American Journal of Infection Control 42 (2014) 516-20

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Audits of the quality of perioperative antibiotic prophylaxis in Shandong Province, China, 2006 to 2011

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Key Words:
Clean surgery
Rational use
Antibiotics

Background: A prospective multicenter survey was conducted to assess the rational use of antibiotics in clean and clean-contaminated elective surgical procedures applied in 53 grade III first class hospitals in Shandong Province, China, from 2006 to 2011. The survey was designed to examine the prevalence of antibiotic prophylaxis, evaluate the quality of perioperative antibiotic prophylaxis (PAP) prescriptions, and investigate the risk factors associated with inappropriate indication for antibiotic prophylaxis.

Methods: Medication charts and medical, anesthetic, and nursing records were reviewed. Antibiotic prescriptions were compared with the Chinese National Antibiotic Guideline on indication, antibiotic combination, antibiotic choice, dose, dosing interval, route of administration, timing of first administration, and duration of prophylaxis.

Results: 14,261 of 14,525 procedures (98.2%) receiving antibiotic prophylaxis. The most frequently encountered noncompliance types were PAP indications (18.6%), duration of prophylaxis (26.7%), and timing of first administration (30.3%). The steps of PAP were justified and correct only in 9.4% of procedures. Risk factors independently associated with inappropriate indication for antibiotic prophylaxis were seen in age, hospital type, hospital size, surgical disciplines, and surgical duration.

Conclusion: Results showed a significantly high rate of antibiotic prophylaxis in clean and clean-contaminated elective surgery and also a high prevalence of inappropriate indication prescriptions. These findings suggest important areas for intervention and implementation of antibiotic stewardship policies in Shandong Province hospitals.

Antibiotic prophylaxis is commonly applied in selected surgical procedures to reduce the risk of postoperative surgical site infections (SSIs). The rational use of antibiotics in surgical prophylaxis prevents or decreases SSIs; this preventive measure also reduces the risk of antibiotic resistance and the cost of health care.[1,2] In China, a restrictive antibiotic policy has been implemented, but this policy lacked a set of national antibiotic guidelines. Hence, the criteria used to assess compliance with antibiotic guidelines were insufficient. Nevertheless, this problem was solved in 2004 when the Chinese Ministry of Health published the Chinese National Antibiotic Guideline (CNAG) to promote the prudent use of antibiotics, particularly in perioperative antibiotic prophylaxis (PAP).[3]

Since CNAG was implemented, studies have determined the quality of PAP in compliance with the specified guideline. Unfortunately, antibiotics have been excessively used; as such, antibiotic prophylaxis has been inappropriately indicated or selected; prophylaxis has been unnecessarily prolonged, particularly in clean surgery, in which the infection rate is $< 2.3\%$; the use of antibiotics is also unnecessary.[4-7] Furthermore, these studies have considered a single center or a small sample.[4-6] To determine the overall quality of PAP in clean and clean-contaminated surgery, we should conduct multicenter and large-sample studies.

In China, hospitals are divided into 3 grades according to size: grade I (1-100 sickbeds), grade II (101-500 sickbeds), and grade III (>501 sickbeds). Grade III hospitals are referral centers for additional care with medical teaching and research facilities. In each grade, hospitals are further subdivided into 3 classes according to medical standards, management, equipment availability, and medical research practice: first class (highest standard); second

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Conflicts of interest: None to report.

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http://dx.doi.org/10.1016/j.ajic.2014.01.001

class; and third class.[8] In general, grade III first class hospitals exhibit the highest standards in terms of medical technology and management level; hence, the quality of antibiotic prescriptions in such hospitals should be observed in best practices related to antibiotic use and management.

Shandong is a province with a large population and medical services. In December 2010, the population in this province reached 115.827 million, the third largest population in China (6.62%).[9] In terms of medical profile, the province is equipped with 1,490 public hospitals with 280,385 sickbeds and 1,888,426 inpatient surgery trips.[10,11] Among 1,490 public hospitals, 77 are classified as grade III first class hospitals.[12]

This survey aimed to evaluate and improve the quality of PAP in clean and clean-contaminated surgery in Shandong Province. This information could be used as baseline data for further antibiotic management and development of surgical prophylaxis guidelines.

METHODS

Hospitals

A total of 53 grade III first class hospitals, which are members of the Shandong Antibiotic Use Surveillance Network, voluntarily and responsibly provided data related to antibiotic usage. Among these hospitals, 7 are university-affiliated hospitals, 2 are maternal-child health hospitals, 2 are specialized hospitals, 1 is a traditional medical center, and 41 are regional public hospitals. The average number of sickbed size is 1,247 (ranging from 515 to 3,273).

Surgery

This study included the patients who were subjected to clean or clean-contaminated surgery and discharged on the second week of March, June, September, and December from 2006 to 2011 from each hospital. A total of 15 procedures was extracted randomly and equidistantly from each week. To observe normal daily routine, we included elective procedures only. In addition, procedures with suspected or established infection during surgery were excluded to avoid difficulties in discriminating prolonged prophylaxis from postoperative therapy. Emergency surgeries were also excluded. The selected surgeries covered the 4 major surgical disciplines: orthopedic, vascular, gynecological, and intestinal surgery.

Data collection

In each hospital, 1 member was designated to collect data using standardized forms. Similar to British researchers, data collectors in this survey were antimicrobial clinical pharmacists and systematically trained by experts from the Antibiotic Therapeutics and Management Committee.[13] Patient characteristics and antibiotic prophylaxis data were extracted from medication charts and medical, anesthetic, and nursing records.

Antimicrobial clinical pharmacists performed the first round of audits to validate the integrity and validity of obtained data. Experts from the Antibiotic Therapeutics and Management Committee performed the second round of audits to determine whether or not the quality of PAP is in compliance with the national guideline for surgical prophylaxis.

Audits for adherence to guidelines

The criteria used to evaluate PAP were based on CNAG, which was thought as gold standard in China. The criteria assessed for PAP in survey were as follows: indication, antibiotic drug combination, antibiotc choice, dose, dosing interval, route of administration, timing of first administration, and duration of prophylaxis. The first criterion evaluated was PAP indication; regardless of whether this criterion was assessed as appropriate or inappropriate, the other criteria were evaluated. Antibiotic prophylaxis prescriptions are considered as inappropriate if any of the assessed criteria appear inappropriate (ie, "inappropriate" indication or antibiotic choice).

If more than 1 antibiotic was prescribed for a single procedure, all of the parameters were evaluated separately for each antibiotic drug. A final assessment of the antibiotic course was conducted by combining these separate antibiotic evaluations. Any divergence from the guideline in the prescription of 1 of the antibiotics led to a final assessment of the prophylactic course as discordant with the guideline. If no antibiotic prescriptions were recorded, the assumption is that no antibiotic was administered. If data on a specific parameter of antibiotic prescription were insufficient, this condition was classified as missing data for this parameter only. The parameters were evaluated separately, such that the missing data of 1 parameter did not preclude the assessment of other data.[14,15]

Statistical analyses

All statistical analyses were performed using SPSS version 19 (SPSS Inc, Chicago, IL). The prevalence of antibiotic prophylaxis was defined as the percentage of the number of procedures receiving any antibiotic out of the total number of procedures studied, and the prevalence of inappropriate indication for antibiotic prophylaxis was defined as the percentage of procedures with inappropriate antibiotic indication out of the total number of procedures receiving any antibiotic. Differences in proportions were compared using the χ^2 test. Multivariate logistic regression was used to identify relationships between an inappropriate antibiotic indication and the variables studied (ie, sex, age, hospital type, hospital size, surgical disciplines, and surgical duration). Variables were screened for inclusion in the multivariate model using bivariate logistic regression models. Candidate variables with $P \leq .25$ were included in the final multivariate model. All reported P values were 2-sided, and a P value $< .05$ was considered statistically significant.

RESULTS

Patient demographics

A total of 19,080 surgical procedures was evaluated, and 14,525 procedures satisfied the inclusion criteria, including 8,039 males (55.3%) and 6,486 females (44.7%), with a mean age of 46.7 $\pm$ 25.3 years (age range, 1-84 years). The majority of the patients surveyed was hospitalized in regional public hospitals (10,757; 74.1%), followed by university-affiliated hospitals (2,313; 15.9%), maternal-child health hospitals (613; 4.2%), specialized hospitals (596; 4.1%), and then traditional medicine hospitals (246; 1.7%). There were 5,149 (35.4%) orthopedic procedures, 3,976 (27.4%) vascular procedures, 3,121 (21.5%) gynecologic procedures, and 2,279 (15.7%) intestinal procedures. Of all procedures, there were 9,574 surgical procedures with surgical duration $<$ 3 hours and 4,951 surgical procedures with surgical duration $\geq$ 3 hours. In accordance with the hospital size division, 39.3% (5,713 of 14,525) of the procedures were from hospitals with 501 to 1,000 beds, 51.4% (7,468 of 14,525) were from hospitals with 1,001 to 2,000 beds, 5.7% (825 of 14,525) were from hospitals with 2,001 to 3,000 beds, and 3.6% (519 of 14,525) were from hospitals with $>$ 3,000 beds.

Prevalence of antibiotic prophylaxis

The overall antibiotic prophylaxis rate was 98.2% (14,261 of 14,525), ranging from 97.2% (3,035 of 3,121) in gynecologic patients