

## Original Research Article

# Compliance of surgical antimicrobial prophylaxis practices in the departments of general surgery and orthopaedics at a tertiary care centre in India

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### ABSTRACT

**Background:** Antimicrobial (AM) prophylaxis is one of the major interventions to prevent surgical site infections. The guideline recommendations are meant for helping the surgeons to select the rationale and effective approach while. This study aimed to assess the compliance of surgical AM prophylaxis in terms of choice of antibiotic, duration and timing of administration using standard international and national guidelines.

**Methods:** A prospective observational study was done in General Surgery and Orthopaedics over a period of one year. All the relevant data was collected and analysed. Results were then compared with standard Clinical Practice Guidelines (CPGAS-2013 and ICMR-2017).

**Results:** In terms of choice of AM, 31.32% of the cases from general surgery and 97.59% of the cases from orthopaedics according to ICMR 2017 guidelines; 28.91% of the cases from general surgery and none of the cases from orthopaedics according to CPGAS 2013 guidelines were found to be compliant. In terms of duration of prophylaxis, 28.91% and 22.89% of the cases from general surgery were found to be compliant to ICMR 2017 and CPGAS 2013 guidelines respectively; but none of the cases from orthopaedics were compliant to either of the guidelines. Timing of administration was found to be compliant with the guidelines in both the departments.

**Conclusions:** Surgical prophylaxis practices were found to be partially compliant with the guidelines in the selected departments.

**Keywords:** AM, Antibiotic, Antimicrobial prophylaxis, Antimicrobial stewardship practices, Compliance

### INTRODUCTION

Antimicrobial (AM) Stewardship Programme practices are at primitive state in Indian healthcare settings despite the existence of standard guidelines, and according to the evidence shown by the national level survey carried out by the Indian Council of Medical Research (ICMR) in the year 2013, only up to 30% of the healthcare institutions have been found out to be practicing the AM stewardship guidelines and recommendations.<sup>1</sup> Analysis of the data regarding the AM consumption between the years 2000 and 2010 shown that there is an increase in the

consumption of AM agents with increased usage of the last resort AMs to treat the infections. All these findings have shown the need for the rationale prescription of these agents and the compliance with the guidelines and recommendations.<sup>2</sup> Most of the data at the global level also shows inappropriateness in the surgical AM prophylaxis.<sup>3</sup> Prophylactic AM administration in order to prevent the infection and there by promoting the wound healing without any complications at the surgical site is the core aspect of undertaking any surgical procedure.

Present study is carried out to see the prescription pattern of AM agents for the surgical prophylaxis taking two major surgical departments into consideration and their compliance with recommendations by the ICMR 2017 and the CPGAS (Clinical Practice Guidelines for AM Prophylaxis in Surgery) 2013 was analysed.<sup>4,5</sup>

**METHODS**

It was a prospective observational study carried out over a period of 12 months from April 2018 to April 2019 in the departments of General Surgery and Orthopaedics after approval by the institutional ethics committee. Patients were recruited prospectively. Case report forms are used to collect the data including patient demographics, diagnosis, AMs used for the prophylaxis including the formulation, dosage, duration etc. Timing of administration before surgical procedure was also noted. Surgical wounds were classified using Centre for Disease Control (CDC) guidelines. The choice of AM agent, duration of prophylaxis and the timing of administration was compared with the national (ICMR 2017) and the International (CPGAS 2013) guidelines to see the compliance of AM prophylaxis with guideline recommendations.

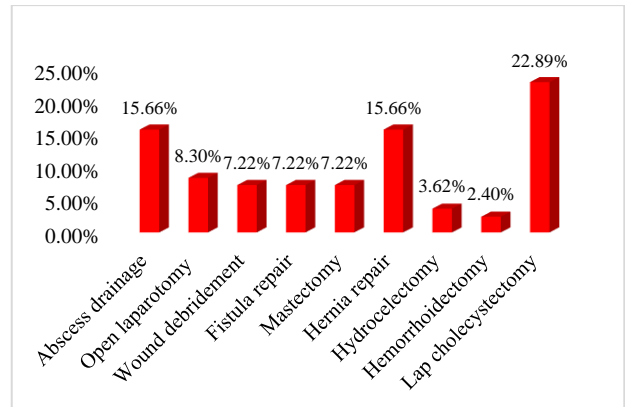
**Statistics**

Data was analysed using the descriptive statistics in SPSS and the results were expressed as means and proportions.

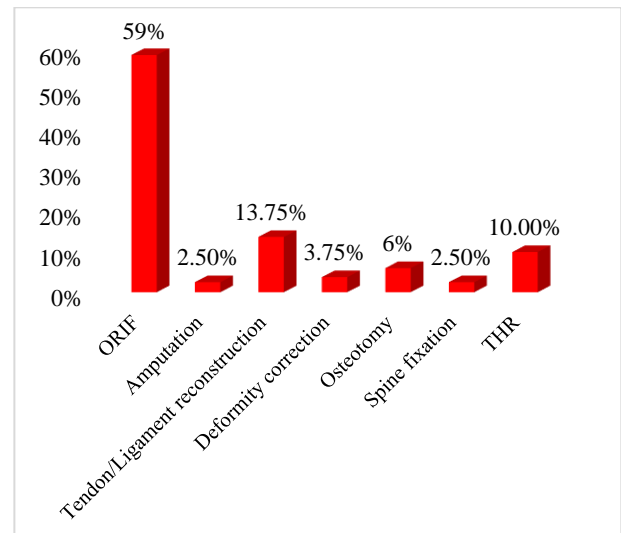
**RESULTS**

In the present study 163 patients underwent various surgical procedures with AM prophylaxis. Age of the patients was ranging from 22 to 65 years (mean-43.79 years) with 86 (42.36%) females and 117 (57.63%) males. Comorbidity analysis showed 4 patients (3.8%) had diabetes in General surgery and 3 patients (3%) were found to be hypertensives in orthopaedics department. Regarding type of wound, 3.6% are infected/class IV wounds and the rest all (97.59%) were clean/class I wounds from the department of orthopaedics; whereas, 26.5% are clean/class I wounds, followed by infected/class IV (36.14%), clean-contaminated/class II (31.32%) and contaminated/ class III (6%) from the department of general surgery. Regarding formulations used, 82.56% of the formulations were injectables and 17.43% were oral formulations from the department of general surgery; whereas, all the formulations were injectables from the department of orthopaedics. Lap cholecystectomy was the major surgery (22.89%) followed by hernia repair and abscess drainage (15.66% each type) in general surgery (Figure 1); open reduction and internal fixation (ORIF) was the most commonly performed surgery (59%) followed by tendon/ligament repair (13.25%) and total hip replacement (thr) (10.84%) in orthopaedics (Figure 2). Table 1 shows the surgeries performed and the AM used for prophylaxis in general surgery. Table 2 shows

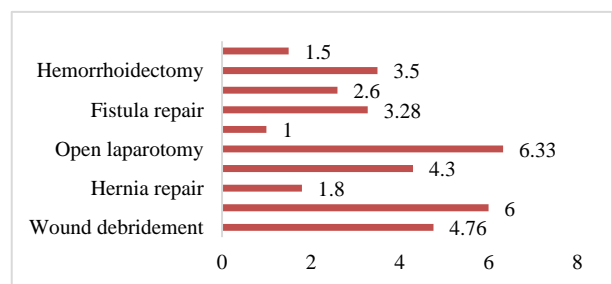
the surgeries performed and the AM used for prophylaxis in orthopaedics.



**Figure 1: Surgeries performed in the department of general surgery.**



**Figure 2: Surgeries performed in the department of orthopaedics.**



**Figure 3: Mean duration of AB treatment (days) in surgery.**

Time of administration of AM was found to be 30 minutes before any surgical procedure in both the departments. Mean duration of AM prophylaxis in general surgery was ranging from 1 day for lap cholecystectomy to 6.33 days for open laparotomy

(Figure 3). Mean duration of AM prophylaxis in orthopaedics was ranging from 2.62 days for tendon/ligament reconstruction to 5.3 days for spine fixation (Figure 4). Choice of AM for prophylaxis, duration of prophylaxis and the timing of administration before commencing the surgical procedure were compared with the ICMR 2017 guidelines and with the CPGAS 2013. In general surgery, according to the ICMR guidelines, the choice of AM for the performed surgeries was found to be appropriate in 31.32% of the cases; while according to the CPGAS guidelines, 22.89% of the procedures were found to have been used the appropriate AM for the prophylaxis. In Orthopaedics, 97.59% of the

procedures were found to be using the appropriate AM for the prophylaxis according to the ICMR guidelines; whereas none of the procedures were found to be using the appropriate AM according to the CPGAS guidelines. Regarding duration of AM prophylaxis, 22.89% of the cases (lap cholecystectomy) from general surgery were compliant to the both ICMR and CPGAS guidelines; but none of the surgical procedures in Orthopaedics were found to be compliant either to the ICMR guidelines or to the CPGAS guidelines. Timing of administration of AM was found to be compliant with both the guidelines from both the departments (Table 3).

**Table 1: Surgeries and AM used for prophylaxis in general surgery.**

Wound class (no. of cases)	Surgeries performed- no. of cases	Antibiotic used for prophylaxis
<b>Clean/class-I (22)</b>	Mastectomy-6; Hernia Repair-13; Hydrocelectomy-3	Ceftriaxone ± metronidazole
<b>Clean contaminated/class-II (26)</b>	Lap Cholecystectomy-19; Anal Fistula Repair-5; Haemorrhoidectomy-2	Ciprofloxacin/ceftriaxone with metronidazole
<b>Contaminated/class-III (5)</b>	Appendectomy-5	Ceftriaxone ± metronidazole
<b>Infected/class IV (30)</b>	Abscess drainage-13; Open laparotomy for Perforation peritonitis-10; wound debridement-6	Ceftriaxone/ piperacillin + tazobactam/ clindamycin with metronidazole

**Table 2: Surgeries and AM used for prophylaxis in orthopaedics.**

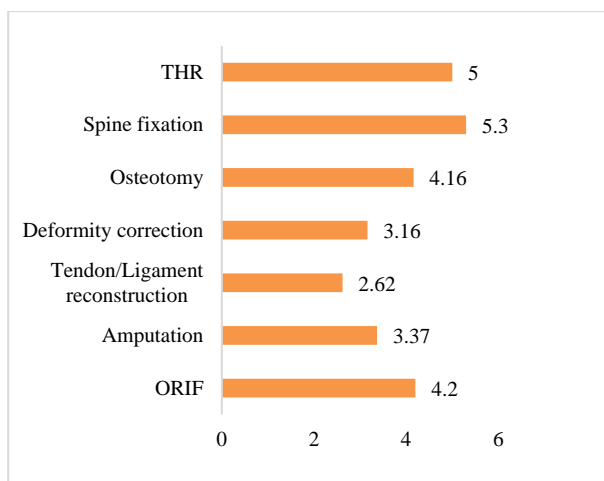
Wound class (no. of cases)	Surgeries performed- no. of cases	Antibiotic used for prophylaxis
<b>Clean/class I (78)</b>	ORIF-49; Tendon/Ligament Reconstruction-11; Deformity correction-3; Osteotomy-5; Spine fixation-2; THR-8	Cefuroxime±amikacin
<b>Infected/class IV (2)</b>	Amputation	Cefuroxime+amikacin+metronidazole

**Table 3: Compliance comparison.**

Department	Compliance					
	Choice of AM (%)		Duration (%)		Timing of administration (%)	
	ICMR 2017	CPGAS 2013	ICMR 2017	CPGAS 2013	ICMR 2017	CPGAS 2013
<b>Surgery</b>	31.32 (26)	28.91 (24)	22.89 (19)	22.89 (19)	100	100
<b>Orthopaedics</b>	97.59 (78)	None	None	None	100	100

**Table 4: Pathogen specific AM therapy according to the pathogen isolated (ICMR 2017 guidelines document).**

Surgical wound classification	Common organisms	Antimicrobial prophylaxis
<b>Class I/clean</b>	Gram positive <i>cocci</i> ( <i>S. aureus</i> , <i>CoNS</i> )	None or single perioperative dose of cefuroxime/ cephalexin (Ideally 2 grams)
<b>Class II/ clean-contaminated</b>	Gram negative <i>Bacilli</i> Anaerobes <i>S. aureus</i>	1 <sup>st</sup> Line: Cefazolin or ampicillin sulbactam or ceftriaxone (in patients of acute cholecystitis or acute biliary tract infections) Alternative: In case of allergies; if mixture of GP and GN is suspected: Ceftriaxone only if not ESBL clindamycin or vancomycin with cefazolin, aztreonam, gentamicin, or single-dose fluoroquinolone in blactam allergic
<b>Class III/contaminated</b>	Gram negative <i>Bacilli</i> anaerobes	1st line: Cefazolin + metronidazole 2nd Line: Metronidazole + aminoglycoside/ fluoroquinolone
<b>Class IV/dirty-infected</b>	Gram negative <i>Bacilli</i> Anaerobes may be mixed with Gram positive bacteria	1 <sup>st</sup> Line: Cefazolin + metronidazole, Treatment for infected surgical wounds ertapenem + clindamycin + aminoglycoside/aztreonam or fluoroquinolone+ metronidazole + aminoglycoside/fluoroquinolone



**Figure 4: Mean duration of AB treatment (days) in orthopedics.**

## DISCUSSION

As the incidence of AM resistance is increasing with a very few numbers of AM being developed in the recent past, there is an immense need for the rational use of AMs to prevent the adverse events associated with the irrational usage of the same. The standard guidelines provide the basis for the rationale prescription of the AMs and thereby help in preventing the development of resistance.<sup>6</sup> This present study had focused on the surgical AM prophylaxis practices among the two major surgical departments i.e., General surgery and orthopaedics. Majority of the formulations used for the surgical prophylaxis were of intravenous agents (General surgery-82.56%; Orthopaedics-100%). These findings were comparable to the studies reported by Andrajati et al, Fennessy et al, and Khan et al.<sup>7,8,9</sup> The Centres for Disease Control and Prevention (CDC) had given a classification system to classify the surgical wounds to indicate the patients who are prone for developing the infections at the site of incision and to prevent the infection during any surgical procedure. So, it is important to know the type of wound before prescribing the AM for the prophylaxis.<sup>10</sup> In this study majority of the wounds were of clean/class I (97.59%) and the rest being of the class IV/infected (3.6%) from the department of Orthopaedics where as in general surgery, all four classes of wounds were reported with class IV/infected wounds being reported at a high percentage (36.14%) during the study. Infection at the site of incision during any surgical procedure is most common incidence to come across as a hospital acquired infection among the patients undergoing various surgeries, and it is important to prescribe appropriate antibiotic before commencing any surgical procedure. Inappropriate use of AMs especially in terms of choice of antibiotic, dose, duration of treatment with the AM agent may not only increase the risk of infections at the surgical site but also development of resistance to the existing antibiotics.<sup>11</sup> Guidelines of national and global importance will help the surgeons to

select an appropriate antibiotic, especially when the institute does not have a well-established AM policy. Indian Council of Medical Research has been a body of utmost importance in providing the guidelines for antimicrobial stewardship programmes in healthcare settings across the nation and thereby ensuring the rational prescription of antibiotics. Whereas, Clinical Practice Guidelines For, antimicrobial prophylaxis in surgery (CPGAS) were developed jointly by the American Society of Health System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS) and the Society for Healthcare Epidemiology of America (SHEA) to guide the healthcare professionals in using the antibiotics appropriately based on the clinical evidence available so far.<sup>12</sup>

In this study we have compared the results in terms of choice of AM prescribed for the prophylaxis, duration and the timing of administration during surgical procedure with the guidelines to see the compliance of antimicrobial surgical prophylaxis practices among the two major surgical departments. According to the ICMR 2017 guidelines, clean/ class I wounds are to be given no or a single peri-operative dose of cefuroxime/cephalexin (Ideally 2 gm). Clean-contaminated/class II wounds are to be given cefazolin/ampicillin-sulbactam/ceftriaxone (in patients of acute cholecystitis and acute biliary tract infections) as first line prophylactic agents. Contaminated/class III wounds are supposed to be given cefazolin + metronidazole as first line and metronidazole +aminoglycoside/fluoroquinolone as the second line agents for prophylaxis. Class IV/dirty-infected wounds are to be given cefazolin and metronidazole, and in case of infected surgical wounds ertapenem and clindamycin and aminoglycoside/aztreonam or fluoroquinolone and metronidazole and aminoglycoside. (Table 4) In this study, class I/clean wounds in the department of general surgery were given ceftriaxone with or without metronidazole which was found to be inappropriate according to the ICMR guidelines. Class II/ clean-contaminated wounds were given either ciprofloxacin or ceftriaxone with or without metronidazole which was considered to be appropriate. Class III wounds were given ceftriaxone and metronidazole whereas class IV wounds were given ceftriaxone or piperacillin + tazobactam or clindamycin along with metronidazole which were again inappropriate according to the ICMR guidelines. Similar findings were reported using the combination of cephalosporin with anti-anaerobe in a study reported by Kulkarni et al.<sup>13</sup> Another Indian study reported by Kamath et al also had shown the increased use of cephalosporins for surgical prophylaxis.<sup>14</sup> In Orthopaedics, clean/class I wounds were given cefuroxime with or without amikacin which was considered to be appropriate and infected/class IV wounds were given cefuroxime + amikacin + metronidazole which was inappropriate according to the guidelines.

According to CPGAS 2013 guidelines, Cefazolin is the antibiotic of choice as a prophylactic agent in many surgical procedures except in few cases like biliary tract infections, appendectomy for uncomplicated cases and small intestinal obstruction where cefoxitin, cefotetan, ceftriaxone, ceftriaxone and metronidazole, ampicillin + sulbactam and cefazolin and metronidazole also can be considered. In this study, in the department of general surgery, only class II and class III wounds were given appropriate antibiotics according to the guidelines (ceftriaxone/ciprofloxacin with or without metronidazole). Administration of AM for a long duration will not provide any extra benefits, rather it will lead to extra burden in terms of cost and unnecessary side effects like toxicity and development of resistance.<sup>15,16</sup> Though the best possible shortest duration of AM prophylaxis is unknown, most of the guidelines including the ICMR and the CPGAS suggest either single dose or duration exceedingly not more than 24 hours for majority of the surgical procedures. In this study duration of administration of antibiotic for prophylaxis was ranging from one day for lap cholecystectomy to 6.33 days for open laparotomy in general surgery and; 2.62 days for tendon/ligament reconstruction to 5.3 days for spine fixation in orthopaedics. Similar results of prolonged duration of AM prophylaxis post-surgery were reported by Nagdeo et al, Hosoglu S et al and Kulkarni et al.<sup>13,16,17</sup> One of the factors ensuring better antimicrobial prophylaxis practices is to administer the drug in the right time, if not, may lead to suboptimal levels of the drug in the plasma, making the surgical site susceptible for development of infection post-surgery. According to both ICMR 2017 and CPGAS 2013 recommendations, the timing of AM administration for prophylaxis should be ideally 30-60 minutes prior to surgery. In this study the timing of administration was half an hour before the incision in all the surgical procedures which was appropriate according to the guideline recommendations. Choice of antibiotic was appropriate in general surgery by 31.32% according to ICMR recommendations and by 28.91% according to CPGAS recommendations. While both the guidelines suggest cefazolin as the prophylactic agent of choice for majority of surgical procedures, most of the patients in general surgery department were given ceftriaxone as a prophylactic agent with or without an anti-anaerobic agent. This finding of lower adherence to guidelines was comparable to a study reported by Ayele et al, where most of the patients were managed by ceftriaxone for prophylaxis despite the guidelines suggesting cefazolin. Other studies reporting the same finding in terms of choice of antibiotic for prophylaxis were Kaya et al which showed 59.1% adherence to the guidelines (CPGAS).<sup>18,19</sup> Musmar et al, Al-Momany et al, Vessal et al, Shah et al also reported lowest adherence to the international guideline recommendations in terms of choice of antibiotic for prophylaxis.<sup>20-23</sup> In contrast, a study reported by Jaggi et al from India had shown better compliance to both the national and international guidelines in choice, duration and timing of administration of prophylactic antibiotics.<sup>24</sup> In this study,

in orthopaedics department, the choice of antibiotic was appropriate in majority of the surgical procedures (97.59%) according to the ICMR recommendations, but, in contrary, none of the procedures were appropriate with regard to choice of AM according to the CPGAS recommendations as the ICMR guidelines recommend cefuroxime/ cefalexin for class I wounds and cefazolin and metronidazole for class IV wounds but CPGAS recommends Cefazolin for the same class of wounds. In this study, all the patients were given cefuroxime with or without amikacin and with metronidazole in addition if the wound is of class IV. One Indian study reported by Mathur et al using the conventional cefuroxime and amikacin regimen had shown no increased risk of surgical site infection compared to cefuroxime alone.<sup>25</sup>

## CONCLUSION

Surgical antimicrobial prophylaxis practices in the selected surgical departments were found to be partially compliant to the guidelines indicating the need for implementation of AMSP and to give feedback to the surgeons in order to consider the benefits of following the guideline recommendations.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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