

Original Article**PROBLEMS ASSOCIATED WITH THE USE OF ENTERIC COATED TABLETS, EXTENDED RELEASE TABLETS AND THE STORAGE OF PAEDIATRIC ANTIBIOTICS AT DEVDAHA MUNICIPALITY IN NEPAL*****Sanjeev Guragain¹, Namrata Upadhayay²**¹Department of Pharmacology, ²Department of Physiology, Devdaha Medical College and Research Institute, Rupandehi, Nepal

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DOI: <https://doi.org/10.3126/mjen.v1i02.51160>**ABSTRACT****Background**

Enteric coated tablets and extended release tablets are such kinds of tablets that should not be taken in crushed form. Pharmacists may advise to break or crush such tablets to manage the dose form that may lead therapeutic failure and increase the side effects of it. Further, they may not advise patients for the storage of paediatric antibiotics at 2-8°C. The first objective of our study is to find the knowledge among pharmacists about dispensing enteric coated and extended release tablets. The second objective is to explore the knowledge and practice of pharmacists about the storage of paediatric antibiotics after its reconstitution.

Methods

This study was community based cross-sectional descriptive study which was carried out in 11 pharmacies of Devdaha Municipality from September 2021 to March 2022. The questionnaire was self-administered and interviewed by the investigator. The collected data were entered in excel and expressed in frequencies.

Results

Almost all (10) pharmacists did not have knowledge regarding the storage of antibiotic in refrigerator (at 2-8°C) after reconstitution. Very few (4/11) pharmacists have knowledge about not consuming enteric coated tablets and extended release tablets in the crushed form. All pharmacists (11/11) have knowledge that psychiatric drugs must not be sold as OTC (Over The Counter) drugs.

Conclusion

There is lack of knowledge among pharmacists about the importance of storage of paediatric antibiotics after reconstitution. Further there is lack of knowledge and practice about the proper dispensing of enteric coated and extended release tablets to the patients. However, the positive aspect is that they have knowledge of not selling antibiotics and psychiatric drugs as OTC drugs.

Keywords: Enteric coated tablets, Extended release tablets, Paediatric antibiotics

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INTRODUCTION

There are various kinds of dosage forms of the drugs. Among them enteric coated tablet is one. The tablets are coated with Cellulose Acid Phthalate (CAP) or shellac or plant fibres, etc (1). The coating is made in such a way that it is resistant to gastric acid but dissolves in intestinal alkaline pH. As a result, the drug is protected from gastric acid and the incidence of gastric irritation is also reduced. Some of these drugs are like diclofenac, aspirin, omeprazole, pantoprazole (2). Thus, enteric coated tablets should not be broken or crushed before administration. If they are broken or crushed before administration, they will be destroyed by the gastric acid and their efficacy will be lost (3).

Sustained release tablets/ extended release tablets are the other dosage forms of the drugs. Similarly to enteric coated tablets, they should not be broken or crushed before the administration. The sustained release drug, Pentoxifylline used for peripheral occlusive arterial disease (4-6) has certain dose related adverse drug effects such as nausea, vomiting, dizziness, diaphoresis, headache, etc. (7). In the same study, it was found that adverse effects of the drug Pentoxifylline were increased when its extended release tablets was crushed and used orally compared to the intact form of the same drug. Sustained release drugs are synthesized in such a way that aggregated drug particles have different types of coating with inert resins so that each type of coating dissolves at different time intervals. Such tablets provide uniform and sustained release of drug for a long period of time (2). This increases the duration of action of such drugs. This dosage form is designed for those drugs which have short half-life so that the patient compliance is increased (2, 8).

There are possible chances that due to the lack of knowledge, some pharmacists may advise to break or crush the enteric coated and extended release tablets before administration to manage the dose form. This could lead to therapeutic failure and may increase the side effects of those drugs. So, the first objective of our study is to find the knowledge among pharmacists about dispensing enteric coated and extended release tablets.

Infectious diseases caused by bacteria and viruses are very common in paediatric population (9-11). For various bacterial diseases, antibiotics are prescribed by the clinicians. Most of the antibiotics prescribed for the paediatric population come in powdered form which has to be reconstituted as oral suspension before administration. Most of the paediatric antibiotics after proper reconstitution should be stored in refrigerator to prevent its degradation. Degraded antibiotics intake will not cure the disease. Therefore, mothers/attendants should read the instructions in the leaflet or should follow the instructions of the doctor or pharmacist for reconstitution and storage of antibi-

otics. Many people misuse the antibiotics by taking them as the over the counter medications. This can increase the chances of overuse or under use of antibiotics (12). Therefore, the pharmacist should properly dispense the drugs to the patients and their attendants. Hence, the second objective of this study is to explore the knowledge and practice of pharmacists about the storage of paediatric antibiotics after its reconstitution.

METHODS

This study was community based cross-sectional descriptive study which was carried out in 11 pharmacies of Devdaha Municipality in Nepal. Pharmacies having licensed to dispense drugs were included in the study. Pharmacies that were not selling psychiatric and paediatric drugs, enteric coated and extended release tablets were excluded from the study. The pharmacists and the CMA (Community Medical Assistant) personnel were included in the study.

Ethical clearance to conduct the research was taken from Institutional Research Committee (IRC) of Devdaha Medical College and Research Institute (DMCRI). Informed consent was taken from the pharmacies prior to the research. Pretest was done in five pharmacies of Devdaha Municipality in Nepal. The questionnaire was then discussed with the subject experts. Ambiguous questions were deleted and the questionnaire was restructured. The questionnaire consists of both closed ended and open ended questions. It consist total of 17 questions. First seven questions were regarding the paediatric antibiotics, next six questions were about the extended release and enteric coated tablets, other two questions were about psychiatric drugs and remaining two questions were about the expiry date of the drugs.

Some of the sample questions included in the questionnaire were as follows:

How do you advice patient parties to keep the reconstituted paediatric antibiotics like Amoxiclav at home?

What type of tablets could not be consumed in crushed form? List them.

Do you know about the enteric coated tablet? If yes, what is it?

Do you know about the extended release tablet?

The questionnaire was self-administered and interviewed by the investigator. The collected data were entered in excel and expressed in frequencies. The results are categorized theme-wise for open ended questions and expressed in percentages.

RESULTS

About 7/ 11 pharmacists have knowledge about not selling antibiotics as OTC (Over the Counter) drugs. The reason for not selling as OTC drugs was the misuse of antibiotics. None of them mentioned that resistance to antibiotic might occur if the antibiotic was not taken for the full course. All pharmacists gave instructions to the patients/ patient parties regarding

the process of reconstitution of antibiotics. However, 10/11 pharmacists did not have knowledge regarding the storage of antibiotic in refrigerator (at 2-8°C) after reconstitution. Moreover, 10/11 pharmacists did not have knowledge about degradation of antibiotic (altered color), if it is not stored in refrigerator (Table 1).

Table 1: Knowledge about dispensing Pediatric antibiotic drugs by Pharmacists, n-11

Items	Yes	No
Antibiotics sold as OTC drugs*	4	7
Giving advice to patients about process of reconstitution (boiled and cooled water, filling up to the mark and mixing it well)	11	0
Knowledge about storage of antibiotic at home after reconstitution (refrigerator)	1	10
Temperature for storage of reconstituted antibiotic (2-8 °C)	1	10
Knowledge about degradation of drug (color change)	1	10

All pharmacists have knowledge that psychiatric drugs should be dispensed only under doctor's prescription. Moreover, about 6/11 pharmacists have knowledge about the meaning of extended release tablets and mentioned the name of drugs used in this form (e.g. metformin, venlafaxine).

About 7/11 pharmacists were not able to define the enteric coated tablets, properly. Similarly, 5/11 pharmacist were not able to mention the meaning of extended release tablets too. On the other hand, 4/11 pharmacists only have knowledge about not consuming these tablets (enteric coated tablets and extended release tablets) in crushed form, (Table 2).

Table 2: Knowledge about dispensing psychiatric drugs, extended release tablets and enteric coated tablets, n-11

Items	Yes	No
Knowledge of psychiatric drugs to be sold under doctor's prescription	11	0
Meaning of enteric coated tablets	4	7
Meaning of extended release tablets	6	5
Knowledge about tablets which could not be consumed in crushed form (enteric coated tablets, extended release tablets)	4	7

The list of extended release and enteric coated tablets mentioned by pharmacists were as follows, (Table 3).

Table 3: Drugs in the form of extended release and enteric coated tablets

Extended release tablets	Enteric coated tablets
Metoprolol XL	Pantoprazole and other Proton Pump Inhibitors
Metformin XL	Aspirin
Aceclofenac XL	Diclofenac Naproxen Sulfasalazine

DISCUSSION

The study was aimed to explore the knowledge of pharmacist in dispensing enteric coated and extended release tablets to the patients in proper way. The other objective was to explore the knowledge of pharmacists about storage of paediatric antibiotics after reconstitution. The study was done among 11 community pharmacies in Devdaha Municipality, Rupandehi, Nepal.

In our study, at Devdaha Municipality, 63.64% pharmacists have the knowledge that paediatric antibiotics must not be sold as OTC drug. However, in the other study done in Kathmandu and Lalitpur, Nepal, all pharmacists having Bachelor's degree (n=28; 100%) have proper knowledge about dispensing the antibiotics only under the doctor's prescription (13). This data suggested that pharmacists in Kathmandu and Lalitpur have proper knowledge that antibiotics must only be dispensed with doctor's prescription whereas some pharmacists in Devdaha Municipality lack this knowledge. So, there is the need of awareness program among pharmacists in Devdaha Municipality.

In our study, almost all (90.91%) pharmacists did not have the knowledge about storage of antibiotics after its reconstitution. They also did not have knowledge about storage temperature for the reconstituted antibiotic. Further, they lack the knowledge about the degradation process of the antibiotics. As it is well known, that certain paediatric antibiotics such as Amoxiclav should be kept at 2-8 °C after its reconstitution. If it is not stored at the recommended temperature the drug will start to degrade and lose its efficacy (14). It was found that oral suspension antibiotics after reconstitution (Cefuroxime axetil, Amoxicillin- Clavulanate Potassium, Azithromycin) were not degraded for at least 5 days when kept in refrigerator at 2 to 8 °C, whereas the same drugs showed degradation on the third day when they were stored in the room temperature (14). Therefore, pharmacist should provide relevant information to the patient's parties regarding reconstitution and storage of antibiotics. Additionally, awareness program has to be conducted to the pharmacist of this municipality.

The positive aspect of our study is that none of the pharmacists dispensed the psychiatric drugs without doctor's prescription. They have sound knowledge regarding dispensing of psychiatric drugs to patients. This is contrast to other study done in Pakistan where 89% (n=178) of pharmacists dispensed the psychotropic medications without doctors' prescription (15).

In our result, 7/11 (63.64%) pharmacists did not know the meaning of enteric coated tablets. Enteric coated tablets should not be broken or crushed before administration. If they are broken or crushed before administration, they will be destroyed by the gastric acid and their efficacy will be lost (3). Therefore, pharmacists

need knowledge about the enteric coated tablets and its mechanism of action for its proper dose adjustment.

We found that 5/11(45.45%) pharmacists did not know the meaning of extended release tablets and 7/11 (63.64%) pharmacist have no knowledge that these drugs (enteric coated and extended release tablets) should not be consumed in crushed form. In contrast to our study, there were only 20% of the pharmacists who do not have knowledge about it (16). Therefore, it seems to conduct an education program for our pharmacists and make them knowledgeable regarding the extended release tablets to increase the patients' compliance. Additionally, this will also help to minimize the chance of adverse drug reactions in the patients. As it was found that adverse drug effects of Pentoxifylline were increased when it was consumed in crushed form as compared to the intact form (7) . The adverse drug reactions found in Pentoxifylline used for peripheral occlusive arterial disease (4-6) were nausea, vomiting, dizziness, diaphoresis, headache on consuming crushed form of it (7) .Sustained release drugs are synthesized in such a way that aggregated drug particles have different types of coating with inert resins so that each type of coating dissolves at different time intervals. Such tablets provide uniform and sustained release of drug for a long period of time (2). This increases the duration of action of such drugs. This dosage form is designed for those drugs which have short half-life so that the patient compliance is increased (2,8). Therefore, the detail meaning of the extended release tablet should be provided to the pharmacist because the consumption of crushed form means consumption of higher dose of it. This will lead to rapid rise of drug concentration in the blood. The rapid rise in the blood is due to early absorption of the drug from the digestive tract. This might lead to development of adverse drug reactions in these patients and decreases

its efficacy and patient compliance.

We found that few pharmacists were able to mention few drugs that should not be taken in crushed form. They have really less knowledge about the types of drugs that should not be taken in crushed form. They listed few of extended release tablets such as Metoprolol XL, Metformin XL, Aceclofenac XL and enteric coated tablets such as Pantoprazole and other Proton Pump Inhibitors, Aspirin, Diclofenac, Naproxen, Sulfasalazine. However, there are many drugs (enteric coated or sustained release) apart from listed by the pharmacists that should not be taken in crushed form (17). Therefore, they need to update their knowledge regarding the types of drugs and new drugs available in the market with their different pharmacokinetics properties.

Main limitation of the study: We could not follow the patients/ patient's attendants for the proper use of enteric coated and extended release tablets and for the storage of paediatric antibiotics.

CONCLUSION

There is lack of knowledge among pharmacists about the importance of storage of paediatric antibiotics after reconstitution and the proper dispensing of enteric coated and extended release tablets to the patients. They also lack the proper practice of dose adjustment for the extended and enteric coated tablets. Therefore, awareness program has to be conducted in Devdaha Municipality to provide knowledge to the pharmacists about the importance of storage of paediatric antibiotics after reconstitution and about the non-splitting nature of enteric coated and extended release tablets to minimize the adverse effect and decrease the therapeutic failure.

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