Comparative Evaluation of Sugar based versus sugar free Oral liquid preparation in Medicare

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Abstract: Oral liquid therapeutic is the most compliable form of therapeutics and a need for neonates to geriatrics where palatability is prime index but sugar based preparation poses threat like drug resistance, decline in self defence and predisposes for erythrocyte toxicity due to persisting infection as compared to oral liquid preparation free of sugar which promote early onset of relief of presentation without any evident alteration in therapeutic absorption.

Thus, to check recurrence, relapse, drug resistance and potentiate therapeutic efficacy without any alteration in self defence. Oral liquid preparation free of sugar is preferred either as therapeutics or adjuvant.

Keywords: Compliable, palatability, drug resistance, self-defence, absorption alteration, absorption, recurrence, relapse, drug resistance, adjuvant)

1. INTRODUCTION

Increasing non dietary products in the food, water and even in soil due to increasing trends of chemicals, fertilizers, pesticides and hormones for maximum yield, thus essential mineralo vitamin and trace elements gets depleted and concentration of competitive inhibitors of the vitamin minerals get increased and results in altered metabolic process either due to potent toxicity of liver,pancreas and reticulo endothelial system.

Clinical evaluation of patients suffering with various recurring manifestation of varied origin reveals increasing trend of hyperglycaemia and glycosuria.

In addition random observation of failure of sugar based oral therapeutics to achieve clinical efficacy at par with sugar free oral preparation, rather sugar based preparation predispose for disease chronicity.

Considering the fact, a study was planned to evaluate the clinical efficacy of sugar free oral liquid preparation versus sugar based in day to day Medicare

2. MATERIALS AND METHODS

Design of the Study
Parallel group comparative evaluation

Objective of the Study
Evaluation of therapeutic significance of Sugar free therapeutics over sugar based preparation and their safety profile in various common clinical conditions
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Material

1000 patients of varied clinical presentation attending various clinics of National Institute of Health & Research having preference for oral liquid preparation were selected for the study.

Exclusion criteria: Patient suffering with Diabetes mellitus are excluded.

Methods

Selected patients or their parent or attendant were thoroughly interrogated, clinically examined and investigated to establish the diagnosis and pre therapy and post therapy bio parameters are assessed to adjudge the safety profile.

For comparative clinical evaluation of oral liquid therapeutics in sugar base versus sugar free base, selected patients were classified in three equal group constituting 333 patients in each Group A and B while 334 in group C.

Each group patients were advocated:

Group A (333) : Sugar free therapeutics or adjuvant
Group B (333) : Sugar based therapeutics Or adjuvant
Group C (334) : Sugar free oral liquid

Patients were assessed as per following index of assessment –

Duration to achieve clinical improvement and clinicopathological outcome
Status of Clinical presentations
Adjuvant required
Hospital stay /duration of treatment to achieve cure
Post withdrawal status
Growth and development
Onset of milestone

Assessment of safety profile:
To assess or adjudge safety profile following bio parameters are considered
Hepatic: SGOT; SGPT, Serum bilirubin, urobilinogen
Renal: urine albumin, blood urea, serum creatinine, urine culture
Haematological: Haemoglobin
Immunological: Recurring or persisting infection (Blood culture /Urine culture)

3. Observation

Selected patients were of age group neonate to 55 years and are 630 male and 370 female, though 20% cases were of age below 5 years and 6.4% were of age >50 years.

Table Showing distribution of patients as per age and sex

| Age group in year | Male | Female | Total |
|------------------|------|--------|-------|
| <1 – 5           | 22   | 12     | 34    |
| 5-10             | 36   | 26     | 62    |
| 10-15            | 34   | 25     | 59    |
| 15-20            | 42   | 24     | 66    |
| 20-25            | 70   | 38     | 108   |
| 25-30            | 80   | 56     | 136   |
| 30-35            | 76   | 40     | 116   |
| 36-40            | 70   | 35     | 105   |
| 40-45            | 90   | 46     | 136   |
| 45-50            | 70   | 36     | 106   |
| 50-55            | 40   | 32     | 72    |
Predominant presenting feature was diarrhoea, Pregnancy, general debility, hypertension, arthritis, urinary tract infection, bone injury and post tube ligation syndrome were also common.

Table Showing distribution of patients as per clinical presentation:

| Clinical condition       | Number of patients |
|--------------------------|--------------------|
| Diarrhoea                | 200                |
| Pregnancy                | 120                |
| General debility         | 100                |
| Hypertension             | 90                 |
| Joint pain               | 70                 |
| Urinary tract infection  | 77                 |
| Recurrent Pruritis       | 90                 |
| Respiratory disease      | 110                |
| Surgical wounds          | 48                 |
| Bone injury              | 42                 |
| Post ligation syndrome   | 53                 |

Group A (Sugar free therapeutics) and Group B (Sugar based therapeutics) constitute 333 patients in each, while Group C (sugar free non therapeutics) 334 patients of varied clinical presentation.

4. RESULT

In Diarrhoeal Disease Management

All cases taking sugar free anti diarrhoeal had marked improvement in the mean duration of 4 hours whether patient taking sugar based anti diarrhoeal only 40% had clinical improvement in mean duration of 10 hrs but no significant effect was observed in control group.

No untoward effects was observed in patients of group A but 60% patients of group B having initial clinical response, 20% of them had marked exacerbation and needed adjuvant therapy. In post therapy state 40% presented with mucous colitis, 20% with UTI and 40% with abdominal distension whether none of group C had neither exacerbation nor abdominal discomfort.
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| Particulars                  | Group A | Group B | Group C |
|-----------------------------|---------|---------|---------|
| Decline in frequency of stool | All     |         |         |
| Duration required           | 4 Hrs   |         |         |
| Exacerbation of presentation | None    |         |         |
| Initial relief with exacerbation | None   |         |         |
| Mucous colitis              | None    |         |         |
| Urinary tract infection     | None    |         |         |
| Abdominal discomfort        | None    |         |         |

Pregnant mothers taking sugar free vitamin mineral supplement delivered healthy baby through normal parturition and without any congenital defect whether of group B only 50% mother had normal parturition ,20% delivered with Low body weight ,10% over weight baby and delivered through lower section caesarian section due to Cephalo pelvic disproportion . In addition neonate developed neonatal pneumonitis with Respiratory Distress Syndrom (RDS) and lost their life . 10 mothers presented with jaundice during 2nd trimester and 7 neonates presented with neonatal jaundice (though no evidence of Rh incompatibility).

| Particulars                  | Group A | Group B | Group C |
|-----------------------------|---------|---------|---------|
| Normal labour               | None    | 50%     | None    |
| Premature water discharge   | None    | 10%     | None    |
| Low birth weight baby       | None    | 20%     | None    |
| Over weight baby            | None    | 10%     | None    |
| Neonatal jaundice           | None    | 07%     | None    |
| Pneumonitis with Respiratory distress syndrome | None | 06% | None |
| Maternal jaundice           | None    | 07%     | None    |

In General Debility (Chronic Fatigue Syndrome)

All patients of general debility taking sugar free vitamin mineral had marked improvement with mean weight gain of 4±0.5 kg in 1 month whether patients taking sugar based preparation (group B) had mean weight gain of 1.5±0.75 kg and control group patient had weight gain of 1±0.25 kg weight gain. No patients of group A had any untoward effect, exacerbation of presentation but 40% cases of group B had exacerbation of presentation and non responsive to continuing therapy whether non of control group had any exacerbation

| Particulars                  | Group A | Group B | Group C |
|-----------------------------|---------|---------|---------|
| Marked improvement in Presentation | All     | 67%     | Non significant |
| Weight gain                 | 3 Kg    | 1.5 Kg  | 1 Kg    |
| Exacerbation of presentation | None    | 40%     | None    |

In Hypertension

Among patients of hypertension patient taking sugar free vitamin mineral adjuvant (group A) had marked improvement and sustained anti hypertensive effect with sustained normotensive state ,but patients of group B had circadian variation of blood pressure and ultimately non responsive to continuing anti hypertensive therapy in 32% in spite of administration at schedule time. Whether no patients of hypertension of control group had non response to continuing anti hypertensive therapy.

| Particulars                  | Group A | Group B | Group C |
|-----------------------------|---------|---------|---------|
| Circadian variation of blood pressure | None    | 42%     | None    |
| Emergence of non response   | None    | 37&     | None    |

In Joint Pain

All patients of group A had progressive relief of clinical presentation without any emergence of drug resistance while group of B only 80% had clinical improvement followed with non response in 48% while no significant effect was observed in patients of control group.
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| Particulars                        | Group A | Group B | Group C |
|-----------------------------------|---------|---------|---------|
| **Progressive relief**            | All     | 84%     | 92%     |
| **Non responsiveness to continuing therapy** | None | 48% | None |

#### In Urinary Tract Infection

All cases of group A had clinicopathological cure without any untoward effect whether group B – 60% show initial improvement followed with relapse in 50% cases and drug resistance to continuing drug in 40% cases while non of control group (group C) had any relapse or emergence of drug resistance.

| Particulars                        | Group A | Group B | Group C |
|-----------------------------------|---------|---------|---------|
| **Progressive improvement**       | All     | 60%     | 93%     |
| **Relapse**                       | None    | 50%     | None    |
| **Emergence of drug resistance**  | None    | 40%     | None    |

#### In Recurrent pruritis

All cases of group A had marked and significant clinicopathological cure without any untoward effect or adjuvant while group B though all had initial response but 47% patients presented with recurrence within a week while no relapse or drug resistance was noted in any case of control group.

| Particulars                        | Group A | Group B | Group C |
|-----------------------------------|---------|---------|---------|
| **Progressive relief**            | All     | 56%     | 60%     |
| **Progressive relief**            | None    | 47%     | None    |

#### In Respiratory Disease

All of group A had earliest relief of clinical presentation without any emergence of drug resistance or adversity while in group B out of 20 cases of pulmonary tuberculosis taking AKT and sugar based supplement, 7 had marked hepatotoxicity,5 developed drug resistance to continuing AKT due to emergence of mutant strain ,but no such effect was observed in any case of control group . Patients of group A and C had marked weight gain and early sputum conversion.

| Particulars                        | Group A | Group B | Group C |
|-----------------------------------|---------|---------|---------|
| **Progressive sputum conversion** | All     | 59%     | 64%     |
| **Drug resistance**               | None    | 20%     | None    |
| **Hepatotoxicity**                | None    | 35%     | 20%     |
| **Weight gain**                   | Progressive | None | None |
| **Mean duration for sputum conversion** | 17 days | 39 days | 31 days |

#### In Surgical wound

All cases of group A show progressive wound healing without any super infection, but 10 cases of group B though had initial regression and healing but had super infection and persistence of wound, control group shows no drug resistance or super infection.

| Particulars                        | Group A | Group B | Group C |
|-----------------------------------|---------|---------|---------|
| **Super infection**               | None    | 10      | None    |
| **Drug resistance**               | None    | 10      | None    |

#### In Bone Injury

99% of group A had progressive bone healing and union with 1% failure due to mal reduction of the closed fracture without any suppuration or deformity, , whether group B only 43% had perfect bone union ,10% had suppuration and 2% needed amputation due to gangrene and septicaemia ,though none of control group had nay amputation or delayed healing .

| Particulars                        | Group A | Group B | Group C |
|-----------------------------------|---------|---------|---------|
| **Progressive bone healing**      | 99%     | 73%     | 82%     |
| **Suppuration**                   | None    | 10%     | None    |
| **Septicemia**                    | None    | 07%     | None    |
| **Delayed healing**               | None    | 20%     | 40%     |
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In Post Ligation Syndrome

Group A patients of Post ligation syndrome presenting with various clinical manifestation but of group B 40% shows exacerbation of presenting manifestation while control group patient shows no such effect.

| Particulars          | Group A | Group B | Group C |
|----------------------|---------|---------|---------|
| Exacerbation of presentation | None    | 40%     | None    |
| Weight gain          | None    | 80%     | 20%     |
| Hypertension         | None    | 56%     | 20%     |
| Exertional dysnoea   | relieved| increased| Non significant |

5. CONCLUSION

Clinicopathological response in patients of varied clinical condition taking sugar free oral liquid therapeutics was more pronounced than patients taking sugar based oral liquid therapeutics or supplement.

Emergence of resistance to continuing therapeutics was common in patients taking sugar based oral liquid therapeutics or adjuvant.

Persistence or relapse and recurrence of the presenting feature was common to patients taking sugar-based formulation but uncommon among patients taking sugar free adjuvant or therapeutics.

Fungal super infection was more common with sugar based oral liquid therapeutics or adjuvant.

6. DISCUSSION

For patient’s compliance liquid oral therapeutics in palatable base is a need for neonates to geriatrics specially in children and female patients. In addition, declining self-defence and increasing organ toxicity due to presence of non nutrient toxic dietary constituents poses threat to normal human physiology resulting in various dreadest illness.

Present study affirm that Non sugar based oral liquid preparation proves better than sugar based oral liquid preparation in achieving clinical cure, duration of therapy and checking relapse, recurrence, resistance, super infection and emergence of drug resistance as control group also reveals absence of these untoward effects.

Thus, can be concluded that sugar part of the liquid oral preparation interferes with intestinal pH, alters absorption of the therapeutics and interferes with minimum inhibitory concentration (MIC) required, thus create drug resistance. Continuing Or persistent infection deprive immune modulators activity thus decline the self-defence.

Thus, at the cost of palatability patient’s self-defence cannot be compromised and this study requires an extensive exploration in the present context of changing dietary structure.

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