Guideline Concordance Evaluation of Antimicrobial Usage in Surgical Patients at University Hospital, Thailand

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Overview: *Several studies have shown antimicrobial usage was non-concordant with clinical practice guidelines for antimicrobial prophylaxis in surgery. However, there have not been any studies related to antimicrobial usage in surgical patients at Ramathibodi Hospital.*
Objective: *The purpose of this study was to characterize the concordance of antimicrobial surgical prophylaxis with the guidelines and to evaluate appropriateness of antimicrobial use during hospitalization.*
Material and Method: *We prospectively collected data from 187 surgical patients receiving antimicrobial at three surgical wards, Ramathibodi Hospital between September and December 2016.*
Results: *There were 159 (85.0%), 129 (69.0%), 36 (19.3%), 147 (78.6%), 136 (72.7%) and 69 (36.9%) patients consistent with indication, drug of choice, dose, timing, re-dosing, and duration, respectively, was concordant with the American Society of Health-System Pharmacists (ASHP) 2013 guideline. Only orthopedic surgery was a significant factor for non-concordance in term of duration (odd ratio [OR] = 3.966, p<0.001, 95% confidence interval [CI] 1.828 to 8.606). Moreover, only 5.9% of patients had appropriate indications for prescribing antimicrobial as home medications.*
Conclusion: *Antimicrobial use for surgical prophylaxis was highly correlated with ASHP 2013 guideline, except for the dose and the duration aspects. However, overall antimicrobial prescriptions in surgical and orthopedic wards were not entirely concordant with the guidelines. Interventions to improve guideline concordance of antimicrobial surgical prophylaxis and to decrease unnecessary antimicrobial prescriptions are required.*

Keywords: *Antimicrobial prophylaxis, Surgery, Surgical prophylaxis, Antibiotic*

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The antimicrobial prophylaxis for surgical patients is one of the methods used to prevent surgical site infections (SSI)[1-3]. In past decades, many publications have described appropriate optimal prophylaxis. Based on those, guidelines for surgical prophylaxis have been developed. Organizations that have promulgated guidelines for antimicrobial prophylaxis in surgical patients, at the international and national level, include the American Society of Health-System Pharmacist (ASHP)[1], Scottish Intercollegiate Guideline Network publication number 104 (SIGN-104)[4], and Thailand Antimicrobial Resistance Containment and Prevention Program (AMRCP)[5]. The main aspects recommended by the three guidelines are as follows (Table 1): (a) antimicrobial prophylaxis should have an indication for surgical patients regarding wound classifications; (b) cefazolin is the antibiotic of choice mostly recommended in the guidelines; (c) the dose of antibiotic prophylaxis should be given following the recommendations; (d) timing of the first dose should be within 60 minutes prior to skin incision, (e) the re-dosing should be given if 1,500-ml blood loss or duration of surgery is twice as antibiotic half-lives occurs; and (f) duration of antimicrobial prophylaxis use should not be longer than 24 hours, except for cardiac surgery patients.

Despite the availability of these guidelines,

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Table 1. Summary of 3 guideline recommendations for surgical antimicrobial prophylaxis[1,4,5]

Guideline, year	Indication	Antibiotic of choice	Dose and route of administration	Preoperative dose timing	Re-dosing	Total duration of antimicrobial use
American Society of Health-System Pharmacist, 2013[1]	Clean high-risk, clean-contaminated and contaminated wound procedures	Cefazolin Cefuroxime Levofloxacin Vancomycin Clindamycin	2 g IV 1.5 g IV 500 mg IV 15 mg/kg IV 900 mg IV	Within 60 minutes before incision. Except for fluoroquinolone and vancomycin; within 120 minutes before incision.	Repeated intraoperatively if the surgery time is more than 2 half-lives or blood loss more than 1,500 ml intraoperatively	24 hours or less after surgery, 48 hours or less after surgery for cardiothoracic surgery.
Scottish Intercollegiate Guideline Network publication number 104[4]	Clean high-risk, clean-contaminated and contaminated wound procedures	No data available	Standard dose	Within 60 minutes before incision. Except for vancomycin; within 90 minutes before incision.	Repeated intraoperatively if surgery is longer than 4 hours when using an antibiotic with pharmacokinetics equivalent to cefazolin or there is blood loss more than 1,500 ml in any surgery.	Single dose
AMRCP[5]	Clean high-risk and clean-contaminated wound procedures	Cefazolin Ceftriaxone Metronidazole	2 g IV 2 g IV 500 mg IV	Within 60 minutes before incision. Except for vancomycin; within 120 minutes before incision.	Repeated intraoperatively if the surgery is more than 2 half-lives or excessive blood loss or contaminated during surgery.	24 hours or less

several studies assessing the current practices of antibiotic use throughout the world have shown that the use was non-concordant with clinical practice guidelines and remains a problem in surgical patients[6-8].

However, there have not been any studies related to antimicrobial usage in surgical patients at our university hospital. Considering the absence of local antimicrobial prophylaxis guideline in our hospital, the present study used the two international guidelines and one local guideline, ASHP, SIGN and AMRCP, to evaluate the appropriateness and compliance of antibiotic prophylaxis practices. We also evaluated an appropriateness of antimicrobial usage, prophylaxis, and therapeutic use, during hospital admissions in surgical patients at surgical wards and orthopedic wards, Ramathibodi Hospital.

Aim of the study

The present study was designed as a prospective survey study to characterize the concordance of antimicrobial surgical prophylaxis and to evaluate antimicrobial use during hospitalization in surgical and orthopedic units at university hospital, Ramathibodi Hospital.

Ethics approval

The protocol of this study was approved by the Institutional Review Board (IRB) at Ramathibodi Hospital (Approval number MURA2016/589) before data collection was started. The study was conducted in accordance with all applicable ethics standards.

Material and Method

Setting

The present study was conducted at two 60-bed surgical units and a 20-bed orthopedic unit at university hospital in Thailand. Cases were prospectively collected during the pharmacist day shift at 8.00 AM through 4.00 PM every weekday.

Study design

Prospective survey study.

Patients

Eligible patients were enrolled in the study after the ethic approval, between September 2016 and December 2016. The inclusion criteria included, 1) patients over 18 years of age, 2) patients admitted to surgical and orthopedic wards, and 3) undergone operative procedure and received antimicrobial. The exclusion criteria included, 1) patients admitted less than 24 hours, and 2) patients who had incomplete data, such as unclassified wound type, no blood loss volume documented, or unclear antimicrobial regimen given.

Primary and secondary outcomes

The primary outcome was to characterize concordance of antimicrobial surgical prophylaxis with the guidelines. Recommendations from the guidelines are described in Table 1 and discordant from the guidelines were counted following criteria in Table 2. The secondary outcomes were to evaluate the appropriateness of antimicrobial indication for therapeutic use and to identify factors related to uses which not compliant with the guidelines.

Data analysis

Statistical analysis was performed using SPSS, version 21.0 for Windows (IBM Corp., Armonk, NY). Categorical variables were compared between the two groups by Chi-square or Fisher's exact test, as appropriate. The Kolmogorov-Smirnov test was used

Table 2. Criteria for assessment of concordance to the guidelines

Parameter	Discordant if
Indication	No indication stated following recommendations
Antibiotic choice	No indication stated following recommendations or drug differed from recommendations
Dose	Dose differed from recommendations
Timing of first dose before incision	Timing of first dose was more than 30 minutes before incision (more than 60 minutes before incision for fluoroquinolones and vancomycin)
Dosing interval during surgery, re-dosing	Re-dosing was not given when there were 1500-ml blood loss during surgery or operation time was more than 2 times of the half-life.
Postoperative duration of antimicrobial	Duration of antimicrobial use exceeded 24 hours after surgery, except cardiac surgery (exceeded 48 hours) without indications documented.

to determine the distribution of continuous variables. All continuous variables were later assessed by Student's t-test or Wilcoxon rank-sum test and described as mean (standard deviation) or median (range) as appropriate. A *p*-value of 0.05 or smaller was considered statistically significant. Associations between two variables were tested by Pearson correlation or binomial logistic regression as appropriate.

Results

There were 197 surgical and orthopedic patients between September 21, 2016 to December 16, 2016. After screening of inclusion and exclusion criteria, 187 patients were enrolled in the study (Fig. 1). Table 3 shows the demographic data of the patients and types of surgeries.

Overall assessment of all parameters

One hundred eighty-seven patients underwent surgical and orthopedic surgeries. Zero (0.0%), nine (4.8%) and two (1.1%) patients adhered to ASHP, SIGN, and AMRCP for all parameters. Discordances from the guidelines were mostly observed in dosing and duration parameters (Table 4).

Indication

One hundred fifty-nine patients (85.0%) had indications of antibiotic prophylaxis according to the ASHP 2013 guideline. Likewise, there were 139 patients (74.3%) and 148 patients (79.1%) having indications of antibiotic prophylaxis regarding SIGN-104 and AMRCP, respectively. However, 21 patients (11.2%) having clean-wound type received antibiotics as surgical prophylaxis. Twelve patients (6.4%) underwent hernia repair surgery, which is an indication to receive antibiotic prophylaxis in ASHP and AMRCP guidelines, but not SIGN guideline.

Antibiotic choice

Antibiotic choice was concordant with the AHSP 2013 and AMRCP for 129 (69.0%) and 77 (41.2%) patients, respectively. Twenty-one patients (11.2%) had no indication for antibiotic prophylaxis, therefore they were automatically counted as discordance to the guidelines regarding antibiotic choice. In the patients who actually had indications for antibiotic prophylaxis, 129 (77.7%) and 77 (46.4%) patients adhered to ASHP and AMRCP guidelines according to antibiotic choice. Moreover, 42 (22.5%)

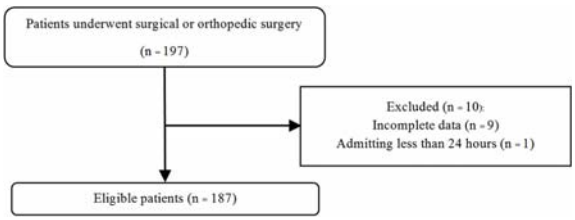

Fig. 1 Patient flow chart.

Table 3. Patient baseline characteristics

Characteristic	n = 187
Age, median (range)	61 (18 to 98) years
Gender, male, n (%)	77 (41.2)
Body weight, median (range)	62.0 (35.9 to 147.0) kilograms
Preoperative hospital stay (hour), median (range)	23 (0 to 380)
ASA classification, n (%)	
1	62 (33.2)
2	78 (41.7)
3	18 (9.6)
4	29 (15.5)
Wound class, n (%)	
Clean	126 (67.4)
Clean-contaminated	52 (27.8)
Contaminated	6 (3.2)
Dirty	3 (1.6)
Urgency of surgery, n (%)	
Elective surgery	161 (86.1)
Emergency surgery	26 (13.9)
Type of surgery, n (%)	
Orthopedic surgery	61 (32.6)
Colorectal surgery	23 (12.3)
Biliary tract surgery	19 (10.2)
Plastic surgery	13 (7.0)
Hernia repair	12 (6.4)
Cardiac surgery	11 (5.9)
Gastroduodenal surgery	10 (5.3)
Thoracic surgery	8 (4.3)
Vascular surgery	7 (3.7)
Others	23 (12.3)
Antimicrobial use, n (%)	
Cefazolin	95 (50.8)
Cefoxitin	42 (22.5)
Ceftriaxone	17 (9.1)
Metronidazole	15 (8.0)
Cefuroxime	14 (7.5)
Clindamycin	8 (4.3)
Vancomycin	5 (2.7)
Others	29 (15.5))

patients received cefoxitin and 14 (7.5%) patients received cefuroxime, which are medications that are not recommended by AMRCP guidelines.

Dosing

The dose was concordant with ASHP 2013 and AMRCP in only 36 (19.3%) and 27 (14.4%) patients, respectively. Ninety-one patients (48.7%) received cefazolin 1 gram, which was lower than recommended in both ASHP and AMRCP guidelines (2 grams). However, there is no definite statement regarding individual dose of antimicrobial in the SIGN guideline. Therefore, compliance to the SIGN guideline was not evaluated.

Timing

Timing was concordant with ASHP, SIGN, and AMRCP for 147 (78.6%), 147 (78.6%) and 145 (77.5%), respectively. Fifteen (8.0%) patients were admitted to trauma units and received antibiotic more than 1 hour before incision. They all received antibiotics early at admission even if they were not planned for any operations.

Re-dosing

Antibiotic doses were repeated in patients who had surgery time of more than twice of antibiotic half-life. Re-dosing was concordant with the guidelines (ASHP, SIGN, and AMRCP) for 136 patients (72.7%). However, of the 187 patients that used antibiotic surgical prophylaxis, none of them received repeated dose during surgeries. Specifically, 56 patients either had longer surgery time than two half-lives of medications or had blood loss of more than 1.5 liter. Only five patients (8.9%) received repeated dose intraoperatively, most of them had cefoxitin as antimicrobial prophylaxis, which has a half-life of one hour.

Duration

Total duration of antimicrobial prophylaxis was concordant with ASHP, SIGN, and AMRCP for 69 (36.9%), 26 (13.9%), and 58 (31.0%) patients, respectively. One hundred eighteen patients (63.1%) received antibiotic prophylaxis after more than 24 hours. Median duration of antimicrobial prophylaxis use was 56.5 hours (range 1 to 743 hours). None of them had sign or symptoms indicating infections. Moreover, we evaluated for factors associated with non-compliance to the ASHP guideline. We found that orthopedic surgery was the only factor that correlated with discordance to the guideline regarding duration aspect (Table 5).

Table 5. Factors associated non-compliance to ASHP regarding duration aspect using binomial logistic regression

Factors	Odd ratio (95% CI)	*p*-value
Diabetes	1.946 (0.858 to 4.414)	0.111
Duration of surgery	0.995 (0.992 to 0.999)	0.013
Orthopedic surgery	3.966 (1.828 to 8.606)	<0.001
Appendectomy surgery	0.216 (0.024 to 1.927)	0.170

Appropriateness of antimicrobial at discharge

Eight-four (44.9%) and 103 patients (55.1%) did not received and received antimicrobial as discharge medications, respectively. Regarding patients receiving antimicrobials, eleven patients (55.9%) had an indication for antimicrobial confirmed by diagnosis written in the medical charts. In contrast, 92 patients (49.2%) had no indication for antimicrobial use at time of discharge.

Discussion

Our study showed that compliance to the guidelines for antimicrobial prophylaxis in surgical and orthopedic patients at a Thai university hospital was low. One of the most surprising finding in the study was that no patient was concordant with all parameters in the guidelines. More than 60% in every parameter, indication, antibiotic choice, timing, re-dosing, and duration, was concordant with ASHP guideline. In contrast, only 19.3% and 36.9% were concordant with ASHP guideline in terms of dosing and duration, respectively. Cefazolin 1 gram was a frequent dose used in the study, which is a lower dose than recommended in both of ASHP and AMRCP guidelines. However, cefazolin 1 gram can be effectively used in patients weighing not more than 80 kilograms in Bratzler, et al study[9]. Therefore, median body weight in our study, 62.0 (range 35.9 to 147.0) kilograms, still be in an acceptable range.

Duration of antimicrobial prophylaxis was longer (median 56.5 hours) than recommended in the guidelines (less than 24 hours). Regarding antimicrobial appropriateness evaluation, we confirmed that there were no indications of antimicrobial by no sign or symptoms of infections found during admission period and no diagnosis documented so, antimicrobial uses

were firmly not indicated. One hundred eighteen patients (63.1%) continued antimicrobial without indications during hospital admissions, and an additional 103 patients (55.1%) received antimicrobial at discharge without any diagnosis of infections. Orthopedic surgery had a trend to use longer duration of antimicrobial prophylaxis than other surgery. However, no study has yet identified the benefit of using longer duration than 24 hours in orthopedic surgery. The reason of longer duration might be that the complexity of SSI in orthopedic surgery was found[10], postoperative infection can prolong hospital stay[11] and sometimes lead to increased morbidity and mortality, especially in complicated patients[12].

Regarding indication of antimicrobial prophylaxis, non-concordance with SIGN guideline[4] was higher than other guidelines[1,5]. SIGN guideline stated that antimicrobial is not required for patients undergoing hernia repair surgery[4]. However, Yin Y et al and Sanchez-Manuel FJ et al found that antimicrobial prophylaxis in hernia repair surgery significantly prevented SSI[13,14]. As a result, antimicrobial prophylaxis is indicated in hernia repair surgery, in conformance with the ASHP and AMRCP recommendations. Most patients who were not concordant with guidelines regarding timing of antibiotic given within 30 minutes before incision were trauma patients. These patients usually received medications early at their hospital admission regardless of surgery plan. Since the trauma patients are high-risk patients who usually have dirty wounds[15], early antimicrobial use might be correct. While there was high concordance of re-dosing parameter, most of surgery time were shorter than two half-lives of given antimicrobials. In contrast, in longer surgery or 1.5 liter-blood loss, there were only 8.9% who correctly re-dosed intraoperatively.

However, Lim MK[7] conducted a study in Malaysia evaluating concordance of antimicrobial prophylaxis to Malaysian local guideline. The rate of adherence to drug of choice (83.6%) and duration (65.5%) was higher than that reported in our study (69.0% and 36.9% for drug of choice and duration recommended by ASHP). Interestingly, timing of antimicrobial given within 30 to 60 minutes before incision was higher in our study (78.6%) than Lim MK et al study. Although rate of skin and soft tissue infection might not be a concern, increased bacterial resistant strains, tentative adverse events, and higher cost from medication overuse might have had happened in our setting.

Previous studies found that adherence to local guidelines for antimicrobial prophylaxis[6,16] was higher than adherence to international guidelines. Although, we studied concordance of antimicrobial prophylaxis to both international (ASHP and SIGN) and local (AMRCP) guidelines, adherence rates of international guidelines were not significantly higher than national guideline. In contrast, adherence to local guideline in some parameters, drug of choice, dosing, timing, was lower than international guidelines. Nevertheless, our local guideline is not that different from the international guidelines. For example, dose of cefazolin, timing of antibiotic given before incision, and re-dosing intraoperatively recommended by ASHP are the same as recommended by AMRCP. In contrast, cefazolin is the only cephalosporin medication recommended by AMRCP compared to ASHP. Therefore, drug of choice was concordant to the ASHP guideline in 69.0% of patients compared to 41.4% for AMRCP. However, adherence to some local guidelines was high because the guidelines were adapted to local pathogen and their antibiotic use pattern. Therefore, local guideline for specific setting might be needed in our setting since there was diversity of pathogen even in the same country.

Strategies to improve antimicrobial use in surgical patients might require the following: 1) structuring the team, comprising surgeon, anesthesiologist, pharmacists, and members of infection control department to conduct a prospective audit and feedback[17,18], 2) creating local guideline based on local bacterial epidemiology pattern, surgeon, and team members preference[18], 3) standing protocol of antimicrobial use with formulary restriction and/or preauthorization[17], and 4) implementation of education, training, and information to provide knowledge promoting a more rational use of antimicrobial[18,19].

Our study has several limitations. First, the study was conducted in tertiary hospital that cannot represent antimicrobial use of the country. Generalization might not be applicable to other levels, such as secondary hospitals, which might not have any complex surgical cases. Secondly, 187 patients might be too small to detect factors associated to non-compliance to the guidelines. In addition, if we have a greater sample size, non-compliance factors related to the guidelines might be shown. Therefore, strategies to improve antimicrobial use could be more specific to some groups of patients. Lastly, cost related inappropriate antimicrobial use was not pursued, thus,

future study should be warranted.

Conclusion

The study shows that in Thailand, compliance to guidelines for surgical prophylaxis is quite good, except for duration aspect. In addition, prolonged use of antimicrobial prophylaxis and inappropriate antimicrobial use during hospital admission were still a concern. Strategies to improve guideline concordance of antimicrobial surgical prophylaxis and overall antimicrobial use during hospitalization are required.

What is already known on this topic?

Worldwide antimicrobial use in surgical patients has not appropriately complied to the guidelines and still be a main problem during hospitalization.

What this study adds?

This study has shown that duration of antimicrobial prophylaxis in surgical patients was longer than 24 hours, which was an optimal duration recommended by the international guidelines. More attention should be drawn to the duration of antimicrobial use in surgical patients to improve overall clinical outcomes of surgical patients during hospitalization.

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Potential conflicts of interest

None.

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ความสอดคล้องตามแนวเวชปฏิบัติของการใช้ยาต้านจุลชีพสำหรับป้องกันการติดเชื้อในผู้ป่วยที่ได้รับการผ่าตัดในโรงพยาบาลมหาวิทยาลัยประเทศไทย

พิชญา ดิลกพัฒนมงคล, ศุภทัต ชุมนุมวัฒน์, ศุภวัฒน์ ตระกูลเตชะ, สิรวิชญ์ ทรงสมบูรณ์, ปรีชา มนทกานติกุล, นันทพร เล็กพิทยา, ปพน สง่าสูงส่ง, ปรีดา สัมฤทธิ์ประดิษฐ์

ภูมิหลัง: *การศึกษาหลายฉบับพบว่าการใช้ยาต้านจุลชีพมีความไม่สอดคล้องกับแนวเวชปฏิบัติสำหรับป้องกันการติดเชื้อจากการผ่าตัด อย่างไรก็ตามยังไม่มีการศึกษาการใช้ยาต้านจุลชีพในผู้ป่วยศัลยกรรม โรงพยาบาลรามาธิบดี*

วัตถุประสงค์: *การศึกษาความสอดคล้องของการใช้ยาต้านจุลชีพเพื่อป้องกันการติดเชื้อจากการผ่าตัดกับคำแนะนำในแนวเวชปฏิบัติและเพื่อประเมินความเหมาะสมของการใช้ยาต้านจุลชีพในขณะที่ผู้ป่วยรักษาตัวในโรงพยาบาล*

วัสดุและวิธีการ: *เก็บข้อมูลผู้ป่วยไปข้างหน้าจากหอผู้ป่วยศัลยกรรม 4 แห่ง ที่โรงพยาบาลรามาธิบดีตั้งแต่ เดือนกันยายน ถึง เดือนธันวาคม พ.ศ. 2559*

ผลการศึกษา: *พบว่ามีผู้ป่วยศัลยกรรมทั้งหมด 187 คน ที่ได้รับยาต้านจุลชีพถูกรวบรวมเข้าการศึกษาเมื่อพิจารณาจากแนวเวชปฏิบัติ American Society of Health-System Pharmacist (ASHP) 2013 มีผู้ป่วยที่ใช้ยาสอดคล้อง 159 คน (ร้อยละ 85.0), 129 คน (ร้อยละ 69.0), 36 คน (ร้อยละ 19.3), 147 คน (ร้อยละ 78.6), 136 คน (ร้อยละ 72.7) และ 69 คน (ร้อยละ 36.9) ในเรื่องข้อบ่งใช้ ชนิดของยาที่เลือกใช้ ขนาดยา เวลาที่ให้ยา การให้ยาซ้ำขณะผ่าตัด และระยะเวลาการให้ยา ตามลำดับ นอกจากนี้ยังพบว่าการผ่าตัดออร์โธปิดิกส์เป็นปัจจัยเดียวที่ทำให้ผู้ป่วยได้รับยาไม่สอดคล้องในเรื่องระยะเวลาการให้ยาอย่างมีนัยสำคัญ (odd ratio [OR] = 3.966, p<0.001, 95% confidence interval [CI] 1.828 ถึง 8.606)*

สรุป: *การใช้ยาต้านจุลชีพเพื่อป้องกันการติดเชื้อจากการผ่าตัดมีความสอดคล้องสูงกับคำแนะนำในแนวเวชปฏิบัติ ASHP 2013 ยกเว้นเรื่องขนาดยาและระยะเวลาการให้ยา การศึกษาถึงมาตรการการใช้ยาต้านจุลชีพอย่างเหมาะสมเพื่อเพิ่มความสอดคล้องกับคำแนะนำในแนวเวชปฏิบัติอาจมีความจำเป็น*