

Research Article

INTERNATIONAL RESEARCH JOURNAL OF PHARMACY



www.irjponline.com

ISSN 2230-8407 [LINKING]

EVALUATION THE CLINICAL EFFECTS AND AUDIT OF INTRODUCING AN
Research Article

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How to cite: Gupta RK, Kumar S. Evaluation The Clinical Effects And Audit Of Introducing An Antibiotic Prescription Audit In Patients Hospitalized To Adult Surgical Intensive Care Units In India. International Research Journal Of Pharmacy, 2023,14:5:23-28.

10.56802/2230-8407.1303505

ABSTRACT

Background: Because antibiotics are widely used for the admission of postoperative patients to intensive care units (ICUs) and because a significant number of sepsis cases are treated there, which can lead to antibiotic resistance in patients who are very sick, mortality and the severity of the disease are reduced with appropriate antibiotic therapy started on time, especially in ICUs.

Objectives: This study evaluated the clinical effects and audit of introducing an antibiotic stewardship program in patients hospitalized to adult surgical intensive care units in India.

Methods: An expert pharmacist audited the antibiotic regimens provided to surgical ICU patients, determining whether or not they were suitable. A microbiologist provided advice on antibiotic susceptibility and appropriate use, while a doctor offered advice on antibiotic prescriptions. The use of a specific antibiotic, mean duration, appropriateness of use, death within a month, source control documentation (by the surgeon), and readmission without a prior plan were the outcomes evaluated in this study.

Results: The mortality rate in the pre-ASP group was 17.30% (n = 18), while in the post-ASP group it was 14.15 (n = 15). At p=0.69, this was statistically not significant. The pre-ASP group had a longer antibiotic duration (p<0.001). In the pre-ASP and post-ASP groups, optimal antibiotic use was observed in 23.07% (n=24) and 86.79% (n=92) of the individuals, respectively. In the pre-ASP and post-ASP groups, appropriate antibiotic selection was observed in 41.34% (n=79) of the participants, respectively (p<0.001). No patients in the pre-ASP group required source-control documentation; however, 62.26% (n=66) of the post-ASP subjects did (p<0.001). (n=43) and 74.52%

Conclusion: The current study comes to the conclusion that using ASP can improve clinical parameters related to antibiotic prescription, optimization, and duration. Additionally, in surgical individuals, perfect adherence to source-control documentation can enhance antibiotic-related variables and parameters.

Keywords: surgical intensive care unit, antibiotic audit, antibiotic resistance, and antibiotic stewardship program.

INTRODUCTION

Antibiotic resistance is becoming more commonplace worldwide, which presents a significant problem to the health care industry, particularly in developing nations like India. This increase can be ascribed to inappropriate immunization, inappropriate infection control practices, inadequate sanitization, inappropriate use of antibiotics, and excessive use of antibiotics, with inappropriate use of antibiotics being the primary cause of antibiotic resistance.

Nonetheless, this variable aids in the appropriate administration of antibiotics to hospitalized people. The Infectious Disease Society of America amended the Antibiotic Stewardship Program (ASP) in 2016 with this goal in mind. It was first introduced in 2007.1.

The ASP program primarily focuses on the judicious and optimal selection and use of different antibiotics for the right amount of time at the right dose in order to have the best possible clinical outcomes, the least amount of drug-related harm, and a low rate of antibiotic resistance. An effective approach that can aid in lowering the incidence of antibiotic resistance is the antibiotic stewardship program, according to a number of prior literature data from pediatric intensive care units and industrialized nations. When it comes to lower death rates, the ideal length of therapy, lower antibiotic resistance, and shorter hospital stays, the ASP is superior. However, there is a dearth of literature data demonstrating ASP's superiority, with some data indicating improved antibiotic trends following ASP deployment in intensive care units.²

Appropriate antibiotic medication initiated on time reduces mortality and the severity of the disease. Due to the admission of postoperative patients and the high frequency of sepsis cases treated there, which can result in antibiotic resistance in patients who are very sick, antibiotics are used extensively in intensive care units (ICUs). Nonetheless, health-related outcomes and general well-being have improved as a result of adhering to recommended antibiotic usage recommendations, with some data from published literature providing additional support.³

The effectiveness of ASP has recently decreased due to a surge in the rate of careless antibiotic usage, particularly in developing nations like India. This is also linked to the lack of application of a multidisciplinary system and the absence of personnel with the necessary training.⁴

Furthermore, it might be difficult to apply ASP in the clinical domain, which results in varying success rates for ASP in various designs and contexts. Healthcare professionals are concerned that the use of ASP could result in higher rates of death, longer hospital stays, more admissions to intensive care units, and a rise in sepsis cases, all of which would raise costs.⁵ Data on the evaluation of ASP application in the surgical adult intensive care unit, however, are few. In order to evaluate the clinical impact and audit of establishing an antibiotic stewardship program in subjects admitted to adult surgical ICU settings in India, the current study was carried out.

MATERIALS AND METHODS

In this retrospective clinical investigation, patients admitted to adult surgical ICU settings in India were evaluated for the clinical impact and audit of the implementation of an antibiotic stewardship program. After receiving informed consent and approval from the relevant ethical committee, the current study was carried out. For ASP, standard operating procedures were created during the designated study time.

Subjects who were prescribed any antibiotics and were hospitalized to the surgical intensive care unit during the study period met the inclusion criteria for the research. The demographics, type of operation, comorbidities, prescription and indication of antibiotics, and appropriate and prudent administration of antibiotics were all gathered from the surgical ICU records.

Additionally, a lone, knowledgeable pharmacist who dealt with infectious diseases gathered all patient-related data, including pathologic, microbiologic, observational, daily progress, and radiologic records. The duration, dosage, route, and time of antibiotics were noted. For every subject that was included, mortality and readmission rates were also recorded.

In order to implement ASP in the surgical intensive care unit, a multidisciplinary strategy involving microbiology, infectious disease, surgery, pharmacy, and critical care units was employed. The pharmacists in charge of these units received support from all of the aforementioned departments of the institution. The use of restricted antibiotics such as colistin, caspofungin, cotrimoxazole, tigecycline, and linezolid was approved in addition by the hospital chief.

In the surgical intensive care unit, preoperative antibiotics included metronidazole, ceftriaxone, and cefazolin. Vancomycin, piperacillin, meropenem, colistin, imipenem, and tazobactam were utilized to treat the postoperative problems.

The professional pharmacist conducted an audit to assess the appropriateness of the prescription antibiotic therapy. A microbiologist provided advice on antibiotic susceptibility and appropriate use, while a doctor offered advice on antibiotic prescriptions. The expert pharmacist made changes to the datasheet as a result of this audit. Subsequently, the pharmacist recorded the audit and optimized its duration, dose, and medicine based on the infection site, accompanying bacteria, and pharmacologic drug qualities.

The use of a specific antibiotic, mean duration, appropriateness of use, death within a month, source control documentation (by the surgeon), and readmission without a prior plan were the outcomes evaluated in this study.

Surgeons reported source management of infection following surgery, which encompassed all actions needed to eradicate the infection, lower the bacterial burden, and restore the physiological state. In instances with identifiable cultures, antibiotic use indications were allocated as targeted therapy, empirical therapy for 5-7 days, and prophylactic therapy for 24-48 hours. Within 30 days following release, unplanned readmission and mortality were taken into consideration. The pharmacist monitored the individuals on day 31 of discharge if there was no readmission, and readmission to any other institution was also taken into account.

The prescription of antibiotics was judged for their appropriateness via assessing discontinuation, drug interaction, blood drug concentration, optimum dose, appropriate antibiotic selection based on pathogen-associated.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation concerning demographics and study outcomes. The level of significance was kept at $p < 0.05$.

RESULTS

In this retrospective clinical investigation, patients admitted to adult surgical ICU settings in India were evaluated for the clinical impact and audit of the implementation of an antibiotic stewardship program. A total of 104 patients, spanning the age range of 38–62 years with a mean age of 51.4 ± 4.26 years, were involved in the study. The subjects were of both genders. Table 1 contains a list of the study individuals' demographic details. Males made up 73.58% ($n=78$) of the post-ASP group and 73.07% ($n=76$) of the pre-ASP group. 19.23% ($n=20$) of the pre-ASP subjects and 20.75% ($n=22$) of the post-ASP subjects received prescriptions for therapeutic antibiotics. The pre- and post-ASP groups received prescriptions for empirical antibiotics in 35.57% ($n=37$) and 34.90% ($n=37$) of the subjects, respectively.

Preventive antibiotics were administered to 45.19% ($n=47$) and 44.33% ($n=47$) of the individuals in the pre- and post-ASP groups, respectively. With $p=0.76$, this difference was statistically not significant. In the pre and post-ASP groups, respectively, no comorbidity was observed in 24.03% ($n=25$) and 24.52% ($n=26$) of the participants.

Diabetes was the most prevalent comorbidity in 21.15% ($n=22$) of the pre-ASP individuals and 22.64% ($n=24$) of the post-ASP subjects. With $p=0.84$, the comorbidities in the two groups were comparable. Vascular, orthopaedic, ENT, general, neurosurgery, and obstetrics and gynecologic surgeries were among the procedures carried out; the difference between the two groups was not statistically significant ($p=0.73$) (Table 1).

Colistin, vancomycin, tazobactam, and carbapenem were administered at doses of 274, 264, 366, and 510 to participants in the pre-ASP group and 114, 86, 120, and 398 to those in the post-ASP group as therapeutic and empirical antibiotics. For colistin ($p=0.22$), the results were not statistically significant; however, for all other antibiotics ($p < 0.001$), they were. Cefazolin, metronidazole, and ceftriaxone were the prophylactic antibiotics utilized; the pre-ASP group received 186, 224, and 378 doses of these drugs, while the post-ASP group received 52, 82, and 74 doses. With $p < 0.001$, this was statistically significant. 14.15 ($n=15$) people died in the post-ASP group compared to 17.30% ($n=18$) in the pre-ASP group. At $p=0.69$, this was statistically not significant.

Additionally, there was no statistically significant difference in readmissions or hospital stay duration ($p=0.2051$ and 0.06 , respectively) between the two groups. The pre-ASP group had a significantly longer duration of antibiotics ($p < 0.001$) for colistin, vancomycin, tazobactam, and carbapenems than the post-ASP group. Similarly, the pre-ASP group had a significantly longer duration of prophylactic antibiotics ($p < 0.001$) for cefazolin, metronidazole, and ceftriaxone.

Antibiotics were stopped in 95.28% ($n = 101$) of the post-ASP group's participants and in 19.23% ($n = 20$) of the pre-ASP group's subjects, according to the parameters linked to antibiotic use. Drug interactions were observed in 11.32% ($n=12$) of the post-ASP group's individuals and 25.96% ($n=27$) of the pre-ASP group's subjects. 23.07% ($n=24$) and 86.79% ($n=92$) of the individuals in the pre-ASP and post-ASP groups, respectively, showed optimal antibiotic usage. 41.34% ($n=43$) and 74.52% ($n=79$) of the individuals in the pre-ASP and post-ASP groups, respectively, showed appropriate antibiotic selection. The post-ASP group showed a statistically significant difference, with $p < 0.001$ (Table 3).

Regarding the intervention in the pre-ASP and post-ASP groups, 62.26% ($n=66$) of the post-ASP patients required source-control documentation, but none of the pre-ASP participants required it. 73.58% ($n=78$) of the individuals in the post-ASP group and 41.34% ($n=43$) of the subjects in the pre-ASP group had therapy for more than five days ($p < 0.001$). Table 4 shows that 48.11% ($n=51$) of the post-ASP group required a pharmacist's intervention; this was statistically significant ($p < 0.001$).

DISCUSSION

In this retrospective clinical investigation, patients admitted to adult surgical ICU settings in India were evaluated for the clinical impact and audit of the implementation of an antibiotic stewardship program. A total of 104 patients, spanning the age range of 38–62 years with a mean age of 51.4 ± 4.26 years, were involved in the study. The subjects were of both genders.

Colistin, vancomycin, tazobactam, and carbapenem were administered at doses of 274, 264, 366, and 510 to participants in the pre-ASP group and 114, 86, 120, and 398 to those in the post-ASP group as therapeutic and empirical antibiotics.

For colistin ($p=0.22$), the results were not statistically significant; however, for all other antibiotics ($p < 0.001$), they were. Cefazolin, metronidazole, and ceftriaxone were the prophylactic antibiotics utilized; the pre-ASP group received 186, 224, and 378 doses of these drugs, while the post-ASP group received 52, 82, and 74 doses. With $p < 0.001$, this was statistically significant. Death rates were 14.15 ($n=15$) in the post-ASP group and 17.30% ($n=18$)

in the pre-ASP group. At $p=0.69$, this was statistically not significant. Additionally, there was no statistically significant difference in readmissions or hospital stay duration ($p=0.2051$ and 0.06 , respectively) between the two groups.

The duration of antibiotics for colistin, vancomycin, tazobactam, and carbapenem was statistically significant for pre-ASP and post-ASP group and was higher for the pre-ASP group with $p<0.001$, whereas, for prophylactic antibiotics, also significantly higher duration was for pre-ASP group concerning cefazolin, metronidazole, and ceftriaxone with $p<0.001$. These findings were consistent with the findings of Haque A et al⁶ in 2018 and Kaki R et al⁷ in 2011 where authors reported clinical parameters concerning antibiotics comparable to the present study.

The current study additionally assessed factors related to antibiotic use, and it found that 95.28% ($n = 101$) of the post-ASP group's subjects and 19.23% ($n = 20$) of the pre-ASP group's subjects had stopped taking antibiotics. 11.32% ($n=12$) of the post-ASP group's patients and 25.96% ($n=27$) of the pre-ASP group's subjects experienced drug interactions. In the pre-ASP and post-ASP groups, optimal antibiotic use was observed in 23.07% ($n=24$) and 86.79% ($n=92$) of the individuals, respectively. In the pre-ASP and post-ASP groups, respectively, apt antibiotic selection was seen in 41.34% ($n = 43$) and 74.52% ($n = 79$) of the participants.

With $p<0.001$, the difference was statistically larger in the post-ASP group. The present study's outcomes were consistent with the research conducted by Davey P et al. (2013) and Dunkel N et al. (2012), whose authors reported stopping antibiotic use and consuming the recommended amount of antibiotics.

Regarding the intervention in the pre-ASP and post-ASP groups, 62.26% ($n=66$) of the post-ASP patients required source-control documentation, but none of the pre-ASP participants required it. 73.58% ($n=78$) of the individuals in the post-ASP group and 41.34% ($n=43$) of the subjects in the pre-ASP group had therapy for more than five days ($p<0.001$). A pharmacist's intervention is required in 48.11% ($n=51$) of the post-ASP group of individuals; this difference was statistically significant ($p<0.001$). These outcomes were comparable to those of the 2015 trials by Walia K et al. (10) and Marquet K et al. (11) with similar interventions that the authors reported pre- and post-ASP.

CONCLUSION

Within its limitations, the present study concludes that antibiotic duration, optimization, and prescription can improve clinical parameters with ASP implementation. Also, complete compliance of source-control documentation can improve antibiotic-related variables and parameters in subjects undergoing surgery. However, the present study had few limitations including a smaller sample size, geographical area biases, short monitoring period, and single-institution nature. Hence, more studies in vivo are warranted to reach a definitive conclusion. Also, ASP sustainability in OPD and other acute cases needs to be explored.

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TABLES

Characteristics	Intervention (Pre-ASP) (n=104)% (n)	Intervention (Post-ASP) (n=106) % (n)	p-value
Mean age (years)	51.28±11.42	53.02±9.72	0.235
Age range (years)	38-61	39-62	
Gender			
Males	73.07 (76)	73.58 (78)	0.66
Females	26.92 (28)	26.14 (28)	
Antibiotic Indication			
Therapeutic	19.23 (20)	20.75 (22)	0.76
Empirical	35.57 (37)	34.90 (37)	
Prophylactic	45.19 (47)	44.33 (47)	
Associated comorbidities			
No comorbidity	24.03 (25)	24.52 (26)	0.84
Diabetes	21.15 (22)	22.64 (24)	
Respiratory disease	4.80 (5)	2.83 (3)	
Cardiovascular disease	17.30 (18)	14.15 (15)	
Renal diseases	16.38 (16)	17.92 (19)	
Malignancies	0 (0)	0 (0)	
Hepatic disease	8.65 (9)	8.49 (9)	
Neuropsychiatric disease	1.92 (2)	3.77(4)	
Combination of any 2	6.73 (7)	5.66 (6)	
Surgeries Performed			
Vascular	2.88 (3)	2.83 (3)	0.73
Orthopedic	10.57 (11)	13.20 (14)	
ENT	4.80 (5)	2.83 (3)	
General Surgery	42.30 (44)	45.28 (48)	
Obstetrics/gynaecology	5.76 (6)	4.721 (5)	
Neurosurgery	33.65 (35)	31.13 (33)	

Table 1: Demographic characteristics of the study subjects

Parameter	Intervention (Pre-ASP) (n=104) % (n)	Intervention (Post-ASP) (n=106) % (n)	p-value
Antibiotics (total) used	328	115	<0.001
Therapeutic and Empirical			<0.001
Colistin	274	114	0.22
Vancomycin	264	86	<0.001
Tazobactam	366	120	<0.001
Carbapenems	510	398	0.26
Prophylactic			
Cefazolin	186	52	<0.001
Metronidazole	224	82	<0.001
Ceftriaxone	378	74	<0.001
Antibiotics (total) doses	3800	2240	<0.001
Mortality	17.30 (18)	14.15 (15)	0.69
Hospital stays duration (days)	5.4±2.9	4.9±2.8	0.2051
Readmissions	23.07 (24)	0.94 (1)	0.06
Duration of antibiotic therapy (mean)			
Therapeutic and Empirical			
Colistin	7.7±4.8	4.6±2.8	<0.001
Vancomycin	6.3±3.9	2.9±1.9	<0.001
Tazobactam	6.5±3.6	2.5±1.4	<0.001
Carbapenems	9.8±3.8	4.2±2.5	<0.001
Prophylactic			
Cefazolin	4.1±2.9	1.7±1.6	<0.001
Metronidazole	2.8±2.4	1.3±0.9	<0.001

Ceftriaxone	5.3±2.5	1.6±1.5	<0.001
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Table 2: Comparison of antibiotics used and clinical parameters in the study subjects

Antibiotic related parameter	Intervention (Pre-ASP) (n=104) % (n)	Intervention (Post-ASP) (n=106) % (n)	p-value
Discontinuation	19.23 (20)	95.28 (101)	<0.001
Drug Interaction	25.96 (27)	11.32 (12)	<0.001
Blood level monitoring	10.57 (11)	79.24 (84)	<0.001
Optimum dose use	23.07 (24)	86.79 (92)	<0.001
Correct antibiotic selection	41.34 (43)	74.52 (79)	<0.001

Table 3: Aptness of antibiotics used in Pre-ASP and Post-ASP study subjects

Variable	Intervention (Pre-ASP) (n=104) % (n)	Intervention (Post-ASP) (n=106) % (n)	p-value
Source-control documentation	0 (0)	62.26 (66)	-
Therapy for >5 days	41.34 (43)	73.58 (78)	<0.001
Antibiotic selection following guidelines	75.96 (79)	13.20 (14)	<0.001
Intervention of Pharmacist	0 (0)	48.11 (51)	-

Table 4: Intervention data comparison in Pre-ASP and Post-ASP study subjects