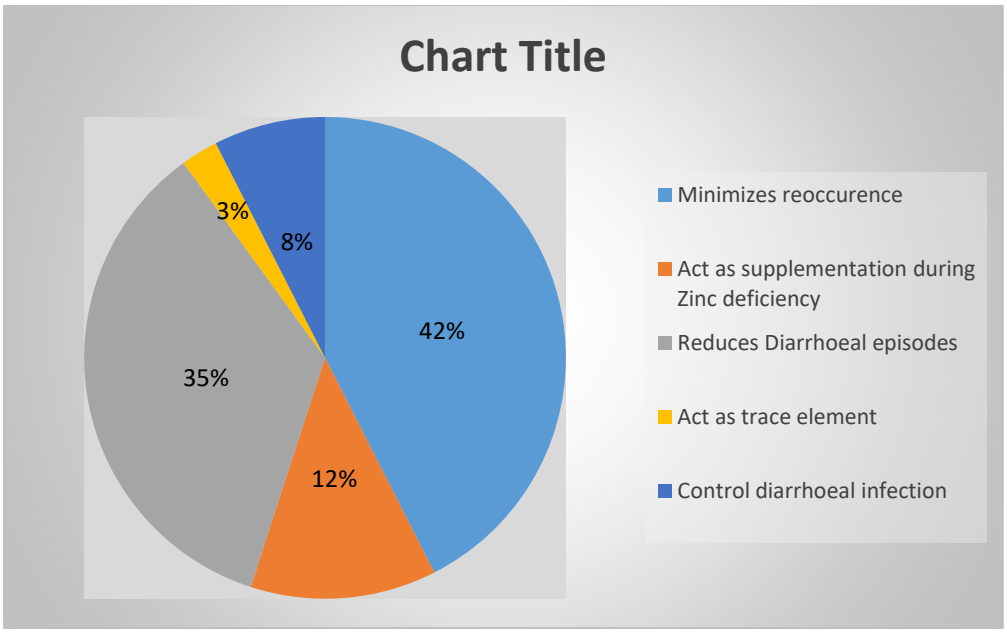
INTERPRETATION: The prescribers of zinc in diarrhoea tend to prescribe zinc in cases of viral diarrhoea in children the most followed by recurrent cases.

Q4) What are the roles/benefits of zinc in diarrhoea?



INTERPRETATION: The benefits of zinc were recorded and it was found that the doctors who prescribe zinc in pedaitric diarrhoea know about the different roles of zinc mainly as an immunity enhancer and for faster relief in diarrhoea among children.

Q5) What clinical outcomes of zinc have you observed in your practice?



INTERPRETATION: The clinical outcomes of zinc in case of pediatric diarrhoea were noted which shows that Zinc has proved to be efficient in controlling diarrhoeal infection and reducing the frequency of diarrhoeal episodes.

DISCUSSION

Key Insights:

- ORS is the first treatment which is prescribed by Pediatricians to its patients during pediatric diarrhoea.
- There is no updation in the treatment of pediatric diarrhoea. The prescription is based on the traditional benefits of ORS for the treatment.
- Knowing the benefits of zinc, only few doctors prescribe Zinc in the treatment of pediatric diarrhoea.
- Zinc has been prescribed by the doctors in case of viral diarrhoea.
- Increased immunity and faster relief are the common benefits which the pediatricians are aware about the Zinc.

CONCLUSION

The conclusions drawn from this study is that, there is a set guideline by the WHO & UNICEF for the treatment of diarrhoea which includes ORS+Zinc, inspite of which there is a lesser knowledge and lesser usage of zinc as a treatment in diarrhoea.

There is a need for awareness of benefits of zinc among the patients as well as the prescribers i.e. the pediatricians. The benefits of zinc and ORS combined together must be presented so that there is acquaintance with the fact that by adding zinc, ORS proves to give a faster recovery.

The traditional use of only ORS as a treatment in diarrhoea has become a barrier in knowing more about the different benefits of zinc for treating diarrhoea thus, less number of prescribers were inclined towards prescribing zinc for pediatric diarrhoea.

RECOMMENDATIONS

- Zinc plays a very important role in Pediatric diarrhoea. ORS gives hydration to the body, but when zinc is given with ORS it provides super hydration to the body, giving a complementary effect. So, the benefits of zinc should be made more clear to the doctors and the patients.
- There should be increased promotion through various campaigns describing the WHO and the UNICEF guidelines to build more understanding of the benefits of zinc among people and doctors.
- Spreading the word will help more and more pediatricians to prescribe zinc in the treatment as well as the patients will get inclined towards using zinc.
- The pediatricians can be made aware about the benefits of the Zinc given in combination with ORS during their CME's. The doctors who prescribe zinc should present the clinical benefits observed to the other pediatricians in meetings and CME's.

APPENDIX

Following was the questionnaire:

1)What is the treatment you prescribe for a child suffering from diarrhoea?

2) Have you ever prescribed zinc in your treatment?

3) When do you prescribe zinc?

4) What are the roles/benefits of zinc in diarrhoea?

5) What clinical outcomes of zinc have you observed in your practice?

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4) Role of Zinc in childhood diarrhea management: a case of Nepal

   Kadir Alam1*, Arjun Poudel2, Subish Palaian3, Bhawesh Koirala1, Pathiyil Ravi

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