CASE STUDY

Compliance with National guidelines for antibiotic prophylaxis use in surgery: A case study in Thu Duc City Hospital, South of Vietnam

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ABSTRACT

Objectives: To evaluate compliance with national guidelines for surgical antibiotic prophylaxis use (SAP) at a general hospital in southern Vietnam and explore the impact of patient and surgery demographics on compliance.

Methods: A cross-sectional study using quantitative methods was used. A total of 270 medical records (MRs) of patients who underwent clean or clean-contaminated surgeries between January 1, 2021, and June 30, 2021, at Thu Duc City Hospital were selected by systematic random sampling. A range of data was collected, which included patient demographics, surgery type, and antibiotic selection, as well as appropriate timing, route of administration, and duration of prophylaxis for each surgical procedure. Evaluating compliance based on the national practice standards for SAP. Data were entered by Epidata 3.0 and analyzed by SPSS 22.0 software.

Results: Of the 270 cases included in the study, the overall compliance rate of SAP use was only 17.0%. Inadequate timing of SAP administration (17.8%) was the major cause of non-compliance, follow by inappropriate antibiotic selection (77.0%). Furthermore, patient and surgery characteristics were found to play a significant role in compliance with guidelines, with gender, surgery type, wound infection condition, and pre-operative hospital stay all having notable correlations.

Conclusion: In conclusion, the overall compliance rate of SAP use was lower than expected, and there was a significant difference among specific types of surgeries. There is a relationship between surgery type, wound infection classification, and length of pre-operative hospital stay with SAP use compliance ($p < .01$). To improve compliance with national guidelines for SAP use, appropriate timing, and antibiotic selection should be emphasized. Further efforts are still needed to improve the standards of antiseptic surgery in Vietnam.

Keywords: *Compliance, adherence, antibiotic prophylaxis, surgery, hospital.*

INTRODUCTION

Surgical site infection (SSI) is a common hospital-acquired infection that poses a significant burden on patients in terms of illness, morbidity, mortality, and associated healthcare and out-of-pocket costs (1). The global incidence of SSI ranges from 2% to 15% depending on the type of surgery, and an estimated 2 million individuals develop SSI annually (2). In Vietnam, SSI occurs in 5% to 10% of surgical patients and is the most common type of hospital-acquired infection (3). Antibiotic prophylaxis (AP) is the administration of antibiotics before surgery, or other invasive procedures, to prevent the development of infection. The goal of antibiotic prophylaxis is to reduce the likelihood of infection occurring in a surgical site, where bacteria are likely to be introduced or result from intervention, which could lead to complications for the patient (4). The implementation of appropriate surgical antibiotic prophylaxis (SAP) protocols is an important step in preventing post-operative SSI; however,

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inappropriate use of antimicrobials is common, especially in resource-limited countries (5) (6). Inappropriate use can lead to patient harm, and risk of surgical site infections, and contribute to the rise of antimicrobial resistance. According to Whitney J Goede et al. (2013), the rate of compliance with all 4 principles of the appropriate use of SAP is 75.4% among the 760 cases, in which antibiotic selection had the lowest incidence of noncompliance (10.8%) (5). In another study by Maria Isabel P. Nabor et al. (2015), the rate of compliance with all 6 criteria of SAP was only 13% (6)

In Vietnam, the Ministry of Health (MOH) has developed national guidelines (Decision No. 708/QĐ/BYT) for the prophylactic use of antibiotics in surgery, which recommend appropriate antibiotic prophylaxis, the use of narrow-spectrum drugs, the optimal dose, the route of administration and duration of treatment, and the importance of per-operative infection control (4). However, adherence to these guidelines is variable between institutions and healthcare providers. Studies by Tran Lan Chi (2018) and Hoang Phuong Khanh (2019) evaluated compliance with SAP at private hospitals using all 6 criteria indicated that the overall compliance rates were 60.5% and 82%, respectively (7) (8). Whereas the study in a public hospital by Nguyen Van Manh (2018) showed that no cases complied with all the principles of SAP (9). Therefore, increasing compliance with national guidelines is critical to ensure the safe and effective use of antibiotics in the management of surgical patients, and to combat the rise of antibiotic resistance levels in Vietnam.

Thu Duc City Hospital located in the south of Vietnam is a first-class hospital with a capacity of 900 beds and over 6,000 daily outpatient visits. With an average of 60 surgical cases per day, the hospital is at risk of high incidence of healthcare-associated infections, antibiotic management practices, therefore, are crucial for the safe and efficient management of surgical interventions. This study aimed to evaluate compliance with national guidelines for antibiotic prophylaxis use in surgery at a general hospital located in southern Vietnam, as well as explore the related factors on SAP compliance.

METHODS

Study design: A cross-sectional study using quantitative methods was used.

Study subjective: Medical records (MRs) of patients who underwent clean or clean-contaminated surgeries between January 1, 2021, and June 30, 2021, at Thu Duc City Hospital. Clean or clean-contaminated surgeries are defined according to the Wound Infection Classification of the MOH (2), (3): Clean wound is an incision in which no inflammation is encountered in a surgical procedure, without a break in sterile technique, and during which the respiratory, alimentary, and genitourinary tracts are not entered; and Clean-contaminated wound is an incision through which the respiratory, alimentary or genitourinary tract is entered under controlled conditions but with no contamination encountered (2), (3). Excluded from the study were patients who had died in the process of surgery, and who were diagnosed with infectious disease.

Study site and time: The study was conducted from January 2021 to September 2021, at Thu Duc City Hospital, Ho Chi Minh City, Vietnam.

Sample size and sampling: Applying the formula for estimation of a single proportion:

$$n = Z^2_{(1 - \alpha/2)} \frac{p(1-p)}{d^2}$$

Where: α: level of significance in statistics; $Z_{(1 - \alpha/2)}$: Confidence level (at 95% confidence, $Z_{(1 - \alpha/2)} = 1.96$); d: tolerated margin of error (d = 0.05); p: estimated compliance rates (p=0.786, based on the AP compliance of the latest similar research at a general hospital in southern Vietnam (15)). The sample size according to the formula is 258.

The samples were selected by using systematic random sampling with a population size was 2798 MRs, an interval (k) was 11 and the random starting point was number 3. Based on this sampling

process, the actual sample size is 270 MRs

Data collection: All eligible selected MRs were reviewed, and data collected by using a standard data collection form. Demographic and clinical data included patient age, sex, body mass index; wound classification, use of antibiotics within 1 week of surgery, characteristics of surgery; prophylactic antibiotics given (including the antibiotic agent used, the route of administration, the dosage, the timing of administration, and duration of prophylaxis).

Evaluate compliance with national practice standards for SAP:

Compliance with national practice standards included meeting the 5 criteria according to the latest MOH's recommendations for antibiotic prophylaxis in surgery are as follows (3):

- Antibiotic prophylaxis indication:

+ AP is indicated for all clean-contaminated surgeries.

+ AP is indicated for clean surgeries with severe surgical interventions, which may affect the patient's survival functions, such as orthopedic surgery, cardiac surgery, neurosurgery, and ophthalmic surgery.

- Antibiotic choice:

+ The type of antibiotic prophylaxis should be spectrum-appropriate for the surgical site and for the antibiotic-resistance status of the hospital.

+ Antibiotics that have the least adverse effects, toxicities, or harmful reactions are preferred. Avoid using antibiotics that can cause unpredictable toxicity or severe toxicity regardless of the dose (e.g., phenicol and sulfamid antibiotics that cause immune-related leukopenia and Lyell syndrome).

+ Antibiotics that do not interact with anesthetic drugs (e.g., polymyxin, aminosids) should be selected.

+ Antibiotics that can diffuse into tissue and achieve concentrations higher than the minimum inhibitory concentration of antibiotics should be selected.

+ Prophylactic antibiotics with lower costs than therapeutic antibiotics intended for clinical treatment should be used.

- Route of administration: Antibiotic prophylaxis should be given intravenously; oral administration may only be used in colorectal or rectal surgery preparation.

- Dose: The recommended doses depend on the antibiotic type. AP should only be given as a single dose. In cases wherein redosing is indicated (e.g. cardiac surgery exceeding 4 hours, operations with a large amount of blood loss (>1500 mL in adults or >25ml/kg in children), the last dose must be given less than 24 h after the surgery.

Table 1. Compliance with SAP doses

Antibiotic	Dose	Redosing (h)
Cefazolin	< 120kg: 2 g ; ≥ 120kg: 3 g	4 (2, if cardiac surgery)
Cefotetan	< 120 kg: 2 g; ≥ 120 kg: 3 g	6
Clindamycin	600 mg	6
Ciprofloxacin	400 mg	8
Gentamicin	5 mg/kg	NA
Metronidazol	500 mg	12
Vancomycin	< 70 kg: 1 g; 71-99 kg: 1.25 g; > 100 kg: 1.5 g	12

- Timing: Antibiotic prophylaxis for surgery must be given within 60 minutes before skin excision. Exceptions included vancomycin and ciprofloxacin, which should be started between 60 and 120 minutes before the incision. For cesarean delivery, AP could be used before skin incision or after cord clamping.

Data analysis: Collected data were entered by Epidata 3.0 and analyzed by SPSS 22.0 software. Descriptive analysis reported proportions for each parameter and for every operation. Statistical analysis using chi-square test with significant value $\alpha = 0.05$ was employed to determine the relationship between patient characteristics and surgical procedures with compliance with SAP use guidelines. If more than 20% of the total expected cell counts are less than 5 or if any cell has a count less than 1, Fisher's exact test will be used as an alternative.

Ethical approval: The study is approved by the Research Ethics Committee of the Hanoi University of Public Health (Decision No. 312/2021/YTCC –HD3).

RESULTS

Patient and operation demographics

Patient and operation demographics of the cases included are presented in Table 2. There were more female (53%) than male (47%) patients; Two-thirds of patients were aged from 18-60, and 10% were older than 60 years.

A total of 270 medical records were reviewed, including 138 cases (66.7%) of general surgery, 49 (18.1%) cases of cesarean sections, 37 (13.7%) cases of colon/rectal surgery, and 4 (1.5%) cases of cardiac surgery. Most frequently (88.5%) operations were elective procedures The common surgical approach was open surgery with 80.7%, while laparoscopic surgery accounted for 19.3%. The majority of surgical incisions were classified as clean-contaminated wounds, making up 72.6%. All operations were completed within 4 hours. The length of pre-operative hospital stay was ≤1 day in 55.9% of cases and >1 day in 44.1% of cases.

Table 2. Patient and operation demographics (n=270)

Characteristics		Frequency (n)	Percentage (%)
Patients	**Gender**		
	Female	143	53.0
	Male	127	47.0
	Age		
	< 18	8	3.0
	18 - 39	150	55.5
	40 - 60	85	31.5
	> 60	27	10
	BMI		
	< 18.5	12	4.4
	18.5 -24.9	188	69.6
	> 25	70	25.9

Characteristics		Frequency (n)	Percentage (%)
Operation	**Surgery specialty**		
	Cesarean section	49	18.1
	Colon/ rectal surgery	37	13.7
	Cardiac surgery	4	1.5
	General surgery	180	66.7
	Surgery type		
	Emergency surgery	31	11.5
	Elective surgery	239	88.5
	Total operating room time (h)		
	≤ 2	103	38.1
	2 - 4	167	61.9
	> 4	0	0
	Pre-operative hospital stay (day)		
	≤ 1	151	55.9
	>1	119	44.1
	Wound infection classification		
	Clean	74	27.4
	Clean-contaminated	196	72.6
	Surgery approach		
	Laparoscopy	52	19.3
	Open surgery	218	80.7

Compliance with national guidelines on antibiotic prophylaxis

Of the 270 MRs of patients who underwent clean or clean-contaminated surgeries included, 249 (92.2%) cases required prophylaxis according to the national guidelines, but the results indicated that all 270 cases were given antibiotics. Amongst all cases receiving prophylaxis, compliance with all other parameters was determined and the results are presented in Table 3.

Table 3. Antibiotic prophylaxis practices among the different surgeries (n=270)

Antibiotic prophylaxis practice	Surgery specialty				Total (n, %)
	Cesarean section (n, %)	Colon/ rectal surgery (n, %)	Cardiac surgery (n, %)	General surgery (n, %)	
AP indication					
AP was given, correct	49 (100%)	37 (100%)	4 (100%)	159 (88.3%)	**249 (92.2%)**
AP was given, incorrect	0 (0%)	0 (100%)	0 (100%)	21 (11.7%)	21 (7.8%)
Antibiotic choice					
Correct choice	44 (89.8%)	26 (70.3%)	4 (100%)	134 (74.4%)	**208 (77.0%)**
Incorrect choice	5 (10.2%)	11 (29.7%)	0 (0%)	46 (25.6%)	**62 (23.0%)**
Dose					
Correct dose	39 (79.6%)	30 (81,1%)	4 (100%)	159 (88.3%)	**232 (85.9%)**
Under dose	10 (20.4%)	7 (18.9%)	0 (0%)	21 (11.7%)	38 (14.1%)
Over dose	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Route of administration					
Intravenous	49 (100%)	36 (97.3%)	4 (100%)	168 (93.3%)	**257 (95.1%)**
Oral route, correct	0 (0%)	1 (2.7%)	0 (0%)	0 (0%)	**1 (0.4%)**
Oral route, incorrect	0 (0%)	0 (0%)	0 (0%)	10 (5.6%)	10 (3,7%)
Others, incorrect	0 (0%)	0 (0%)	0 (0%)	2 (1.1%)	2 (0.8%)
Timing					
≤ 60 minutes before	5 (10.2%)	7 (18.9%)	4 (100%)	32 (17.8%)	**48 (17.8%)**
>60 minutes before, correct	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0 (0%)**
After cord clamping, correct	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
> 60 minutes before, incorrect	0 (0%)	0 (0%)	0 (0%)	8 (4.4%)	8 (3.0%)
After incision	44 (89.8%)	30 (81.1%)	0 (100%)	140 (77.8%)	214 (79.2%)
Overall compliant					
Compliant in all aspects	5 (10.2%)	7 (18.9%)	4 (100%)	30 (16.7%)	**46 (17.0%)**

Note: Italic indicates practices recommended by the national guideline.

Results in Table 3 indicated that, of the 270 surgeries in which prophylaxis was administered, the wrong antibiotic was given in 23.0%. This was most commonly the case in colon/rectal surgery and general surgery, in which the incorrect antibiotic was administered in 29.7% and 25.6% of cases respectively. The most commonly used SAP was cefazolin and other first-generation cephalosporin (63,7%), followed by gentamycin (3.7%). In the inappropriate antibiotic selections, cefotaxim (a third-generation cephalosporin) was commonly administered. The right dose was administered in most cases (85.9%) and the rest wrong one was underdosed administration

(14.1%). Almost (95.5%) of antibiotics were administered in line with recommendations, including intravenous or oral route in case of colon/ rectal operations. Only 17.5% of antibiotics were correctly given within 60 min before incision. The percentage of SAP use after skin incision was 79.2%. Inadequate timing of SAP administration was the major cause of non-compliance, follow by inappropriate antibiotic selection.

Of the 270 cases included in the study, the overall compliance rate of SAP use was only 17.0%. Compliance rates among specific types of surgeries were 10.2% for cesarean sections, 18.9% for colon/rectal surgery, 100,0% for cardiac surgery, and 16.7% for general surgery. Among the four types of surgeries, the cardiac section had the highest compliance rate (100%), and the cesarean section had the lowest (10.2%). There was a significant difference in the compliance rates among the four types of surgeries ($p<0.05$).

Associations between patient and surgery demographics with the SAP use compliance

The associations between patient and surgery demographics with compliance with national guidelines for antibiotic prophylaxis use in surgery were presented in Table 4.

Table 4. Association between patient and surgery demographics with SAP compliance (n=270)

Factors	SAP use compliance		p-value. OR
	Compliant (n=46)	Noncompliant (n=224)	
Age			
< 40	36 (22.8%)	122 (77.2%)	**p < 0.05 OR =3.00**
≥ 40	10 (8.9%)	102 (91.1%)	
Surgery type			
Elective surgery	46 (19.2%)	193 (80.8%)	**p < 0.001**
Emergency surgery	0	31 (100%)	
Wound infection classification			
Clean-contaminated	44 (22.4%)	152 (77.6%)	**p < 0.001 OR= 10.42**
Clean	2 (2.7%)	72 (97.3%)	
Pre-operative hospital stay (day)			
≤ 1	10 (8.1%)	113 (91.9%)	**p < 0.001 OR= 0.27**
>1	36 (24.5%)	111 (75.5%)	

The results indicated that there was no significant association between patient and surgery characteristics such as sex, BMI, surgery approach, and operation duration with SAP use compliance (p-value >0.05).

Several patient and surgery demographics were found to be significant predictors of compliance. Specifically, surgeries in patients who were under 40 years were more likely to be compliant with guidelines (p-value <0.05; OR=3.00). Surgery type (emergency or elective surgery) was associated with SAP use compliance (p-value<0.001). There was an association between wound infection classification/pre-operative hospital stay duration and compliance

(p-value<0.001): the compliance rate for patients with a clean-contaminated wound classification (22.4%) was significantly 10.42 times higher than that of patients with a clean wound classification (2.7%); patients who were hospitalized less than 1 day prior to surgery had a compliance rate of 8.1%, which was lower than that of patients hospitalized for more than 1 day who had a compliance rate of 24.5% (OR=0.27).

DISCUSSION

Compliance with the national guidelines on SAP use

Antibiotic prophylaxis is a proven strategy for decreasing surgical site infections. However, in this study, of the 270 surgical cases reviewed, full compliance with guidance in terms of AP indication, antibiotic choice, dose, route of administration, and timing only occurred in 17.0% (46/270) of cases. Several other facility-based studies around the world as well as in Viet Nam suggest that failure to comply fully with appropriate guidelines is not uncommon. A study in an Australian hospital of 2641 cardiac, orthopedic, and colorectal surgeries found that optimal prophylactic practice according to the national guidelines was seldom practiced (10). A study conducted in the USA found that, amongst 100 pediatric surgeries in which prophylaxis was indicated, compliance was recorded in the electronic medical record in all cases, nearly always because the appropriate antibiotic was administered. However, prophylaxis complied with guidelines on appropriate administration, type, timing, weight-based dosing, and redosing only in 48% of cases (11). In a recent study in 26 healthcare facilities, both public and private, in France, the general rate of antibiotic prophylaxis compliance was 64% (12). Full compliance with appropriate guidelines was observed in only 7% of pediatric surgery cases in an Israeli study, and 2% of abdominal, orthopedic, and gynecological surgeries in a Palestinian study (13), (14). In Vietnam, the results of a study by Tran Thi Huong Ngat indicated there were no cases that adhered to all 6 criteria (indication, selection, dose, route, timing, and redosing) (15). Whereas the results of a study by Tran Lan Chi, compliance with the general prophylactic antibiotic protocol is 60.5% (evaluated based on 6 criteria: antibiotic selection, dose, route, timing, redosing, and duration) (7).

Of the 270 surgical cases studied, 249 (92.2%) patients complied with the AP indication, similar to the result of a study conducted by Nongyao Kasatpibal in Thailand, but higher than Pham Huu Doan's study at Binh Dan Hospital where the rate of antibiotic prophylaxis prescription was 63.8% (16). All of the 21 cases (7.8%)) that did not adhere to the SAP use guideline were surgeries with a clean wound - which is recommended to not use AP but still prescribed. This implied that the overuse of antibiotics in Vietnam has been a major concern. This was also the reality in many hospitals in Vietnam; doctors have been always worried about SSI and tend to prescribe AP unnecessarily (4, 9, 15, 16).

Our study shows that the rate of compliance in antibiotic selection was 77.0%, which was lower compared to Phan Thi Hong Loan's study at Dong Nai International Hospital with 96.4% (17). Nabor's study (in the Philippines) also showed a lower rate of appropriate antibiotic selection at 44% (5). The most commonly AP chosen was Cefazolin a first-generation cephalosporin, accounting for 56.3%, similar to Tran Lan Chi's study result at a rate of 60.5% (6). Nongyao Kasatpibal's study showed that metronidazole and gentamicin were the most commonly AP used with a rate of 64.2% (18). In this study, most of the cases in which incorrect antibiotics were given were colon/rectal surgery, the majority of which were given Cefotaxim – a third-generation cephalosporin that has not been recommended in the national guidelines.

A rate of the correct dosage of 85.9% in this study appeared good compared with rates in the USA, and Israeli studies of 77% and 52% respectively (11), (14). Currently, dosages are clearly stated in the instructions for the use of each type of medication, making adherence to the

prescription much easier. The compliance rate for prophylactic antibiotic dosage in some studies in Vietnam was also quite high (15) (16).

The main route for using prophylactic antibiotics is intravenous injection, accounting for 95.5%. This was consistent with recommendations for prophylactic antibiotic use via intravenous injection, which is optimal due to the rapid attainment of drug concentration in the blood and tissue to inhibit bacterial growth at the site of the incision (4).

According to MOH guidelines, AP should be used within 60 minutes prior to surgery and close to the time of incision. Intravenous cephalosporins are injected 3-5 minutes before surgery and reach the necessary concentration in the tissue after a few minutes. Exclusion is vancomycin and ciprofloxacin, which need to be administrated over one hour before surgery but should be completed before incision. For cesarean delivery, AP may be used either before the skin incision or after cord clamping (4). In this study adherence to guidelines on the timing of 17.8% is at the lower end of a wide range of adherence rates reported by studies from other regions: a Greek study reports100%, an Australian study 93%, a USA study 73%, a Palestinian study 60%, and an Israeli study 32% (10), (13) (14). However, his rate was higher than that found in a study at Cam Pha Regional General Hospital, Quang Ninh province, where appropriate antibiotic use accounted for only 0.5% (15)

Factors associated with compliance with SAP use

Wound infection classification: Surgeries with clean wounds had a compliance rate of SAP that was 10.421 times higher than those with clean-contaminated wounds ($p<0.001$). On the contrary, Gouvea et. al. reported that in surgeries with clean-contaminated wounds, the compliance rate of SAP use was higher than in those with clean wounds, with $p < 0.05$ (18). Evidence showed that the risk of infection from clean wounds is 1-5%, and from clean-contaminated wounds is 5-10% (4). Therefore, the infection status of the surgical site is often related to the use of prophylactic antibiotics.

Type of surgery: Emergency cases had a low rate of SAP use compliance compared with elective ones, this result was similar to a number of studies in Vietnam, such as Pham Huu Doan'study at Binh Dan Hospital (16), or according to Phan Thi Hong Loan's study in Dong Nai International Hospital, the use of AP was more difficult than in elective one because, in elective surgeries, doctors and nurses were more proactive in preparing the patient (17).

Pre-operation hospital stay duration: This factor is related to adherence to SAP use compliance. Patients who were hospitalized for 1 day or less before the operation, both emergency and elective surgeries, had less time for preparation, leading to a lower rate of adherence to prophylactic antibiotic use.

Limitations of this study

Although this study had access to well-reported data on perioperative prophylaxis and was adequately powered, some limitations must be acknowledged. The absence of data on other factors may hinder interpretation in some cases. For example, the risk of infectious complications, and the drugs that were indicated before. It is possible there may have been some other indication for the giving of antibiotics after the surgery which is not reflected in the medical records.

CONCLUSIONS

In conclusion, the overall compliance rate of SAP use was lower than expected, and there was a significant difference among specific types of surgeries. There is a relationship between surgery type, wound infection classification, and length of pre-operative hospital stay with SAP use compliance ($p < .01$). To improve compliance with national guidelines for SAP use, appropriate timing, and antibiotic selection should be emphasized. Further efforts are still needed to improve the standards of antiseptic surgery in Vietnam.

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