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Research Article

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

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.

Material and Method

- **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.
- **Material**: 1000 patients of varied clinical presentation attending various clinics of National Institute of Health and 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 mile stone

Assessment of safety profile

To asses 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)

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)	Number of patients		
	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

Table 1

Figure 1

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 (Table 2).

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 (Figure 2).

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

Table 2

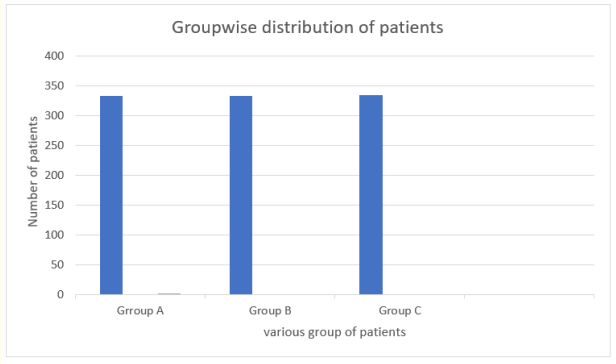

Figure 2

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.

Particulars	Group A	Group B	Group C
Decline in frequency of stool	All	40%	None
Duration required	4 Hrs	10 Hrs	>12Hrs
Exacerbation of presentation	none	20%	none
Initial relief with exacerbation	None	60%	none
Mucous colitis	none	40%	None
Urinary tract infection	None	20%	None
Abdominal discomfort	None	40%	None

Table 3

In Pregnancy

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 caeserian 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	All	50%	All
Premature water discharge	None	10%	None
Low birth weight baby	None	20%	None
Overweight baby	None	10%	None
Neonatal jaundice	None	07%	None
Pneumonitis with Respiratory distress syndrome	None	06%	None
Maternal jaundice	None	07%	None

Table 4

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

Table 5

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

Table 6

In joint pain

All patients of group A had progressive relief of clinical presentation without any emergence of drug resistance while of group B only 80% had clinical improvement followed with non response in 48% while no significant effect was observed in patients of control group.

Particulars	Group A	Group B	Group C
Progressive relief	All	84%	92%
Non responsiveness to continuing therapy	None	48%	None

Table 7

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

Table 8

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%
Relapse	None	47%	None

Table 9

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

Table 10

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

Table 11

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%

Table 12

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 dyspnoea	relieved	increased	Non significant

Table 13

Discussion

For patients 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 can not be compromised and this study requires an extensive exploration in the present context of changing dietary structure.

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.

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Volume 3 Issue 8 August 2019