Original Article

Assessment of Adherence to Surgical Antimicrobial Prophylaxis Guidelines: A Prospective Observational Study in A Tertiary Care Hospital

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Abstract

Background: Surgical site infection (SSI) is leading cause of hospital acquired infection leading to extended stay in hospital and higher mortality rate thereby increasing financial and clinical burden. Surgical antimicrobial prophylaxis (SAP) is an important preventive measure helpful in reducing the incidence of SSI. There are numerous guidelines which emphasize on rational and judicious use of antimicrobials to prevent SSIs. Hence, we aimed our research to study practices of AMA use for prevention of SSI at our tertiary care teaching hospital, using ASHP and NCDC guidelines for prevention of SSIs. **Material and Methods:** Between 1st March 2018 to 31st August 2019 data was collected prospectively in case record form (CRF) after getting approval from institutional ethics committee. Total 1019 CRFs were recorded and analysed for adherence to SAP criterion given in ASHP and NCDC guidelines. **Results:** Out of 1019 cases, 489 were males (47.99%) and 530 cases were females (52.01%). Most common surgical wounds encountered were clean (47.50%), and clean-contaminated (46.61%) to which guidelines are applied. Except for one patient (0.1%) almost all patients received AMAs for the period of two day or more. Considering timing of administration, in around 25.02% cases AMA was administered within 60 minutes of surgical incision whereas in 74.98% AMA was administered before 60 minutes of surgical incision. **Conclusion:** The present research demonstrated that the use of surgical antimicrobial prophylaxis (SAP) was not in accordance with national and international guidelines.

Keywords: Surgical wound infection, guideline adherence, Anti-Bacterial Agents, Antibiotic Prophylaxis.

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Introduction

Surgical site infection (SSI) is one of the most common types of hospital acquired infection. Incidence of SSI varies from 0.5% to 20% globally, depending on various factors related to surgery and underlying condition of patients.[1] In India, incidence of SSI varies from as low as 2.5% to as high as 21%.[2]

According United States Centre for Disease Control and Prevention (CDC), SSI refers to an infection that occurs after surgery in the part of the body where the surgery has taken place.[3] Since centuries, SSI has always been a major complication of surgery and trauma.

The word 'Hospitalism' was introduced by Sir James Simpson in Edinburgh to describe what we now call hospital-acquired SSI.[4] The term 'surgical site infection' (SSI) was introduced in 1992 to replace the previous term 'surgical wound infection'.[5]

Patients who develop an SSI tend to have 2 to 11 times higher mortality rate than those who do not.[6] In one of the US based research, extra hospital stay attributable to SSI was 9.7 days with increased costs of US$ 20,842 per admission.[7] Hence SSIs represent a significant clinical and financial burden in present healthcare system.

Antimicrobial agent (AMA) is given just prior to surgery to maintain adequate tissue concentration at the time of surgical incision.[7] In view of the principle of 'prevention is better than cure', we have various national and international guidelines urging judicious use of AMAs for prevention of SSI.

Improvements in the timing of initial administration, the appropriate choice of AMA and shorter durations of administration will help in rationalising use of SAP. Hence, we aimed our research to study practices of AMA use for prevention of SSI at our tertiary care teaching hospital, using American Society of Health-System Pharmacists (ASHP,2013) & National

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Centre for Disease Control (NCDC,2016) for prevention of SSIs.

Materials and Methods

This study was prospective observational study. During study period, clinical case papers of patients operated under various departments viz, Otorhinolaryngology (ENT), Orthopaedics, OBGY, and General Surgery; within the duration of 1st March 2018 to 31st August 2019 were analysed.

Permission was obtained from Head of Department of General Surgery, OBGY, ENT, Orthopaedic Surgery before the start of study. Study was started only after written permission from Institutional Ethics Committee (ECR/1532/XXXXXXXXX/Inst/MH). Throughout the study and even after completion of research, complete confidentiality of data was maintained, as per prevalent guidelines.

Case records of patients of any age & gender and also operated in either elective or emergency operation theatre (OT) under departments of General Surgery, OBGY, ENT, Orthopaedic Surgery were included in the study. Whereas Case records of patients with incomplete case papers, referral to higher Centre and the patient whose stay in their respective ward for less than 24 hours post-operatively were excluded from the study.

Sample size of the study was 1019 and it was as per the guidelines given by WHO.8 Simple computer-generated random numbers were used for randomisation. Data was entered on Microsoft Excel 2016 in the form of percentage, mean, standard deviation etc. 'p' value of less than 0.05 was considered as statistically significant. Data was analyzed at the end of data collection by Graph pad prism ver. 5.01.

Each case paper was evaluated for use of AMA. All the data was evaluated using clinical practice guidelines for antimicrobial prophylaxis in surgery by ASHP and national treatment guidelines given by NCDC for their adherence to these guidelines. Each surgery was classified as Clean, Clean-contaminated, Contaminated and Dirty according to wound contamination classfication.[3,7-9] The criteria for adherence to guideline was not applied to the dirty and contaminated surgical wounds as AMA was also used for treatment of underlying infection in addition to provide SAP. SAP will be considered adherent to ASHP or NCDC guidelines if it follows all 3 criteria and non-adherent if it doesn't follow any single criterion viz Choice of AMA, Timing of AMA administration before surgical incision & duration of prophylaxis as per ASHP & NCDC guidelines for clean and clean-contaminated surgical wounds.

This was a non-funded study; hence any incidental minor charges were borne by principal investigator from his own pocket. There was no conflict of interest involved in this study.

Results

After collection and analysing the data, we found following observations. most of the patients which were included in our study were from 21-30 years of age group which constitutes 30.91% of total cases, followed by 31-40 years of age group (197 cases, 19.33%), 41-50 years of age group (134 cases, 13.15%), 11-20 years of age group (126 cases, 12.37%).out of the total 1019 cases, 489 were males (47.99%) and 530 cases were females (52.01%). Except for the department of OBGY there was overall male predominance.

In our study, the most common surgical wounds encountered were clean (47.50%), and clean-contaminated (46.61%). The dirty (3.93%) and contaminated (1.96%) wounds requiring aggressive AMT were very few.

Table 1: List of AMA prescribed Pre-operatively and post operatively

Sr. No.	Class	All AMA	No. of patients
1	Aminoglycosides	Amikacin	181 (17.76%)
		Gentamicin	113 (11.09%)
2	Carbapenem	Imipenem-Cilastatin	1 (0.1%)
		Meropenem	19 (1.86%)
3	Cephalosporins	Cefepime	3 (0.29%)
		Cefixime	1 (0.1%)
		Cefoperazone-Sulbactam	9 (0.88%)
		Cefotaxime	623 (61.14%)
		Ceftazidime	4 (0.39%)
		Ceftriaxone	279 (27.38%)
4	Glycopeptide	Vancomycin	3 (0.29%)
5	Lincosamide	Clindamycin	1 (0.1%)
6	Macrolide	Azithromycin	6 (0.59%)
7	Nitroimidazole	Metronidazole	639 (62.71%)
8	Penicillin	Amoxicillin	476 (46.71%)
		Co-amoxiclav	387 (37.98%)
		Piperacillin-Tazobactam	47 (4.61%)
9	Quinolones	Ciprofloxacin	97 (9.52%)
		Levofloxacin	6 (0.59%)
		Moxifloxacin	10 (0.98%)
10	Sulfonamides	Cotrimoxazole	192 (18.84%)

* AMA- Antimicrobial Agent

Most commonly used AMA was Metronidazole, which was prescribed in 639 (62.71%) operated patients, followed by Cefotaxime, used in 623 (61.14%) patients. Other commonly employed AMAs were amoxicillin (476 cases, 46.71%), Co-amoxiclav (387 cases, 37.98%), and Ceftriaxone (279 cases, 27.38%). Cefotaxime was most commonly used injectable AMA (623 cases, 61.14%) whereas Amoxicillin (476 cases, 46.71%) was most commonly used oral formulation.

Table 2: List of AMA used for intraoperative dose

AMA of choice	No. of Patients				
	ENT	ORTHO	OBGY	SURG	Total
Cefotaxime	11(4.26)	11(4.3)	105(41.34)	29(11.55)	156(15.31)
Ceftriaxone	4(1.55)	2(0.78)	49(19.29)	10(3.98)	65(6.38)
Co-amoxiclav	2(0.78)	4(1.56)	14(5.51)	11(4.38)	31(3.04)
Piperacillin-Tazobactam	0	1(0.39)	0	2(0.8)	3(0.3)
Total	17(6.59)	18(7.03)	168(66.14)	52(20.72)	255(25.03)
No use of AMA	241(93.41)	238(92.97)	86(33.86)	199(79.28)	764(74.98)

Intra-operative dose, was a dose of AMA given in the operation theatre within 60 minutes before surgical incision. It is observed that, out of 1019 cases, 255 (25.03%) received AMA within 60 minutes before surgical incision and 764 received AMA in the wards of respective department more than 60 minutes before surgical incision. Four AMA were used commonly for this purpose viz. Cefotaxime, Ceftriaxone, Co-amoxiclav and Piperacillin-Tazobactam. Most common AMA used intraoperatively was Cefotaxime (156 cases, 15.31%). Redosing of AMA i.e. additional dose of AMA in case of prolonged surgery or heavy blood loss, wasn't given to any patient intraoperatively.

For most of the patients (652 cases, 63.98%) and in all four departments AMAs were administered for 6 to 10 days followed by more than or equal to 11 days (261 cases, 25.61%). In 253 (98.02%) ENT patients, 208 (81.25%) Orthopaedic patients, 236 (92.91%) patients, 216 (86.06%) General surgery patients, AMAs were administered for 6 or more days. Only 1 patient (0.1%) received AMAs for the period of 24 hrs.

Table 3: Duration for which AMA was administered.

No. of days	ENT	ORTHO	OBGY	SURG	Total
0	0	0	0	0	0
1	0	0	1(0.39%)	0	1(0.1%)
2	0	0	0	1(0.4%)	1(0.1%)
3	1(0.39%)	18(7.03%)	6(2.36%)	4(1.59%)	29(2.85%)
4	1(0.39%)	11(4.3%)	4(1.57%)	11(4.38%)	27(2.65%)
5	3(1.16%)	19(7.42%)	7(2.76%)	19(7.57%)	48(4.71%)
6 - 10	163(63.18%)	139(54.3%)	198(77.95%)	152(60.56%)	652(63.98%)
≥11	90(34.88%)	69(26.95%)	38(14.96%)	64(25.5%)	261(25.61%)
Total	258	256	254	251	1019

It was seen that for most of the patients (652 cases, 63.98%) and in all four departments AMAs were administered for 6 to 10 days followed by more than or equal to 11 days (261 cases, 25.61%). In 253 (98.02%) ENT patients, 208 (81.25%) Orthopaedic patients, 236 (92.91%) patients, 216 (86.06%) General surgery patients, AMAs were administered for 6 or more days. Only 1 patient (0.1%) received AMAs for the period of 24 hrs.

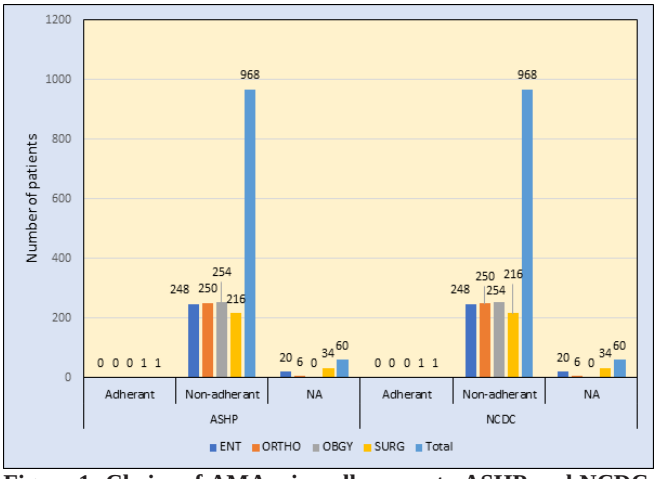

Figure 1: Choice of AMA wise adherence to ASHP and NCDC guideline.

Only one case (0.1%) was adherent to the choice of AMA criteria. Almost all cases in all four departments were non-adherent to the choice of AMA.

In around 25.02% cases AMA was administered within 60 minutes of surgical incision and in 74.98% AMA was administered before 60 minutes of AMA administration.

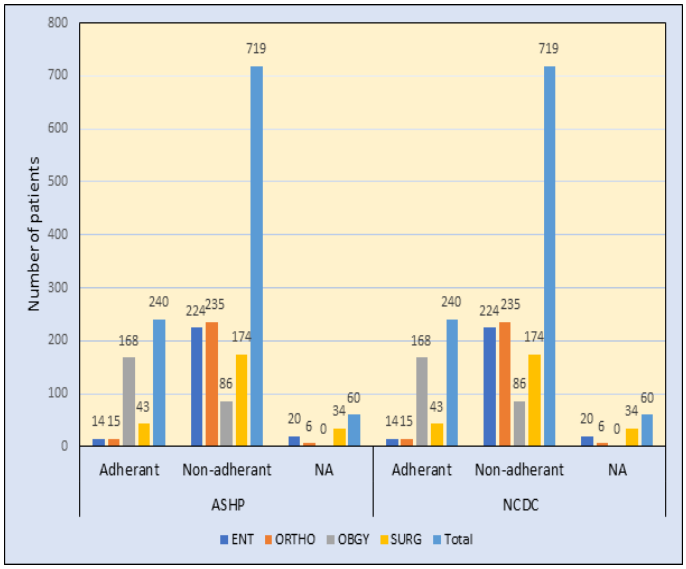

Figure 2: Timing of administration wise adherence to ASHP and NCDC guideline.

Table 4: No. of patients in which SAP given is adherent or non-adherent to ASHP and NCDC guidelines.

Sr. No.	Departments	Wound Contamination class	ASHP			NCDC		
			Adherent	Non-adherent	NA	Adherent	Non-adherent	NA
1	ENT	Clean	0	169	0	0	169	0
		Clean-contaminated	0	69	0	0	69	0
		Contaminated	0	0	8	0	0	8
		Dirty	0	0	12	0	0	12
2	ORTHO	Clean	0	162	0	0	162	0
		Clean-contaminated	0	88	0	0	88	0
		Contaminated	0	0	3	0	0	3
		Dirty	0	0	3	0	0	3
3	OBGY	Clean	0	23	0	0	23	0
		Clean-contaminated	0	231	0	0	231	0
		Contaminated	0	0	0	0	0	0
		Dirty	0	0	0	0	0	0
4	SURG	Clean	0	130	0	0	130	0
		Clean-contaminated	0	87	0	0	87	0
		Contaminated	0	0	9	0	0	9
		Dirty	0	0	25	0	0	25
5	Total		0	959	60	0	959	60

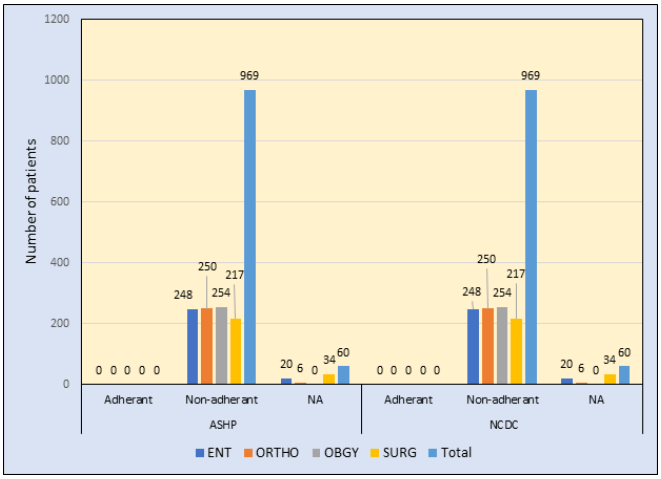

Figure 3: Duration wise adherence to ASHP and NCDC guideline.

When the duration of SAP was considered, almost all cases (99.9%) found non-adherent to both the guidelines.

As depicted in table 20 for 60 cases out of 1019, guidelines didn't apply as these cases belonged to contaminated and dirty wounds, because AMAs were used for treatment of underlying infection in addition to provide SAP. Hence out of 959 cases, no case was found to be adherent to both ASHP and NCDC guidelines for the use AMA for surgical prophylaxis.

Discussion

We aimed our study to evaluate practices of AMA prophylaxis for prevention of SSI. For the same we screened 1019 case papers of four departments viz. ENT, Orthopaedics, OBGY and General surgery, from the duration of 1st March 2018 to 31st August 2019. From the collected data we observed few findings, worth discussion as follows.

The mean age of the patient in this study was 36.04 ± 17.21 years which was comparable to the study conducted by Durando et al and Khan et al.[10,11] In this study 47.99% were male and 52.01% were females that was consistent with Durando et al10 and Alavi et al.[12]

We observed that, the most common surgical wounds encountered were clean (47.50%), and clean-contaminated (46.61%). The dirty (3.93%) and contaminated (1.96%) wounds, which require AMAs for their prophylaxis or treatment were very few.

There were many researchers, who made observations, in concordance with us viz. Sutariya et al,[1] Durando et al,[10] Mohamoud et al,[13] Alp et al,[14] Napolitano et al,[15] Disseldorp et al,[16] Parulekar et al,[17] in India as well as internationally. Thus, Clean and clean-contaminated are the commonly encountered wound in any hospital set up.

In this study the most commonly used AMA was Metronidazole, prescribed in 62.71% cases. (Table 1) Next commonly used AMAs were Cefotaxime (61.14%), Amoxicillin (46.71%), Co-amoxiclav (37.98%), and Ceftriaxone (27.38%).

As found in our study, Khakhkhar et al,[18] also reported Metronidazole to be the chief AMA used. Khan et al,[11] observed, Cefotaxime (72%) to be used most commonly, which was second most common in our study.

In most of the studies like Parulekar et al,[17] Steinberg et al,[19] Rafati et al,[20] Askarian et al,[21] cephalosporins were the most commonly used class of AMAs as well. Use of third generation cephalosporin in our study was reported to be greater than that reported in Durando et al,[10] Hosoglu et al.[22] Most commonly used Cephalosporin found in our study were Cefotaxime and Ceftriaxone, while Parulekar et al,[17] Rafati et al,[20] Askarian et al,[21] reported Cefazolin as most frequently used. Using third generation AMA instead of recommended second generation AMA is the result of supply of drug from the central drug store of our hospital. Ours being a large tertiary care hospital, we follow a central purchase & supply system. Hence on many instances availability is an issue, which forces the prescribers to change the AMA.

The cause of deviation from the recommended AMA in this study may be due to the non-availability of AMA, lack of awareness of the guidelines, false belief of low efficacy of older AMA as compared to newer ones. This was also reported by some researchers such as Shing Ng et al,[23] Khan et al,[24] and Al-Azzam et al.[25]

Almost all 99.61% patients were cured and discharged at our set

up. Mortality rate of patients included in our study was found to be 1.59%. Referred patients were excluded from our study. Amongst the published researches, only Bratzler et al,26 reported mortality outcomes in their papers, which was more or less similar to our results.

The selection of AMA was based on surgeon's experience and local antimicrobial sensitivity was not considered while prescribing AMAs, this was consistent with Khade et al.[27] Third generation cephalosporins were used along with Metronidazole and Amikacin in 4.9% and in 12.86% cases in pre-operative period and post-operative period respectively to cover anaerobes and gram-negative bacteria, however studies shows no significant difference in efficacy by addition of aminoglycoside to third generation cephalosporins as both have gram negative coverage providing no additional benefit.[28-31] Meropenem is a broad spectrum AMA; it has activity against gram-positive, gram-negative organism, aerobic and anaerobic bacteria still it was used along with Amikacin, Clindamycin, Metronidazole, Piperacillin-Tazobactam. Piperacillin-Tazobactam have activity against gram-positive and gram-negative bacteria, yet we found its use along with Moxifloxacin, Levofloxacin, Amikacin or Meropenem.[32] This was an unnecessary use of AMAs.

All cases received SAP, out of which 25.03% received dose of AMA in the operation theatre and 74.97% received AMA in the ward before entering operation theatre. Following AMAs were commonly used intraoperatively viz. Cefotaxime, Ceftriaxone, Co-amoxiclav and Piperacillin-Tazobactam. [Table 2]

Appropriate timing of AMA administration i.e. within 60 minutes before surgical incision was much lower than studies conducted by Durando et al,[10] Napolitano et al,[15] Parulekar et al.[17] Askarian et al,[21] Lee et al,[33] Friedman et al,[34] Momany et al.[35]

From table 3 it is predicted that, 94.31% cases received AMAs beyond 96 hours after surgery. In 63.98% cases, AMAs were administered for 6 to 10 days and in 25.61% cases received AMAs for up to 11 days. Overall AMA administered for an average period of 9.02 days. Such long duration AMA use was not in concordance with other studies published by Khan et al,[11] Parulekar et al,[17] Rafati et al,[20] Askarian et al,[21] Bratzler et al,[26] Lee et al.[33] Only ENT department has used AMAs for a duration which was as per other published researches.[17]

- Choice: As per adherence to ASHP and NCDC guideline, only one case (0.1%) was adherent to the choice of AMA criteria. Almost all cases in all four departments were non-adherent to the choice of AMA. [Figure 1] Napolitano et al,[15] Parulekar et al,[17] Steinberg et al,[19] Bratzler et al,[26] Lee et al.[33] found that adherence to the choice of AMA as per guidelines was way higher than the present study.
- Timing: In 25.02% cases AMA was administered within 60 minutes before surgical incision and in 74.98% cases, more than 60 minutes before surgical incision. [Figure 2] Napolitano et al,[15] Parulekar et al,[17] Bratzler et al,[26] Lee et al,[33] found adherence to the timing of AMA administration higher than reported in this study. Pre-operative dose is ideally administered within 60 minutes before surgical incision as per guidelines used by us i.e. ASHP and NCDC. However, WHO has relaxed this period to 120 minutes i.e. within 120 minutes before surgical incision.[7] Hence, we may get more number of cases following this criterion, if we go with WHO guidelines. Documentation about timing of pre-operative AMA administration in case papers was poorly maintained as found in other researches.[15] Redosing of AMA in long duration surgeries lasting more than 4 hours or heavy blood loss during surgery wasn't reported as in study conducted by Khan et al.[11]
- Duration: When the duration of SAP was considered, almost all cases (99.9%) were non-adherent to both the guidelines. [Figure 3] Parulekar et al,[17] Steinberg et al,[19] Bratzler et al,[26] Lee et al,[33] found adherence to the duration of AMA administration was higher than ours. When all the three criteria for the adherence to ASHP and NCDC guidelines were considered i.e. choice of AMA, timing of AMA administration, duration of SAP, out of 959 cases, not a single case was found to be adherent to all the criteria from both ASHP and NCDC guidelines. All the cases included in our research were not following either of the criteria from the subjected guidelines.

Askarian et al,[21] also reported that only 0.9% cases were adherent to guidelines. Such findings should alarm us to spread awareness of SAP in clinicians. However, there were few publications, which reported higher adherence to guidelines.[10,15-17,19,20]

Overall appropriateness or adherence to guidelines in the studies conducted by Steinberg et al,[19] Rafati et al,[20] Lee et al,[33] Napolitano et al,[15] Durando et al,[10] Disseldorp et al,[16] and Parulekar et al,[17] were higher than our study.

There was rampant use of AMA as 78.7% received AMA preoperatively and almost all received AMA postoperatively as observed in our study. Such use of AMA was also observed in researches conducted by Khan et al,[11] Khan et al,[24] Kulkarni et al,[31] Ramasubramanian et al.[36]

Clean (47.50%) and clean-contaminated (46.61%) surgical wound forms the bulk of the cases of this study. Even though guidelines suggested no use of AMA in clean surgery, we found that AMAs were routinely administered in such cases at our setup. There are few studies which reported such finding.[10,15,16,20]

Limitation:

1. This study was performed prospectively at a single tertiary care centre. Therefore, results may not be generalizable to the other institutions whose patient population and local AMA resistance pattern may vary.
2. Lack of standardized protocol at our tertiary care centre regarding SAP makes it difficult to assess proper decisions. Antimicrobial unavailability that was recommended by guidelines may have also played a role in altering antimicrobial choices. In addition, certain patients may have hypersensitivity to certain AMA, thereby preventing its use; wasn't evaluated in this study.
3. The study did not evaluate local microbial flora, antimicrobial

sensitivity patterns, or resistance profiles, which may influence the choice of prophylactic antibiotics. All these factors weren't considered in this study while evaluating non-adherence to the guidelines.

4. Being an observational study, it assessed prescribing patterns and adherence to guidelines but could not establish a causal relationship between inappropriate SAP practices and clinical outcomes.
5. The reasons for non-adherence to SAP were beyond the scope of the current study. However, the aim of the study was to provide an overview of the AMA use and its adherence to current national and international guidelines and we do believe that the data provide insights into daily clinical practice.

Conclusion

Present research was conducted with an intention to evaluate the practices of SAP for prevention of SSI. We found the practice of AMA use for SAP was inappropriate, in view of present national and international guidelines.

Broad spectrum and newer AMAs were prescribed empirically more often than narrow spectrum AMAs. More often the duration of prophylaxis was way beyond than suggested by current guidelines. Timing of AMA administration before surgical incision was also found to be non-adherent to recommendation provided by ASHP and NCDC. It was also seen that combination therapy was used, where single AMA was sufficient, leading to excessive use of AMAs. Third generation cephalosporins, aminoglycosides, nitroimidazoles were rampantly used instead of Cefazolin. It was surprising to see that, even in cases of clean wounds, a combination of AMAs was used, also for a longer duration than recommended.

Hence our study has identified areas for improvement with respect to current practice of SAP at our tertiary care centre. We found that, there is an urgent need of establishing an hospital AMA policy, based on local antimicrobial sensitivity pattern in collaboration with the pre¬scribers. Our institute needs to standardize SAP administration, according to national and international guidelines. At the same time, ongoing education and communication with prescribers is required to create awareness. With the limited development of new AMAs and rapid emergence of AMA resistance, judicious use of AMA is a need of the hour. We can conclude that, following guidelines for SAP will not only help in appropriate and reasonable use of AMAs in SAP, but also reduce implications related to their excessive us.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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