

Evaluation of Sugar Based Antidiarrheal Agent Versus Sugar Free Anti Diarrhoeal Preparation in Paediatric Diarrhoea

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Abstract: Lactose intolerance diarrhoea and increasing threat of Organo toxicity due to increasing non dietary constituents in the food and drinks, even contamination of milk poses problems in diarrhoea management in spite of big antidiarrheal armamentarium.

In addition for the sake of convenience even injudicious combination of potent antimicrobials and antiprotozoal being used inspite of FDA warnings .Thus in the context the present study to evaluate the sugar free Norfloxacin and Sugar free Tinidazole suspension administered separately in therapeutic dose proves worth as compared to sugar based norfloxacin and Tinidazole suspension separately or in combination as Sugar free Tinidazole and Sugar free Norfloxacin administered separately every 12 hours achieves remission without any untoward effects ,drug related toxicity ,relapse ,recurrence and post therapeutic sequel even in neonates .

Keywords: Lactose intolerance, Organotoxicity ,FDA,relapse ,untoward effects

1. INTRODUCTION

Diarrhoea remains a major killer inspite of available varied range of antidiarrhoeal agents.In addition lactose intolerance diarrhoea and documented hazards of sugar based oral liquid preparation i.e.-exacerbation of diarrhoeal presentation due to reversed mucosal transport of fluid and electrolytes in the intestine ,poses threat in care of children diarrhoea .

Current study affirms clinical superiority of Tinidaazole – Norfloxacin over existing anti diarrhoeal in vogue though FDA declared either irrational or band.Thus with consideration a comparative clinical evaluation of Norfloxacin and Tinidazole liquid oral preparation in non-sugar base ,administered separately was planned to adjudge the therapeutic efficacy and safety profile .

2. MATERIAL & METHODS

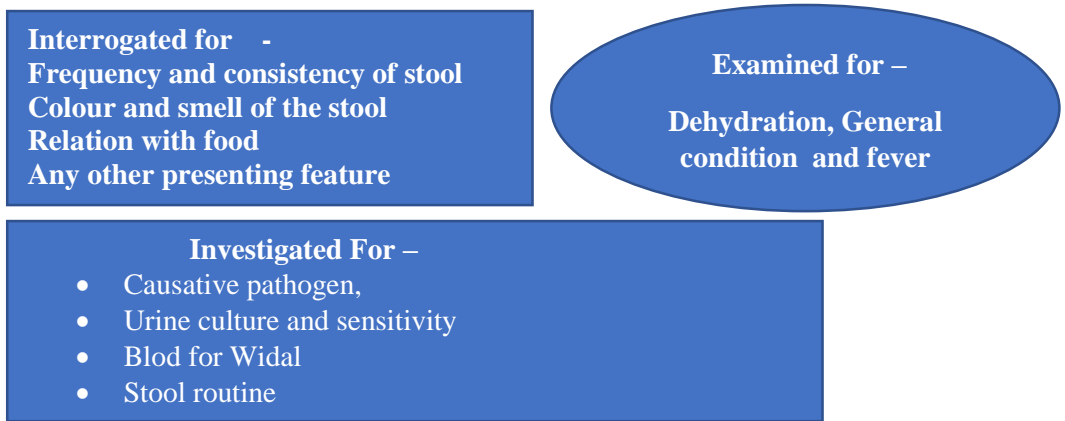
Design of study: parallel group comparative study to determine the therapeutic status of sugar free Tinidazole and Norfloxacin oral liquid preparation administered separately with vigil watch on safety profile and drug compliance.

2.1. Patients

320 patients of diarrhoea presenting at Centre for Diarrhoeal Disease Research of National Institute of Health & Research Warisaliganj (Nawada) Bihar were selected. Patients of fungal diarrhoea and helminthic diarrhoea been excluded from the study

2.2. Methods

Parent of the children under study were thoroughly interrogated for presenting features ,duration and treatment taken ,their clinical response ,examined for clinical status and investigated for pathological status .



Based on clinicopathological status patients were graded as –

Grades of Severity	Characteristics
Mild	Irritable and thirsty
Moderate	irritable, pulse weak, reduced urine volume Depressed fontanelle, shunken eyes dry and pinched face, liips parched, dry buccal mucosa , loss of skin turgor and thirsty
Severe	moribund, apathetic, signs of peripheral circulatory failure (cold and calm extremity decreased urine output) Depressed fontanelle, shunken eyes dry and pinched face, liips parched, dry buccal mucosa, loss of skin turgor and thirsty

For comparative analysis selected patients were classified in to three groups constituting equal number of patients i.e. Group A, Group B and Group C and were advocated the therapeutics as per follows – Each group were administered Norfloxacin and Tinidazole oral preparation in various forms in therapeutic dose.

Group A:	Sugar free Norfloxacin and Tinidazole suspension in separate pack; Dose: 0.5ml /kg both drug every 12 hours
Group B	Sugar based norfloxacin and Tinidazole suspension separately in dose of 0.5ml/kg both drugs every 12 hours
Group C:	Sugar based Norfloxacin and Tinidazole composite in dose of 0.5ml/kg every 12 hours

2.3. Assesment

Clinical efficacy was assessed as per following index of assessment i.e.-

- Frequency and consistency of stool
- Dehydration status
- Duration of therapy
- Time required for clinical improvement

Post therapy status was assessed as per –

Patients were followed up for 4 weeks to asses –

- Any relapse ,recurrence or persistence
- Urinary complaints and confirmation by urine culture and sensitivity
- Persistent pyrexia
- Hepato renal status by evaluating serum bilirubin ,SGOT,SGPT,Akaline phosphatase ,Blood urea,Serumcreatinine and urine albumin .

Based on the clinical response ,therapeutic response was graded as –

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Grades of clinical response	Characteristics
Grade I	Complete resolution of signs and symptom,formed stool,absence of tenesmus decrease in stool frequency ,absence of causative pathogenand drug relatd or post therapy after effects .
Grade II	improvement of signs and symptom without any absence of causative pathogens
Grade III	No response Or persistence of presenting feature and causative pathogens

3. OBSERVATION

Selected patients were of age group neonates to 5 years and among them 183 and 117 were male and female respectively and 31% patients were presenting with lose motion 10 per 12 hours (table -1, Fig 1) Among the selected patients 48% were with mild dehydration ,28% with moderate and 24% were with severe dehydration (Table -2)

Commonest isolated pathogen were Escheresia coli,salmonella ,Shigella and protozoa (Table -3)

Among the selected patients 52% were with associated vomiting though associated presentations like fever, abdominal colic ,abdominal dissension were also present (Table -4)

Table1. Distribution of patients as per age, sex and frequency of motion every 12 hours

Age	Number of patients							
	4-6		7-9		10-12		>12	
Frequency of motion/12hrs	Male	Female	Male	Female	Male	Female	Male	Female
Up to 1 year	24	12	9	6	9	6	6	3
1-2	18	9	12	9	9	6	6	6
2-3	21	9	9	6	6	6	3	3
3-4	15	9	9	6	3	3	3	3
4-5	12	6	3	3	3	3	3	3

Pie diagram showing male female composition

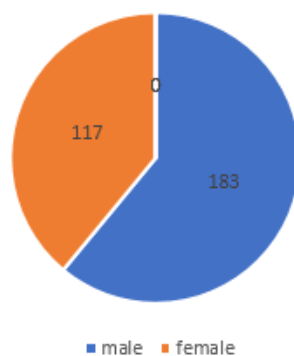


Fig1. Pie diagram showing male female composition

Table2. Shows distribution of patients as per associated clinical presentation

Associated presentations	Number of patients		
	Male	Female	Total
Pain in abdomen	40	27	67
Vomiting	42	28	70
Fever	24	15	39
Vomiting & pain in abdomen	24	14	38
Vomiting & Fever	14	8	22
Vomiting, Fever and pain in abdomen	24	14	38
Pain in abdomen & Fever	15	11	26

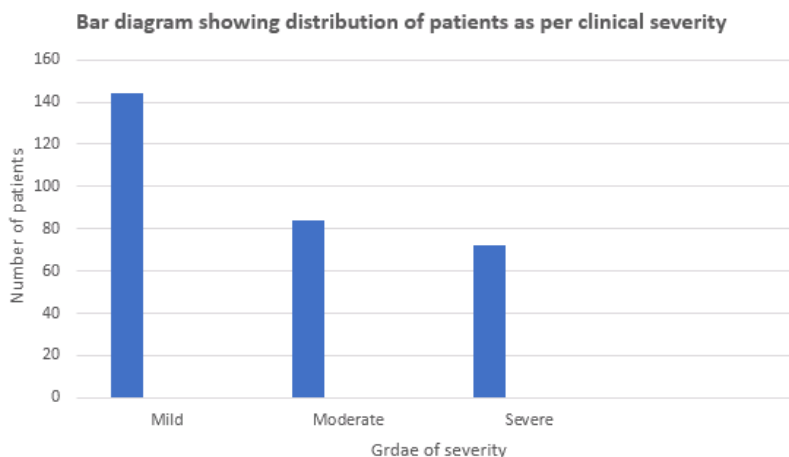


Figure2. Bar diagram showing distribution of patients as per degree of severity

Table3. Distribution of patients as per isolated causative pathogen

Isolated causative pathogen	Number of patients		
	Male	Female	Total
Escherichia coli & Protozoa	21	12	33
Shigella & Protozoa	42	24	66
Salmonella & protozoa	51	30	81
Salmonella	30	21	51
Shigella	21	18	39
Escherichia coli	18	12	30

Table4. Outcome of the study

Particulars Clinical cure:	Group A	Group B	Group C
Grade I	100%	82%	56%
Grade II	-	14%	32%
Grade III	-	4%	12%
Pathological cure :			
Sterile sample	100%	82%	56%
Presence of pathogen	-	18%	44%
Fungal super infection	-	9%	16%
Adjuvant required	None	18%	44%
Dehydration exacerbation	None	18%	42%
Oliguria	None	7%	22%
Therapy related untoward effects:			
Abdominal distension	None	14%	28%
Vomiting	None	10%	30%
Irritability	None	15%	6%
Post therapy sequel			
Urinary tract infection	None	12%	20%
Mucous colitis	None	6%	9%
Diarrhoeal persistence	None	2%	7%

4. RESULTS

All patients on sugar free Tinidazole and Norfloxacin oral liquid administered separately achieved grade I clinical response whether only 82% of group B and 56% of group C respectively.

All patients of group A had absence of causative pathogens without any persistence of infection or super infection

None of group A required any adjuvant therapy or had any exacerbation of dehydration while 18 and 44 of group B and group C respectively required adjuvant therapy whether 18 and 42 of group B and group C respectively had exacerbation of dehydration requiring intravenous supplementation.

07 and 22 of group B and group C respectively had oliguria ,in addition 14 and 28 patients of group B and group C had abdominal distension ,10 and 30 had vomiting ,15 and 16 had irritability, 12 and 20

had UTI ,06 and 09 mucous colitis , 02 and 07 with persistent diarrhoea respectively ,though none of the group A had any such complaints.

5. DISCUSSION

Diarrhoea a most common treatable children killer disease and increasing non dietary constituents in the food stuff possess problems like hyperglycemic syndromedue to declined hepatopancreatic function as a result of organotoxicity .in addition sugar promotes microbial growth, increases hepatic overload and norfloxacin a least absorbing quinolone and Tinidazole a potent antiprotozoal, a known anti diarrhoeal.

Present comparative clinical study of sugar free Tinidazole and Norfloxacin oral liquid administered separately as compared to sugar based norfloxacin and tinidazole either separately or in combination reveals clinical superiority over the sugar based preparation as This achieves complete clinical and pathological cure in minimum duration without any adjuvant ,untoward effects either during therapy or in post therapy period whether only 82% and 56% of group B and group C respectively had grade I clinical response though relapse ,untoward effects and adjuvant is required in the patients of group B and group C . and this marked difference suggest clinical superiority of sugar free oral anti diarrhoeal preparation may be due to varied bio availability of the anti-diarrhoeal composist or increased virulence of the causative pathogen.

In addition, sugar base may cause altered drug concentration acting on the intestinal microbes and marked exacerbation of dehydration, persistence of causative pathogens and super infection, altered antimicrobial absorption, thus induces development of resistant strain resulting in post therapy UTI, mucous colitis, persistence of causative pathogens and exacerbation of presenting symptoms. in addition, altered intestinal pH results in excessive fermentation and gaseous distension of abdomen and reflux nausea.

Hence conclusively to check diarrhoea in children sugar free antidiarrhoel preparation to be used separately in therapeutic dose.

6. CONCLUSION

Sugar free oral liquid preparation of Tinidazole and Norfloxacin in dose of Tinidazole 15mg /Kg and Norfloxacin 10mg /Kg every 12 hours administered separately proves worth in children's diarrhoea management

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Citation: Dr. Avinash Shankar, et.al. (2019). "Evaluation of Sugar Based Antidiarrheal Agent Versus Sugar Free Anti Diarrhoeal Preparation in Paediatric Diarrhoea". *International Journal of Clinical Chemistry and Laboratory Medicine (IJCCLM)*, 5(3), pp.1-5, DOI: <http://dx.doi.org/10.20431/2455-7153.0503001>.

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