

A Study on the Sale of Antimicrobial Agents without Prescriptions in Pharmacies in an Urban Area in South India

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ABSTRACT

Introduction: Antimicrobial drug resistance is a fast emerging problem worldwide. It is a consequence of the use, particularly of the misuse of drugs. In most of the developing countries, antibiotics can be purchased without prescriptions, even when the practice is not legal. Presently, in India, Schedule H, under the Drug and Cosmetics Act and Rules, provides a list of over 536 drugs which include Antimicrobial Agents [AMAs], which are required to be sold on the prescription of a registered medical practitioner.

Objectives: To evaluate the Over the Counter (OTC) sales of antimicrobial agents in allopathic pharmacies [community] within the city corporation limits. To describe the degree of difficulty which is faced in obtaining antibiotics without a prescription. To find out as to what advice, if any, was given by the pharmacists with regards to the administration of the medicines which had been sold.

Methods: Three diseases were simulated by two medical

students who presented as patients in randomly selected pharmacies at an Urban location. They then requested the pharmacists for medications for their illnesses. AMAs were requested for, if they were not issued at the first instance.

Results and Discussion: Nearly 50% of the pharmacists declined to issue AMAs. Amoxicillin was the most common of the AMAs which were dispensed by the pharmacists. The duration and the frequency of the treatment which was advised by the pharmacists were mostly wrong.

Conclusion: This study showed that the practice of dispensing AMAs without prescriptions was widely prevalent among the dispensaries which were located even in urban areas. Not only were the AMAs dispensed, but also they were dispensed without taking any history of hypersensitivity. What makes the practice worse is that the duration and the frequency of administration of these drugs are wrongly advised more often than not.

Key Words: Heart rate Variability, Time domain method, Frequency domain method, Mobile phone users and non-users

INTRODUCTION

Antimicrobial drug resistance is a worldwide problem. It is the result of the use, particularly of the misuse of antimicrobial agents. The advent of antimicrobial resistance can be attributed to a number of causes such as the inappropriate use of antimicrobials by health care providers [1] or the easy availability of AMAs without a physician's prescription. In most of the developing countries, antibiotics can be purchased without prescriptions, even when the practice is not legal. In many African, Asian and Latin American countries, antibiotics are readily available on demand from pharmacies, drug stores, roadside stalls and hawkers [2]. Presently in India, Schedule H, under the Drug and Cosmetics Act and Rules, has provided a list of over 536 drugs, including antibiotics, which are required to be sold on the prescription of a registered medical practitioner and the manufacturer is required to label the drug with the symbol Rx and with the following words: "Schedule H drug - warning: To be sold by retail on the prescription of a Registered Medical Practitioner only" [3].

The Lancet, in a recently published article about the 'Superbug', has insinuated that the large scale antibiotic misuse in India has resulted in many strains of bacteria becoming resistant to many antibiotics [4]. In response, the Government of India has created a committee to frame a new antibiotic policy for the country. The antibiotic policy which has been written by this committee is

Schedule HX which is currently under review by the Union Law Ministry, after which it will be reviewed by the Drugs Technical Advisory Board [5].

The increasing resistance of microorganisms calls for serious interventions to prevent the emergence of new resistant strains and the spread of the existing ones. One approach is to control the inappropriate use of antibiotics in both the hospital and the community settings [6] and their sale without prescription.

Studies which have been conducted across various parts of the world have shown that AMAs could be obtained easily from local pharmacies despite the regulations [7-10].

A study which was conducted in Spain, found that antibiotics were obtained from 79.7% pharmacies when a urinary tract infection was simulated, from 34.8% pharmacies when a sore throat was simulated and from 16.9% of 59 pharmacies when acute bronchitis was simulated. A similar study which was conducted in Brazil, found that antibiotics were offered in 58% of the pharmacies, and that this offer was increased to 74% after the investigator insisted on having them [7].

An interview based study was conducted in Nagpur, India, where it was found that drugs were dispensed without prescriptions, despite the prohibition by the Indian Pharmaceutical Act. Sales

of antimicrobial drugs, which had accounted for 17.5% of the purchases. The most common indications were upper respiratory, gastrointestinal and nonspecific complaints. The dispenser rarely offered advice or instructions on the use of the prescribed antimicrobials [11].

It is widely believed that antimicrobial agents are available over the counter in most of the parts of India. This study was planned to evaluate the availability of antimicrobial agents without prescriptions in allopathic dispensaries in a city of south India. This study was inspired by a similar study which was carried out in Spain in 2008. We hope to provide data about the availability and the ease/difficulty which is faced in the availability of AMAs without prescriptions. Our study results may strengthen the legal process which is underway in restricting the use of antimicrobial agents.

OBJECTIVES

1. To evaluate the Over The Counter (OTC) sale of AMAs in the allopathic pharmacies [community] which are within a city corporation limits.
2. To describe the degree of difficulty which is faced in obtaining antibiotics without a prescription.
3. To find out what advice, if any, is given by the pharmacist with regards to the administration of the medicines which are sold.

MATERIALS AND METHODS

A prospective study was carried out from October to December 2011 among the dispensaries in a corporation area in south India. A complete list of all the pharmacies in this area was obtained from various sources. Only community based dispensaries were included in the study. All the homeopathic pharmacies, ayurvedic pharmacies and the pharmacies in hospitals and nursing homes were excluded from the study. These pharmacies were grouped into the wards [administrative units] of the city corporation to which they belonged. One pharmacy from each of the 60 wards in the city was randomly selected. These 60 pharmacies formed the sample for the study. two medical students [1 boy and 1 girl] visited these pharmacies and play acted as patients. Any one of three different well rehearsed clinical scenarios was presented in a pharmacy. The clinical conditions which had to be presented in each of the pharmacies were randomly allocated. One scenario was presented in 20 pharmacies. The three clinical conditions which were presented were (1) Upper Respiratory Tract Infection [URTI] (2) Acute bronchitis and (3) Diarrhoea. Symptoms to be presented were:

1. **URTI:** Running nose, severe headache, body ache and fever.
2. **Acute bronchitis:** Cough with expectoration and fever.
3. **Diarrhoea:** Loose stools 5-6 times, pain in the abdomen and fever.

These symptoms were rehearsed with the aid of senior members of the department of pharmacology to obtain the standardization of the simulation of these diseases. The male student always presented the symptoms of URTI or diarrhoea and the female student presented the symptoms of acute bronchitis. The investigators used two levels of demand. First, the investigator asked for some medicine to alleviate the symptoms. If this initial request did not yield antibiotics, then the investigator used the second level of demand, which was to directly ask for AMAs. A note was made as to whether the pharmacist demanded a prescription, asked any

leading questions about the illness, and gave any instructions as to how often and how long the medicines had to be taken. If no such instructions were offered, the investigator asked for the frequency and the durations of use of the AMAs. In all the cases, the investigators were very polite and they did not get into any sort of arguments. The data was collected in a semi-structured proforma. The details were recorded soon after the encounter. Prior approval was obtained from the institutional ethics committee and the names of the dispensaries and the city limits where the study was carried out were not revealed in this study, as was suggested by the ethics committee.

We performed descriptive statistical analyses of the results and used Chi square tests to compare the qualitative variables. The differences were considered to be significant if p was <0.05.

RESULTS

The three diseases, namely, upper respiratory infections, acute bronchitis and diarrhoea were simulated by the investigators in 20 pharmacies for each disease, among 60 randomly selected pharmacies in an urban administrative location, as was described in the methodology.

Ease of obtaining the AMAs: Among the 60 pharmacies, 29 [48.3%], declined to issue antimicrobial agents even when they were asked for by the investigator. However, the investigators could get AMAs from 16[26.7%] pharmacies when they were requested for. The rest [25%] issued AMAs as soon as the symptoms were presented. In case of diarrhoea, 70% of the dispensaries did not dispense AMAs, whereas 75% of the dispensaries issued AMAs when URTI was presented. The breakdown of the ease in obtaining AMAs from the dispensaries for each of the simulated diseases has been shown in [Table/Fig-1].

The type of AMAs which were dispensed: [Table/Fig-2] shows the type of AMAs which were dispensed against the various simulated diseases. Amoxicillin was the most common AMA which was dispensed by the pharmacies.

Details of the illnesses: The details of the illnesses were not enquired by 47[79%] of the dispensing persons. The others asked for a few details but none asked for a history of the drug allergy.

Advice by the pharmacists about the duration/ frequency of dosing: The number of pharmacies where the duration and the frequency of the AMAs were advised either on their own or after asking has been shown in [Table/Fig- 3]. If the duration / frequency of the administration of the AMAs was advised after asking for, it was mostly wrong. A higher frequency of wrong advices were given after asking for them as compared to the frequency of the advices which were given without asking for them and this was

Level of demand	Clinical cases and issue of [%] AMAs		
	URTI n=20	Acute bronchitis n=20	Diarrhoea n=20
Can I have something for my symptoms?[1]	7[35]	4[20]	4[20]
I would like an AMA [2]	8[40]	6[30]	2[10]
All [1+2]	15[75]	10[50]	6[30]
AMAs not obtained	5[25]	10[50]	14[70]

[Table/Fig-1]: Sale of antimicrobial agents [AMAs] according to clinical case, level of difficulty to obtain them

AMAs	Simulated disease			Total[%]
	URTI[%]	Acute bronchitis[%]	Diarrhea [%]	
Amoxicillin	12[60]	6[30]	1[5]	19[31.7]
Erythromycin	1[5]	-	-	1[1.7]
Ampicillin+cloxacillin	1[5]	-	-	1[1.7]
Azithromycin	1[5]	3[6.7]	-	4[6.7]

[Table/Fig-2]: Antimicrobial agent [AMAs] dispensed

Advice by the pharmacist	Correct	Wrong	Total
Frequency advised without asking	6[33.3]	12[66.7]	18[100]
Frequency advised after asking	1[7.7]	12[92.3]*	13[100]
Duration advised without asking	6[31.6]	13[68.4]	19[100]
Frequency advised after asking	0[0]	12[100]*	12[100]

[Table/Fig-3]: Advice given by the pharmacist about duration and frequency of administration of AMAs to simulated patients [%]

found to be statistically significant [$p < 0.05$].

DISCUSSION

Many studies from various parts of the world have revealed that antibiotics could be obtained from almost 70%- 97% of the local pharmacies despite the regulations [7]. However, in the present study, nearly 50% of the dispensaries refused to issue AMAs. Almost half of the pharmacies, who dispensed AMAs, dispensed them as soon as the symptoms were presented and AMAs could be obtained from the rest only after specifically asking for the AMAs to be issued.

Details of the illness and a history of allergy are particularly important to be asked about before dispensing AMAs to patients. A history of hypersensitivity is very important if betalactam antibiotics are dispensed. The details of the illnesses were not enquired for by 79% of the pharmacists. Some details of the symptoms were enquired about by the rest, but none asked about drug hypersensitivity. This could be dangerous, as anaphylaxis is a possibility even when betalactams are administered orally.

Amoxicillin was the commonest AMA which was dispensed when the symptoms of URTI and acute bronchitis were presented. When diarrhoea was presented as a symptom, 70% of the dispensaries refused to issue AMAs. Fluroquinolones alone, or in combination with tiindazole, were dispensed by other dispensaries for diarrhoea.

Among the 31 pharmacies that sold AMAs, only 18 pharmacists advised on the frequency of taking AMAs and 19 advised about the duration of the treatment, without the investigators asking for them. Other pharmacists gave the advice only after they were asked for by the investigators. In a similar study which was done in Spain among pharmacies that sold antibiotics, 84.3% of the pharmacists explained the number of times per day that the drug had to be taken and 68.7% explained the duration of the treatment [7]. In our study, more than 60% of the dispensaries gave wrong advice. Another interesting finding in this study was that if the person who dispensed the AMAs gave out the advice on his/her own without asking, he/she was likely to be right and if the information was given only after it was asked for, it was more likely to be wrong [$p < 0.05$]. In other words, if the dispensing person was sure of the frequency and the duration of the treatment of AMAs, he/she would advice routinely as the drug was dispensed.

But if the advice was obtained only after asking for it, after the dispensing person had failed to provide the advice on his/her own, it was more likely to be a wrong advice.

CONCLUSION

Many studies which had been carried out in different parts of the world have shown that AMAs could be obtained in 70%-97% of the pharmacies, without prescriptions. But the present study has shown that almost 50% of the pharmacists declined to dispense AMAs. But this figure is no reason for any solace, as AMAs should not be dispensed at all without a physician's advice, for the fear of the organisms developing resistance. It is quite possible that instead of simulating the disease, if AMAs are directly asked for, the results could be different. This study showed that the practice of dispensing AMAs without prescriptions was widely prevalent among the dispensaries which were located even in the urban areas. Not only were the AMAs dispensed, they are dispensed without taking any history of the subject's hypersensitivity. What made the practice worse was that the duration and the frequency of the administration of these drugs were wrongly advised more often than not.

REFERENCES

- [1] National Institute of Allergy and Infectious Diseases [Internet]. Understanding Antimicrobial (Drug) Resistance [Updated on 2011 December 21; cited 2011 nov 15]. Available from: <http://www.niaid.nih.gov/topics/antimicrobialResistance/Understanding/Pages/causes.aspx>.
- [2] Okeke IN, Lamikanra A, Edelman R. Socioeconomic and behavioral factors which lead to an acquired bacterial resistance to antibiotics in the developing countries. *Emerg Infect Dis* 1999; 5: 18-27.
- [3] Srivastava RK. A review on the current situation regarding the manufacture, use and the misuse of antibiotics in the country. In: National Policy for the Containment of Antimicrobial Resistance. New Delhi. Published by Directorate General of Health Services; 2011; 14-7 .
- [4] Kumarasamy KK. Emergence of a new antibiotic resistance mechanism in India, Pakistan, and the UK: a molecular, biological, and epidemiological study. *Lancet Infect Dis*.2010; 109: 597-602.
- [5] CDDEP [Internet]. Regulating Over-the-Counter Antibiotic Sales: What Will "Schedule HX" Mean for India? [updated 2011 Aug 2; cited 2011 Sep 2011]. Available from: http://www.cddep.org/blog/posts/regulating_over_the_counter_antibiotic_sales_what_will_schedule_hx_mean_india.
- [6] Aranda CMA, Mazzotti LR. Teaching the appropriate antibiotic use in the developing countries. In: Anibal de J Sosa, editor. Antimicrobial resistance in the developing countries, 1st edn. New York: Springer; 2010; 491-504.
- [7] Llor C, Cots JM. The sale of antibiotics without prescriptions in pharmacies in Catalonia, Spain. *Clin Infect Dis* .2009; 48: 1345-9.
- [8] Volpato DE, De Souza BV, Dalla Rosa LG, Melo LH, Daudt CA, Deboni L. The use of antibiotics without medical prescriptions. *Braz J Infect Dis*. 2005; 9: 288-91.
- [9] Al-Faham Z, Habboub G, Takriti F. The sale of antibiotics without prescriptions in pharmacies in Damascus, Syria. *J Infect Dev Ctries*. 2011; 5: 396-9.
- [10] Lansang MA, Lucas-Aquino R, Tupasi TE, Mina VS, Salazar LS, Juban N, et al. The purchase of antibiotics without prescriptions in Manila, the Philippines. Inappropriate choices and doses. *J Clin Epidemiol* .1990; 43: 61-7.
- [11] Dua V, Kunin CM, White LV. The use of antimicrobial drugs in Nagpur, India. A window on the medical care in a developing country. *Soc Sci Med* .1994; 38: 717-24.

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