

The application of quality control circle to improve the quality of samples

A SQUIRE-compliant quality-improving study

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Abstract

Since its application in medical institutions in China, quality control circle (QCC) has gained achievements in medical care and thus earned more attention from the administrative department of health.

In order to improve the quality of laboratory specimens, we launched a QCC activity to solve the problems and evaluate the effect of it. The data of 30,105 unqualified specimens in our hospital were collected from February to June 2017. After the QCC activity, the data of 43,125 specimens taken from July to December 2017 were collected.

The defect rate of the specimens before the QCC activity was 0.98% (297/30105), and after the QCC activity, it was 0.45% (193/43125), showing a significant statistical difference ($P < .05$). The achievement rate and improvement rate were 108.2% and 54.1%, respectively.

After the implementation of QCC, the defect rate of specimens in clinical laboratories was significantly decreased, and the intangible factors were also improved, which demonstrated the positive effects of QCC on the quality control of specimens.

Abbreviations: PDCA = (plan, do, check and act), PRL = prolactin, QCC = quality control circle, SOP = standard operation procedure.

Keywords: quality control circle, quality management, specimen in clinical laboratory

1. Introduction

With the implementation of the 2-children policy, the proportion of older mothers is gradually increasing, leading to an increased number of pregnant women with high risk pregnancy.^[1] In this context, the quality of specimen examination is of vital importance because it can detect potential diseases and related complications

for both the pregnant women and their children, and also provide solid evidence to avoid the latent medical disputes.^[2] With the advancement of testing instruments, the pre-test standard quality control is the a key factor to determine the accuracy of the results and ensure the quality of specimen.^[3] Accuracy, timeliness, precision, and authority are 4 indicators of effective work in laboratory, and accuracy is paramount. The Ministry of Health of the People's Republic of China formulated, issued, and implemented the measures for the management of clinical laboratory in 2006,^[4] which specify the requirements for laboratory quality management. The "Special Requirements of Medical Laboratory Quality and Ability" (ISO/IEC15189) also emphasizes quality management, pointing out that the most important component of quality management is specimen management.^[5]

Quality Control Circle (QCC) originated from the statistics and management courses by Professor Deming and Professor Juran in the 1950s. In the 1990s, it was used for quality management in the medical and health fields in Taiwan.^[6] In 2001, QCC was introduced to medical institutions in China, aiming to improve the quality of medical service by raising the awareness of the medical workers to spot and solve problems in their work.^[7-9] So far, QCC has achieved good results in clinical application of many hospitals across China, and more and more attention has been paid to it.^[10-12] QCC refers to the people who share the work in a certain field. They spontaneously work as a team to solve the actual problems using the quality control methods like Pareto and fishbone diagrams, in order to improve efficiency and personnel quality.^[13-15] In order to reduce the defect rate of specimens in the laboratory of our hospital, from July to December 2017, we launched a QCC activity to investigate, analyze and improve specimen management and achieved satisfying results.

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There are no conflicts of interest.

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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2. Methodology

2.1. Ethic statement

The present study obeyed the Helsinki Declaration and was based on the standards for quality improvement reporting excellence (SQUIRE, version 2.0).^[16,17] The institutes review board waived a requirement of written informed consent because only anonymous secondary data were retrospectively analyzed. The privacy of patients and staffs involved were adequately protected. Only validated data retrospectively retrieved from our institutes quality-improving and accreditation database were used for analysis. All data used were reported.

2.2. Formation of QCC

The “hand-in-hand test circle” composed of 8 medical technicians from the laboratory of the hospital was formed to solve the problems in hospital work in July 2017. First, 4 candidate topics were proposed by quality control commissioners in the group. Then the topics were scored from 4 perspectives including government policies, importance, urgency and ability of the circle. Finally, improving the specimen quality was determined as the most urgent problem because the unqualified

specimens received by clinical laboratory would negatively impact clinical diagnosis and treatment, resulting in poor laboratory management and a decline in patients satisfaction.

2.3. Planning and implementation

The steps of carrying out the improvement were designed and evaluated. Then the person in charge of each step was selected. Next, the Gantt chart was drawn. Finally, the improvement procedure was conducted according to the plan. The director of the medical examination center was in charge of the whole procedure. The Medical Affairs Department of the hospital provided support and guidance. The whole procedure was recorded.

2.4. Investigation of the status quo and goal setting

The defective rate of specimens was investigated by a flow chart for improvement and a checklist for unqualified specimens (Fig. 1). Among the 30,105 blood samples examined from February to June 2017, 297 (0.98%) were unqualified (Table 1). The ability of circle was evaluated. Taking the full score as 40 (100%), the ability score of the circle was 24 points (60%). According to the principle of 80/20, the major causes of

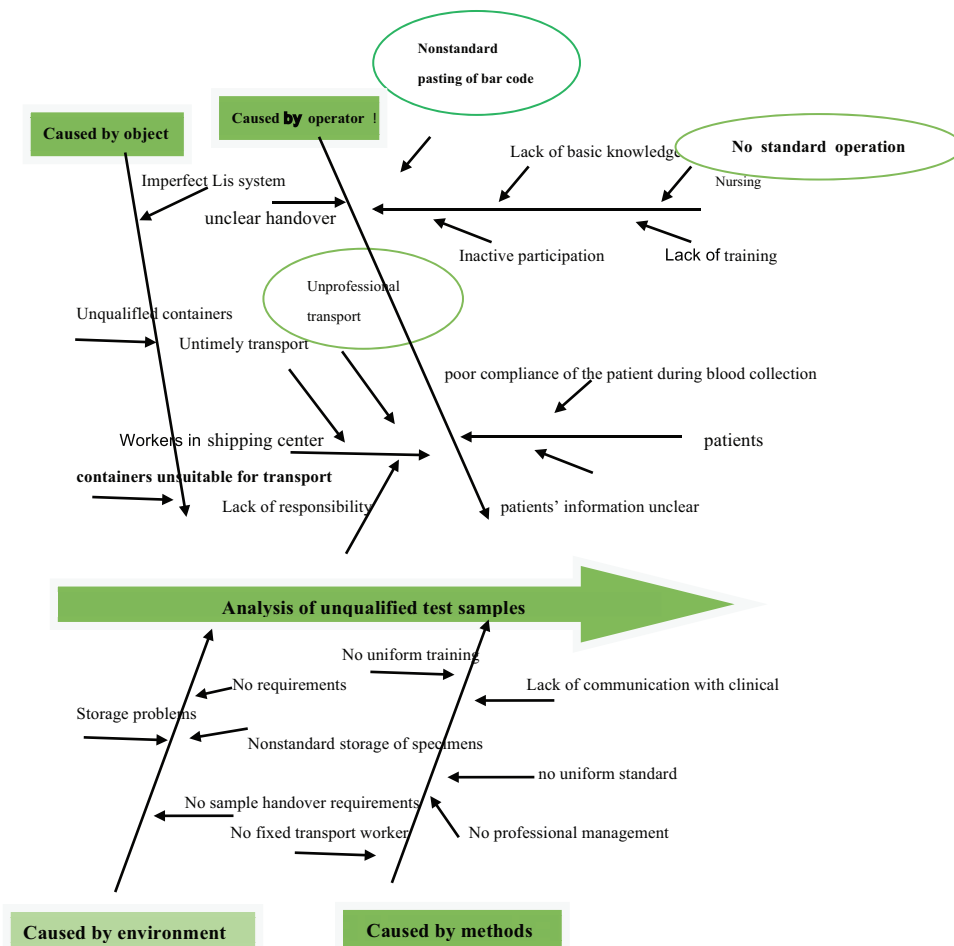


Figure 1. Fishbone diagram to analyze the causes of unqualified specimens. QCC members analyzed the causes of unqualified specimens from the perspectives of operators, methods, materials and environment, drew the fishbone diagram. The following factors were determined as the key causes of unqualified specimens: “nonstandard pasting of bar code”, “poor the compliance of the patient during blood collection”, “lack of basic knowledge”, “no sample handover requirements”, “nonstandard storage of specimens”.

Table 1**Comparison of unqualified rate of blood samples before and after QCC activity.**

Time	Number of specimens	Number of qualified specimens	Number of unqualified specimens	Unqualified specimen rate
Before QCC activity	30105	29808	297	0.98
After QCC activity	43125	42932	193	0.45
Note	$\chi^2 = 65.2$	$P < .05$		

Before the QCC activity, the defect rate of the specimens was 0.98% (297/30105), and after QCC activity, the defect rate was reduced to 0.45% (193/43125), showing a significant statistical difference ($P < .05$). QCC: Quality control circle.

unqualified specimens, including insufficient sample quantity, the blood agglutination, barcode failure and specimen pollution, were selected.

2.5. Essential factor analysis

Brainstorming was conducted among the QCC members. They analyzed the causes of unqualified specimens from the perspectives of operators, methods, materials and environment, pinpointed the major causes and drew the fishbone diagram. At the same time, a survey was carried out among the hospital staff (the doctors, nurses and staff of the delivery center) who were asked to fill in a questionnaire. Finally, the following factors were determined as the key causes of unqualified specimens: “nonstandard pasting of bar code”, “poor the compliance of the patient during blood collection”, “lack of basic knowledge”, “no sample handover requirements”, “nonstandard storage of specimens”.

2.6. Strategies and implementations

Strategy I: The standard operation procedure (SOP) guidelines for specimen collection were formulated, pasted in each ward and displayed on the electronic screen at the nursing station. Tips were printed and given to the patients prior to blood collection.

Strategy II: The SOP guideline training was carried out among the hospital staff involved in specimen collection from June 2017. A nurse in charge was chosen in each ward as the specimen quality controller. Unified, lidded transporting boxes were used to ensure the safe transport of specimens.

Strategy III: Slides of specimen collection requirements were made and posted on Lis working intranet for all the staff to learn.

Strategy IV: Each clinical department was required to designate a staff member who had received specimen transport training to deliver specimens and record the whole transfer procedure.

2.7. Confirmation of effectiveness

The duration of this quality control circle activity was set as 5 months (from July to December 2017). The basic steps of QCC activity generally followed the Deming cycle (PDCA cycle). The 4 stages (plan, do, check, and act) were realized through 10 basic steps (Fig. 2). The effect, including tangible and intangible results, was evaluated after the implementation of the strategies. The tangible results included achievement rate and improvement rate. The intangible results were presented by multiple indicators in a radar map.

2.8. Standardization

After the evaluation and confirmation of the effect, the standardized documents:

sample collection specification; common specimen collection operation instruction, were formulated and implemented.

2.9. Statistical processing

The indices to evaluate achievements were calculated using the following formula: target index = present value - (present value \times key improvement \times ability of circle), the target index set as 0.49; achievement rate = [(data value after improvement - data value before improvement)/(data value before improvement - target index)] \times 100%; improvement rate = [(data value after improvement - data value before improvement)/data value before improvement] \times 100%. SPSS 16.0 (IBM, NY, USA) was used for statistical analysis, Chi-Squared value was calculated for the comparison between groups, and $P < .05$ was considered statistically significant.

3. Results

3.1. Tangible results

From July to December 2017, the defective rate of blood specimens dropped from 0.98% to 0.45% ($P < .05$). The achievement rate and improvement rate were 108.2% and 54.1%, respectively (Tables 1–3 and Fig. 3). In the QCC activity, SOP related to specimen collection was developed. All the nursing staff received the training of specimen collection, and the pass rate of examination raised from 72.33% to 98.5% after the training.

3.2. Intangible results

In the QCC activity, obvious improvements were found in the circle members in terms of confidence, responsibility, communication skills, harmony, team cohesion and motivation, and skills of quality control (Fig. 4).

4. Discussion

Quality control circle (QCC), first established in Japan in 1962, has been widely used in medical and health care fields in Germany, Austria and Thailand.^[13–19] Unqualified blood specimens can result in the loss of patients information, exerting negative impact on diagnosis and treatment, and even leading to medical disputes.^[12] According to the reports in some countries, the defective rates of blood specimens range from 0.13% to 0.699%, and are mostly lower than 0.5%.^[20–22] By contrast, in China, the blood specimens in hospitals has a significantly higher defective rate, with the highest rate up to 10.06%,^[23,24] indicating the insufficient management of specimen quality in Chinese hospitals.

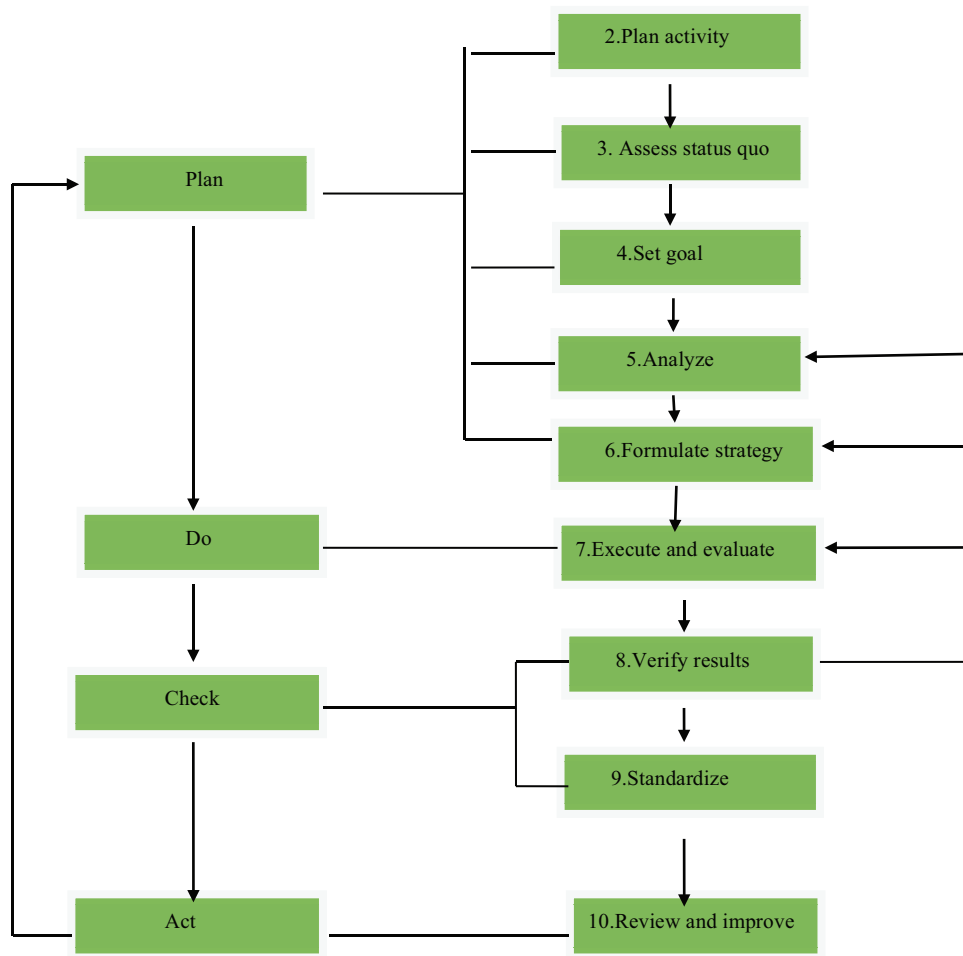


Figure 2. Protocol of the quality control circle. The basic steps of QCC activity generally followed the Deming cycle (PDCA cycle). The 4 stages (plan, do, check, and act) were realized through 10 basic steps.

In the present study, the following preliminary strategies were developed to solve the existing problems:

1. The blood collector should be properly trained to tilt the tube to a 30- to 40-degree angle immediately, slowly blend the blood up and down several times to avoid coagulation, and then label the tube correctly.

2. Blood sample should be submitted immediately after collection, otherwise be kept in the refrigerator (2–8 degrees) for no more than 2 hours.^[26] Because the biochemical components will change after long-time storage. For example, glucose will decompose due to the consumption of leukocyte, erythrocyte

Table 2
Causes of unqualified specimens before QCC activity.

Causes	Before QCC activity	Percentage (%)	Cumulative percentage
Insufficient amount of specimens	109	36.7	36.7
Blood clots	67	22.6	59.3
Bar code failure	51	17.2	76.5
Polluted Specimen pollution	20	6.7	83.2
Non-compliant specimen	19	6.4	89.6
Wrong container	18	6.1	95.7
No specimen in the container	10	3.4	99.1
Other causes	3	0.9	100.0

The top 3 causes of unqualified specimens before QCC activity are: Insufficient amount of specimens (36.7%), Blood clots (22.6%), bar code failure (17.2%), followed by Polluted specimen (6.7%), Non-compliant specimen (6.4%), Wrong container (6.1%), No specimen in the container (3.4%) and Other causes (0.9%).

Table 3
Causes of unqualified specimens after QCC activity.

Causes	After QCC activity	Percentage (%)	Cumulative percentage	No. of changes
Insufficient amount of specimen	53	27.5	27.5	56
Blood clots	57	29.5	57.0	10
Bar code failure	32	16.6	73.6	19
Polluted specimen	17	8.8	82.4	3
Non-compliant specimen	14	7.3	89.7	5
Wrong container	14	7.3	97.0	4
No samples in the container	5	2.5	99.5	5
Other causes	1	0.5	100.0	2
Total	193			104

After the QCC activity, the number of unqualified samples was decreased. The numbers of unqualified samples caused by the top 3 causes were significantly reduced compared with those before the QCC activity, with a decrease of 56, 10 and 19 samples respectively.

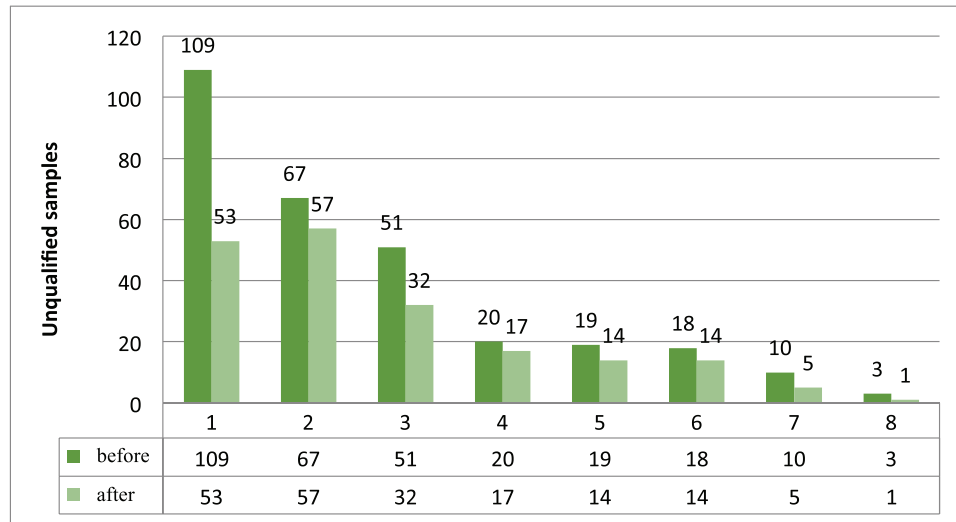


Figure 3. Analysis of causes of unqualified specimens before and after QCC activity. After the QCC activity, the number of unqualified samples was decreased. 1. Insufficient amount; 2. Blood clots; 3. Bar code failure; 4. Polluted specimen; 5. Non-compliant specimen; 6. Wrong container; 7. No specimen in the container; 8. Other causes.

and contaminated bacteria. K^+ ions will be released into blood from the damaged erythrocyte, causing pseudo serum potassium elevation. CO_2 release will alter the results.

3. Operation standardization should be conducted. In clinical practice, to avoid re-puncture and reduce the patients pain, the blood collector often collects blood through the vessel undergoing infusion, or even directly from the infusion channel. In this way, the blood collected is diluted and may contain drugs (such as antibiotics and glucose), so the test results will be greatly different from the actual ones. In addition, the secretion of prolactin (PRL) can be affected by mood, exercise and food intake. The detection of PRL needs to be performed with an empty stomach and after more than a half hour of sitting to reduce the above influence. To test the basic sex hormone levels, sex hormone drugs should not be used for at least 1 month before testing. Additionally, few studies have been conducted regarding the influence of pre-

analytic blood sample collection factors (such as fasting time, time of day of blood collection, or season of blood collection) on the levels of metabolites measured by metabolomics profiling platforms.^[25–27] Failure to control these influencing factors could lead to measurement error, decreased power of statistical tests, and biased association assessment.^[28]

4. Routine blood samples should be collected and examined within 2 hours; prompt blood samples should be checked within 30 minutes; the barcode should be pasted in a standard way; damage be prevented during delivery; the transportation center should designate dedicated workers to deliver the specimens.
5. One barcode should correspond to 1 specimen. In some cases, repeated prescriptions for blood testing may occur due to misinformation during shift handover, which can lead to repeated collections using the same bar code. Therefore, standard operation is urgently needed to solve the above-mentioned problems. And we have achieved it through the QCC activity.

To avoid pediatric hemolysis, inadequate amount of blood and blood clots, corresponding strategies regarding blood collection were made and implemented.

The key to the quality of venous blood collection was to make sure that the needle punctures the skin and enters the vessel in a correct way.

1. The order of patients for blood collection was properly arranged. The pediatric patients with no difficulty in blood collection were dealt with firstly and then those who with difficulty to collect blood were handled. To ensure successful blood sampling, the nurses should evaluate the orientation, depth, mobility of the vein before puncturing.
2. The operation procedure was standardized. Using direct puncture to the vein could effectively avoid the accompanying nerves and the pain caused by puncturing.

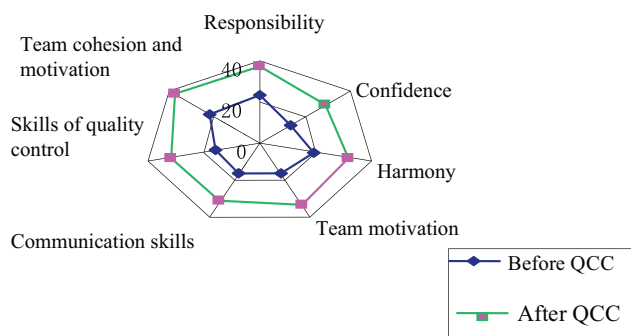


Figure 4. Intangible results. Obvious improvements were found in the circle members in terms of confidence, responsibility, communication skills, harmony, team cohesion and motivation, and skills of quality control.

3. During clinical operation, each junior nurse was assigned a tutor who gave advice and corrected mistakes promptly.
4. Theoretical learning was highlighted. Nurses were provided with PPT slides to know more about blood sampling in the newborns, like the anatomical location of vessels, the skin surrounding the puncture point, the thickness of subcutaneous fat, angle of puncturing, time, and location of using the tourniquet.

QCC has been successfully carried out in business circles for several decades and gradually extended to hospital management in recent years. The participants can learn about scientific quality management, raise their own awareness of amending problems, and improve their work efficiency. QCC also helps to establish a harmonious work team, which can improve the quality of medical service and lower the operating costs of the hospital.^[29]

In the present QCC activity, after brainstorming, literature review, and evaluation of quality control methods, strategies were formulated from the perspective of doctors, nurses and patients, and then carried out. For example, to standardize specimen collection, requirements were informed in multiple channels like specimen collection manuals for the patients and LIS network for nurses and doctors. Through our efforts, favorable results have been achieved. Improvement was also made in specimen transport. The designated staff members delivered the specimens using the special boxes, which ensured the safe and successful transport of the specimens.^[30] The results of laboratory specimen testing provide significant information for clinical diagnosis and treatment.

This study also presents some limitation and suggestions. First, after being submitted in the ward, the sample information sometimes could not be retrieved via the LIS network in the laboratory, leading to bar code failure. Therefore, we suggest that the information system and software should be updated regularly. Second, the QCC activity is a continuous activity that needs frequent optimization. The improvement achieved does not mean the end of the activity. The QCC team should resume the work, pinpointing the new problems and setting new targets. Hopefully, after another round of QCC activity, the quality of the specimens could be furthered improved.

In conclusion, in the QCC activity, we analyzed the problems in blood specimen collection, and implemented the corresponding strategies, which reduced the incidence of adverse events and increased the rate of qualified specimens. Promoting QCC activity can stimulate work morale, improve the skills of the staff, encourage positive work attitudes, and reduce institutional costs.^[31] QCC can also improve the accuracy of clinical diagnosis and lower the potential of medical disputes, which is beneficial to the reputation of the hospital.

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Author contributions

K.S.L and X.D.M designed the study, K.S.L. and Z.R.X. performed the study and wrote the manuscript, K.S.L, Y.J.C and X.D.M collected the data and analyzed the data, K.S.L and X.D.W prepared the figures and tables, and all the authors reviewed the manuscript.

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