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Acceptability of Two Oral Unani Dosage Forms in Pediatric Patients

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ABSTRACT

Objective: Unani compound formulations in various dosage forms are frequently prescribed to pediatric population for treatment and management of various diseases. The information about the acceptability of these formulations in pediatric population remains scarce even though this multi-faceted concept is a major factor to determine patient compliance and the limited understanding hinders the development of acceptable, age-appropriate medicines. Present study was designed to record the acceptability of oral Unani dosage forms in pediatric patients treated in an Unani hospital in J&K India.
Methods: An observational cross-sectional study was carried out in patients aged 3 years to 10 years attending taking Jawarish (semi-solid) and Sharbat (Syrup) two Oral Unani formulations. VAS Acceptability Score Test tool was used to record the acceptability scores and parental preferences.
Results: 387 patients were recruited out of which only 157 completed the study. Out of 157 evaluations 47.77 % were for Jawarish (semi-solid) and 52.22 evaluations were for Sharbat (Syrup). Irrespective of therapeutic use and age, the Sharbat (Syrup) weas 'positively accepted' in both age groups and genders. Parental preference was also significantly higher for Sharbat (Syrup) as compared to Jawarish (semi-solid).
Conclusion: We conclude that Sharbat (Syrup) is an acceptable dose form in Unani System of medicine, Development of novel dosage forms which are acceptable and preferred in pediatric patients for formulations like Jawarish will increase the therapeutic options to treat pediatric patients

Key Words: Pediatric; Dosage form; Unani; Jawarish; Sharbat.

INTRODUCTION

Traditional systems of medicine including Unani System of Medicine have been known for centuries and have been employed for treatment of diseases according to their principles of treatment. All these systems of medicine used herbs as a major source of drugs besides animal products or minerals. [1] These herbal medicines are used either singularly or in combination with other herbs to achieve the therapeutic effects both in adult as well as pediatric population. Although, there are compound dosage forms in Unani pharmacopoeia that are exclusively used in pediatric patients, but majority of drugs prescribed to pediatric patients and adults are same even if reduced dosages are used in the former group.

There is a need to understand the acceptability of different dosage forms in the pediatric patients in order to address the issue of lack of age appropriate medicines for children.[2] Even though Ayush systems of medicine including Unani are gaining global popularity and acceptance there is still lot of scope to develop dosage forms that are acceptable in the pediatric patients.

The development of acceptable, age-appropriate medicines is limited by the absence of sufficient evidence needed to make an informed decision on acceptability and preference of age appropriate dosage forms.[3] Most of the acceptability studies published are conducted on conventional system of medicine and there are no records on acceptability of Unani dosage forms in pediatric population.

World Health Organization has also emphasized the importance of methodological research to access the acceptability of dosage forms. Economic and cultural context of the children and ease of administration in both hospital and home care setting are to be considered in the development of appropriate formulations for children. [4] Present observational study was conducted in a hospital in J&K, India to investigate the acceptability of oral Unani dosage forms in the local pediatric population.

METHODS

Study design:

This prospective, cross-sectional, observational study was carried out in the outpatient department of a Government Unani Medical College, Ganderbal. J&K, India. The participants observed in the study were pediatric patients aged 3-10 years.

***Participants and recruitment*:**

Inclusion criteria required that patients were more than 3 years and less than 10 years old receiving any of the two dosage forms Jawarish (Semi solid) or Sharbat (Syrup) from the pharmacy of the hospital. Patients were excluded if they were below 3 years of age and above 10 years of age, were suffering from injuries or inflammations of the oral cavity or throat; suffering from dysphagia, were prescribed dosage forms other than Jawarish (Semi solid) or Sharbat (Syrup) and missed dose for two consecutive days. No randomization was carried out for recruitment of participants. Verbal consent was obtained from the parent/legal guardian, and from the patient wherever possible.

***Intervention and Collection of Data*:**

The Parents of the child were asked to administer oral Unani formulations Jawarish (Semi solid) or Sharbat (Syrup) in conformity with the prescription issued to the child by the treating physician in the same way as they would be administering any other prescribed medicine, however, the gap of administration between other drugs and study formulation should be at least 30 minutes. There should be no physical or physiological pressure. Mixing of dosage form with water/drinks/food/sweetener was forbidden.

Acceptability after each administration was analyzed using a (1) visual analogue scale (VAS) score for child acceptability as observed by parents on a scale of 0–10 cm VAS scale; from 0 very unpleasant/bothersome etc., to 10 not at all unpleasant/bothersome etc. and (2) intake outcome according to the parent's observation that included full dose swallowed, parts of the dose swallowed, dose not swallowed at all. The observations were recorded for three consecutive days on the VAS scale/format provided to the patient and in case of a forgotten dose the result of the intake was considered "missing values". In the event of the dose not being administered due to some other reason the absent VAS scores were set at '0' and the absent results of the intake at 'not swallowed' (Figure 1).

The end points of the study included the most preferred Unani formulation of the child according to the parents' observation and the single most preferred formulation of the parents for the child.

Data analysis:

The data was entered in a Microsoft Excel spreadsheet and analyzed using SPSS 23 version. Categorical variables were expressed as frequencies and percentages. VAS scale was expressed in the form of Mean±S.D. Pearson's Chi square

test/Fischer exact test was used to determine association between categorical variables. Independent sample T test used was used to determine the association between continuous and categorical variable. P value <0.05 was considered statistically significant.

Ethical clearance: the study was approved by the institutional ethical committee.

RESULTS

Between July 2021 to June 2022, 387 children/parents/caregivers who were eligible for inclusion in the study were verbally approached for participation in the study. Out of 387 children 71 children/parents/caregivers refused for participation in the study. Out of the remaining 316 children 62 were excluded as none of the study drug was prescribed to them by the treating physician. 21 children were excluded due to other exclusion criteria. Verbal consent/assent was obtained from the remaining 233 children/ parents/caregivers who were recruited for the present study. Out of included 233 children 112 (48.06 %) were male and 121(51.93 %) were female. After inclusion in the study 29 children (13 male and 16 female) had to be excluded for reasons that, they did not appear in the hospital after the study period, 18 children (7 male and 11 female) missed dose for two consecutive days and 17 children (7 male and 10 female) changed over to conventional system of medicine. A total 169 children completed the study and out of these 169 12 children (5 male 7 female) returned the inappropriately filled VAS format (Figure 2). Age wise distribution of participants is given in Figure3 and Figure 4.

Figure 1 Visual Analogue score (VAS) for reporting the acceptability of formulation by the child.

Figure 2 Participant flow through the study

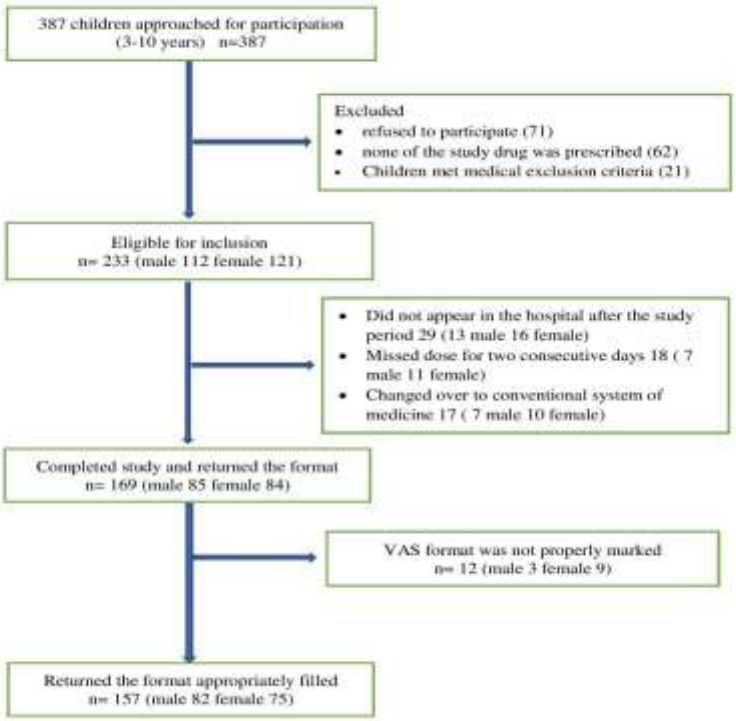


Table 1 depicts the sociodemographic characteristics of study participants. Age and gender wise evaluation of oral formulations is depicted in figure 2 and 3 respectively. Among 157 evaluations 75 (47.77 %) were Jawarish (Semi-solid) and 82 (52.22 %) were sharbat (Syrup). In the age group 3-6 years Jawarish (Semi-solid) represented 56% (n=42) (Male 18 Female 24) while in age group 7-10 years Jawarish (Semi-solid) represented 44% (n= 33) (Male 21 female 12). In the age group 3-6 years Sharbat (Syrup) represented 45.12 % (n=37) (Male 17 Female 20) while in age group 7-10 years Sharbat (Syrup) represented 54.87 % (n= 45) (Male 24 female 21).

Figure 3: Age wise evaluation of formulations

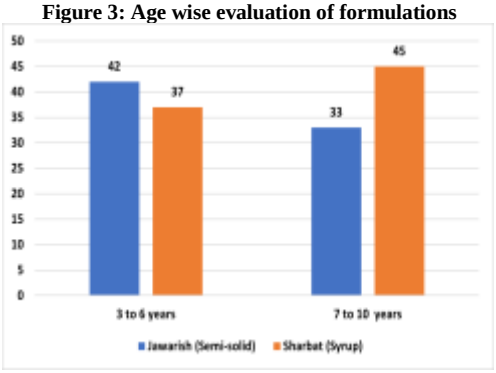
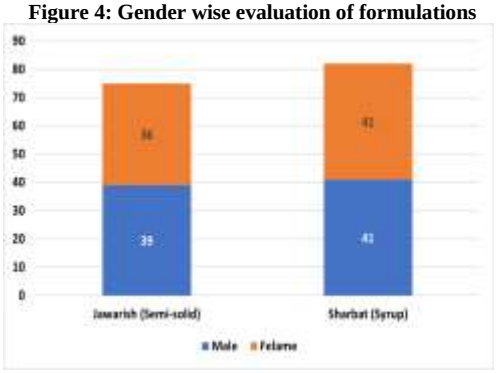


Figure 4: Gender wise evaluation of formulations



03 distinct Jawarish (Semi solid) formulations and 05 sharbat (Syrup) formulations were assessed. Each formulation was a polyherbal composition containing multiple herbs. Most were anti-spasmodic/carminatives (32%) and cough suppressants (37%). The remaining evaluations included anti pyretics, anti-emetics, anti- diarrheal and expectorants.

The mean (SD) of VAS score for semi solid and syrup formulations were 3.1(0.9) and 8.9 (2.5) with a significant p value ($p<0.001$) (Table 2). Acceptance for syrup formulations was significantly higher as compared to semi solid ones. While analysing results according to the parent's observation, we found a significant association between full dose swallowed and syrup type of formulation with a significant p value (Table 3). Age was found be significantly associated with syrup form of formulation with a p value of <0.05 (Table 4)

Table 1: Sociodemographic characteristics of study participants.

Variable	Frequency (n= 157)	Percentage (%)
Age (years)		
3- 6	79	50.3
7-10	78	49.7
Gender		
Male	80	50.9
Female	77	49.1
Residence		
Urban	52	33.1
Rural	105	66.9
Education of father		
Illiterate	22	14.0
Primary school certified	25	15.9
Middle school certified	42	26.7
High school and above	68	43.4

Table 2: Association between type of formulations and VAS scale.

Type of formulation	VAS scale	
	Mean ± S. D	*P value
Jawarish (Semi solid)	3.1±0.9	<0.05
Sharbat (Syrup)	8.9± 2.5	

*Independent sample t test

Table 3: Acceptance according to parent's observation.

Parental observation	VAS score		*P value
	Jawarish (Semi solid)	Sharbat (Syrup)	
Full dose swallowed	4.4±1.8	8.7 ± 2.1	<0.05
Parts of dose swallowed	3.1±1.1	7.9 ± 1.9	
Does not swallow	1.9±0.4	6.4±2.7	

*Independent sample t test

Table 4: Association between Type of formulation used and baseline characteristics of study participants.

	Type of formulation used		
Variable	Semi solid	Syrup	*P value
Age (years)			
3-6 years	42	37	<0.05
7-10 years	33	45	
Gender			
Male	39	41	0.06
Female	36	41	

Chi square test

DISCUSSION

Acceptability of Unani system of medicine has increased over the last few decades. Significant number of pediatric patients are turning to this traditional system for treatment of various ailments. Jawarish a semi solid dosage form is used in Unani system of medicine for the management of functional disorders of GIT including dyspepsia, flatulence and indigestion both in adults as well as pediatric populations.[5] Similarly, Sharbats are syrups used for multitude of disorders ranging and from upper respiratory infections, urinary infections, diseases of GIT, and as anti pyretics.[6] Acceptability of oral medicine in children has been studied for many years. [7,8,9] None of the studies has however, till date studied acceptability of Unani dosage forms as such.

Comparing tablet, a solid drug dosage form with syrup formulations in 155 children from 0-5 years of age for the treatment of malaria, a study concluded that adherence to tablet formulation was better and resulted in reduction in wrong dosages. [10] Similarly comparing uncoated placebo tablets with a sweet syrup in 60 patients aged 6 months to 6 years a study concluded that acceptability of tablet was at least as good as that of the syrup. Although both the studies have compared solid drug dosage to liquid form and there which is a contrast to our study where we are comparing a semi solid drug with a liquid syrup. Beside there is key contrast in the study age group. We tried to search the data base for studies comparing acceptability semi solid dosage forms with liquid syrups but could not find any and all the studies conducted have compared dosage forms like powder, mini tablets, tablets, lozenges, wafers, suspension, solutions and syrups etc. [11,12]

This study is also first cross sectional study for evaluation of child and parent acceptability of two most frequently used dosage forms of Unani System of medicine in pediatric age group of 3 to 10 years. This study is also novel in nature by way of investigating dosage forms in domiciliary rather than in patient settings

In the present study mean VAS acceptability score was found significantly higher for the Sharbat (Syrup) as compared to Jawarish (Semi-solid) dose form. The parents also preferred Sharbat (Syrup) over Jawarish (Semi-solid). The parent reported child preference was significantly in favour of Sharbat (Syrup) and Jawarish (Semi-solid) was least preferred by the children. Results of this study also establish the fact that children versus parent preference and acceptability although being different outcomes provide matching information.

The limitations of this study included absence of supervision by the researchers and the only source of information was parent reports. To reduce the errors in information obtained from parents, stress was laid upon explanation of method of administration and reporting to parents. Secondly the taste aspect of the dosage form may be varied depending upon their composition although most of the Jawarish taste similar and same is true for Sharbats used in Unani system of medicine.

CONCLUSION

This study showed that the acceptability of Jawarish (Semi-solid) is much lower as compared to Sharbat (Syrup). The lower acceptability of a dosage form results in administration of lower doses in comparison to recommended doses and therefore, the

ailment for which the formulation is prescribed may not be treated at all or may be treated in completely. Ayush systems of medicine are gaining importance and researchers in the field of drug development should focus on development of acceptable dosage forms for Unani formulations that will be well acceptable in the pediatric population. The availability of these dosage forms will increase the horizon of treatments available for the pediatric patients both in conventional as well as traditional systems of medicine.

Declaration by Authors
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