Appropriateness and adherence to guidelines in perioperative antimicrobial prophylaxis in patients undergoing clean surgery: results from a Quality Control Circle intervention

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Abstract

The present study aimed to exam the effect of quality control circle (QCC) activities on promoting the appropriate implementation of preoperative antibiotic prophylaxis in clean surgery. A QCC activity team was established to grasp the current situation of PAP in clean surgery procedure, set target, formulated corresponding countermeasures and implement and review them in stages. The plan-do-check-act method was cyclically applied. The appropriateness of PAP before (July to December 2018) and after (April to September 2019) the implementation of QCC activities were evaluated based on relevant international and Chinese perioperative antimicrobial prophylaxis guidelines. The appropriate rate of PAP was significantly improved from 68.72% ($n=406$) before QCC to 93.7% ($n=508$) post QCC implementation ($P=0.01$). A significant improvement ($P=0.05$) was also determined for each category: *selection* (from 78.82 to 96.06%), *duration* (from 90.15 to 96.46%), *indication* (from 94.09 to 97.64%), *timing of first dose* (from 96.55 to 99.21%), *antibiotic usage* (from 96.8 to 99.41%), re-dosing of antibiotic (from 96.55 to 99.21%). The appropriate application of PAP is improved through QCC activities, providing a useful reference for the prevention of antimicrobial-resistant bacteria and the development of medical quality improvement activities.

Introduction

Antimicrobial resistance (AMR) proposes a global challenge for both patients and health-care system^[1], is currently high on the global political agenda^[2]. Microorganisms resistance is the main causative elements of hospital acquired infections (HAIs), of which surgical site infections (SSIs) are the most reported and surveyed type of HAI, and accounting for up to 20% of all HAI^[3]. SSI is one of the most common and severe clinical complications after surgeries, often causes prolonged hospitalization and delayed postoperative therapy, and substantially increase the health-care costs^[4, 5]. Clean surgery is defined as uninfected operative wound without inflammation, respiratory, alimentary, or genital of uninfected urinary track not entered according to the modified National Research Council wound classification criteria^[6, 7]. Although perioperative antimicrobial prophylaxis (PAP) guidelines across a wide array of surgical procedures have been proposed^[8, 9]. Still, suboptimal use of antimicrobial for surgical prophylaxis is a common phenomenon worldwide, such as without indication, inappropriate selection or dosing of antimicrobial agents, prolonged duration of antimicrobial agents, incorrect timing of prophylaxis, which may result in AMR and higher healthcare costs^[10].

Quality control circle (QCC) is a process management and problem-solving technique founded in 1962 by Dr. Kaoru Ishikawa of Japan, which is viewed as a powerful tool to solve the problems in work and improve the complex work flow by the joint efforts of all members composed of staff from the same or similar or complementary workplaces^[11]. Until 2001, QCC activities was introduced to healthcare industry in China, and numerous studies have reveled that the application of QCC could effectively raise the quality of medical service and ensure the safety of patients^[12–14]. In our present study, a QCC program was carried out to improve the rational application of surgical antimicrobial prophylaxis in clean surgery

procedures, and the plan-do-check-act (PDCA) method was implemented for 12 months. This was the first time that QCC program was implemented for the promotion of rational application of surgical antimicrobial prophylaxis in our hospital, after 12 months of continuous improvement, satisfied results have been achieved, as reported below.

Material And Methods

This study was carried out in the People's Hospital of Pengzhou, a tertiary hospital with 1,106 beds, 356 doctors and 485 nurses in Chengdu, China. The medical records of a total of 1092 patients underwent clean surgical procedures from July to December 2018 (before QCC) in our hospital were manually reviewed. In total, 1142 patients subjected to clean surgical procedures from January to June 2019 were enrolled as the intervention group (after QCC).

A total of 8 members QCC team was established. The director of pharmaceutical department served as the head of QCC group, and the circle members includes surgeon, clinical pharmacist, nurses, anesthetist, clinical microbiologist, infection control practitioner. The circle members proposed the theme of the QCC was 'to improve the appropriate implementation rate of surgical antimicrobial prophylaxis following brainstorming and voting, and the 'Spark Circle' was selected as circle name, meant to convey the concept of 'A single spark can start a prairie fire'.

Gantt chart was adopted to draw up the activities and duration of the separate steps of the implementation plan according to the processes and the theme of QCC, the person in charge of each step was confirmed. It was expected to take 24 weeks to complete all procedures, and 1-2 circle members are designated to supervise and implement each step.

A total of 1092 patients who underwent clean surgery from July to December 2019 were investigated, of which 406 patients received prophylactic antibiotics, and there have 182 problems during perioperative period, and the overall appropriate rate of PAP was 68.72% (127/406). The appropriate rate of implementation was analyzed by a flow chart for improvement and a checklist for irrational administration. The leading deficient quality indicators of PAP identified were inappropriate selection of antibiotics, prolonged duration of prophylaxis and PAP without indication. Furthermore, the circle capacity was set at 80% according the circle members' activeness and group cooperation following brainstorming and discussing, according to the formula of the target value, the target value = current value $\times$ (current value $\times$ value of focus $\times$ ability of circle) = 68.72% $\times$ (68.72% $\times$ 84.7% $\times$ 80%) = 22.16%, the target value was to improve the implementation rate by 22.16% so as to achieve the appropriate rate of PAP in 90.88%.

The cause of the inappropriate administration of PAP were analyzed by QCC members following brainstorming. Fishbone diagram was performed to facilitate root cause analysis discussion from the perspectives of people, equipment, materials, management, environment (Fig 1). Meanwhile, a questionnaire of hospital survey among doctors and nurses was carried out to assess hospital staff's perceptions of PAP. According to the 80/20 principle, Pareto chart was adapted to demonstrate the

essential causes of the inappropriate implementation that need to be improved are fear of SSI, lack of professional training, inadequate supervision, lack of standardized process and insufficient assessment (Fig 2).

According to the three key problems that can be solved, the final improvement strategies were implemented following brainstorming based on the comprehensive evaluation of the feasibility, autonomy and ability of QCC members. The leader of the QCC summarizes and evaluates the various methods, and then analyzes and modifies the methods through quality control tools. The specific methods are as follows:

Training about the knowledge of PAP: Experts in the field of anti-infection were invited to interpret the guidelines related to PAP and provided professional training and sufficient assessment for front-line doctors and nurses. In addition, various forms of publicity and training were carried out among surgeons, nurses, standard-trained doctors and new physicians. Furthermore, a booklet documented the standard operating procedure of PAP for various clean procedures according to the established criteria was distributed to each surgeons.

Strengthen pre-supervision of the whole-process: Clinical pharmacists participate in the formulation of prescriptions and conduct a real-time supervision on the whole process of PAP. Clinical pharmacist should remind the surgeons to modify the prescription immediately when irrational antibiotics were prescribed. If the opinions of pharmacist with surgeons are inconsistent, the pharmacist should consider the doctor's appeal and suggestions, and check the rationality of the prescription again, revising the evaluation standard if necessary.

Strengthen the evaluation of the rationality of prescription: Data on the characteristics of the surgical patients were collected from the hospital information system, the rationality of the PAP were evaluated by clinical pharmacists according to the established criteria. Clinical pharmacists summarized and analyzed the data of the unreasonable application of antimicrobial during the perioperative period, and reported to the medical management department every week. Furthermore, in view of some common problems of inappropriate application of PAP, hierarchical training were conducted by clinical pharmacists for key departments to elevate the professional knowledge of medical staff.

The differences on the appropriate implementation rate of PAP before and after the QCC activity were compared after the implementation of the QCC activities. The evaluation indicators including the indication, choice, duration and usage of antibiotics administered during perioperative period.

Statistical analysis. Data were represented as means $\pm$ SEM. Statistical analyses were performed by using the SPSS 20.0 software (SPSS Inc.; IL, USA). Statistical comparisons between two groups were conducted by using One-way analysis of variance (ANOVA) followed by Bonferroni *post hoc test*. Difference between groups were considered statistically significant when a value of $P < 0.05$.

Results

The comparison of the appropriateness of the perioperative antimicrobial prophylaxis between before and after the QCC activity was drawn. As shown in Tab 1, A significant improvement was also determined for each category: selection (from 78.82 to 96.06%), duration (from 90.15 to 96.46%), indication (from 94.09 to 97.64%), timing of first dose (from 96.55 to 99.21%), antibiotic usage (from 96.8 to 99.41%), re-dosing of antibiotic (from 96.55 to 99.21%), all the differences above were statistically significant ($P \leq 0.05$). The total rate of appropriate surgical prophylaxis was significantly improved from 68.72% (279/406) to 93.7% (476/508) after QCC intervention ($P \leq 0.01$). After the QCC activity, the setting goal was achieved. Target reach rate=(improvement value-current value)/(target value-current value) $\times 100\%$ = (93.7%-68.72%) / (90.88%-68.72%)=112.73%, progress rate= (improvement value-current value)/current value $\times 100\%$ =36.35%. Furthermore, the incidence of SSI, other surgical complications and antibiotic-related ADR between before and after QCC activity were no statistically significant ($P \geq 0.05$) (Tab 2).

In this QCC activity, obvious improvements of circle members were founded in terms of self-confidence, responsibility, work enthusiasm, problem-solving capability, communication skills, teamwork and motivation and skills of quality control (Fig 3). The implementation of QCC project not only enhances the individual ability, but also enables the whole team to form a highly enthusiastic atmosphere of study and work.

After the continuous improvement of the QCC activity, a standardized operation flow for the appropriate implementation of surgical antimicrobial prophylaxis in clean incision operations was established.

Discussion

Antimicrobial misuse and overuse are leading causes in the emergence of antimicrobial-resistant bacteria^[15]. In our present study, only 68.72% of PAP were deemed to be appropriate before QCC activity when compared the current clinical practice of PAP with guidelines for antimicrobial prophylaxis in surgery published by China Ministry of Health, the leading deficient quality indicators of PAP identified were inappropriate choice of broad spectrum antibiotics, unnecessarily prolonged duration of prophylaxis, along with no indication to implementation of PAP without any reason. While the QCC intervention has a significant impact on the appropriateness of PAP in patients undergoing clean surgery, the overall compliance rate to guidelines rose to 93.7%.

Although the availability of consensus guidelines for antibiotic prophylaxis in surgery clearly demonstrated the PAP indication, antibiotics selection, timing of first dose, antibiotic usage, duration of prophylaxis and re-dosing of antibiotic and all the parameters for clean surgical operations^[9]. However, significant discrepancies between clinical practice of PAP and the guidelines in clean surgical procedures were founded before QCC in our hospital. Previous studies reported that lack of sufficient and effective education among surgeons seems to be the main barrier to adherence with PAP guidelines^[16], surgeons prescribe antibiotics according to their own principle that they trained in a wrong way in the past and it was counterintuitive for them to accept the new clinical practice guidelines about PAP^[16]. Surgeons were accustomed to prescribe antibiotic prophylaxis and prolonged use of antibiotics in cases, as they falsely

believed that maintaining antibiotics in the bloodstream of a post-operative patient was an effective precaution against SSIs^[17]. Thus, testing the compliance and acceptance of clinical guidelines among surgeons is of great significance for their effective implementation.

One of the most crucial issues for appropriate PAP depending on possible contaminating bacteria and their susceptibility to antimicrobials, whether antibiotics can reach an effective concentration at the surgical site^[18]. In accordance with the international and native guidelines, first- or second- generation injectable cephalosporins was appropriately selected and administered than other classes of antibiotics, cefazolin and cefuroxime were the first antibiotics of choice for majority of the surgical procedures according to the guidelines composed by China Ministry of Health. In our study, although the most frequently prescribed antimicrobials were cefazolin and cefuroxime, antibiotic selection was found to be inappropriate in 21.18% of cases before QCC intervention. Lower rates of appropriateness were demonstrated where broad-spectrum antibiotics such as third-generation cephalosporins, piperacillin/tazobactam, etc. were prescribed, as they are associated with increased emergence of extended-spectrum β -lactamases and *Clostridioides difficile* strains. The selection of appropriate antimicrobial agents in the present study pre QCC intervention (78.82%) was higher to that of a recent study (55.3%)^[19], but lower to that reported by Pittalis et al (84.5%)^[20]. While after the QCC intervention almost 96% received the appropriate antimicrobial agents for their surgical procedure.

Current antimicrobial prophylaxis in surgery guidelines recommend that the duration of PAP should not beyond 24 h after incision for clean procedures^[21]. However, in almost 10% of the procedures in our study, the duration of PAP exceeded this time limit. Previous studies demonstrated that prolonged PAP can alter the institutional antibiogram and an individual's microbiome, which can lead to the emergence of bacterial resistance and may increase the incidence of antibiotic-associated complications^[22, 23]. Other studies revealed that a single intravenous dose or within 24 h administration of PAP is enough to prevent postoperative infection in clean operations^[23]. In line with prior studies, our results showed that shorter antimicrobial prophylaxis after QCC intervention has no effect on the incidence of SSI, other surgical complications and antibiotic-related ADR.

According to the international and native guidelines, some clean surgeries (such as breast and thyroid surgery, inguinal without a mesh, vascular vessel angiography, physical ablation of the tumor), antimicrobial prophylaxis was not recommended. However, in almost 6% of the procedures have no indication to use antimicrobial prophylaxis in our study. Antimicrobial overuse is the leading cause of AMR, and more than 30% of prescriptions are unnecessary according to the estimates of the US Centers for Disease Control and Prevention^[24]. While after the QCC intervention, 99% of the antimicrobial prophylaxis have indication. Our finding highlight the importance of limiting antibiotics use in PAP.

In conclusion, the QCC activity has achieved good results in promoting the appropriateness of PAP in patients undergoing clean surgery. The principal finding of this study is that QCC implementation is associated with increased surgeon's perceptions of PAP. Moreover, QCC activities could effectively

improve the self-confidence, problem-solving capability and skills of quality control of medical staff, and deserved application and promotion in medical quality improvement activities.

Declarations

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Author contributions

Jian Zou and Jia-yun Zhong conceived the study. Yu Liu and Dan Huang performed data collection and analysis. Yan-xin Liu, Xi-wen Li, Wen-jun Gong and Jia Tao conduct the QCC activities. Jian Zou prepared the manuscript. All authors reviewed and edited the manuscript.

Competing interests

The authors declare that they have no competing interests

Availability of data and materials

Datasets used and/or analysed during the present study are available from the corresponding author on reasonable request.

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Tables

Table 1. Comparison appropriateness of PAP before and after QCC activity

Variables	Before QCC (n=406)		After QCC (n=508)		c ²	P
	N	%	N	%		
Antibiotic selection						
1.1 Appropriate implementation	320	78.82%	488	96.06%	9.324	0.005
1.2 Inappropriate implementation	86	21.18%	20	3.94%		
Duration of prophylaxis						
2.1 Appropriate implementation	366	90.15%	490	96.46%	6.417	0.011
2.2 Inappropriate implementation	40	9.85%	18	3.54%		
PAP indication						
3.1 Appropriate implementation	382	94.09%	496	97.64%	5.161	0.019
3.2 Inappropriate implementation	24	5.91%	12	2.36%		
Timing of first dose						
4.1 Appropriate implementation	392	96.55%	504	99.21%	7.354	0.023
4.2 Inappropriate implementation	14	3.45%	4	0.79%		
Antibiotic usage						
5.1 Appropriate implementation	393	96.8%	505	99.41%	6.983	0.028
5.2 Inappropriate implementation	13	3.20%	3	0.59%		
Re-dosing of antibiotic						
6.1 Appropriate implementation	401	98.77%	507	99.8%	7.025	0.039
6.2 Inappropriate implementation	5	1.23%	1	0.20%		

Table 2. Comparison of surgical complications and antibiotic-related ADR before and after QCC intervention

Variables	Before QCC	After QCC	<i>P</i> Value
<i>SSI</i>	2	1	0.289
<i>Other surgical complications</i>			
Partial skin necrosis	1	0	0.368
Hematoma or seroma	6	4	0.542
Wound dehiscence	3	2	0.435
<i>Antibiotic-related ADR</i>			
Allergic reaction(skin Rash, itching, flushing, macules, urticaria)	7	6	0.586
Digestive system(nausea, vomiting, acid reflux, abdominal discomfort)	6	4	0.542
Cardiovascular system(phlebitis, palpitations, induration of infusion site)	0	0	-
Nervous system(headache, convulsions, dizziness, quadriplegia)	1	0	0.356

Figures

Figure 1

Analysis of the root causes of inappropriate implementation of PAP in clean surgery by Fishbone diagram

Figure 2

Pareto chart demonstrates the essential causes of the inappropriate implementation of PAP in clean surgery that need to be improved

Figure 3

Analysis of the circle capability by radar diagram