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Original Research Article

# Antibiotic Utilization Study in the Department of Surgery of a Teaching Hospital and Research Centre

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Abstract: Antibiotics are medications that are used to prevent and treat bacterial infections. Irrational use of antibiotics is a common problem which leads to antibiotic resistance and adverse reactions. In general surgeries there are a number of antibiotics that are being used for number of conditions however judicious selection and use of antibiotics are of utmost importance. This study tries to find the antibiotics used in General Surgery in different patients and find out if there are any adverse reactions reported by their use. The study was conducted in Shadan Medical College Hospital and Research Center the patients were randomly selected from the Department of General Surgery and 100 cases were selected and studied. All the data was recorded including the drug efficiency and compliance and ADR based on Naranjo Scale. Most common condition causing the use of antibiotics was Cholecystitis 29% followed by Inguinal Hernia 25% and Appendicitis 20%. Most common Route of administration was IV 82%, most common IV antibiotics used were Beta-Lactum group 66.65% most common of antibiotic used was Cefipime + Sulbactam 19.5%. Around 25% of subjects reported with Adverse Drug Reactions, the commonest ADR was Nausea 8% Vomiting 5% Diarrhoea 4%. Antibiotics are commonly prescribed before, during and after surgical procedures. The best results were obtained from Beta-lactam class of antibiotics were as Fluroquinolones and Antifungal agents were found to be effective only 50% of patients. Adverse Drug Reactions were minor and well managed. However use of culture and sensitivity and more strict prescription pattern should be followed in order to overcome the bacterial antibiotic resistance which is a potential threat for use of antibiotics.

Keywords: Antibiotics, Drug utilization, Anti-Microbial Agents

### INTRODUCTION

Discovery of antibiotics has started a new era in modern medicine with change in approach and treatment of infectious diseases. Antibiotics are most commonly are prescribed drugs in hospital setup [1]. Antimicrobial agents are costliest group of drugs and accounts together for 20-50% of total drug expenditure [2-4]. In developing countries like India cost of drugs is one of the major concern both to health care professionals and patients. It is generally estimated that up to 50% of antibiotic prescriptions for therapy and prophylaxis are inappropriate [5]. Surgical patients are generally high consumers of antibiotics as there are high incidences of infections. Surgical site infections are most common hospital acquired infections in patients undergoing surgery and it can result in extended hospitalization and increased health care burden [6]. Antimicrobial prophylaxis has been included on infection control options. During the past

three decades, the use of surgical antimicrobial prophylaxis has markedly reduced the incidence of SSIs [7, 8]. But Sepsis is still one of the most common causes of death in surgical patients treated in the intensive care unit [9]. Superficial and deep surgical site infections are the third most frequently reported type of nosocomial infection, accounting for over 10% of all health care related infections. The promptness of diagnosis and treatment of postoperative infections are important, influencing outcome. Postoperative infections may be disastrous [10]. They always result in suffering for the patient and often prolonged hospitalization. Furthermore, they result in additional expenses to cover the cost of antibiotics, blood derivatives, total parenteral nutrition, nursing and additional surgical procedures. However indiscriminate use of antibiotics in hospitals has resulted in emergence of resistant microorganisms increased costs and ADRs and treatment failures. Inappropriate use of broad

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spectrum antimicrobial agents by clinicians for treatment of infections has caused emergence of antibiotic resistance opportunist pathogens [11, 12]. In past few years nearly half of antibiotic drug prescriptions were found to be poorly selected or inadequate [13]. Several studies have underlined the importance of strict adherence to validated guidelines for prescription of antimicrobials and development of monitoring system with each institution for antimicrobial usage [14, 15]. Most of the studies published on antibiotic prescribing in every practice have analyzed the follow up evidences based on guidelines, costs and microbial resistance [16]. Those studies which have focused on ADR of antibiotic prescribing at the population level are equivocal on the question of whether higher antibiotic prescribing rates leads to increased hospital admission rates due to serious complication from bacterial infections higher rates of antibiotic prescribing have been found to lead to increased likely hood of preventable ADRs [17]. With this background we tried to evaluate the effectiveness of antibiotic usage in a Teaching Hospital and Research center located in Hyderabad.

# MATERIALS AND METHODS

This prospective study was done to assess the pattern of AMA use for surgical patients in Shadan institute of Medical Sciences Hospital, criteria for selection, efficacy and tolerability of AMAs to evaluate the treatment outcome. Approval and clearance from the institutional ethics committee was obtained before starting the study. Written informed consent was obtained from the patients/legal representatives after fully explaining in their own language to their satisfaction. Purposive sampling involving 100 consecutive subjects admitted for surgery in various specialties and receiving AMAs were included in the study. The clinical history relevant to present surgical problem, comorbid illness and drug history were documented. The laboratory data including blood culture sensitivity/resistance pattern were also recorded. The AMAs/AMA combinations used the criteria for selection, dose, route, frequency and duration of administration and any change in AMA therapy was recorded. The efficacy of AMA therapy was assessed treatment outcome based on clinical and by bacteriological criteria. The tolerability of AMAs/AMA combinations was assessed by monitoring adverse events and drug interactions if any were recorded. All the relevant date were entered and documented in case record forms (CRF). The data collected were analyzed by using descriptive statistics, namely mean and standard deviation for quantitative variables.

### Inclusion criteria

- Hospitalized subjects under specialty Surgery in the age group of 18-65 years from either gender with common surgical problems
- Willingness to give written informed consent and available for further follow-up, if any.

### Exclusion criteria

- Age group <18
- Pregnant and lactating women
- Subjects admitted in Intensive Care Unit

### RESULTS

The patients were included in age group between 18 to 65 years. There were about 44% of males and 56% females included in the study. The most common diagnosis for patients was cholecystitis 29 % followed by inguinal hernia 25% and Appendicitis. Abcess accounted for 10% surgical cases and Hemorrhoids for 8%. Others included Hydrocele, Perineal Tear 5% and 3% respectively

|                                | Male   | Female | Total   |
|--------------------------------|--------|--------|---------|
| Predominant type of infection* | (n=44) | (n=56) | (n=100) |
|                                | n      | n      | %       |
| Sepsis                         | 18     | 17     | 35      |
| Cystitis                       | 10     | 20     | 30      |
| Abscess                        | 7      | 8      | 15      |
| Generalized Infection          | 4      | 2      | 6       |
| Nonspecific <sup>†</sup>       | 7      | 7      | 14      |

**Table 1: Predominant Type of Infection** 

In general 35% of the subjects had sepsis and 30% had cystitis and 15% had abscess and 14% had Non-specific infection and 6% had generalized infection. Out of the subjects 26% had more than one

type of infection shown in table 1. Severity of infection seen was mild infection in 20% of the patients and moderate in 70% and severe in 9% of the individuals and one individuals was with frank septicemia.



Fig 1: Shows the Route of administration of AMAs in patients

|     | Table 2. Anti-Microbial Agents used or any |           |     |        |     |       |        |
|-----|--|-----------|-----|--------|-----|-------|--------|
|     |  |           | Ma  | le     | Fer | nale  | Total  |
|     | AMA class & generic name                   | Dosage    | (n= | (n=11) |     | 7)    | (n=18) |
|     |  |           | n   | %      | n   | %     |        |
| Ι   | Flouroquinolones                           |           |     |        |     |       |        |
|     | Ofloxacin                                  | 200mg BID | 2   | 11.11  | 1   | 5.55  | 3      |
|     | Ciprofloxacin                              | 500mg BID | 0   | 0      | 0   | 0     | 0      |
|     | Levofloxacin                               | 500mg BID | 1   | 5.55   | 0   | 0     | 1      |
|     | Norfloxacin                                | 500mg BID | 0   | 0      | 0   | 0     | 0      |
| II  | Beta-lactams                               |           |     |        |     |       |        |
|     | Cefixime                                   | 200mg BID | 5   | 27.77  | 2   | 11.11 | 7      |
|     | Cefpodoxime proxetil                       | 200mg BID | 3   | 16.66  | 2   | 11.11 | 5      |
| III | III Antifungal agents                      |           |     |        |     |       |        |
|     | Fluconazole                                | 200mg OD  | 0   | 0      | 2   | 11.11 | 2      |

The oral Anti-Microbial Agents AMAs were used in 18% of the patients most commonly used were the Beta-lactum group used in 12 patients followed by Fluorquinolones in 4 patients and antifungal agents in 2 patients shown in table 2

|     | AMA class & generic name | Dosage         | Male<br>(n=33) |      | Female<br>(n=49) |       | Total<br>(n= 82) |
|-----|--------------------------|----------------|----------------|------|------------------|-------|------------------|
| T   |                          |                | n              | %    | n                | %     |                  |
| I   | Floroquinolones          |                |                |      |                  |       |                  |
|     | Ofloxacin                | 200mg BID      | 4              | 4.87 | 2                | 2.43  | 6                |
|     | Levofloxacin             | 500mg OD       | 1              | 1.21 | 1                | 1.21  | 2                |
| II  | Beta-Lactams             |                |                |      |                  |       |                  |
|     | Piperacillin+ Tazobactam | 2.25-4.5Gm BID | 2              | 2.43 | 0                | 0     | 2                |
|     | Cefuroxime+Sulbactam     | 1.5Gm BID      | 2              | 2.43 | 6                | 7.31  | 8                |
|     | Ceftriaxone              | 1-2Gm BID      | 4              | 4.81 | 9                | 10.97 | 13               |
|     | Ceftriaxone+Sulbactam    | 1.5Gm BID      | 2              | 2.43 | 2                | 2.43  | 4                |
|     | Cefoperazone+Sulbact     | 1.5Gm BID      | 5              | 6.09 | 9                | 10.97 | 14               |
|     | Cefipime+Sulbactam       | 1.5Gm BID      | 7              | 8.53 | 9                | 10.97 | 16               |
|     | Meropenem                | 1Gm BID        | 0              | 0    | 2                | 2.43  | 2                |
| III | Aminoglycosides          |                |                |      |                  |       |                  |
|     | Amikacin                 | 250-500mg BID  | 3              | 3.65 | 3                | 3.65  | 6                |
|     | Gentamicin               | 60 mg BID      | 0              | 0    | 2                | 2.43  | 2                |
| IV  | Nitroimidazoles          |                |                |      |                  |       |                  |
|     | Metronidazole            | 500mg TID      | 2              | 2.43 | 3                | 3.65  | 5                |
|     | Ornidazole               | 200 mg BID     | 0              | 0    | 1                | 1.21  | 1                |
| V   | Lincosamides             |                |                |      |                  |       |                  |
|     | Clindamycin              | 600mg BID      | 1              | 1.21 | 0                | 0     | 1                |

| Table 3. Anti-Microbial Agents used Intravenou            | nslv | ΓIV | 1 |
|---|------|-----|---|
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The table 3 shows that most commonly used Intravenous Antibiotics were the Beta-lactum group which accounted of 59 patients out of the total 82 patients (71.95%) and in 8 (9.75%) patients Fluoroquinolones as well as Aminoglycosides were used Nitroimidazoles were used in 6 (7.32%) and Lincosamides was used in 1 patient only. Most of the AMAs were used in their standard adult titrated doses and frequency Fluoroquinolones and Nitroimidazoles were given as intravenous infusions Clindamycin was used in subject (n=1) was given in combination with Meropenem empirically in subject who had associated renal infection. The total duration of treatment varied from 5 days to 12 days and mean duration recorded was 9.2 days. Apart from AMAs, adjuvants like urine alkalizing agents sodium citrate, sodium bicarbonate, urinary anti-spasmodics like Flavoxate, Dicyclomine, Hyoscine and Probiotics (lactobacilli) were also used.

Among 18 of total patients subjected to oral AMA therapy based on the severity of infection 2 out of 4 subjects treated with Flouroquinolones did not show positive outcomes. And among 82 patients subjected to Intravenous AMA therapy highest outcome was seen in patients treated with Beta-lactam antibiotics. 2 subjects treated with Flouroquinolones and Lincosamides respectively did not show positive response. So the drugs were changed accordingly.

|                       | Male   | Female | Total  |  |  |
|-----------------------|--------|--------|--------|--|--|
| Adverse events*       | (n=12) | (n=13) | (n=25) |  |  |
| Nausea                | 4      | 4      | 8      |  |  |
| Nausea with vomiting  | 4      | 1      | 5      |  |  |
| Diarrhea              | 2      | 2      | 4      |  |  |
| Abdominal pain/cramps | 0      | 3      | 3      |  |  |
| Skin rashes           | 0      | 1      | 1      |  |  |
| Altered taste         | 2      | 2      | 4      |  |  |

**Table 4: Adverse Drug Reactions ADRs** 

As shown in the table 4 the total numbers of people with ADRs were found in 25% of the total 100 patients studied. Most common adverse reaction was Nausea and Nausea with vomiting was seen in 5 patients. Other minor reactions varied from abdominal pain to rashes and altered taste was seen in 4 individuals. The mild skin rashes observed in one subjects were probably due to Ceftriaxone and was selflimiting, did not require change in. No serious complications were noted during the therapy.

### DISCUSSION

In the present study the pattern of AMA use surgical patients was assessed in 100 hospitalized subjects in various specialties of SIMS hospital and research Centre. The study tries to provide a detailed outlook about antibiotic prescription pattern in a teaching Hospital. However lack of computerized software regarding the drug utilization analysis makes this kind of study a time consuming exercise. The general antibiotic prescription pattern in the hospital was empirical and samples were seldom sent for culture and sensitivity testing in spite of available facilities. In the present study if was found that IV route of drug administration was mainly preferred as it was used in 82% of the patients and oral route was only used in 18% of the patients. Generally IV routes are preferred in surgical patients because antibiotics are more effective with quicker onset of action, rapid attainment of desired plasma levels and higher efficacy which is usually required in surgical procedures. Also Surgical Site Infections SSIs are most common complication

following surgery 1% of patients undergoing clean surgeries (Ex hernia) and 11% of undergoing cleancontaminated surgery experiences SSIs [18]. The SSIs poses several problems to the patients who include pain, delay in wound healing, delay in subsequent treatment and loss of time and work. Patients who experience SSIs are five times more likely to be readmitted and die as compared to those without.

The Anti-Microbial Agents [AMAs] used by the oral route included the FQs (Ofloxacin, Ciprofloxacin, Levofloxacin and Norfloxacin), 3rd generation cephalosporin's (Cefixime, Cefpodoxime-Proxetil), Nitro furans (Nitrofurantoin) and the azole antifungal agent (Fluconazole). These oral AMAs were preferred as first-line agents because of their good oral bioavailability and tolerability, particularly in cases of mild infections without any complicating factors, or as oral switch-over therapy following initial parenteral therapy with the respective AMAs of the same class. These observations were consistent with the other studies. The dose of the AMAs was in accordance to the standard guidelines [19]. The most commonly used AMAs by Intravenous route were Beta-lactams 72% and Fluroquinolones (10%) The most commonly used Fluoroquinolone was Ofloxacin (7%) and among the beta-lactams, ceftriaxone (16%) was used. Other classes of AMAs used were aminoglycosides including amikacin. Fluroquinolones and the Nitroimidazoles were given by IV infusion and others by slow IV injection [19].

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In majority of the subjects (88%) the duration of therapy ranged from 6-10 days with the mean duration of  $9.2 \pm 2$  days, the duration of the therapy was >10 days in only 9 % of the subjects and <5 days in 3% of the subjects. There were no gender related differences in the duration of therapy. Subjects with mild symptoms showing rapid clinical improvement required a shorter duration of therapy of < 5 days. A longer duration of therapy of >10 days was required in subjects with comorbid conditions and for infections involving resistant organisms. In other studies the overall duration of therapy ranged from 5- 20 days. Though there are no standardized guidelines for optimal duration of AMA therapy, the duration of therapy is generally determined by the site and severity of infection. the likely pathogens and their susceptibility/resistance patterns and also on the management/control of comorbid conditions and risk factors.[20] The adverse events related to AMA therapy were recorded only 25% of the subjects Minor ADRs were noted based on Naranjo scale (3-5 score) [21] had the adverse events which were mainly gastrointestinal (Nausea, Vomiting, Diarrhea, Abdominal Pain/cramps), cutaneous (skin rashes) and taste disturbances (altered taste). However the causality of various adverse events could not be ascertained because of the concomitant administration of several AMAs.

### CONCLUSIONS

The overall scenario of antibiotic usage in a Teaching Hospital was as per standard recommendations and all the antibiotics used were according to their standard adult and titrated doses and frequencies. The best results were obtained from Beta-lactam class of antibiotics were as Fluroquinolones and Antifungal agents were found to be effective only 50% of patients. Adverse Drug Reactions were minor and well managed. However use of culture and sensitivity and more strict prescription pattern should be followed in order to overcome the bacterial antibiotic resistance which is a potential threat for use of antibiotics.

### CONFLICT OF INTEREST: None

### SOURCE OF SUPPORT: Nil

### ETHICAL PERMISSION: Obtained

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