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Original Research Article

Factors affecting compliance of drug therapy in outpatient children

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ABSTRACT

Background: Adherence to a medical treatment regimen is an essential determinant of clinical success and professional success of doctor as well. Compared with the thousands of trials for individual drugs and treatments, there are few relatively rigorous trials of adherence interventions. Our study is a small effort towards understanding reasons for poor compliance among paediatric patients.
Methods: The 256 cases that were selected for study had various clinical conditions. Compliance definition was applied only for those who received antibiotics. For other cases who received drugs other than antibiotics, we asked number of skipped doses. Data collected by paediatrician during follow-up or next visit because of some other illness and by telephone call to parents by assistant. Parents and kids were asked about the reasons for skipping the doses and also about their personal preferences towards medicines.
Results: Out of 256 children 93 were prescribed antibiotics, 37.63% had good compliance and 62.36% had poor compliance.7% never skipped any medicine, 62% skipped less often (≤5 times) and 31% skipped. Very often (≥6 times), taste (67%), quantity (52%), apparent recovery (62%), school (65%), sleeping (56%), timing with food (47%) and bottle getting finished (49%) were the most common reasons for missing the dose of any medicine. Adherence was better when less number of doses were given less often. Chocolate flavor was liked by most kids.
Conclusions: Prescribing medications should involve parents, children and practitioners in an open discussion around the most suitable, palatable formulations for successful treatment outcomes.

Keywords: Adherence, Children, Compliance, Drug, Medication, Taste

INTRODUCTION

Making children adhere to treatment regimen is a big challenge to pediatrician treating in his daily OPD practice. Not only in India, Pediatric medication nonadherence is a major problem in the United States health care system.[1]

Adherence to a medical treatment regimen is an essential determinant of clinical success and professional success of doctor as well. Non-adherence to prescribed treatments is the primary cause of treatment failure in pediatric long-term conditions.[2] Unlike at inpatient care where nursing staff will ensure timely delivery of parenteral and/or enteral drugs, it is very difficult at outpatient care where doctor will be unable to ensure timely delivery of oral drugs.

Due the immaturity of age and inability to understand seriousness of disease children often refuse to take drugs, parents usually due to lack of time forget to give medications to their kids. We tried to find few modifiable factors which affect compliance to outpatient therapy in children which can help a doctor to achieve higher adherence rates in their paediatric patients.

METHODS

The study was a prospective observational study conducted at a clinical setting at Hubballi, studied over a period of 5 months. Study population consisted of children visiting clinic for various illnesses, who were treated on outpatient (OP) basis with non- parenteral drug regimens. Adherence data was collected during follow up visit or next visit due to some illness or by telephone conversation with parents. Total of 320 cases were considered for study, but in only 256 cases we could collect the adherence data.

Inclusion criteria

- Children's from 4 years to 14 years.

Exclusion criteria

- Children less than 4 years.
- Children with intellectual disabilities.

Study period was From January 2019 to May 2019.

Population of the Study 256 children aged from 4 years to 14 years.

Methodology

The 256 cases that were selected for study had various clinical conditions, like Upper respiratory infections, Gastroenteritis, dysentery, Stable pneumonias, asthma and bronchiolitis, simple urinary tract infection, bacterial skin infections, viral fevers including exanthemas, etc. compliance definition was applied only for those who received antibiotics. For other cases who received drugs other than antibiotics, we asked number of skipped doses. Data collected by pediatrician during follow-up or next visit because of some other illness and by telephone call to parents by assistant. Parents and kids were asked about the reasons for skipping the doses and also about their personal preferences towards medicines. Compliance to antibiotics was considered good if less than 2 doses are missed in antibiotic course.

RESULTS

Out of 320 cases chosen for study, 256 participated which constituted the study population, 140were male and 116 were female (Table 1). Children aged 4-7 years were 40.62%, 7-10 years were 37.5% and 10-14 years were 21.87% (Table 2). Out of 256 children 93 were prescribed antibiotics, 35 (37.63%) had good compliance and 58 (62.36%) had poor compliance (Table 3). Antibiotic compliance was poor among mothers whose education level was beyond High school 23(39.5%) compared to mothers who's education was primary school or less 19(33%) (Table 4). When mothers are not employed 26(74%) compliance for antibiotics was better compared to employed mothers 9(26%) (Table 5).

Among total 256 children, 18(7%) never skipped any medicine, 159(62%) skipped less often (≤5 times) and 79(31%) skipped Very often (≥6 times) (Table 6).

Table 1: Sex distribution.

Sex	Male	Female
Number	140	116

Table 2: Age distribution.

Age	Number(256)	Percentage (%)
4-7	104	40.62
7-10	96	37.5
10-14	56	21.87

Table 3: Compliance.

Compliance (only for antibiotics)	N=93 (percentage)
Good compliance	35 (37.63%)
Poor Compliance	58 (62.36%)

Table 4: Education of mother affecting adherence to antibiotics.

Education of mother	Good compliance(N=35)	Poor compliance(N=58)
Primary school or less	18(51%)	19(33%)
High school	8(23%)	16(27.5%)
Beyond High school	9(26%)	23(39.5%)

Table 5: Working of parents affecting adherence to antibiotics.

Work	Good compliance (N=35)	Poor compliance (N=58)
Both parents working	9(26%)	30(52%)
Only Father working	26(74%)	28(48%)

Table 6: Skipped doses for drugs including antibiotics.

Skipped doses	N=256(percentage)
Never skipped	18(7%)
Less often (≤5 times)	159(62%)
Very often (≥6 times)	79(31%)

Taste (67%), quantity (52%), apparent recovery (62%), school (65%), sleeping (56%), timing with food (47%)

and bottle getting finished (49%) were the most common reasons for missing the dose of any medicine (Table 7).

Table 7: Common Reasons for missing antibiotics and other drugs.

Reasons	Antibiotics (N=58)	Other drugs(N=238)
Taste	30 (51%)	159 (67%)
Quantity	15 (26%)	123 (52%)
Frequency of dosing	19 (32%)	80 (34%)
Vomiting after intake	23 (39%)	96 (40%)
Fear of adverse effects	03 (5%)	78 (33%)
Multiple drugs	26 (45%)	98 (41%)
Apparent recovery	19 (32%)	147 (62%)
School	31 (53%)	154 (65%)
Sleeping	09 (15%)	133 (56%)
Just Forgot	11 (19%)	59 (25%)
Bottle got finished	15 (26%)	112 (47%)
Timing with food	19 (32%)	118 (49%)
Busy parents	05 (9%)	39 (16%)
Influence of neighbours	02 (3%)	12 (5%)
Didn't understood	02 (3%)	12 (5%)

Table 8: Opinions of parents/kids regarding frequency of dosing in acceptance of any drugs.

Frequency of dosing	Preference (N=256)
Once a day	90%
Twice a day	85%
Thrice a day	50%
≥4 times a day	10%

Most of them (80%) preferred ≤2 drugs compared 5% who were okay with 6 or more drugs. Chocolate flavor (85%) was most liked flavor. Acceptance was better (90%) when the volume of drug is ≤2.5ml (Tables 9,10,11).

Table 9: Use of Multiple drugs in acceptance of any drugs.

Multiple drugs	Preference (N=256)
≤2	80%
3-5	30%
≥6	5%

Table 10: Taste/flavour of drug affecting the compliance.

Taste of the drug	Preference(N=256)
Mint flavour	5%
Fruit flavour	40%
Chocolate flavour	85%

When parents and their kids were asked about opinions regarding preferred Frequency of dosing, use of multiple drugs, most liked flavor of the drug and preferred volume of dosage we got following results. Once a day (90%) or twice day (85%) dosing was most preferred schedule compared to thrice a day (50%) schedule (Table 8).

Table 11: Volume of the dose affecting the compliance to drugs.

Volume of dosage	Preference(N=256)
≤2.5 ml	90%
2.5-5.0 ml	45%
≥5.0	10%

DISCUSSION

Pediatricians have considerable difficulty in understanding and managing poor adherence to medications. Good adherence has direct correlation with better clinical outcome. Compared with the thousands of trials for individual drugs and treatments, there are few relatively rigorous trials of adherence interventions.[3] Our study is a small effort towards understanding reasons for poor compliance among paediatric patients.

For parents and children, the daily hassles of living, stress, and typical family conflict are the biggest barriers to medication adherence. Reasons why children do not take their medications include parents' lack of understanding of the diagnosis, concerns about drug therapy effectiveness, and fear of medication side effects.[4]

We included children above age 4 years as European Medicines Evaluation Agency Report acknowledges the difficulty of assessing taste in children below 5 years of age.[5]

Among 256 patients 93 were given antibiotics, good compliance was noted only in 35 (37.63%) patients and poor in 58 (62.36%). Unfortunately compliance was poor among mothers whose education was beyond High school (39.5%) compared 33% mothers who attended Primary school or less. It correlates to our common feeling of "children of educated parents are difficult to treat". Probable reasons may be influence of media, fear of side effects, their judgement of improvement and employment. Compliance was better when mothers are at home caring their children.

Taste of the medicine was most important determinant of acceptance by children. In this study, 51% of children receiving antibiotics and 67% children getting other medicine missed doses because of taste. Majority of our children (85%) liked chocolate flavored medicines and mint was least (<5%) liked flavor.

Children prefer sweet and salty flavors, and dislike bitter and peppermint taste.[6]

Chocolate flavouring often is preferred because it effectively masks the taste of bitter medications.[7]

Palatability is so significant in ensuring successful administration of a course of treatment that a recent call has been made for the evaluation of palatability and taste before European marketing authorization is granted.[8] Better tasting antibiotics should therefore correlate with higher levels of adherence.

When multiple drugs are prescribed compliance goes down significantly. Most of the parents/kids (80%) liked ≤2 drugs a day. About 30% blamed increased frequency of dosing was the reason for missing the drug. Most preferred ≤twice a day. As per other study Once or twice daily dosing are the most comfortable regimens for school age children because parents can remind children to take medications or directly observe administration of the therapy.[9] This usually doesn't come in the way of schooling of child which again is a factor decreasing compliance (53% for antibiotics and 65% for others). When drug is advised to be consumed with relation to timing of food consumption many of the parents forgot to give the drugs.

In Japan study the child's refusal to take the drug was the second most common reason for non-adherence after parental judgement that the child was better.[10] In Saudi Arabia, the reasons most frequently mentioned were the rapid improvement of symptoms, the bitter taste of the drug, forgetfulness and frequent dosing.[11]

Diarrhoea after amoxicillin or co-amoxiclav was the common reason for missing/stopping the medication in our study population, vomiting was the other reason.

A number of factors usually influence the doctor's choice of antibiotic and patient adherence. These include the likely causative organism and its sensitivities, and the site and severity of infection. The child's age and known allergies, and drug route, formulation, degree of penetration, side effects and toxicology are also important issues. However, the taste of an antibiotic and the child's ability to tolerate oral drugs, although widely cited, is often not considered. Acknowledging the importance of palatability to children and parents in patient-centered management will improve adherence and influence clinical outcome. The majority of doctors have not tasted every antibiotic they prescribe.[12]

Seven drugs (azithromycin, clarithromycin, erythromycin, norfloxacin, sulfamethoxazole/ trimethoprim and amantadine) were judged more bitter than quinine. Cephalosporins to be better tasting although more expensive than penicillin's and macrolides.[13] A number of randomized controlled trials have shown azithromycin and cefdinir to be more palatable alternatives to amoxicillin/ clavulanate while also being easier for parents to administer for acute streptococcal pharyngitis, acute otitis media.[14]

It is important to remind parents that regular eating utensils (e.g., spoons) can differ in volumes, causing inaccurate dosing. A recent study showed that a color-coding chart and medication dispenser reduced dosing errors.[15]

It is critical to empower children to learn to take their medications and be responsible for caring for their own health. Incorporate dosing into daily routines and take medication at the same time each day (e.g., after brushing teeth, before a meal). Mixing medication with a small amount of food or juice, using rewards, or other strategies might help increase compliance in young children.

Most ideal method of checking compliance to a drug is checking empty blister of tablet pack or the amount of drug left in bottle, which was not done in our study. Limitations of the study includes:

- Many parents forgot the number of doses they missed for previous illness.
- Data collection by telephone was done by non-medical person.
- Parent's story was believed without confirming the truthfulness of matter.
- Few parents provided incomplete data.
- Actual taste of medicine was not tested by doctor/parent.

CONCLUSION

The cost of poor adherence resulting treatment failure, complications and the development of drug resistance cannot be over emphasised. Prescribing medications should involve parents, children and practitioners in an open discussion around the most suitable, palatable formulations for successful treatment outcomes. The taste of an antibiotic is often not taken into account by practitioners, although there is significant evidence to show palatability correlates strongly with adherence. Social economic factors of parents need to be considered when prescribing medication. Drug formulations used in paediatric pharmacotherapy should be adapted to children's needs to suit their age, size, physiologic condition, and treatment requirements. Aim for higher compliance than aiming for higher antibiotics.

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