



## **APPRAISAL OF ANTIBIOTIC PROPHYLAXIS ADMINISTRATION IN GENERAL SURGERY DEPARTMENT OF A MAJOR REFERRAL HOSPITAL**

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### **ABSTRACT**

Antibiotic prophylaxis use lead to substantial decrease in both quantity as well as variations of surgical site infections, although antibiotic prophylaxis practices are tend to be evidence based but generally either that evidence doesn't have that much quality or recommended as expert opinion. To evaluate the efficacy of present practice we have utilized NNIS score and incidence of SSIs. Prospective observational study commenced in a major referral hospital. Patients previously on antibiotics were excluded from the study along with patients severely ill, NRC dirty wound category patients, Cancer Patients and patients with systemic infections. To evaluate efficiency of present practice SSIs incidence was analyzed using NNIS index score and its association with compliance with ASHP SAP guidelines. Overall surgical antibiotic prophylaxis (SAP) administration at study site was done in 96 cases (86.5%) out of all 111; in cases with no SAP administered 46.6% developed SSIs which is far greater than 7.2% cases where SAP was administered. In high risk patients (patients with NNIS score >1), Incidence of SSIs was seen greater than that in patients at lower risk patients with NNIS score ≤1. Full compliance with SAP guidelines comes with an ultimate benefit of reduction in incidence of SSIs which will lead to sure reduction in hospitalization due to SSIs and cost of therapy. Thus SAP administration should be compliant with evidence based recommendations to control emergence of SSIs in general surgery patients whether they are at high risk to develop SSIs or not.

**Key words:** Surgical antibiotic prophylaxis, NNIS, SAP evaluation, PharmD skills, clinical pharmacist, SAP compliance, SAP non compliance, SSIs.

### **INTRODUCTION**

Antibiotic prophylaxis use lead to substantial decrease in both quantity as well as variations of surgical site infections, although antibiotic prophylaxis practices are tend to be evidence based but generally either that evidence doesn't have that much quality or recommended as expert opinion [1]. Thus an appraisal of local institutional surgical antibiotic guidelines with an internationally recommended guideline can surely resolve problems associated with surgical antibiotic prophylaxis like over prescription and unjustified use of antibiotics [2]. Antibiotics inappropriate use lead to increase in resistant pathogens and significantly raised the risk associated with infectious diseases, unnecessary prescription of broad spectrum agents in situations which are well susceptible to more specific agent has lead to a drastic situation that so many of antimicrobials are of no use today [3]. Literature review have shown immediate need of rationalizing use of

antibiotics specially if we are not willing to jeopardize many more effective agents, moreover studies have shown appropriate antibiotic usage significantly decrease hospitalization duration and cost of therapy [4]. Antibiotic inappropriate use can be detected early by review of prescriptions and analyzing them against appropriate guidelines, because prevalence of resistance is more amongst generally used agents [5]. Some regimens for antibiotic prophylaxis used against any guidelines are influenced by righteous factors like antimicrobial resistance and effective treatment during previous use [6]. Besides these factors it is beneficial to establish evidence based guidelines for antibiotic prophylaxis to reduce the risk of surgical site infection (SSIs) [7]. Surgical site infection (SSI) as a term constitutes surgical wound and infection involving body cavity, organ, tissues and region of body involved in surgery [8].

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An inappropriate use of antibiotics enhances the usage of antibiotics, which confirms rational antibiotic therapy can reduce the excessive use of antibiotics [9]. Implementation of guidelines can reduce irrationality in antibiotic usage and additionally improves risk of resistance and cost of therapy [10]. This inappropriateness of antibiotic use has nothing to do with patient burden or any specific age patients but only prescriber's choice influence the use of antibiotics [11]. Longer duration of antibiotic use in prophylaxis doesn't lead to enhanced result in aspects of SSI incidence or mortality [12]. Studies have shown that administration of antibiotic prophylaxis at time other than that specified in guidelines can increase the risk of SSIs [13].

An appropriate antibiotic agent used during prophylaxis ensures desired amount of concentration in blood, tissue and organ during fulltime of procedure reducing any chances of colonization [14]. Although studies revealed resistance of physicians to pharmacists opinion in their practice, strict guidelines of antibiotic use can ensure reduction in antibiotic misuse and chance of antimicrobial resistance [15].

Clinical therapeutics guidelines for antimicrobial prophylaxis in surgery we are using here to appraise hospitals practice is approved by American society of healthcare-system pharmacists (ASHP). They are drafted jointly by ASHP, infectious disease society of America (IDSA) and surgical infection society (SIS); these guidelines intended to guide practitioners based on standardized approach to rational and appropriate use of antimicrobial agents in antibiotic prophylaxis to reduce SSIs [16]. To evaluate the efficacy of present practice we have utilized National Nosocomial infection surveillance (NNIS), wound classification given by National research council (NRC) and American society of anesthesiologists (ASA) score in reduction of risk of SSIs [17].

Antibiotic prophylaxis guideline should drafted keeping in mind local settings which will increase acceptance from practitioners [18]. A study (2009-2011), demonstrated a massive 33% reduction in mean SSI incidence rate from 27.3% without implementation of special surgical protocols including enhancement of compliance with antibiotic prophylaxis to 18.2% during study period [19]. An American study (2009) demonstrated a reduction in infection after implementing preoperative protocols for Surgical Antibiotic Prophylaxis (SAP) in cesarean delivery in women during 4 months, SSIs incidence were brought down from 5.4% to 2.5% along with an improvement in overall compliance with SAP protocols [20]. Thus overall implementation of SAP guidelines leads to reduction in SSIs risk in surgery patients.

## METHODS

Prospective observational study commenced in a major referral hospital. Hospital premises have three units in general surgery department and a total of 100 bed capacity. Well equipped with latest medical equipments. Hospital also concerns with various other departments like general medicine, cardiology, dermatology, orthopedics,

ophthalmology, ENT, gynecology and obstetrics, pediatrics, psychiatry, nuclear medicine, oncology and neurosurgery. Data collection form designed and approved by research advisory board of institution. Data was collected from November 2014 to April 2015, all the adult patients undergoing surgery in general surgery department were included in study. To prevent misinterpretation of SAP from therapeutic antibiotic use, patients previously on antibiotics were excluded from the study along with patients having ASA score 4 and 5. Patients come under NRC dirty wound category were also excluded from study to avoid difficulty in differentiating prolong prophylaxis from SAP. Cancer Patients and patients with systemic infections were also excluded from the study. Data was collected for appropriateness of SAP amongst factors like choice of agent, indication, dose, frequency, continuation and timing of administration. To evaluate efficiency of present practice SSIs incidence was analyzed using NNIS index score and its association with compliance with ASHP SAP guidelines. Data was analyzed, frequency and percentages were calculated.

## RESULTS

Overall surgical antibiotic prophylaxis (SAP) administration at study site was done in 96 cases (86.5%) out of all 111 cases during study period from November 2014 to April 2015 and 15 cases (13.5%) were not administered with any SAP. In cases with no SAP administered 46.6% developed SSIs which is far greater than 7.2% cases where SAP was administered. However from 111 cases only 91 cases required SAP administration but in only 82 cases (73.8%) SAP administration was opted, 8.1% cases required SAP administration but not administered, 20 cases were the ones which did not require SAP administration, however in 14 cases SAP was administered without requirement and lead to overall SAP indication compliance of 79.2% with its counterpart i.e. SAP indication non-compliance of 20.7% as shown in (Table 1).

Amongst all surgical procedures done; Incision and drainage, Appendectomy, Pyelolithotomy, Haemorrhoidectomy, Parotidectomy, Cystolithotomy, Submandibular Gland Excision, G. S. V. Stripping and Thyroidectomy were completely compliant with ASHP recommendations as per SAP agents selected for every surgery (Table 2). Lower compliance in aspect of choice of agent was seen in Feeding Jejunostomy (0%), Ileostomy closure (33.3%), Hernioplasty (40%), Laparotomy (50%), Fistulotomy (50%). But small sample did not allow this study to reach conclusive result in this aspect.

Full compliance to ASHP guidelines for antimicrobial use as prophylaxis in general surgery patients according to present practice at study site goes, in only 6.3% of all the cases were seen with no incidence of SSIs (Table 3). Maximum incidence of SSIs 12.5% was seen in cases where only correct choice of agent was done without compliance to any other parameter of SAP administration, thus to choose a right agent is not enough for controlling SSI incidence in general surgery patients.

In the cases where SAP had been administered, cases with non compliant SAP 29.7% were maximum with 4 SSIs cases out of 33 cases an SSI incidence of 12.1% (Table 3).

In high risk patients (patients with NNIS score >1), Incidence of SSIs was seen greater than that in patients at lower risk patients with NNIS score ≤1 (Table 4). In patients with highest risk (patients with NNIS score 3), all were administered with Partial compliant SAP and emerged with the highest SSIs incidence of 60%. In cases with NNIS score 2, 4 administered with compliant SAP with nil SSIs incidence and 8 were given with Partial compliant SAP with 25% of SSIs incidence. Where as in 7 patients with NNIS score 2, were not administered with

SAP at all which lead to an emergence of 3 (42.8%) cases with SSIs. Even with low risk patients where No SAP was administered, SSIs incidence was found to be more than that of Partial compliant SAP i.e. 50% to 2.5% respectively.

On the whole Compliant SAP administration came with a greater control over SSIs incidence; even patients which were administered with Partial compliant SAP had a less incidence as compare to patients with SAP was not administered. Thus complete compliance with ASHP SAP guidelines did come along with greater control over SSIs incidence in general surgery patients.

**Table 1. SAP indication compliance**

Sr. No.	Surgical Antibiotic Prophylaxis	No. of Cases	Percentage (%)
1	Indicated and Administered	82	73.8%
2	Not Indicated and Not Administered	06	5.4%
3	Indicated but Not Administered	09	8.1%
4	Not Indicated but Administered	14	12.6%

**Table 2. Surgical Antibiotic Prophylaxis agent Prescribed**

Surgical procedure	Antibiotic Regimen Administered	No. of patients
Laparotomy	☐ Cefazolin	8
	☒ Cefuroxime	4
Open Cholecystectomy	☐ Cefazolin	5
	☐ Ampicillin-Salbactam	3
	☒ Cefuroxime	3
CBD Exploration	☐ Cefazolin	7
	☐ Ampicillin-Salbactam	1
	☒ Cefuroxime	3
Laparoscopic Cholecystectomy	☐ Cefazolin	9
	☒ Cefuroxime	2
Hernioraphy	☐ Cefazolin	3
	☐ Vancomycin	3
	☒ Cefuroxime	2
Incision and Drainage	☐ Ampicillin-Salbactam	2
Hernioplasty	☐ Cefazolin	1
	☐ Vancomycin	1
	☒ Cefuroxime	3
Pyelolithotomy	☐ Cefazolin	2
	☐ Ampicillin-Salbactam	1
Appendectomy	☐ Cefazolin + Metronidazole	1
Choledochoduodenostomy	☐ Cefazolin	2
	☒ Cefuroxime	1
Haemorrhoidectomy	☐ Cefazolin + Metronidazole	1
	☐ Ampicillin-Salbactam	1
Ileostomy Closure	☐ Cefazolin	1
	☒ Cefparazone	2
Multiple Gastrointestinal Surgeries	☐ Cefazolin	2
	☒ Cefparazone	3
Fistulotomy	☐ Cefazolin	1
	☒ Cefuroxime	1
Parotidectomy	☐ Cefazolin + Metronidazole	1
	☐ Cefuroxime + Metronidazole	1
G. S. V. Stripping	☐ Cefazolin	1
Submandibuller Gland Excision	☐ Cefuroxime + Metronidazole	1

Cystolithotomy	⊂	Cefazolin	1
Feeding Jeujenostomy	⊄	Cefparazone	1
Thyroidectomy	⊂	Cefazolin	1

Where,

⊂ : Compliant Regimen with SAP guidelines by ASHP

⊄ : Non Compliant Regimen with SAP guidelines by ASHP

**Table 3. SAP Administration compliance and SSI incidence impact**

Surgical Antibiotic Prophylaxis Administration	No. of Cases	Percentage (%)	No. of SSIs	Percentage (%)
Non Compliant Choice of Antibiotic Agent	33	29.7%	4	12.1%
Correct Choice of Antibiotic Agent	25	22.5%	2	12.5%
Correct Choice + Correct Dose	15	13.5%	1	6.7%
Correct Choice + Correct Dose + Correct Time	07	6.3%	0	0%
Correct Choice + Correct Dose + Correct Continuation	09	8.1%	0	0%
Correct Choice + Correct Dose + Correct Time + Correct Continuation	07	6.3%	0	0%

**Table 4. Impact of SAP guidelines compliance and administration on high SSIs risk patients**

NNIS Score	Compliant SAP			Partial Compliant SAP			No SAP		
	No. of Cases	SSIs	Percentage (%)	No. of Cases	SSIs	Percentage (%)	No. of Cases	SSIs	Percentage (%)
0	2	0	0%	37	1	2.7%	0	0	-
1	1	0	0%	39	1	2.5%	8	4	50.0%
2	4	0	0%	08	2	25%	7	3	42.8%
3	0	0	-	05	3	60%	0	0	-

## DISCUSSION

Presented study reported compliance to the ASHP guidelines for SAP in our hospital was not at par. Only 6.3% of surgical procedures were found to be compliant to all guideline parameters. These results were as in same tone as in same studies at sites across world like in Nicaragua, Iran and Jordan, where rates of complete adherence to practice guidelines were 0.3% [21] and zero [22] respectively. On the contrary studies had demonstrated greater compliance with SAP guidelines. France [23] reported adherence rates of 28%, 41% and approximately 50% in their respective studies. SAP was administered in 86.4% of the procedures, while in only 81.9% of the surgeries it was indicated as per the guidelines. This suggests that surgeons at study site were aware of the importance of antibiotic choice in preventing SSIs, but as in some other studies [24], overuse of antibiotics was common.

The choice of antibiotic complied with ASHP guidelines in only 56.7% of the surgical procedures in this study. This rate was much higher in the United States of Brazil (75%) [25]. And higher than reported in Jordan (1.7%) [22]. This result in our study may be because of the unavailability of a unit-based clinical pharmacist to assist physicians according to guidelines. The ASHP recommends cefazolin as a single agent for most procedures for SAP. In the present study cefazolin was the most common regimen used, while the use of third generation cephalosporins was also not rare. In the present study antibiotics were continued in 34.2% of the procedures that required prophylactic antibiotics, however continuation was not recommended in 19.8% of these

surgeries. According to guidelines, a single dose of antibiotic is enough for most surgical procedures. Unnecessary long duration antibiotic prophylaxis is not only of zero benefit but also very harmful to patients because of toxicity, risk of super-infection and the risk of inducing more antibiotics resistance [22, 26].

The timing of administration of prophylactic antibiotics is important and this was correct in 20.7% of the surgeries performed; which was lot less to the studies in Canada [27] and France [22], who showed the timing of administration, was correct in 72% and 61.4% of cases respectively.

With respect to high risk patients i.e. patients having National Nosocomial infection surveillance risk index score more than 1. Cases included with 'NNIS score 2' were 19. Among them 4 of the cases were provided with full compliant SAP, in those cases incidence of SSIs were none. Under the same category, 8 cases were administered with partial compliant SAP. In those cases incidence of SSIs was 25%. And 7 of those cases with 'NNIS score 2' no surgical antibiotic prophylaxis was given which lead to a massive 42.8% incidence of SSIs. Cases included with 'NNIS score 3' were 5. Among them, all were provided with partial compliant SAP and out of 5, 3 of the cases were clinically diagnosed for SSIs with 60% incidence.

Although prospective data collection is more accurate because some information may not be found in patient's charts, we were able to extract all the information we needed from the charts. Care was taken to read all the notes and laboratory reports and make sure that the patient did not have any signs or symptoms of a true infection.

Patients with these signs or symptoms were excluded from the study as the antibiotic administration would then be for therapeutic treatment rather than prophylactic purposes. Although ASHP recommendations were used as rational and evidenced-based international guidelines, ASHP recommendations may not in fact be practical in our patients and setting or for the situation in India. This is because different countries and institutions may have different microbial flora, resistance patterns, antibiotic availability and rate of post-operative surgical site infection and operation room sterility. It is sound practice therefore for each centre to have its own guidelines, although the difference between the guidelines would not be expected to be significant.

Thus developing a local hospital guideline may be more appropriate. Our study shows that there is an urgent need to develop such guidelines for surgical prophylaxis in our hospital. The guidelines should include type of surgery, the optimal time of antibiotic administration, choice of antibiotic and an alternative, address intraoperative redosing and duration of use. They should also be based on hospital specific bacterial epidemiology patterns, the best evidence derived from the literature. The support and collaboration of hospital administrators and medical staff of such guidelines is essential for their development, implementation and maintenance.

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## CONCLUSION

From the above analyzed result of study, full compliance with SAP guidelines comes with an ultimate benefit of reduction in incidence of SSIs which will lead to sure reduction in hospitalization due to SSIs and cost of therapy. With inclusion of NNIS risk index scoring system, study concluded that high risk patients demand an efficient and appropriate SAP administration to keep SSIs incidence to a minimum. Even with partial compliant SAP administration in high risk patients, control of incidence for SSIs was not found to be optimum but it was better than not administering SAP at all. Thus these associated results of compliance analysis of SAP practice with SSI risk in patients lead to findings like need of SAP administration in patients undergoing surgery, controlled SSIs incidence with compliant SAP administration, Parameters which are more prone to non compliance like choice of agent, dose and continuation and their association with SSIs emergence. Thus SAP administration should be compliant with evidence based recommendations to control emergence of SSIs in general surgery patients whether they are at high risk to develop SSIs or not.

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## CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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