DRUG UTILIZATION STUDY OF ANTI-MICROBIAL AGENTS IN MAHAGAON PRIMARY HEALTH CENTRE IN RURAL GULBARGA, KARNATAKA
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ABSTRACT: The WHO in 1977 provided the proper definition of drug utilization. It has been defined as the marketing, distribution, prescription and use of drugs in society with special emphasis on the resulting medical and social consequences. Antibiotics are a commonly prescribed group of drugs and the problem of their overuse is a global phenomenon. Studies from India have shown that the use of antimicrobial agents varies from 24 to 67 percent. Primary Health care is integral part of any country’s health care delivery system, its importance is vital when considered for the developing countries. AIMS: To evaluate prescription pattern and criteria for selection of antimicrobial agents (AMAs) in Primary Health Centre and to analyze rationality among the prescriptions. To monitor Adverse Drug Reactions (ADRs) encountered during the course of the study. METHODS AND MATERIALS: This prospective, observational and analytical study was done to assess the pattern of antimicrobial agent (AMA) use in patients attending Mahagaon Primary Health Centre (PHC) in Gulbarga district, Karnataka. The reason for AMA use, criteria for selection, AMA susceptibility, efficacy and tolerability of AMAs and treatment outcome of AMAs were evaluated. Patients receiving AMA therapy of either gender, of any age, seeking out-patient treatment from Mahagaon PHC, were included in this study. The study was carried out between March, 2014 and May, 2014 (3 months). Three hundred (300) consecutive patients receiving AMAs, were included in the study. RESULTS AND CONCLUSION: The results indicate that a satisfactory standard has been maintained in several areas in the studied PHC. Even more judicious use of antibiotics is recommended and specific therapy should be promoted over empirical therapy.

KEYWORDS: Drug utilization study, pharmacoepidemiology, anti-microbial agents, primary health centre.

INTRODUCTION: The WHO in 1977 provided the proper definition of drug utilization. It has been defined as the marketing, distribution, prescription and use of drugs in society with special emphasis on the resulting medical and social consequences.¹ Drug utilization research is an essential part of pharmacoepidemiology as it describes the extent, nature of drug exposure.² Pharmacoepidemiology is defined as the study of uses and effects of drugs in large number of people. Pharmacoepidemiology is a discipline that provides us with valuable information regarding clinical and economic outcomes of drugs, devices and biologics, particularly after their approval for clinical use. Antibiotics have the most potential impact on preventable mortality in the developing world.³ Antibiotics are a commonly prescribed group of drugs and the problem of their overuse is a global phenomenon. Studies from India have shown that the use of antimicrobial agents varies from 24 to 67 percent.⁴⁵ Primary Health care is integral part of any country’s health care delivery system, its importance is vital when considered for the developing countries. India adopted primary health care
in 1978 at Alma Ata Conference to achieve "health for all" at that time and presently "Millennium Development Goals". The Alma Ata conference defined Primary health care as “essential health care made universally accessible to individuals and acceptance to them, through their full participation and at a cost the community and country can afford”.

Primary health care practitioners have been shown to account for the majority of antibiotic prescribing. To prevent overprescribing, detailed data on antibiotic utilization should be obtained.

Rational drug usage, rational prescriptions and importance of essential medicines are included in MCI curriculum and it is the duty of us pharmacologists to teach these fundamentals to medical undergraduate students. Our study has tried to find out whether practical application of above knowledge in common practice had been incorporated by rural doctors of Gulbarga district, Karnataka.

OBJECTIVES:
1. To evaluate prescription pattern and criteria for selection of antimicrobial agents (AMAs) in Primary Health Centre.
2. To analyze rationality among the prescriptions.
3. To monitor Adverse Drug Reactions (ADRs) encountered during the course of the study.

MATERIALS AND METHODS: This prospective, observational and analytical study was done to assess the pattern of antimicrobial agent (AMA) use in patients attending Mahagaon Primary Health Centre (PHC) in Gulbarga district, Karnataka. The reason for AMA use, criteria for selection, AMA susceptibility, efficacy and tolerability of AMAs and treatment outcome of AMAs were evaluated.

Patients receiving AMA therapy of either gender, of any age, seeking out-patient treatment from Mahagaon PHC, were included in this study. Approval and clearance from the institutional ethics committee was obtained before starting the study. The study was carried out between March, 2014 and May, 2014 (3 months). Three hundred (300) consecutive patients receiving AMAs, were included in the study.

Data Analysis: Data was analyzed on MS Excel and descriptive statistics was used for analyzing the result of study.

RESULTS:

| Age (in years) | No. of Patients (N=300) |
|---------------|------------------------|
| < 1           | 21                     |
| 1-10          | 75                     |
| 11-20         | 48                     |
| 21-30         | 99                     |
| 31-40         | 30                     |
| 41-50         | 18                     |
| > 50          | 09                     |

Table 1: Depicts the distribution of patients according to age
Gender No. of Patients (N=300)
Male 162
Female 138

Table 2: Depicts the distribution of patients by gender

| Organ System | No. of Patients (N=300) |
|--------------|-------------------------|
| RTI          | 96                      |
| UTI          | 21                      |
| Skin & VD    | 33                      |
| GIT          | 102                     |
| ENT          | 15                      |
| Trauma       | 24                      |
| Eye          | 9                       |

Table 3: Depicts the distribution according to the organ system involved
Days | No. of Patients (N=300)
--- | ---
1-3 | 45
4-5 | 150
> 5 | 105

Table 4: Gives us the distribution of patients according to the duration of treatment

| Mode of Administration | No. of Patients (N=300) |
|------------------------|-------------------------|
| Oral Tablet            | 183                     |
| Oral Syrup             | 63                      |
| Parenteral             | 18                      |
| Local/Others           | 36                      |

Table 5: Provides us with the distribution of patients according to the mode of administration of the anti-microbial agent
Table 6: Gives us the distribution according to the total number of drugs prescribed per patient

| No. of Drugs | No. of Patients (N=300) |
|--------------|-------------------------|
| 1-3          | 255                     |
| 4-5          | 45                      |
| > 5          | 0                       |

Table 7: Gives us the availability of the prescribed anti-microbial agent in the primary health centre pharmacy

| Availability    | No. of Patients (N=300) |
|-----------------|-------------------------|
| At PHC          | 174                     |
| From Outside    | 126                     |
### Table 8: Gives us the distribution of patients according to the intended purpose of treatment

| Treatment Strategy | No. of Patients (N=300) |
|--------------------|-------------------------|
| Therapeutic        | 282                     |
| Prophylactic       | 18                      |

### Table 9: Gives us the distribution of patients according to outcome of treatment

| Outcome of Treatment | No. of Patients (N=300) |
|----------------------|-------------------------|
| Better               | 273                     |
| Worse                | 24                      |
| Dead                 | 3                       |
Drug | No. of Patients (N=300)
---|---
Amoxicillin | 21
Ciprofloxacin | 24
Norfloxacin | 9
Metronidazole | 15
Ofloxacin | 24
Cephalexin | 3
Cefixime | 33
Doxycycline | 3
Levofloxacin | 6
Ceftriaxone | 9
Azithromycin | 9
Ketoconazole | 6
Fluconazole | 3
Albendazole | 6
Roxithromycin | 3
Cefadoxime | 3
Fusidic Acid | 15
Amoxicillin + Clavulanic Acid | 21
Trimethoprim + Sulfamethoxazole | 27
Ampicillin + Amoxicillin | 12
Ciprofloxacin + Metronidazole | 6
Ciprofloxacin + Tinidazole | 3
Ofloxacin + Ornidazole | 30
Cefixime + Azithromycin | 3
Cefixime + Ofloxacin | 3
Ofloxacin + Azithromycin | 3
ATT (HRZE) | 3
Chloroquine + Primaquine + Artesunate | 3
Paracetamol 180
Cetirizine 21
Chlorpheniramine 135
Diclofenac 75
Pantoprazole 36
Salbutamol 15
Dicyclomine 33
Domperidone 33
Prednisolone 18
Loperamide 3
Multivitamin 3

Table 10: depicts distribution of patients according to single drug, anti-microbial agent, combination anti-microbial agent and adjuvant therapy

DISCUSSION: Drug utilization studies are important for obtaining data about the patterns and quality of use, the determinants of drug use and the outcomes of use. The main aim is to facilitate the rational use of medicines in populations.

Antibiotics are one of the most common medicines prescribed in hospitals today. It has been estimated that up to a third of all patients receive at least one antibiotic during treatment/hospitalization. The cost involved is therefore correspondingly high and up to 40% of a hospital’s drug expenditure may be devoted to the purchase of antibiotics.11-13
The present study prospectively analyzed 300 AMA prescriptions obtained from Mahagaon PHC in rural Gulbarga. This is the first of its kind study conducted in a PHC in rural Gulbarga, thus a prior comparator study was lacking.

Regarding immune status, we know that extremes of age i.e. pediatric and geriatric population groups are susceptible to be immune-compromised. However, data from our study suggests that the maximum use of AMAs were in the young-adult age group. A majority of our patients (~30%), were from the age group 21-30 years (table 1). Sex wise distribution was almost uniform as depicted in table 2, with a male: female ratio of 54: 46.

In our study we find that the maximum number of patients either had gastrointestinal tract infections (30.6%) or respiratory tract infections (29%). Eye and ENT related problems were encountered the least in our study (table 3).

From table 4 of the study, we conclude that 50% of the patients were prescribed AMA therapy for 4-5 days. This is in concordance with the fact that most of the antibiotics have a dosing regimen ranging around 5 days. Thus overtly prolonged and irrationally short regimens were avoided.

Most of the AMAs prescribed in the study were administered by the oral route (table 5). Table 5 clearly states that whopping 82% (246) of all prescribed AMAs were administered by oral route. Out of them, 183 were oral tablets and 63 were oral syrup formulations. Parenteral AMAs were used in only 18 patients (6%).

Table 6 of the study deals with the number of drugs prescribed per prescription. From this table we conclude that 85% of the patients were administered 1-3 drugs/prescription. This is a positive finding as we see a decline in the practice of polypharmacy.

Table 7 of our study deals with the availability of the prescribed drugs in the PHC pharmacy. A majority of the prescribed drugs (58%) were found to be available in the PHC pharmacy. This is also a positive finding as it is beneficial for the patients of poor socio-economic background. However, as responsible physicians, our aim should be to raise this percentage even higher.

Next we deal with the treatment administered according to the intent. Table 8 states that 94% of the patients were given therapeutic treatment, while prophylactic treatment was employed only in 6% of the cases. Prophylactic treatment was mostly employed in the cases of trauma to prevent infection.

Table 9 from the study deals with the outcome of AMA treatment administered to the patients in the PHC. A majority of the patients (91%) reported alleviation of their symptoms. Three (3) patients in the study expired due to severity of the disease process and because their treatment was started late.

Table 10 of the study deals with the various drugs employed in therapy of patients attending the PHC. From our study we see that the AMA prescribed most commonly was Cefixime (~11%), a 3rd generation cephalosporin. The other commonly prescribed AMAs were Ofloxacin, Ciprofloxacin and Amoxicillin. Next we deal with the combinational AMA therapy used. Table 10 of the study shows that the most commonly used AMA combination was Ofloxacin + Ornidazole (~10%). This was followed by the well-known synergistic drug combination Cotrimoxazole, i.e. Trimethoprim + Sulfamethoxazole (~7%).

Table 10 of our study also deals with the adjuvant drugs prescribed along with the AMAs. From this we conclude that Paracetamol (~60%) was prescribed as an adjuvant to a vast majority of the patients. Other common drugs used were, Chlorpheniramine (n=135) and Diclofenac (n=75).
**SUMMARY:** Rational use of antibiotics is an area where physicians can harmonize their efforts with a multidisciplinary team for assuring best possible drug use. The results indicate that a satisfactory standard has been maintained in several areas in the studied PHC. Even more judicious use of antibiotics is recommended and specific therapy should be promoted over empirical therapy.

This study needs to be extended and repeated over time to maintain good quality healthcare in the PHC.

**LIMITATIONS:** Time and financial constraints limited our ability to follow-up the patients, thus probable side effects and ADRs might have been overlooked.

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