

## Sucralfate - Oxetacain Suspension in Management of Persistent Gastroenteritis of Varied Origin

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**Abstract:** Present therapeutics in vogue not only fails to secure cure but persistence of diarrhea even with present therapeutics usually turns fatal or present with sequel like – mucous colitis, UTI, vague abdominal pain and heaviness in the abdomen, But present study affirms the clinical supremacy of sucralfate-oxetacain composite ( SFT-O) as adjuvant with continuing therapeutics in early resolution of presenting sign and symptoms without any drug or disease related sequel with 100% compliance in both children and elders.

### 1. INTRODUCTION

Persistent gastroenteritis of varied origin either in children or adult poses life threaten due to loss of fluid and electrolyte loss non responsive to conventional anti diarrhea agent ,fluid and electrolyte supplementation and other adjuvant drugs due to continued provocation of fluid and electrolyte transport in the gut by the toxin.

Hence a study was planned to evaluate a cyto protective and local anesthetic combination as an adjuvant in gastroenteritis management at RA. Hospital & Research Center, Warisaliganj (Nawada), Bihar, India.

### 2. MATERIAL AND METHOD

#### 2.1. Design of the Study

Comparative clinical study was done to asses the clinical efficacy and safety profile of the cyto protective and local anaesthetic combination as an adjuvant in persistent gastroenteritis non responsive to conventional therapeutics.

#### 2.2. Patients

Patients of gastroenteritis non responsive to conventional therapeutics attending at RA. Hospital & Research Centre, Warisaliganj (Nawada) with following complaints were included in the study while patients with other associated diseases been excluded.

#### 2.3. Method

Parent of the patient or patients were thoroughly interrogated for their presenting complaints i.e.- consistency and frequency of stool, frequency of vomiting, nausea ,passage of urine and its frequency, drugs consumed and assessed clinically thoroughly for type of diarrhea, status of dehydration, renal status and other vital statistics.

Selected patients were thoroughly investigated for serum electrolyte, basic hematological, hepatic and renal status to adjudge the safety profile of the adjuvant drug.

Patient’s stool was examined to ascertain the causative pathogens and urine for super infection.

**2.4. Drug**

Selected patients were categorized in two groups for comparative evaluation and advocated –

Group A : Conventional therapeutics and fluid and electrolyte replacement.

Group B : Conventional therapeutics and fluid electrolyte replacement and Cytoprotective –local anesthetic combination SUCRALFATE-OXETACAINE (SFT-O SUSPENSION)

|  |                            |
|--|----------------------------|
| Dose schedule: Adjuvant trial drug been administered in dose of- |                            |
| Adult  | : 5 ml every 6 hours       |
| Children   | : 2.5 ml every 6 hours     |
| Infant   | : 0.5ml-1ml every 6 hours. |

Fluid replacement is 100ml/kg in schedule of 30% in first 30 minutes, 30% in 1 hour and rest 40% in 2 hours while electrolyte supplementation is done as per serum electrolyte status.

Selected patients were observed for –

- Nausea and frequency of vomiting
- Consistency and frequency of stool
- Abdominal distention ,pain and cramps

Post therapy sequel can be assessed by-

- Constipation
- Mucous colitis
- Persistent pyrexia suggestive of UTI
- Prolapse rectum

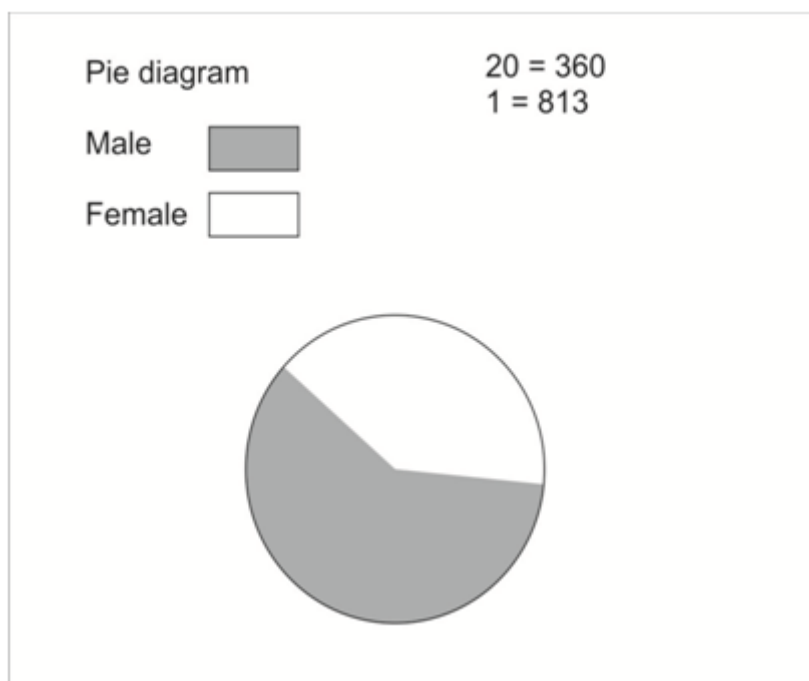
Safety profile is assessed by estimating serum electrolyte, hepatic function hematological status, renal function test and urine culture and sensitivity

**3. OBSERVATION**

Among 1282 selected patients 7% were infants (<1 year),27% were children (<15 years) while 66% were adult out of which 15% were of age >35 years. Sex wise distribution of patient is 11:9 (55% male and 45% female).

**Table1.** *Distribution of patients as per age and sex*

| Age group (in year) | Number of patients |        |       |
|---------------------|--------------------|--------|-------|
|                     | Male               | Female | Total |
| <1                  | 48                 | 38     | 86    |
| 1-5                 | 62                 | 42     | 104   |
| 5-10                | 64                 | 51     | 115   |
| 10-15               | 70                 | 60     | 130   |
| 15-20               | 88                 | 67     | 155   |
| 20-25               | 92                 | 74     | 166   |
| 25-30               | 86                 | 67     | 153   |
| 30-35               | 98                 | 77     | 175   |
| > 35                | 101                | 97     | 198   |
|                     | 709                | 573    | 1282  |



*Pie diagram showing male –female composition*

Majority patients presented with complaints of persistent vomiting and watery loose motion in spite of conventional therapeutics while 436(34%), 532(41%) and 384(30%) presented with abdominal distention, abdominal colic and passage of round worm per oral or per rectal respectively.

**Table2.** *Distribution of patients as per their presenting symptom*

| Presenting complaints                 | Number of patients |
|---------------------------------------|--------------------|
| Persistent watery loose motion        | 1282               |
| Persistent vomiting                   | 1282               |
| Abdominal distention                  | 436                |
| Abdominal colic                       | 532                |
| Passage of round worm per oral/rectum | 384                |

Out of all 48%, 31% and 21% were of dehydration status grade I, grade II and grade III

**Table3.** *Organism isolated on stool examination*

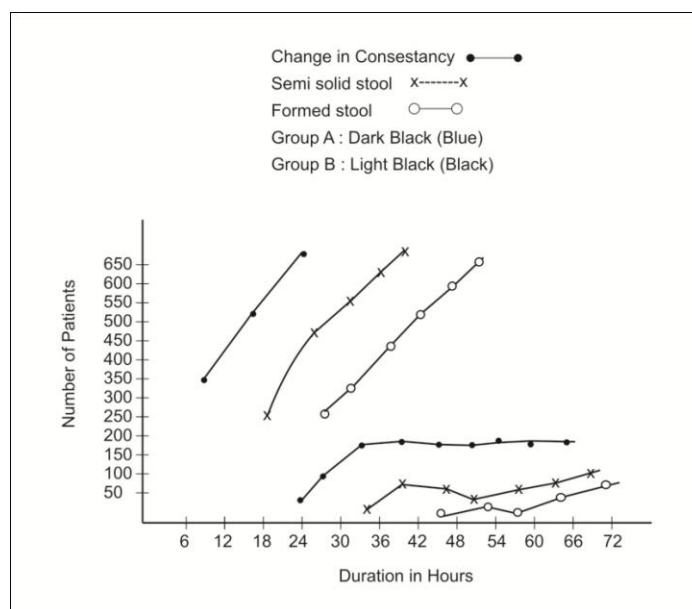
| Organism isolated          | Number of patients |
|----------------------------|--------------------|
| Non specific (No organism) | 632                |
| V. Cholera                 | 336                |
| Salmonella typhi           | 314                |
| Protozoa                   | 704                |
| Helminth ova               | 584                |

49% patient's stool reveals absence of pathogens while 27% and 24% reveals presence of V.Cholerae and Salmonella respectively. In addition 55% and 46% patients revealed presence of associated protozoa and helminthes.

**Table4.** *Distribution of patients as per their dehydration status*

| Dehydration state | Number of patients |
|-------------------|--------------------|
| Grade I           | 612                |
| Grade II          | 398                |
| Grade III         | 272                |

400( 62%) patients of trial group had change in consistency of stool by 12 hours while only 30(5%) patients of control group by 24 hours.200(31%) patients of trial group had formed stool by 30 hours while only 12(2%) of control group had formed stool by 48 hours. All the patients of trial group had formed stool by 72 hours of therapy while only 75(12%) patients had formed stool by 72 hours.



Graph showing change in consistency of stool in two groups

Average time required for decline in frequency of stool in trial and control group is 7-9 hours and 24-48 hours respectively.

No patients of trial group show decline in hydration status while 321 patient of control group had decline in hydration status.

Post therapy stool examination shows absence of causative pathogens in all the trial group patients while only 53% patients of control group, 47% control group shows persistence of causative pathogen and 17% of control group show fungal super infection.

Post therapy culture and sensitivity of urine of patients presenting with pyrexia reveals no growth in trial group cases while 13% of control group shows growth of significant colonies of Escherichia coli.

Post therapy assessment of hepatic function shows serum bilirubin <1mg in 98% and 70% of trial and control group patients while 5% and 20% of trial and control group patient show serum bilirubin >1mg but <2mg, though 10% of control group patients show serum bilirubin > 2mg%.

192(30%) patients of control group show altered hepatic function marked by raised serum bilirubin and other hepatic functions while 62 patients of control group show markedly raised serum bilirubin i.e.->2mg%

As per renal status 04 patients of control group show blood urea >30 mg% and 02 patients of control group present with albuminuria while non of trial group had any alteration in renal function parameter.

67% patients of trial group show improved hemoglobin while 28% patients of control group show decline in basic hemoglobin status.

In addition post therapy complaints like nausea, vomiting, fever, mucous colitis, abdominal pain and heaviness in the abdomen was completely absent among the trial group patient while common in control group patients.

**Table 5.** Outcome of the study

| Particulars                           | Remarks   |             |
|---------------------------------------|-----------|-------------|
|                                       | Group A   | Group B     |
| Time required to decline              |           |             |
| In frequency of stool                 | 7-9 hours | 24-48 hours |
| Hydration status:                     |           |             |
| Decline                               | None      | 321         |
| Maintained                            | 219       | 320         |
| Improved                              | 422       | -           |
| Status of stool after 72 hrs therapy: |           |             |

|                       |      |     |
|-----------------------|------|-----|
| Absence of pathogen   | 641  | 342 |
| Presence of pathogen  | None | 299 |
| Super infection       | None | 112 |
| Status of urine:      |      |     |
| Positive culture      | None | 086 |
| No growth             | 641  | 555 |
| Hepatic status:       |      |     |
| Serum bilirubin :     |      |     |
| < 1mg                 | 609  | 449 |
| <2mg                  | 032  | 130 |
| >2mg                  | None | 062 |
| SGOT:                 |      |     |
| >35 IU                | None | 192 |
| <35 IU                | 641  | 449 |
| Renal status:         |      |     |
| Blood urea:           |      |     |
| <30mg                 | 641  | 004 |
| >30mg                 | None | 637 |
| Serum creatinine:     |      |     |
| <1.5 mg               | 641  | 630 |
| >1.5mg                | None | 011 |
| Albuminuria :         |      |     |
| Absent                | 641  | 630 |
| Present               | None | 011 |
| Hematological status: |      |     |
| Hemoglobin :          |      |     |
| Declined              | None | 178 |
| Improved              | 432  | -   |
| Maintained            | 209  | 463 |

**Table6.** Distribution of patients as per their post therapy presentation

| Particulars              | Number of patients |         |
|--------------------------|--------------------|---------|
|                          | Group A            | Group B |
| Nausea                   | None               | 146     |
| Vomiting                 | None               | 013     |
| Formed stool             | All                | 123     |
| Mucous colitis           | None               | 212     |
| Fever                    | None               | 312     |
| Abdominal pain           | None               | 292     |
| Heaviness in the abdomen | None               | 321     |

#### 4. DISCUSSION

Persistent diarrhea and vomiting are common presentation in rural area in spite of advocacy of conventional therapeutics i.e.- potent antiemetic, antidiarrheal and rehydration ,usually associated with recurrence ,relapse and various post therapy consequent sequelae, but the present study reveals clinical supremacy of adjuvant Cytoprotective-local anaesthetic composite

SUCRALFATE-OXETACAIN combination in gel form can be explained as-

SUCRALFATE ,a potent cyto protective coats the intestinal mucosa and prevent toxin or pathogen action over the intestinal mucosa and fails to alter the fluid and electrolyte transport system ,thus check increase in intestinal load ,hyper peristalsis and finally diarrhea frequency.

OXETACAINE (also known as oxethazaine), a potent local anesthetic produces local anesthesia ceases intestinal mucosal nerve endings and check tenesmus and abdominal colic.

Sucralfate also increases prostaglandin synthesis thus promote fluid and electrolyte transport from the intestine.

Cytoprotection of intestinal mucous membrane due to formation of a complex with mucosalprotein abstain the causative pathogen to invade the mucous membrane which check post therapy mucous colitis and urinary tract infection, in addition also restrict super infection.

Due to coating of intestinal mucous membrane and inability to invade the mucous membrane the causative pathogen is exposed maximally to administered potent antibacterial and anti protozoal drug and virtually eliminate the causative pathogens.

Cytoprotective effect of the SUCRALFATE ensures natural healing to the underlying mucous membrane which restrict persistence of mucosal erosion.

### REFERENCE

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