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ORIGINAL RESEARCH

Sustained Improvement of Appropriateness in Surgical Antimicrobial Prophylaxis with the Application of Quality Control Circle

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Purpose: Quality control circle (QCC) has acquired success in many fields in healthcare industry as a process management tool, whereas its efficacy in surgical antimicrobial prophylaxis (SAP) remains unknown. This study aimed to implement QCC interventions to improve the appropriateness of SAP.

Methods: A QCC activity team was established to grasp the current situation of SAP in clean surgery procedure, set target, formulate corresponding countermeasures and implement and review them in stages. The plan-do-check-act (PDCA) method was cyclically applied.

Results: The appropriateness of antibiotic prophylaxis before (January to December 2020) and after (January to December 2021) the implementation of QCC activities were evaluated based on relevant international and Chinese SAP guidelines. The overall SAP appropriateness was significantly improved from 68.72% before QCC to 93.7% 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%), antimicrobial usage (from 96.8% to 99.41%), re-dosing of antimicrobial (from 96.55% to 99.21%).

Conclusion: Implementation of a QCC program can optimize the use of antibiotics and improve the appropriateness of SAP and is of practical importance to their standardization.

Keywords: surgical antimicrobial prophylaxis, quality control circle, appropriateness

Introduction

Antimicrobial resistance (AMR) is a global threat to human health and well-being.[1] AMR has generated an unprecedented amount of global attention, this increase in attention around AMR has coincided with a rise in focus on this topic at various multilateral organizations and international fora.[2] Microorganisms resistance is the main causative element of hospital acquired infections (HAIs), of which surgical site infections (SSIs) are considered to be a major cause of morbidity and mortality related to HAIs.[3] SSIs are one of the most common and severe clinical complications after surgeries, often causes prolonged hospitalization and delayed postoperative therapy, and substantially increase the healthcare costs.[4,5] Clean surgery is defined as uninfected operative wound, where no inflammation is encountered and the respiratory, alimentary, and genital of uninfected urinary track are not opened.[6,7] Although the principles of surgical antimicrobial prophylaxis (SAP) are clearly established and relevant guidelines have been published.[8,9] However, unnecessary or suboptimal prescriptions of antimicrobial prophylaxis is a common phenomenon worldwide, including excessive use of antibiotics, inappropriate selection or dosages, prolonged duration or incorrect timing of first dose, which may result in antibiotic resistance and higher healthcare costs.[10]

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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 complementary workplaces.[11] Until 2001, QCC activities was introduced to healthcare industry in China, and numerous studies have revealed that the application of QCC could effectively raise the quality of medical service and ensure the safety of patients.[12–14] Despite the extensive application of QCC in healthcare industry, few studies have formally determined its association with SAP. In this study, a QCC program was carried out to optimize the use of antibiotics and improve the appropriateness of SAP.

Methods

Clinical Materials

A QCC program was launched in the People's Hospital of Pengzhou, a tertiary hospital in Chengdu, China. Our study was approved by the ethical committee of the People's Hospital of Pengzhou and the data was anonymized or maintained with confidentiality. This study complied with the tenets of the Declaration of Helsinki and was based on the standard for quality improvement reporting excellence (SQUIRE, version 2.0). Retrospective data of 1092 patients who had undergone clean surgical procedures from January to December 2020 at our hospital was included (before QCC). In addition, 1142 patients who underwent clean surgical procedures from January to December 2021 were regarded as the intervention group (after QCC).

Formation of QCC and Theme Selection

We carried out the activities strictly in accordance with four stages and 10 steps of QCC (as shown in Figure 1): identification of a problem, developing an action plan, status analysis of the problem, goal setting, cause effect analysis, generating solutions, implementation of solutions, result confirmation, standardization, and review. A total of 8 members QCC team was established, a pharmacist was appointed as leader, responsible for program management and outcomes, the circle members includes surgeon, clinical pharmacist, infectious diseases physician, nurse, anesthetist, clinical microbiologist and infection control practitioners.

Developing an Action Plan

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.

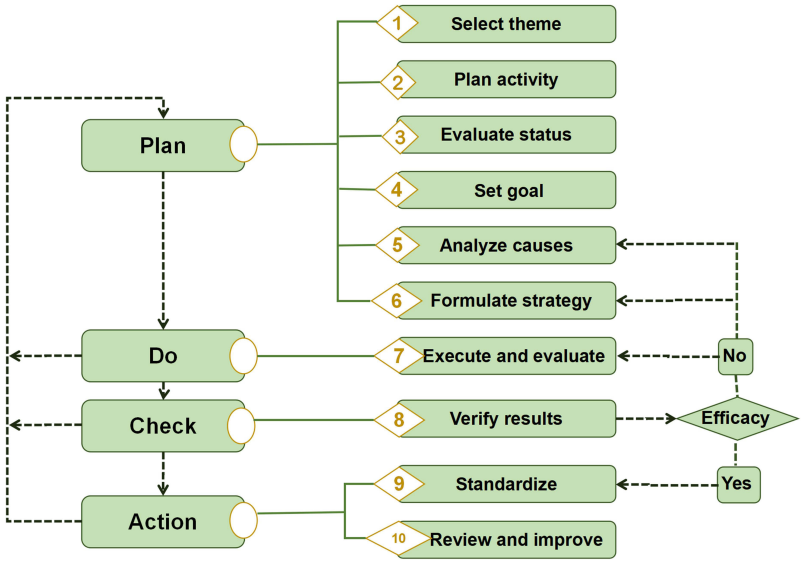

Figure 1 A flow diagram illustrating the ten QCC steps beside the PDCA workflow.

Status Analysis and Goal Setting

A total of 1092 patients who underwent clean surgery from January to December 2020 were investigated, of which 406 patients received antimicrobial, while 686 patients did not. The appropriateness of SAP was assessed based on relevant national guidelines and Chinese national guidelines available at the time of assessment.[8,9] The rate of the appropriate utilization of SAP was analyzed by a Pareto chart for improvement and a checklist for irrational prescriptions, the overall appropriate rate was 68.72%. According to the 80/20 rule, we determined the 3 major deficiencies, which were incorrect antibiotics selection, over-extended duration and no indication of prophylaxis, they accounted for 84.70% of the total defects, as shown in Figure 2. According to the formula of the target value,[15] the target value =current value-(current value×value of focus×ability of circle) = 68.72%-(68.72%×84.7%×80%)=22.16%, the target value was to improve the appropriate rate of SAP by 22.16% so as to achieve the appropriate rate of SAP in 90.88%.

Cause Effect Analysis

Based on the current situation investigation, a brainstorming method was conducted by QCC members to analyze the cause of SAP inappropriateness from the perspectives of people, equipment, materials, management and environment, a Fishbone diagram was constructed (Figure 3). Subsequently, a questionnaire regarding the causes of inappropriateness in antimicrobial prophylaxis prescribing practices was conducted among antimicrobial prescribing surgeons of our hospital to assess hospital staff's perceptions of SAP. According to the 80/20 principle, Pareto chart was adapted to demonstrate the essential causes of the SAP inappropriateness that need to be improved are fear of SSI, lack of professional training, inadequate supervision, lack of standardized process and insufficient assessment, as shown in Figure 4.

Solutions Generating and Implementation

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 and Education

We invited microbiologists and anti-infective specialists to interpret the guidelines related to SAP, and provided related knowledge training and regular management for surgeons. In addition, various forms of publicity and training were carried

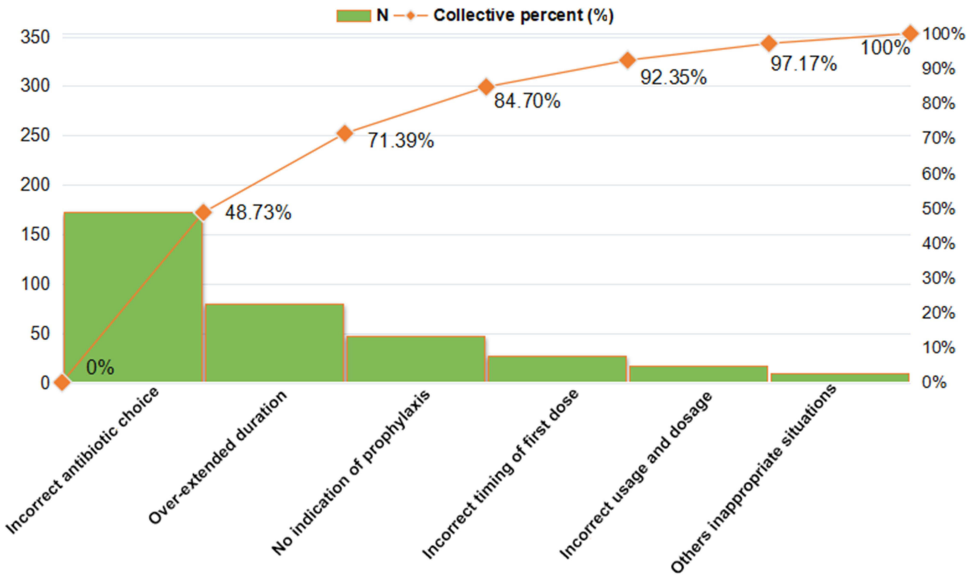

Figure 2 The key problems of the inappropriate implementation of SAP in clean surgery that need to be improved.

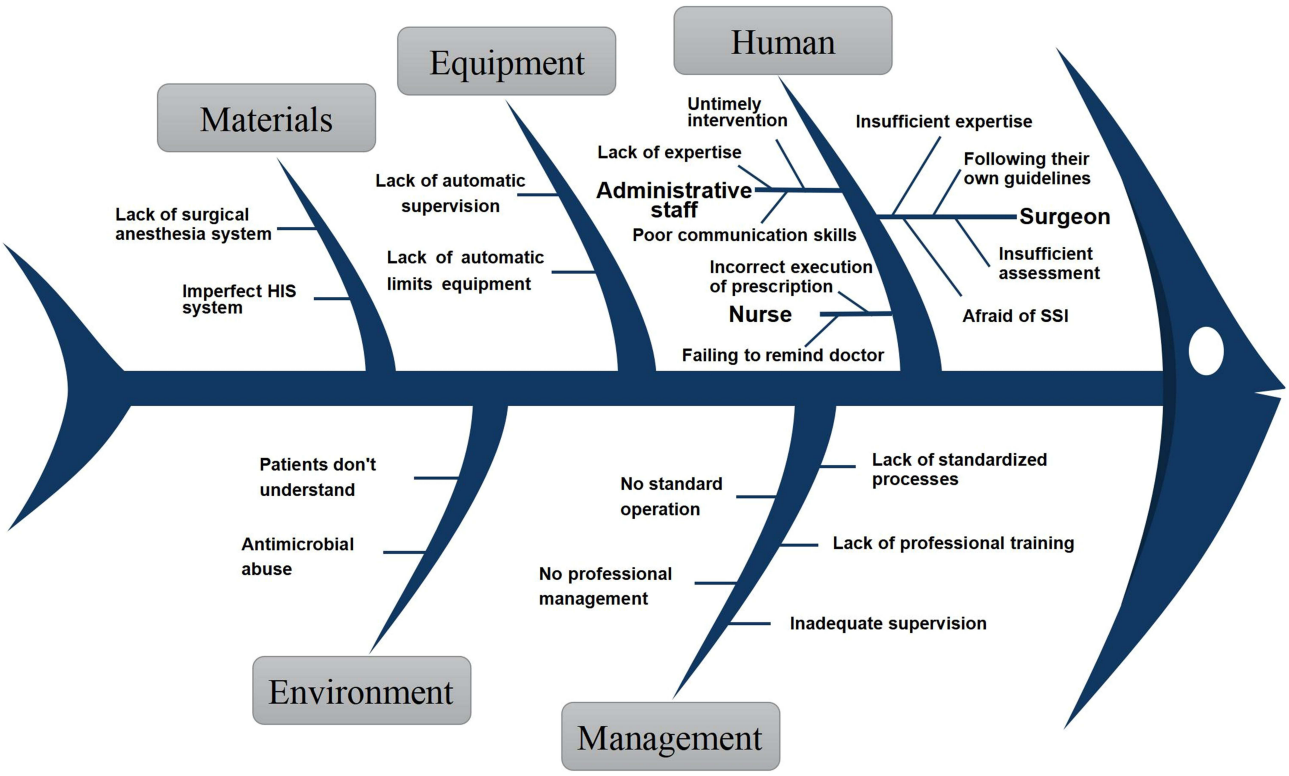

Figure 3 Analysis of the root causes of inappropriate implementation of SAP in clean surgery by Fishbone diagram.

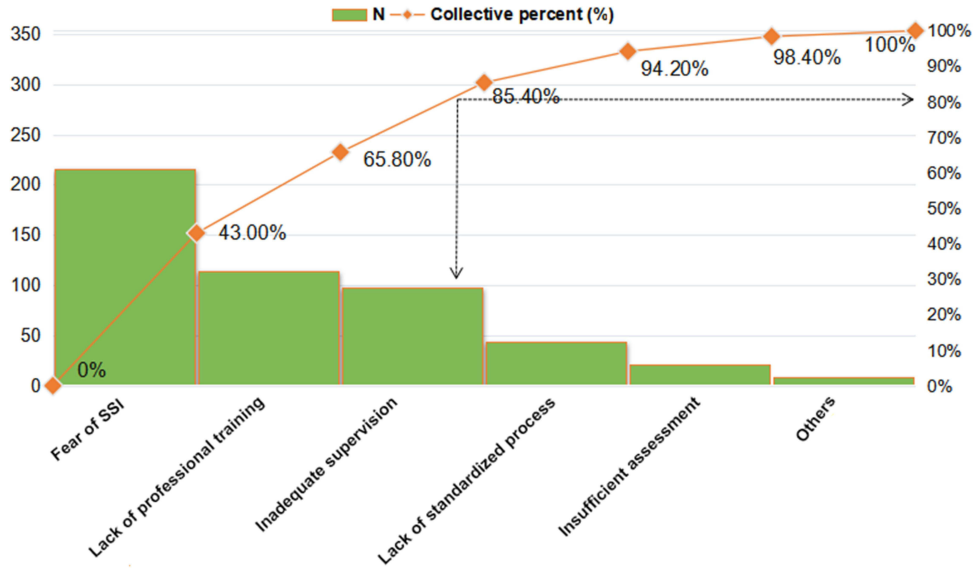

Figure 4 Pareto chart demonstrates the essential causes of the inappropriate administration of SAP in clean surgery that need to be improved.

out among surgeons, nurses, standard-trained doctors and new physicians. Furthermore, a booklet documented the standard operating procedure of SAP for various clean procedures according to the established criteria was distributed to each surgeon.

Monitor and Intervention

Clinical pharmacists participate in the formulation of prescriptions and conduct a real-time supervision on the whole process of SAP by using a computerized system. Clinical pharmacist should remind the surgeons through the

computerized hospital system to modify the prescription immediately when inappropriate antimicrobial prophylaxis 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.

Evaluation and Reporting

Data on the characteristics of the surgical patients were collected from the hospital information system, the rationality of the SAP was evaluated by clinical pharmacists according to the established criteria. Clinical pharmacists summarized and analyzed the information of the use of antimicrobial prophylaxis, and reported to prescribers and hospital leadership every week. Furthermore, in view of some common problems of inappropriate application of SAP, hierarchical training were conducted by clinical pharmacists for key departments to elevate the professional knowledge of medical staff.

Effect Evaluation

The effects of QCC intervention were evaluated and other data were recorded, including the occurrence of SSIs, other surgical complications and antibiotic-associated side effects. Appropriate use of antibiotic prophylaxis in terms of correct indication, antibiotic choice, dose, timing of first dose, frequency and duration were determined after comparing with standard protocols as per evaluation criteria in the footnotes of Table 2.[6,7,9] The differences of appropriate rate of SAP and the incidence of SSIs, other surgical complications and antibiotic-associated side effects before and after QCC intervention were compared.

Statistical Analysis

Data were represented as means ± 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*. Enumeration data were analyzed using the χ^2-test. Difference between groups were considered statistically significant when a value of $P<0.05$.

Results

Tangible Results

The types of surgeries in pre- and post-QCC interventions are summarized in Table 1, there was no significant difference in types of surgeries between the two groups. As shown in Table 2, the overall appropriateness was significantly increased from 68.72% before QCC to 93.7% post QCC interventions ($P<0.01$), and a significant improvement was also promoted for each indicator: 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%), antimicrobial usage (from 96.8% to 99.41%), re-dosing of antimicrobial (from 96.55% to 99.21%), all the differences above were statistically significant ($P<0.05$). After the QCC intervention, the setting goal was achieved. Target

Table 1 Type of Surgical Procedures

Clean Surgeries	Before QCC n (%)	After QCC n (%)
Hernia repair	241 (22.07%)	227 (19.88%)
Thyroidectomy	174 (15.93%)	189 (16.55)
Breast surgery	139 (12.73%)	117 (10.25%)
Internal fixation of bone	124 (11.36%)	133 (11.65%)
Ophthalmic surgery	103 (9.43)	121 (10.60%)
Brain surgery	92 (8.42%)	108 (9.46%)
Joint replacement plasty	87 (7.97%)	125 (10.95%)
Spinal cord operation	35 (3.21%)	33 (2.89%)
Carotid endarterectomy	26 (2.38%)	19 (1.66%)
Varicose vein surgical treatment	19 (1.74%)	24 (2.10%)
Others	52 (4.76%)	46 (4.03%)
Total	1092	1142

Table 2 SAP Appropriateness Before and After QCC Intervention

Variables	Before QCC n (%)	After QCC n (%)	χ^2	*P*
Receiving SAP				
Overall appropriateness[a]	279 (68.72%)	476 (93.7%)	11.542	0.003
Appropriateness in selection[b]	320 (78.82%)	488 (96.06%)	9.324	0.005
Cefazolin	213 (52.46%)	293 (57.68%)		
Cefuroxime	107 (26.35%)	195 (38.39%)		
Piperacillin tazobactam	34 (8.37%)	2 (0.39%)		
Third generation cephalosporins	21 (5.17%)	11 (2.16%)		
Others	31 (7.64%)	7 (1.38%)		
Appropriateness in duration[c]	366 (90.15%)	490 (96.46%)	6.417	0.011
Single dose	81 (19.95%)	97 (19.09%)		
<24 h	285 (70.20%)	393 (77.35%)		
>24 h	40 (9.85%)	18 (3.54%)		
Appropriateness in indication[d]	382 (94.09%)	496 (97.64%)	5.161	0.019
Appropriateness in time of first dose[e]	392 (96.55%)	504 (99.21%)	7.354	0.023
At the beginning of anesthesia	54 (13.30%)	63 (12.40%)		
30–60 min before incision	338 (83.25%)	441 (86.81%)		
During or post operative	14 (3.45%)	4 (0.79%)		
Appropriateness in usage[f]	393 (96.8%)	505 (99.41%)	6.983	0.028
Appropriateness in re-dosing[g]	401 (98.77%)	507 (99.8%)	7.025	0.039
Received re-dosing	15 (3.69%)	26 (5.12%)		
Re-dosing is necessary	20	27		
Not receiving SAP				
Appropriateness in indication[d]	671 (97.81%)	625 (98.58%)	6.753	0.047

Notes: [a]SAP prescriptions fully adherent to guidelines, [b]Cefazolin or cefuroxime (Vancomycin is recommended for high-risk patients in healthcare facilities with a high incidence of MRSA), [c]Not exceed 24 h after surgery completion, [d]SAP administered only if indicated in guidelines or not administered if not recommended for the specific surgical procedure, [e]Antimicrobial should be administered within 30–60 min before incision or at the beginning of anesthesia, [f]Cefazolin: Adults: 2 g (3 g for patients weighing ≥ 120 kg); Pediatrics: 30 mg/kg, Cefuroxime: Adults: 1.5 g; Pediatrics: 30 mg/kg, Vancomycin: 15 mg/kg, [g]Repeated doses in cases of procedures lasting > 3 h or prolonged beyond two times the half-life of the administered antibiotic or when blood loss exceeds 1500 mL during the procedure.

reach rate = (improvement value−current value)/(target value−current value)×100%=(93.7%−68.72%) / (90.88%−68.72%) = 112.73%, progress rate = (improvement value−current value)/current value×100% = 36.35%. These results demonstrated that QCC interventions could significantly optimized the use of antibiotics and improved the appropriateness of SAP. Furthermore, we also compared the incidence of SSI, other surgical and antibiotic-related complications between the two groups. As shown in Table 3, there was no significant difference in SSI, other surgical and antibiotic-related complications in pre and post-QCC interventions.

Table 3 Surgical and Antibiotic-Related Complications After Clean Surgery in Two Groups

Variables	Before QCC	After QCC	*P* value
SSI	4	3	0.442
Other surgical complications			
Partial skin necrosis	2	1	0.353
Hematoma or seroma	8	7	0.581
Wound dehiscence	3	2	0.435
Antibiotic-related ADR			
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)	1	0	0.356
Nervous system (headache, convulsions, dizziness, quadriplegia)	1	0	0.356

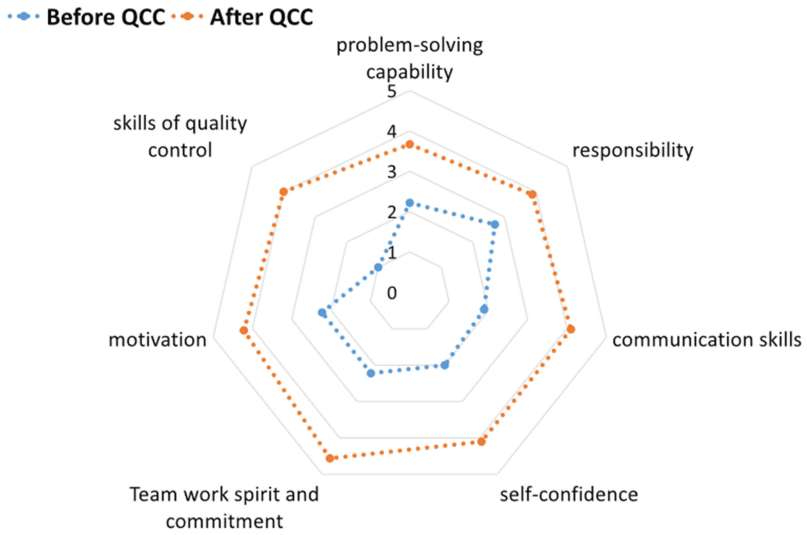

Figure 5 Analysis of the circle capability by radar diagram.

Intangible Results

A self-evaluation questionnaire concerning self-confidence, responsibility, team-work spirit and commitment, problem-solving capability, communication skills and skills of quality control of circle members were completed, with the highest score of 5 and the lowest score of 1 for each item. The result is plotted as a radar map. As shown in Figure 5, all aspects above mentioned of circle members were significantly improved after the QCC activities.

Standardization

After the continuous improvement of the QCC intervention, a standardized operation flow for the appropriate prescriptions of prophylactic antibiotics in clean incision operations was established.

Discussion

Statement of Principal Findings

Antimicrobial misuse and overuse play a key role in the emergence of AMR, creating an urgency to improve antimicrobial prescribing. In the current study, we retrospective evaluated the use of antimicrobial prophylaxis in patients who underwent clean surgery procedures, only 68.72% of antimicrobial prophylaxis were deemed to be appropriate. After the QCC interventions, the overall appropriateness of antimicrobial prophylaxis improved to 93.7%. In addition, the indication of antimicrobial prophylaxis, antibiotics selection and dosage, prophylaxis duration, timing of first dose and re-dosing of antibiotics were significantly optimized, suggested the effectiveness of QCC interventions.

Strengths and Limitations

There are several strengths and limitations in our study. Strengths include that QCC activity significantly improve the appropriateness of SAP. Moreover, QCC interventions effectively promote the surgeon's perceptions of SAP and thereby improve the appropriateness of selection, duration, indication, timing of first dose, dosage and re-dosing of antimicrobial prophylaxis. Finally, QCC interventions could effectively promote the self-confidence, problem-solving capability and skills of quality control of medical staff, and deserved application in medical quality improvement activities.

However, several limitations of our study should be born in mind. This was a single-center study, relatively small number of observations, and inclusion of only those who underwent clean surgical procedures. In the future, we will expand the sample and make continuous quality improvements to more accurately reflect the sustainability of the QCC program to provide more clinically meaningful and valuable results.

Interpretation Within the Context of the Wider Literature

Antimicrobial misuse and overuse are leading causes in the emergence of antimicrobial-resistant bacteria.[16] Although the availability of consensus guidelines for antimicrobial prophylaxis in surgery clearly demonstrated the SAP indication, antimicrobial selection, timing of first dose, antimicrobial usage, duration of prophylaxis and re-dosing of antimicrobial and all the parameters for clean surgical operations.[9] However, significant discrepancies between clinical practice of SAP 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 SAP guidelines,[17] surgeons prescribe antimicrobial 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 SAP.[17] Surgeons were accustomed to prescribe antimicrobial prophylaxis and prolonged use of antimicrobial in cases, as they falsely believed that maintaining antimicrobial in the bloodstream of a post-operative patient was an effective precaution against SSIs.[18] 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 SAP depending on possible contaminating bacteria and their susceptibility to antimicrobial, whether antimicrobial can reach an effective concentration at the surgical site.[19] In accordance with the international and native guidelines, first- or second- generation cephalosporin was appropriately selected and administered than other classes of antimicrobial, cefazolin and cefuroxime were the first antimicrobial 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 antimicrobial were cefazolin and cefuroxime, antimicrobial selection was found to be inappropriate in 21.18% of cases before QCC intervention. Lower rates of appropriateness were demonstrated where broad-spectrum antimicrobial 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%),[20] but lower to that reported by Pittalis (84.5%).[21] 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 SAP should not beyond 24 h after incision for clean procedures.[22] However, in almost 10% of the procedures in our study, the duration of SAP exceeded this time limit. Previous studies demonstrated that prolonged SAP 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 antimicrobial-associated complications. Other studies revealed that a single intravenous dose or within 24 h administration of antimicrobial is enough to prevent postoperative infection in clean operations.[23] In line with prior studies, our results showed that QCC intervention has no effect on the incidence of SSI, other surgical complications and antimicrobial-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 antimicrobial resistance, and more than 30% of prescriptions are unnecessary according to the estimates of the United States Centers for Disease Control and Prevention.[24] While after the QCC intervention, 99% of the antimicrobial prophylaxis have indication. Our findings highlight the importance of limiting antimicrobial use in SAP.

Implications for Policy, Practice and Research

Present study has implications for policy, practice and research into SAP. It highlights the reliability of the QCC activity in improving the appropriateness of SAP, supporting the use of quality management tools to carry out continuous quality improvement activities. Moreover, QCC activities cannot only acquire tangible results but also obtain several intangible results. Firstly, our present QCC activities enhanced the problem-solving capability of the circle members through regularly meet to identify, analyse and solve problems by integrating various quality management tools. Secondly, cross-

professional cooperation is the ideal way to solve the problem in healthcare institutions. QCC activities allow multi-disciplinary teamwork to participate together, which is helpful to cultivate the team spirit during the implementation process of QCC, and brings greater benefits.

Conclusions

In conclusion, the QCC activity has achieved good results in promoting the appropriateness of SAP in patients undergoing clean surgery. 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.

Data Sharing Statement

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

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Disclosure

The authors declare that they have no competing interests in this work.

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