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# Journal of Advances in Medicine Science

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## Review

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ARTICLE

# Application Research of Clinical Nursing Teaching Model Based on PBL Mode

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ABSTRACT

**Objective:** To explore the application effect of PBL mode in clinical nursing teaching model. **Methods:** 40 nursing students who were internships from June 2017 to April 2018 in our hospital were selected as subjects. They were divided into two groups, the control group and the experimental group, with 20 in each group. The control group used the traditional teaching model, and the experimental group used the PBL teaching model to compare the clinical teaching effects of the two groups of nursing students. **Results:** There was no significant difference between the two groups of nursing students in the basic nursing knowledge, the professional practice operation under the simulated clinical operating environment and the basic nursing operation ($P>0.05$), in the clinical operation environment, the professional practice evaluation results of the experimental group were significantly better than those of the control group, and the difference was statistically significant ($P<0.05$). **Conclusion:** The PBL teaching model has a good teaching effect in clinical nursing teaching, which can effectively improve the professional practice level of nursing students in the clinical environment and meet the requirements of modern clinical nursing professional ability level, therefore, the PBL mode is worthy of popularization and application in clinical nursing teaching.

## 1. Introduction

The PBL teaching model is a new type of teaching method, which is mainly problem-oriented and aims to improve students' comprehensive ability and interest in learning. In clinical nursing teaching, the traditional teaching model has a good teaching effect in theoretical knowledge and simulation practice. However, with the development of society, the quality of teaching for clinical nursing is getting higher and higher. In order to improve the professional literacy and professional knowledge and skills of clinical nursing students, so that they can become professional talents to adapt to social

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development and job requirements, it is very feasible to apply PBL teaching model in clinical nursing teaching[1]. In this research, 40 nursing students who were internships from June 2017 to April 2018 in our hospital will be studied. The PBL teaching model will be applied in clinical nursing teaching, and the application effect will be analyzed and discussed.

## 2. Data and Methods

### 2.1 Clinical Data

The 40 nursing students who were internships from June 2017 to April 2018 in our hospital were divided into the control group and the experimental group, with 20 in each group. In the control group, 2 males and 18 females; the average age was (20.39±0.75) years old, including 8 undergraduates and 12 specialists; in the experimental group, there were 3 males and 17 females; the average age was (20.45±0.72) years, including 7 undergraduates and 13 specialists. Differences in age, education, and gender between the two groups of nursing students were not statistically significant and could be compared.

### 2.2 Teaching Methods

In this clinical nursing teaching research, all teachers are undergraduate or above, with titles of supervisors and above, and engaged in clinical nursing work for more than 10 years. Teachers not only have a high level of professional knowledge and practical skills, but also have a wealth of practical experience and comprehensive ability. The teaching contents of the two groups of nursing students are the basic knowledge and practical skills of clinical nursing. The contents of the teaching materials are the same. Multimedia teaching is used in the teaching of theoretical knowledge; in the teaching of practical skills in the simulated clinical operating environment, physical demonstration teaching is used; in the clinical operating environment, practical skill teaching uses on-the-spot teaching. The two groups of nursing students use the same practical equipment in teaching. Teachers write the syllabus according to the characteristics of their teaching methods, and fully prepare for the development of teaching activities.

In the clinical nursing teaching of the nursing students in the control group, the traditional teaching model was adopted. The teacher teaches the basic theoretical knowledge of nursing students' clinical nursing, and then selects some common cases for teaching, so that the nursing students can evaluate their condition through the patient's case data, and then carry out nursing work according to the patient's physiological characteristics and psychological characteristics; for some typical cases, the teacher asks the students to observe their own treatment and then guides the students to care for them. At the same time, after the theoretical knowledge teaching, the clinical environment can be simulated to allow the nursing students to operate, so that the nursing students can effectively combine the theoretical knowledge and practice in the learning process, thereby effectively improving the teaching efficiency.

In the clinical nursing teaching of the experimental group nursing students, the teaching of theoretical knowledge still adopts the traditional teaching model. The PBL teaching model is adopted in the practical skills teaching in the simulated clinical operating environment and the practical skills teaching in the clinical operating environment. First of all, before the practical skills teaching, teachers can reasonably design clinical nursing tasks and nursing problems according to the teaching content, and prepare some common or typical teaching cases. Then, the nursing students are divided into 4 groups, 5 in each group, and the patient's medical records are sent to each nursing student, so that the nursing students can analyze the clinical symptoms of the patients by consulting network information resources, teaching materials, books, etc. The group discussed the search questions, and then the teacher collected the results of the student discussions, evaluated them, and added explanations to the deficiencies to improve the student's knowledge system. In terms of nursing students, teachers should introduce the PBL teaching model to the nursing students before class, so that they have a comprehensive and detailed understanding of the PBL teaching model, so that the PBL teaching model can be smoothly implemented in clinical nursing teaching. Finally, in the teaching process, we must ensure that the time of study is unchanged, promote the consistency of teaching, and combine the PBL teaching model with the traditional teaching model to complement and infiltrate each other. Answer and extend the problem of nursing students, enrich the practical skills of nursing students, and let the nursing students summarize and summarize the learning content after the study. The teacher will test and evaluate the students' summary report.

### 2.3 Effect Evaluation

The two groups of nursing students were evaluated in terms of theoretical knowledge, basic nursing operation; practical operation skills under simulated operating environment and practical operation skills in clinical operating environment, and then the scores of the two groups of nursing students were counted. At the same time, investigate and analyze the learning enthusiasm, problem-solv-



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ing ability, patient satisfaction, language expression ability and theoretical knowledge of the two groups of nursing students, and explore the teaching effects of two different teaching models from various aspects.

### 2.4 Statistical Analysis

The statistical data were analyzed by SPSS 16.0 statistical software. The scores were expressed by mean ± standard deviation, and the two groups of data were processed by t-value and $x^2$. P<0.05 indicates that the difference between the data is statistically significant, if P>0.05, the difference is statistically insignificant.

## 3. Results

### 3.1 Performance Assessment of Theoretical Knowledge

After the end of the two groups of nursing students, their theoretical knowledge was assessed, and the scores of the two groups of nursing students were compared and analyzed. It was found that the difference between the two groups was not significant, and it was statistically insignificant (P>0.05), and the specific results are shown in Table 1.

**Table 1.** The theoretical knowledge assessment scores of the nursing students in two groups

| Group | Number of students | Basic nursing knowledge assessment (score) | Professional theoretical knowledge assessment (score) |
|---|---|---|---|
| Experimental group | 20 | 88.01±4.85 | 91.20±3.57 |
| Control group | 20 | 87.96±4.53 | 90.00±3.15 |
| *t*-value | - | 0.034 | 1.127 |
| P-value | - | >0.05 | >0.05 |

### 3.2 Performance Assessment of Practical Skills

The statistics of the practice evaluation results of the two groups of nursing students are mainly included in the basic nursing operation, the professional practice operation skill assessment under the simulated clinical operation environment and the three assessment contents of the professional practice operation skills in the clinical operation environment. In the basic nursing operation assessment and the simulated clinical operation environment, the difference between the two groups of nursing students' performance was not statistically significant (P>0.05), in the professional practice skills assessment in the clinical operating environment, the performance of the nursing students in the experimental group was significantly better than the control group, and the difference was statistically significant (P<0.05). The specific data is shown in Table 2.

**Table 2.** The nursing practice assessment scores of the nursing students in two groups

| Group | Number of students | Basic nursing operation | Professional practice operation assessment (in simulated clinical operation environment) | Professional practical operation assessment (in clinical operation environment) |
|---|---|---|---|---|
| Experimental group | 20 | 89.00±2.55 | 88.00±5.73 | 85.00±3.27 |
| Control group | 20 | 90.00±2.05 | 87.00±3.98 | 80.00±3.15 |
| *t*-value | - | 1.367 | 0.641 | 4.925 |
| P-value | - | >0.05 | >0.05 | <0.05 |

### 3.3 Student Self-evaluation Satisfaction

After the assessment, the two groups of nursing students' ability to analyze problems, problem-solving skills, learning ability, professional knowledge application ability, team writing ability, and communication ability were investigated through questionnaires. The satisfaction of the nursing students in the experimental group was higher than that of the control group. Especially in the application of professional knowledge and ability to solve problems, the satisfaction of the two groups of nursing students was significantly lower than other aspects. Teachers still need to improve their teaching in these aspects.

## 4. Discussion

### 4.1 The Connotation of PBL Teaching Model

The PBL mode is also called problem-based learning mode. It appeared in the 1950s and was applied to medical education. The PBL teaching model is mainly a set of learning methods based on problem-oriented and design learning situations[2]. The main steps are first of all the teacher asks the question, and then the student finds the relevant information and conducts group discussion. Finally, the teacher summarizes the knowledge points. As an open teaching model, PBL mode requires teachers to have good logical thinking ability and organizational management ability[3], which can be taught through lively activities, so that each student can actively participate in the teaching activities and effectively control the rhythm of the classroom. Only in this way can the teaching effect of the PBL mode be fully utilized. In addition, teachers need to strengthen communication with students, so that students have a comprehensive and detailed understanding of the PBL mode, and then can actively cooperate with teaching activities, so that the PBL mode can be successfully carried out in teaching[4]. As a transition period

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from nursing to nurses, clinical nursing teaching has an important influence on the work and learning after nursing students. It is very feasible to apply PBL mode in clinical nursing teaching process.

### 4.2 The Application of PBL Mode in Clinical Nursing Teaching

The application of PBL mode in clinical nursing teaching is mainly divided into three stages: pre-course preparation, problem discussion and inductive summarization. For each teaching stage, its application characteristics are also different[5,6].

Firstly, in the pre-class preparation stage, teachers should carefully design the representative nursing problems according to the professional practice skills. The design problems should attract the interest of the nursing students, so that the nursing students can actively participate in the teaching activities, at the same time, it is necessary to ensure that the nursing students can complete the tasks in the clinical nursing work in the process of exploring the problem and achieve the purpose of clinical nursing teaching. At this stage, in addition to the need for teachers to have a certain logical thinking ability, teachers also need a comprehensive understanding of the psychological characteristics of nursing students[7], therefore, before implementing the PBL teaching model, teachers must strengthen communication and communication with nursing students to ensure the smooth development of teaching activities.

Secondly, in the problem discussion stage, teachers should prepare some typical cases in advance for the nursing students to learn and distribute the patient's medical records to the nursing students, let them characteristics, psychological characteristics, etc., through the nursing students search, access to information, to understand the relevant knowledge of the patient's signs, eventually, the nursing students will conduct a group discussion on the questions raised by the teachers, and write the results of the discussion into a summary report and submit them to the teacher for evaluation. In this process, active participation of nursing students is required to carry out, therefore, the teacher should let the nursing students have a full understanding of the PBL teaching model before class, which is convenient for the normal development of teaching activities. In this process, teachers need to have strong organizational management capabilities and effectively control the progress of teaching activities.

Finally, in the induction and summary stage, the teacher mainly improves the knowledge system of the nursing students through the analysis and analysis of the nursing students' summary report. Allow nursing students to effectively apply the theoretical knowledge they have learned to the practical operation process in the real situation, thus promoting the comprehensive ability of nursing students' knowledge application ability and practical operation ability[8].

### 4.3 The Practice Effect of PBL Mode in Clinical Nursing Teaching

In the PBL mode clinical nursing teaching, it is mainly a series of teaching activities initiated by nursing students, which starts with a problem that needs to be solved, and then the teacher guides the nursing students to explore the problem in a real clinical nursing environment[9], in this process, the nursing students can cooperate with each other, discuss and solve the problems together, and finally summarize them by the teachers, accordingly, the nursing students complete the whole learning process and achieve the teaching purpose of improving the comprehensive ability of nursing students' learning ability, theoretical knowledge application ability and problem solving ability[10]. In this research, the PBL teaching model of nursing students in the clinical operating environment is significantly higher than the traditional teaching model of nursing students; therefore, the application of PBL teaching model in clinical nursing teaching is beneficial to the generation of practical talents with high level of theoretical knowledge and practical operation.

## 5. Conclusion

In summary, the PBL mode has significant application effects in clinical nursing teaching, and it focuses on improving the practical operation ability of nursing students in the clinical surgical environment, which enables the nursing students to have strong practical ability in the real working environment and can effectively improve their clinical nursing level. The PBL mode has great promotion value and application significance in clinical nursing teaching.

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ARTICLE

# The Exploration of the Clinical Treatment of Chronic Atrophic Gastritis

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ABSTRACT

**Purpose:** To explore the effect of the clinical treatment of chronic atrophic gastritis **Methods:** 70 patients with chronic atrophic gastritis treated in our hospital from October 2017 to November 2018 were selected and randomly divided into an observation group and a control group with 35 patients in each group. The control group received standard triad treatment with gastroprokinetic drug orally. On the basis of the control group, patients in the observation group received Xianlu Pazhu Wan. The treatment efficiency, eradication rate of helicobacter pylori (H. pylori), incidence of adverse effects and length of stay were compared between the two groups. **Results:** Compared with the control group, patients in the observation group had higher treatment efficiency, higher H. pylori eradication rate, lower incidence of adverse effects, and shorter length of stay with statistical significance ($P< 0.05$). **Conclusion:** In the clinical treatment of patients with chronic atrophic gastritis, adding Xianlu Pazhu Wan into the basic medication plan can have better treatment efficiency, reduce the incidence of adverse effects, and shorten the length of stay. Therefore, Xianlu Pazhu Wan should be promoted in the practice.

## 1. Introduction

Chronic atrophic gastritis, a common and frequently disease of the digestive system, is a chronic gastric disease in which the amount of mucosal glandular cells decreases or intestinal metaplasia or dysplasia occurs on the basis of inflammation of the gastric mucosa. This disease commonly develops from non-chronic atrophic gastritis caused by H. pylori infection[1]. In addition, the onset of gastric cancer is very directly connected to chronic atrophic gastritis. In 1978, the World Health Organization defined chronic atrophic gastritis as the transitional period before the onset of gastric cancer. Therefore, treatment is essential to the chronic atrophic gastritis, and can effectively prevent further deterioration and development of the disease[2]. Therefore, this study mainly investigated the clinical treatment of chronic atrophic gastritis. The specific research process and results are as follows.

## 2. General Data and Method

### 2.1 Clinical Data

70 patients with chronic atrophic gastritis diagnosed electronic gastroscopy and pathology, and treated between October 2017 and November 2018 in our hospital were selected. They were divided into an observation group and a control group with 35 patients in each group. The patients in these two groups were treated with different therapies. There were 20 male and 15 female patients in the control group, ranging in age from 25 to 65 years, with an

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average age of (45.1±19.9) years. The course of disease ranged from 6 months to 10 years, with an average duration of (5.2±1.7) years. There were 23 mild atrophic patients, 8 moderate atrophic patients, and 4 severe atrophic patients. There were 18 male and 17 female patients in the observation group, ranging in age from 28 to 71 years, with an average age of (46.3±20.1) years. The course of disease ranged from 6 months to 10 years, with an average duration of (4.2±1.5) years. There were 25 mild atrophic patients, 5 moderate atrophic patients, and 5 severe atrophic patients. The age, gender, course of disease and other clinical data of patients in the observation group and the control group were compared. The difference was not statistically significant (P> 0.05) and could be compared in groups.

### 2.2 Disease Diagnosis

(1) Inclusion criteria: All patients had varying degrees of nausea and loss of appetite, and a few of patients had anemia, weight loss and other symptoms. The gastroscopy showed that the gastric mucosa was thinner and the blood vessels beneath the mucosa were exposed. Moreover, after the pathological biopsy of gastric mucosa, it was found that the gastric mucosa glands of the patients had a tendency of atrophy[3].

(2) Exclusion criteria: The patient of drug allergy, functional injury of viscera, mental disorder and malignancy excludes completely[4].

### 2.3 Therapeutic Methods

The control group patients were treated with standard triad therapy, which was omeprazole (20mg), amoxicillin (1.0g), metronidazole (0.4g) with domperidone 10mg 30 minutes before meal, three times a day for four continuous weeks. The observation group patients were treated on the basis of the control group with adding Xianlu Pazhu Wan 2-2.5g per time, twice a day for 4 continuous weeks. The clinical manifestations of patients in two groups were observed[5].

### 2.4 Efficacy Evaluation Standard

The therapeutic effects of the patients were divided into obvious, effective and no effect. Obvious referred to the patient's abdominal pain, abdominal distension, nausea and other clinical symptoms had completely disappeared, and no abnormality was found by gastroscopy; Effective referred to the patient's abdominal pain, abdominal distension, nausea and other clinical symptoms basically disappeared, and a slight abnormality was found by gastroscopy; No effect referred to the patient's abdominal distension, abdominal pain, nausea and other clinical symptoms not only did not get any relief, there were even signs of aggravation. The patient had have dyspepsia, loss of appetite and other symptoms. The total effective rate of the treatment = (obvious + effective)/total number of the patients *100% In addition, the eradication rate of H. pylori, incidence of adverse effects and length of stay in the two groups should also be observed and calculated.

### 2.5 Statistical Processing

Statistical software SPSS20 was used to process all the data obtained in the research process. Among them, t test was used to verify the quantitative data. Percentage was used to represent the enumeration data. $x^2$ test was used to verify the enumeration data. If P<0.05, the difference was statistically significant.

## 3. Results

### 3.1 Comparison of Treatment Efficiency and H. pylori Eradication Rate between the Two Groups

After the two groups of patients were treated with different treatment methods, the treatment efficiency and H. pylori eradication rate of the two groups were observed, calculated and compared. The final results showed that the total treatment efficiency of the observed patients was 94.29%, and the H. pylori eradication rate was 88.57%. However, the total treatment efficiency of the patients in the control group was 80.00%, and the H. pylori eradication rate was 62.86%. This meant that the treatment efficiency of the observation group was significantly better comparing with the control group, which was statistically significant (P<0.05). The details are shown in Table 1 and 2 below.

**Table 1.** Comparison of effective rate of treatment between the two groups

| Efficacy | Observation group (n=35) | | Control group (n=35) | |
|---|---|---|---|---|
| | Number of people | Incidence | Number of people | Incidence |
| Obvious | 26 | 74.29% | 10 | 28.57% |
| Effective | 7 | 20.00% | 18 | 51.43% |
| No effect | 2 | 5.71% | 7 | 20.00% |
| Total effective rate | 35 | 94.29% | 35 | 80.00% |

**Table 2.** Comparison of H. pylori eradication rate between the two groups

| Grouping | Number of people | Eradicated | Not eradicated | Total eradication rate |
|---|---|---|---|---|
| Observation group | 35 | 31 | 4 | 88.57% |
| Control group | 35 | 22 | 13 | 62.86% |


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### 3.2 Comparison of Incidence of Adverse Effects between the Two Groups

After different clinical treatment methods were applied to the two groups of patients, it was found that 1 patient in the observation group presented vomiting and 1 patient presented diarrhea. The total incidence of adverse effects was 8.57%. In the control group, 4 patients had vomiting, 5 patients had diarrhea, and 1 patient had rashes. The total incidence of adverse effects was 28.58%. This also indicated that compared with the control group, the incidence of adverse effects in the observation group was lower, which was statistically significant (P< 0.05). The details are shown in Table 3 below.

**Table 3.** Comparison of incidence of adverse effects between two groups

| Adverse effects | Observation group (n=35) | | Control group (n=35) | |
|---|---|---|---|---|
| | Number of people | Incidence | Number of people | Incidence |
| Nausea and vomiting | 2 | 5.71% | 4 | 11.43% |
| Diarrhea | 1 | 2.86% | 5 | 14.29 |
| Rash | 0 | 0.00% | 1 | 2.86% |
| Total | 3 | 8.57% | 10 | 28.58% |

### 3.3 Comparison of Length of Stay between the Two Groups

Compared with the control group, the length of stay in the observation group was significantly shorter, which was statistically significant (P<0.05). The details are shown in Table 4 below.

**Table 4.** Comparison of length of stay between the two groups

| Grouping | Number of people | Length of stay (days) |
|---|---|---|
| Observation group | 35 | 5.71±2.01 |
| Control group | 35 | 14.12±1.56 |

## 4. Summary

### 4.1 Overview of Chronic Atrophic Gastritis

Chronic atrophic gastritis, a common and frequently disease of the digestive system, is a chronic gastric disease in which the amount of mucosal glandular cells decreases or intestinal metaplasia or dysplasia occurs on the basis of inflammation of the gastric mucosa. Clinical symptoms included abdominal pain, abdominal distension, dyspepsia, vomiting, etc. In addition, there are also secretion function degeneration, gastric motility insufficiency, poor blood circulation, gastric mucous membrane quantity reduction etc. According to the professional investigation results of relevant personnel, age is one of the major factors leading to chronic atrophic gastritis. In addition, the emergence of chronic atrophic gastritis is also associated with the following factors: First, genetic factors. Compared with the population without family genetic history, the incidence of chronic atrophic gastritis in the population with family genetic history is relatively higher. According to the relevant data, the specific incidence can reach about 20%. Second, anemia. If the body is in the state of ischemia for a long time, it will lead to chronic atrophic gastritis. Third, direct long-term contact with metals. For those workers who have been exposed to lead for a long time, it is very easy to damage the gastrointestinal mucosa and develop chronic atrophic gastritis. Fourth, dietary habits. People who have smoking and drinking habits for a long time are more likely to suffer from gastric mucosal damage and chronic atrophic gastritis if they take in a large amount of stimulating food. Fifth, immune factors. Generally speaking, there are factor antibodies in gastric juice and blood of patients with chronic atrophic gastritis. Therefore, the immunoreaction of human body is directly related to the occurrence of chronic atrophic gastritis.

### 4.2 The Necessity and Effect of Clinical Medication and Treatment

In the process of sustained and rapid social and economic development in China, people's quality of life and living standards have been further improved. At the same time, people's dietary habits and dietary structure have also undergone tremendous changes, which makes the incidence of chronic atrophic gastritis presents a gradually increasing trend [6]. The so-called chronic atrophic gastritis mainly refers to a disease that causes inflammation in the stomach of patients due to the influence of different factors. This disease is very common in digestive internal medicine. The specific clinical manifestations include abdominal pain, abdominal distension, dyspepsia, vomiting, etc. When suffering from this disease, it is likely to further deteriorate into gastric cancer if patients do not receive timely and effective treatment, which will also pose a threat to the patients' quality of life, physical health and life safety [7]. Xianlu Pazhu Wan is a kind of Tibetan medicine pill in Tibetan minority areas of China. It is mainly used for the treatment of chronic gastropathy in Tibetan areas. The main functions are strengthening stomach and dispelling cold, eliminating phlegm, breaking tumors and keeping health and strength. It is the classic secret recipe of Tibetan medicine for more than 1000 years after continuous summary of experience, scientific development and inheritance. The prescription



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contains high purity natural medicines in snow regions at an altitude of 6,000 meters. The recipe contains 15 main medicines and more than 20 adjuvant medicines, among which the main medicinal herb myrobalan has the effect of promoting qi, relieving pain and dispelling cold in the warm. Pterocephalus hookeri heck has the functions of sterilizing, eliminating putridity and engendering flesh. Tibetans have applied pterocephalus hookeri heck to treat trauma directly. Gypsum rubrum has the functions of digestion, acid-making, clearing heat and stomach. Neohymenopogon parasiticus can strengthen spleen and stomach, regulate qi and relieve depression, relieve cold distention, distension and pain, hiccup and other symptoms. Xianlu Pazhu Wan contains many bioactive substances, which can directly target the lesion. Therefore, on the basis of conventional western medicine treatment, we combined with Xianlu Pazhu Wan to treat chronic atrophic gastritis, in order to improve the efficiency of treatment and reduce the incidence of adverse effects. In the specific clinical treatment process, we should also focus on the following issues: Firstly, the patient's body needs to be thoroughly examined before treatment to exclude whether they also have other diseases with other types of symptoms. Secondly, the patient's physical changes during treatment should be recorded carefully and comprehensively, and analyzed and studied, so as to provide effective reference for the adjustment of treatment methods. Thirdly, the patient's disease situation and the necessity of treatment should be explained to the patients' family members patiently, improve their cooperation in the treatment process, and ensure the smooth development and advancement of the treatment work. Fourthly, most patients with chronic atrophic gastritis have deep roots and are difficult to be cured completely in a short period. Therefore, patients must be treated comprehensively in clinical practice, and be told that they must take medicine according to doctor's advice, and that they should not stop or change medication at will, so as to ensure a good therapeutic effect [8].

From the results of this paper, it can be seen that in the clinical treatment of chronic atrophic gastritis, compared with the control group treated with conventional Western medicine, the observation group treated with Xianlu Pazhu Wan on the basis of conventional western medicine has better therapeutic effect. The total effective rate of treatment is as high as 94.29%, and the observation group of patients with H. pylori eradication rate is relatively higher, the incidence of adverse effects is only 8.57%, the length of stay of patients is relatively shorter, and P is less than 0.05, differences were statistically significant.

## 5. Conclusion

To sum up, in the process of treating chronic atrophic gastritis patients, reasonable and effective treatment methods should be determained according to the actual physical conditions of patients, and guide patients to adhere to the treatment of taking appropriate oral dose of Xianlu Pazhu Wan. During the treatment period, the patient must give up spicy, strong tea and coffee, smoking and alcohol, and keep a light diet. In order to ensure good clinical therapeutic effect and improve the treatment efficiency, reduce the incidence of adverse effects, help patients in a shorter period to restore health.

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ARTICLE

# Clinical Distribution and Drug Resistance of 224 Strains of Pseudomonas Aeruginosa

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ABSTRACT

**Objective:** To provide evidence for a rational and effective prevention and treatment of Pseudomonas aeruginosa, the clinical characteristics and the resistance to various antibiotics of were investigated. **Methods:** A retrospective analysis of 224 strains of Pseudomonas aeruginosa isolated from various specimens from various clinical departments of our hospital (April 1, 2018 to June 31, 2019) were conducted. Identification and drug susceptibility test of isolated strains was performed using a fully automatic bacterial identification analyzer (MicroScan WalkAway-96 plus), and data analysis was performed using WH0NET5.6 software. **Results:** Among all the bacteria isolated in our hospital during the above period, Pseudomonas aeruginosa accounted for 10.09% of them all and 12.57% of Gram-negative bacilli, respectively. These isolates were mainly derived from sputum specimens (68.75%), mainly from male patients (70.54%), and mostly 61-70 (27.23%) or 51-60 (22.77%) years old. Pseudomonas aeruginosa isolates are mainly from Rehabilitation Ward, ICU, and Liver Transplantation Unit, accounted for 29.91%, 12.95% and 10.27% of all isolates, respectively. The sensitivity of Pseudomonas aeruginosa to various antibacterial drugs, in the order of high to low were carbapenems, aztreonam, quinolones, cephalosporins, piperacillin/ tazobactam, aminoglycoside, with a lowest resistance rate (2.4%) to amikacin and a highest resistance rate to imipenem (33.0%). **Conclusion:** The isolation rate of Pseudomonas aeruginosa was relatively stable during the study period, and among all the P. aeruginosa detected, most of them were from the respiratory secretions of elderly male patients. The resistance rate of Pseudomonas aeruginosa isolates to various antibiotics is mainly within 30%. Clinical units such as Rehabilitation Ward, ICU, and Liver Transplantation Unit have a high detection rate; therefore, these departments should be monitored in a focused manner. Our research provides a scientific basis for the rational use of antibiotics and a better control of Pseudomonas aeruginosa infection.

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## 1. Introduction

Pseudomonas aeruginosa is a common conditional pathogen in clinical practice, widely distributed in the natural environment and exists in human skin, respiratory tract and intestine. When the body's natural defenses declines due to surgery, chemotherapy, radiotherapy, hormone therapy, etc. they tend to cause pulmonary infections, urinary tract infections, otitis media, bacteremia and infections of burn wound[1-3]. In recent years, due to the widespread use of broad-spectrum antibacterial drugs, the drug resistance of the bacteria has increased significantly, and caused a severe challenge to an effective anti-infective in clinic settings. In this study, we analyzed the characteristics, such as drug resistance, of 224 strains of Pseudomonas aeruginosa isolated from our hospital from April 1, 2018 to June 31, 2019, and expects for a reliable basis for a rational antibiotic policy and a better prevention of infection in the future.

## 2. Materials and Methods

### 2.1 Strain Specimens and Standard Strains

After removing duplicate strains isolated from the same site of the same patient, 224 strains of Pseudomonas aeruginosa isolated from various specimens from every clinical departments of Lingnan Hospital of the Third Affiliated Hospital of Sun Yat-sen University (April 1, 2018 to June 30, 2019) were included in this analysis. Escherichia coli ATCC25922 and Pseudomonas aeruginosa ATCC27853 were used as quality control strains and provided by the Guangdong Center for Clinical Laboratory.

### 2.2 Instruments and Reagents

MicroScan Walk-Away 96 plus (Siemens AG, Germany), a fully automated bacterial identification and susceptibility analyzer (including supporting reagents and slats) was used. Blood agar plate and chocolate agar plate were provided by Crmicrobio Trading Co., Ltd (Jiangmen, China).

### 2.3 Strain Identification and Drug Sensitivity Test

The culture operations of the specimens sent by the clinical departments are strictly carried out in accordance with the National Clinical Laboratory Procedures (4th Edition). Identification and susceptibility testing of all strains were performed using MicroScan Walk-Away 96 plus, determination of the drug susceptibility test results was carried out in accordance with the CLSI 2018 standard.

### 2.4 Statistical Processing

Data analysis was performed using WH0NET5.6 and Excel 2007 software.

## 3. Results

### 3.1 Isolation Rate of Pseudomonas Aeruginosa

Pseudomonas aeruginosa accounted for 10.09% of all the bacteria isolated in our hospital from April 1, 2018 to June 30, 2019, and for Gram-negative bacilli, 12.57% of them were Pseudomonas aeruginosa, as shown in Table 1.

**Table1.** Isolation rate of Pseudomonas aeruginosa

| Date | Total number of strains | number of G-b strains | PA | | |
|---|---|---|---|---|---|
| | | | number of strains | PA/ Total number of strains (%) | PA/ G-b (%) |
| April-June 2018 (summer) | 465 | 378 | 43 | 9.25 | 11.38 |
| July-September 2018 (autumn) | 452 | 372 | 48 | 10.62 | 12.90 |
| October-December 2018 (Winter) | 388 | 315 | 46 | 11.86 | 14.60 |
| January to March 2019 (spring) | 410 | 321 | 32 | 7.80 | 9.97 |
| April-June 2019 (summer) | 506 | 396 | 55 | 10.87 | 13.89 |
| Total | 2221 | 1782 | 224 | 10.09 | 12.57 |

### 3.2 Gender and Age Distribution of Pseudomonas Aeruginosa Infections

Of all Pseudomonas aeruginosa strains detected, 158 strains (70.54%) were isolated from male patients, and 66 strains (29.46%) were isolated from female patients. It was isolated at all ages, but mainly from 61 -70 (27.23%) and 51-60 (22.77%) years old patients. In the remaining groups, the detection rate of Pseudomonas aeruginosa in patients aged 71-80 years was 14.73%, and it was 13.39% in the group of 41-50 years old patients, as shown in Table 2.

**Table 2.** Gender and age distribution of Pseudomonas aeruginosa infections.

| age | number of patients | percentage (%) |
|---|---|---|
| <1 | 2 | 0.89 |
| 1-10 | 4 | 1.79 |
| 11-20 | 7 | 3.13 |
| 21-30 | 14 | 6.25 |
| 31-40 | 16 | 7.14 |
| 41-50 | 30 | 13.39 |
| 51-60 | 51 | 22.77 |
| 61-70 | 61 | 27.23 |
| 71-80 | 33 | 14.73 |
| 81-90 | 6 | 2.68 |
| Total | 224 | 100.00 |


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### 3.3 Distribution of Pseudomonas Aeruginosa Infections in Clinical Units

The Pseudomonas aeruginosa cases detected were mainly from the Rehabilitation Ward (29.91%), ICU (12.95%), Liver Transplantation Unit (10.27%) and Neurosurgery department (8.48%). See Table 3.

**Table 3.** Distribution of Pseudomonas aeruginosa infections in clinical units

| clinical units | number of cases | percentage（%） |
|---|---|---|
| Rehabilitation Ward | 67 | 29.91 |
| ICU | 29 | 12.95 |
| Liver Transplantation Unit | 23 | 10.27 |
| Neurosurgery department | 19 | 8.48 |
| Respiratory Ward | 10 | 4.46 |
| Department of Infected disease | 9 | 4.02 |
| Cardiac surgery unit | 8 | 3.57 |
| Urological ward | 8 | 3.57 |
| Wound care clinic | 6 | 2.68 |
| Rheumatology unit | 6 | 2.68 |
| Others | 39 | 17.41 |
| Total | 224 | 100.00 |

### 3.4 The Distribution of Pseudomonas Aeruginosa Positive Specimen

The Pseudomonas aeruginosa strains detected were mainly isolated from samples such as sputum, urine, wound secretions, drainage, organ lavage and blood, as shown in Table 4.

**Table 4.** The distribution of Pseudomonas aeruginosa positive Specimen

| Source of specimen | number of cases | percentage（%） |
|---|---|---|
| sputum | 154 | 68.75 |
| urine | 16 | 7.14 |
| wound secretions | 15 | 6.70 |
| drainage | 9 | 4.02 |
| organ lavage | 8 | 3.57 |
| blood | 5 | 2.23 |
| others | 17 | 7.59 |

### 3.5 Susceptibility of Pseudomonas Aeruginosa to Various Antimicrobial Agents

The Susceptibility of Pseudomonas aeruginosa strains to various antibiotics in this study, ranked from high to low, was as follows: imipenem, meropenem, aztreonam, levofloxacin, ring Ciprofloxacin, ceftazidime, cefepime, piperacillin/tazobactam, gentamicin, tobramycin and amikacin. We observed a lowest resistance rate to amikacin (2.4%), while the resistance to imipenem was the highest (33.0%). The resistance rate of those Pseudomonas aeruginosa strains to carbapenem antibiotics increased in 2018, but declined in 2019, and it dropped to the lowest in the second quarter of 2019 when the resistance rates to imipenem and meropenem were 25.5% and 18.2%, respectively. See Table 5.

## 4. Discussion

Pseudomonas aeruginosa is one of the most common conditional pathogenic bacteria in nosocomial infections[4]. Because of its unique characteristics, such as easy coloni-

**Table 5.** Susceptibility of Pseudomonas aeruginosa strains to antimicrobial agents (%)

| | In total | | Summer,2018 | | Autumn,2018 | | Winter,2018 | | Spring,2019 | | Summer, 2019 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| antimicrobial agents | R | S | R | S | R | S | R | S | R | S | R | S |
| Piperacillin/tazobactam | 11.5 | 78.2 | 9.3 | 79.1 | 6.2 | 91.7 | 13.0 | 67.4 | 12.5 | 78.1 | 16.4 | 74.5 |
| Ceftazidime | 13.4 | 80.4 | 14.0 | 83.7 | 4.2 | 93.8 | 17.4 | 73.9 | 9.4 | 78.1 | 21.8 | 72.7 |
| Cefepime | 11.8 | 75.4 | 16.3 | 76.7 | 4.2 | 87.5 | 10.9 | 71.7 | 9.4 | 71.9 | 18.2 | 69.1 |
| Aztreonam | 24.9 | 57.7 | 34.9 | 55.8 | 16.7 | 62.5 | 30.4 | 54.3 | 18.8 | 59.4 | 23.6 | 56.4 |
| Imipenem | 33.0 | 60.1 | 30.2 | 67.4 | 37.5 | 54.2 | 43.5 | 39.1 | 28.1 | 68.8 | 25.5 | 70.9 |
| Meropenem | 27.6 | 66.9 | 23.3 | 69.8 | 31.2 | 60.4 | 37.0 | 54.3 | 28.1 | 71.9 | 18.2 | 78.2 |
| Amikacin | 2.4 | 90.5 | 0.0 | 88.4 | 4.2 | 89.6 | 0.0 | 95.7 | 6.2 | 84.4 | 1.8 | 94.5 |
| Gentamicin | 10.1 | 75.8 | 11.6 | 69.8 | 4.2 | 83.3 | 10.9 | 80.4 | 9.4 | 78.1 | 14.5 | 67.3 |
| Tobramycin | 5.5 | 92.1 | 4.7 | 90.7 | 4.2 | 95.8 | 6.5 | 91.3 | 3.1 | 93.8 | 9.1 | 89.1 |
| Ciprofloxacin | 18.4 | 75.3 | 18.6 | 72.1 | 10.4 | 83.3 | 15.2 | 73.9 | 18.8 | 78.1 | 29.1 | 69.1 |
| Levofloxacin | 21.3 | 69.0 | 27.9 | 67.4 | 16.7 | 70.8 | 19.6 | 69.6 | 18.8 | 71.9 | 23.6 | 65.5 |



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zation, variation and multi-drug resistance[5], the infection with Pseudomonas aeruginosa often presents a great threat to patients, especially those with low immune function and those who were admitted to intensive care units[6]. It is of great benefit to study the clinical and pathogenic characteristics of Pseudomonas aeruginosa in clinical settings.

In this study, the detection rate of Pseudomonas aeruginosa was 10.09%, which was consistent with the report of Longo et al.[7], in which, Pseudomonas aeruginosa infections accounts for 10%-15% of nosocomial infections. 68.75% of our isolates were from respiratory specimens. The high retention rate of sputum specimen from those affected patients plays a part, but the most possible reason, as reported elsewhere[8], is that Pseudomonas aeruginosa is the main Gram-negative bacillus causing hospital-acquired pneumonia and ventilator-associated pneumonia, most possible due to the reduction of the respiratory function by the polysaccharide capsule of Pseudomonas aeruginosa. 50% of the isolates were from 51-70 years old patients, and 53.13% of the isolates were from Rehabilitation Ward, ICU, and Liver Transplantation Unit. This situation is mainly related to the fact that patients of the above-mentioned age group or from the above-mentioned wards have more primary disease, generally have lower immunity, are subjected to various invasive operations, prolonged hospital stays and the frequent use of broad-spectrum antibacterials, etc.

Pseudomonas aeruginosa has multiple drug resistance mechanisms[9-11], mainly, active efflux systems, changes of target sites, Bacterial biofilm, inactivated enzyme, and foreign resistance genes. According to the results of 2017 CHINET China bacterial resistance monitoring[12], the resistance rate of 16562 strains of Pseudomonas aeruginosa to antimicrobial agents were as follows: aztreonam (31.4%), imipenem (23.6%), ceftazidime (21.4%), Meropenem (20.9%), Cefepime (18.7%), Ciprofloxacin (14.8%), Piperacillin/tazobactam (13.4%) , Gentamicin (10.7%) and Amikacin (6.1%). In our study, except for the slightly higher resistance rates to imipenem, meropenem, and ciprofloxacin, the resistance rates for the remaining antibiotics were relatively lower than those of the above study. The resistance to aztreonam, quinolones, cephalosporins and piperacillin/tazobactam of the strains that were in our research were between 11.5% and 24.9%. In the past decade, carbapenems have been considered as the last line of defense against Gram-negative bacilli. But with the increasing use of those drugs, the probability of detecting carbapenem-resistant Pseudomonas aeruginosa is gradually increasing[13]. In this study, we also noticed an increased resistance rate to carbapenem antibiotics in 2018, however, in 2019, the resistance to imipenem and meropenem were controlled and a correspondingly downward trend emerged. In the second quarter of 2019, resistance rates to the two drugs fell to a minimum of 25.5% and 18.2%, respectively. This was in line with our hospitals' close monitoring of microbial resistance as well as our clinicians' effect of strict controlling the use of antibiotics, in particular, carbapenem antibiotics. Pseudomonas aeruginosa has the lowest resistance rate to aminoglycosides, especially amikacin (2.4%). This may be due to the fact that aminoglycosides are nephrotoxic and are rarely used in clinic, and also because of the substrate specificity of aminoglycoside modifying enzyme mediated resistance.

## 5. Conclusion

In summary, Pseudomonas aeruginosa is widely distributed in clinical practice and is one of the most important pathogen of nosocomial infections. To effectively prevent and control Pseudomonas aeruginosa related nosocomial infections, as discussed above, medical staff should pay great attention to the rational use of drugs, proper choice of antibiotics, the monitoring of pathogens and microbial resistance.

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ARTICLE

# Combined Detection of Mean Platelet Volume and Immunoglobins as a Strategy for the Diagnosis of Systemic Lupus Erythematosus

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ABSTRACT

**Objective:** To explore the possibility of diagnosing and monitoring patients with systemic lupus erythematosus (SLE) using the combination of mean platelet volume (MPV) and routine immunoglobulin test. **Methods:** 116 patients with SLE were divided into 3 groups according to their clinical characteristics, including 29 patients with renal impairment, 44 cases of active stage and 43 cases of inactive patients. 40 healthy subjects were randomly selected as controls. Subjects were tested for routine blood test and plasma Immunoglobins, such as IgG, IgA, IgM, C3, C4, CH50, CRP. The results were analyzed and the characteristics of each group of subjects were determined, the correlation between test results and diagnosis were studied. **Results:** In comparison to the control group, the serum level of MPV, C3 and C4 were decreased ($P<0.05$), and C reactive protein level was elevated ($P<0.001$) in the three groups of SLE patients. The IgG level in active and inactive SLE patients was increased ($P<0.0001$), CH50 level was decreased in patients with inactive SLE ($P<0.05$), IgA level of active SLE subjects was found to be elevated ($P<0.05$), IgM in patients with renal impairment was decreased ($P<0.05$). Other than that, no other significant characteristic were found. **Conclusion:** The pathogenesis of SLE is a complex process involving multiple factors. The changes of MPV, IgG, IgA, IgM, C3, C4, CH50 and CRP in SLE patients are characteristic parameters. The combination of the above indicators can help to determine the diagnosis and staging of SLE. The timely diagnosis and treatment of SLE patients has important clinical significance in protecting the organ function of SLE patients and improving the prognosis.

## 1. Introduction

Systemic lupus erythematosus is a recurrent and relapsing autoimmune disorder that invades the skin and multiple organs[1]. At present, the exact cause of SLE has not been fully elucidated. SLE patients exhibit numerous aberrations in the immune system. In this study, we examined routine blood test and plasma Immunoglobins, such as IgG, IgA, IgM, C3, C4, CH50, CRP in SLE

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patients and healthy controls, exploring the characteristics of the above results in patients with SLE at different stages, providing a new reference for the diagnosis and treatment of SLE.

## 2. Materials and Methods

### 2.1 Subjects

116 SLE patients admitted to the Department of Rheumatology, Nephrology, and Dermatology of Lingnan Hospital from January 2012 to December 2016, were selected for this study. There were 106 females and 10 males, aged between 15 and 73 years, with an average age of 34.0 ± 13.0 years. All subjects met the SLE diagnostic criteria revised by the American College of Rheumatology (ACR) in 1997[2]. None of the patients received anti-lupus treatment before admission.

Patients with other diseases, such as dyslipidemia, blood system diseases, inflammatory diseases, etc. are excluded. The activity of SLE was evaluated by systemic lupus erythematosus disease activity index (SLEDAI). SLE-DAI≥10 were defined active SLE group, and SLEDAI<10 were defined in inactive SLE group. 73 patients were in the active SLE group, including 29 patients with renal impairment (LN) and 44 patients without renal impairment, and there were 43 cases in the non-active period group. 40 healthy controls were randomly selected as controls, including 9 males and 31 females with an average age of (30.2±6.6) years. There were no significant differences in gender, age, BMI, etc. between the active SLE group, SLE active with renal injury group, the inactive SLE group and the control group (P>0.05).

### 2.2 Methods

6 mL of venous blood sample were collected from each test subjects in fasting state on second morning of admission, or at 9am on the day of the medical examination. Each blood sample was dispensed into 3 tubes, and corresponding pretreatment was performed according to the purpose of the test. IgG, IgA, IgM, C3, C4, CH50 and C-reactive protein (CRP) levels were measured by immunoturbidimetry using a automatic biochemical analyzer(Hitachi 7180, Japan) , and the routine blood test was performed using automatic blood cell meter(Sysmex XE-5000, Japan) .

All tests and result interpretation were operated in strict accordance with the procedures instructions, all reagents used were within the validity period.

### 2.3 Statistical Analysis

Statistical analysis was performed using SPSS 13.0 software. Inter-group comparisons of measurement data were performed using unpaired t-test, and Spearman rank correlation analysis were performed.

**Table 1.** Comparison of different SLE groups and healthy controls

| Group | cases（n） | MPV（fL） | IgG（g/L） | IgA（g/L） | IgM（g/L） | C3（g/L） | C4（g/L） | CH50（U/mL） | CRP（mg/L） |
|---|---|---|---|---|---|---|---|---|---|
| in-active SLE | 43 | 9.669±0.139a | 17.85±1.497a | 2.36±0.155 | 1.069±0.084 | 0.581±0.039a | 0.122±0.014a | 29.16±2.268a | 4.336±1.041a |
| active SLE | 44 | 9.824±0.135a | 16.88±0.943a | 2.506±0.127a | 1.037±0.105 | 0.713±0.049a | 0.156±0.018a | 33.41±2.633a | 8.676±2.107a |
| active SLE plus renal impairment | 29 | 9.558±0.124a | 10.77±1.149 | 1.93±0.169 | 0.792±0.095a | 0.668±0.044a | 0.156±0.016a | 36.07±3.003 | 6.617±1.414a |
| Control | 40 | 10.48±0.144 | 12.24±0.337 | 2.04±0.075 | 1.126±0.063 | 1.029±0.027 | 0.240±0.009 | 37.2±0.999 | 1.399±0.273 |

***Notes:*** a: compared with healthy controls, P < 0.05.

**Table 2.** Comparison of inactive SLE group, active SLE plus renal impairment group, and active SLE group

| Group | cases（n） | MPV（fL） | IgG（g/L） | IgA（g/L） | IgM（g/L） | C3（g/L） | C4（g/L） | CH50（U/mL） | CRP（mg/L） |
|---|---|---|---|---|---|---|---|---|---|
| inactive SLE | 43 | 9.669±0.139 | 17.85±1.497 | 2.36±0.155 | 1.069±0.084 | 0.581±0.039a | 0.122±0.014 | 29.16±2.268 | 4.336±1.041 |
| active SLE | 44 | 9.824±0.135 | 16.88±0.943 | 2.506±0.127 | 1.037±0.105 | 0.713±0.049 | 0.156±0.018 | 33.41±2.633 | 8.676±2.107 |
| active SLE plus renal impairment | 29 | 9.558±0.124 | 10.77±1.149a | 1.93±0.169a | 0.792±0.095 | 0.668±0.044 | 0.156±0.016 | 36.07±3.003 | 6.617±1.414 |

***Notes:*** a: compared with the active SLE group, P < 0.05.



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## 3. Results

### 3.1 Comparison of Different SLE Groups and Healthy Controls

MPV, C3 and C4 were decreased (P<0.05), and CRP was increased (P<0.001) in the in-active SLE group, active SLE group, active SLE plus renal impairment group. The IgG level in active and inactive SLE patients was increased (P<0.0001), CH50 level was decreased in patients with inactive SLE (P<0.05), IgA level of active SLE subjects was found to be elevated (P<0.05), IgM in patients with renal impairment was decreased (P<0.05). See the table below.

### 3.2 Comparison between Different SLE Groups

As shown in the table below, C3 were increased in the inactive SLE group (P<0.05), compared with the active SLE group, both IgG and IgA were decreased in the active SLE subjects but not in the active SLE plus renal impairment group (P<0.01; P<0.05).

## 4. Discussion

At present, the etiology of SLE is still unclear. It is an immune disease characterized by multiple system damage and accompanied by a variety of autoantibodies. The main clinical symptoms of SLE include joint pain, fever, skin erythema, etc[3]. Hematological damage also is a common manifestation. Studies have shown that SLE may develop immune-mediated leukopenia, thrombocytopenia and anemia[4], among which thrombocytopenia is the most common, accounting for about 7% to 30% of all cases. In SLE patients, it is an important cause of death. A careful observation of peripheral blood cells parameters is necessary for early detection and a proper assessment of SLE progression and prognosis[5]. The reduction of platelet count in patients with SLE has become a consensus[6]. In this study, we found that platelet mean volume decreased in patients with SLE. Size and volume are closely related to the ultrastructure, enzyme activity and functional status of platelets. Bulk platelets contain more glycogen, adenine, nucleotides and orthophosphate, are also more active. A decrease in platelet volume indicates a decrease in tangible substances, activity, and function. In this study, the MPV of SLE patients were significantly reduced compared with the control group, indicating that the reduction of the number and volume of platelets in SLE patients may cause platelet dysfunction.

The serum markers for clinical diagnosis of SLE are mainly autoantibodies and inflammatory factors. Autoantibodies are specific for the diagnosis of SLE. It is generally believed that when used to diagnose SLE, anti-nuclear antibody (ANA) is more sensitive, but has lower specificity. If it is tested alone, it can only be used as a screening test. Anti-Smith(Sm) antibody, anti-double strand DNA( dsDNA) antibody, anti-nucleosome antibody( AnuA) and anti-ribosomal P protein antibody were some specific indicator for the diagnosis of SLE. However, the positive rates of Anti-Smith(Sm) antibody, anti-double strand DNA( dsDNA) antibody are 37.9% and 32.7%, respectively[7], so that even though the diagnosis of SLE with both of them has greater specificity, but the diagnostic sensitivity is low, easy to miss, and the project is difficult for primary clinics to practice.

Our study found that the serum levels of C3 and C4 in the three groups of SLE patients were decreased. This may be because a large number of circulating immune complexes were formed in the patient, complement system were activated and thus consumed a large amount of complement C3, C4, which is consistent with other studies[8,9]. The increase in CRP also reflects the state of immune dysfunction. We have found that IgG and IgA produced by B cells from patients with SLE increased to varying degrees, indicating that the humoral immune system is hyperactive. In the inactive group, IgG was increased, while IgA was increased in active SLE patients, and IgM was decreased in active plus renal injury group, suggesting that there is a certain correlation between immunoglobulin levels and disease activity. Dynamic observation of changes in serum immunoglobulin levels may be helpful in analyzing disease progression[10].

## 5. Conclusion

In summary, this study found that levels of C3 and C4 were reduced in different subgroups of SLE patients with a different but characteristic immunoglobulin change. If supported by a larger sample of clinic data, these specific changes, combined with other examinations and clinic symptoms and signs, may have a significant value for the diagnosis and staging of SLE, thereby improving the prognosis of this complicated disease.

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ARTICLE

# In Vitro Antibacterial Activity of *Galla Chinensis* Combined with Different Antibacterial Drugs against Carbapenem-Resistant E.Coli

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ABSTRACT

**Objective:** To evaluate the antibacterial effects of meropenem and levofloxacin respectively combined with *Galla chinensis* on carbapenem-resistant *Escherichia coli* in vitro. **Methods:** The protocol was designed with checkerboard method and the carbapenem-resistant *E.coli* was isolated in our hospital. The minimum inhibitory concentrations(MICs) of *G. chinensis* alone and combined with 2 antimicrobial agents against carbapenem-resistant *E.coli* were determined by broth dilution method and the fractional inhibitory concentration index (FICI) was calculated according to MICs results. Result: the combined use of *G. chinensis* and meropenem (or levofloxacin) significantly decreased both MIC50 and MIC90; After the combination of *G. chinensis* and meropenem, the synergistic effect was 86.7%, and the additive effect was 13.3%, no irrelevant and antagonistic effects. After combined use of *G. chinensis* and levofloxacin, the synergistic effect was 66.7%, and the additive effect was 33.3%. No irrelevant and antagonistic effects. **Conclusion:** *Galla chinensis* combined with meropenem or levofloxacin has synergistic and additive antibacterial effect, with certain combined antibacterial activity.

## 1. Introduction

*Escherichia coli* (*E. coli*) is a common Gram-negative pathogen in the hospital and is widely found in nature. It is a normal flora in the human and animal gut[1]. E. coli can cause a variety of infections when the body's immunity is reduced, the colony of the flora changes, or the flora is out of tune. According to the monitoring of bacterial resistance in China, E. coli is the highest-prevalence Gram-negative bacteria in the clinic, which can cause diarrhea, urinary tract infection, wound infection, bacteremia, meningitis and other diseases[2,3].

In recent years, with the increasing use of antibiotics, the detection rate of multidrug-resistant (MDR) E. coli in the clinic has increased year by year. It has posed a major challenge to clinical anti-infective treatment. In the face of this severe clinical anti-infective situation, carbapenem antibiotics are often used as clinically effective antibacterial drugs for clinical treatment[4]. However, with the increase in the clinical use of carbapenem antibiotics, more

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and more clinical detection of carbapenem-resistant E. coli has brought great challenges to clinical anti-infective treatment. With the continuous development and deepening of the research work on anti-infection of traditional Chinese medicine by domestic medical workers, the researchers found that some of the traditional Chinese medicines have effective antibacterial activity and can be used for antibacterial therapy or combined other antibacterial drugs for combined antibacterial therapy[5,6]. Studies have shown that *G. chinensis* in traditional Chinese medicine have good effective biological activities such as antibacterial, anti-caries, anti-mutation and anti-oxidation[6,7]. Therefore, this study will conduct a basic study on the antibacterial activity in vitro of *G. chinensis*s combined with different antibacterial drugs against carbapenem-resistant *E.coli*, in order to provide a basis for finding a reasonable and effective antibiotic treatment in the clinic.

## 2. Materials and Methods

### 2.1 Strain Specimens and Standard Strains

After removing duplicate strains isolated from the same site of the same patient, 30 strains of carbapenem-resistant *E.coli* isolated from Lingnan Hospital of the Third Affiliated Hospital of Sun Yat-sen University (June 2016 to June 2017). Identification and drug susceptibility test of isolated strains was performed using a fully automatic bacterial identification analyzer (MicroScan WalkAway-96 plus). 30 specimens of carbapenem-resistant *E.coli* were mainly derived from sputum, accounting for 50% (15/30), followed by blood 20% (6/30) and urine 10% (3/30), other specimens 20% (6/30). *E.coli* ATCC25922 and *Pseudomonas aeruginosa* ATCC27853 were used as quality control strains and provided by the Guangdong Center for Clinical Laboratory.

### 2.2 Instruments and Reagents

MicroScan Walk-Away 96 plus (Siemens, Germany), a fully automated bacterial identification and susceptibility analyzer (including supporting reagents and slats) was used. DR100 turbidimeter (Biomerieux, France); ultra-clean workbench (Beijing Donglian Haar Instrument Manufacturing Company, China)); 96-well plate (Corning, USA); MH (Mueller-Hinton) broth, sterile Saline, meropenem and levofloxacin standard (Wenzhou Kangtai Biological Company, China); Galla (Guangdong side pharmaceutical company, China).

### 2.3 Preparation of Bacterial Suspension

After the culture on the blood plate for 18~24h, pick up 3~5 pure colonies, use a sterile cotton swab to grind and mix in sterile physiological saline, and adjust the turbidity to 0.5 Mcfarland standard using DR100 type turbidimeter, and then use MH broth to dilute the turbidity-adjusted bacterial liquid by a factor of 100.

### 2.4 Preparation of Antibacterial Drugs

Weigh the appropriate amount of each drug with an analytical balance. *G. chinensis* was dissolved in ddH2O at a concentration of 10240 μg/mL. According to the requirements of the CLSI standard, the concentration of meropenem and levofloxacin was 5120 μg/mL.

### 2.5 The Micro Broth Dilution Method

Each antibacterial drug was diluted to 10 concentration gradients according to the dilution method by using MH broth sterilized in an autoclave. The concentration of *G. chinensis* was 10μg/ml~5120 μg/mL, the concentration of meropenem was 0.5μg/ml~2560μg/mL, and the concentration of levofloxacin was 2.5μg/ml~1280μg/mL. First, add 100 μL of different concentrations of antibiotics to each of the 1st to 10th holes of each horizontal row of the sterile 96-well culture plate, and then add 100 μL of bacterial suspension to each well. In addition, the negative control and the blank control were simultaneously used as quality control during the test. The culture plate with the added bacterial solution was placed in an incubator at 37°C for 16h to 20h. After the completion of the culture, the minimum inhibitory concentration (MIC) value of the different antibacterial drugs used alone was recorded ($MIC_{alone}$). The test was repeated 3 times.

### 2.6 The Micro Broth Checkerboard Dilution Method

According to the checkerboard method, the antibacterial combination design was carried out. First, different experimental antibacterial drugs were double diluted with MH broth to 8 different antimicrobial concentration gradients according to the 2 times MIC value of using the single drug. Take meropenem and levofloxacin respectively combined with *Galla chinensis*, and then add 50 μL of each antibiotic suspension to each well. Finally, add 100 μL of the diluted strain suspension, and incubate at 37 °C for 16 h to 20 h. After observing the test results and recording the MIC value of each antibacterial drug in the best combination of antibacterial drugs, in addition, the fractional inhibitory concentration index (FICI) value was calculated.

### 2.7 Calculation and Judgment of FICI Value[8]

The FICI value is considered the standard reference pa-



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rameter to quantify pairwise drug interactions in antimicrobial research. The FIC of drug A (FICA) is defined as the MIC of drug A in the presence of drug B divided by the MIC of drug A alone (FICA = [MICA(B)/MICA]); and vice versa (FICB = [MICB(A)/MICB]). The sum of FICA plus FICB gives the FICI (FICI = FICA + FICB), an indication of the degree of drug interaction. When FICI ≤ 0.5, it is synergistic. When 0.5 < FICI ≤ 1.0, it is additive. When 1.0 < FICI ≤ 2.0, it is irrelevant. When FICI > 2.0, it is antagonistic.

### 2.8 Statistical Analysis

Statistical analysis of the experimental data was performed using SPSS 22.0 statistical software. The synergistic rate between the two groups of antibiotics was compared by $\chi 2$ test. p Value <0.05 was considered to indicate statistical significance.

## 3. Results

### 3.1 Comparison of MIC Values of Antibacterial Drugs against Carbapenem-resistant E. coli When Used Alone or in Combination

The results showed that when *G. chinensis* was combined with meropenem, the MIC50(the MIC required for 50% of the bacteria to be inhibited) and the MIC90 (the MIC required for 90% of the bacteria to be inhibited) of the two antibacterial drugs were significant declined. The MIC50 and MIC90 of *G. chinensis* were 1/4 of that when the drug was used alone, and the MIC50 and MIC90 of meropenem were 1/32 and 1/4 of that of the drug was used alone; When *G. chinensis* was combined with levofloxacin, the MIC50 and MIC90 of *G. chinensis* were 1/4 of that when the drug was used alone, and the MIC50 and MIC90 of levofloxacin were 1/8 and 1/64 of that of the drug was used alone, as shown in Table 1.

**Table 1.** MIC values of *G. chinensis* with meropenem and levofloxacin alone or in combination against carbapenem-resistant *E.coli* (n=30, μg/mL)

| Antibacterial drug | | Alone | | | Combination | |
|---|---|---|---|---|---|---|
| | $MIC_{50}$ | $MIC_{90}$ | range | $MIC_{50}$ | $MIC_{90}$ | range |
| *G. chinensis* | 640 | 2560 | 80~5120 | 160 | 640 | 40~640 |
| Meropenem | 640 | 1280 | 20~2560 | 20 | 320 | 5~320 |
| *G. chinensis* | 640 | 2560 | 80~5120 | 160 | 640 | 40~1280 |
| Levofloxacin | 40 | 640 | 10~1280 | 5 | 10 | 1.25~10 |

### 3.2 The FICI Distribution of *G. chinensis* against Carbapenem-resistant E. coli When Combined with Meropenem or Levofloxacin

When *G. chinensis* was combined with meropenem, the synergistic effect was 86.7%, the additive effect was 13.3%, and the irrelevance and antagonism were 0; When *G. chinensis* was used in combination with levofloxacin, the synergistic effect was 66.7%, the additive effect was 33.3%, and the irrelevance and antagonism also were 0,as shown in Table 2. The synergistic ratio (synergistic effect+additive effect) of the two different antimicrobial combinations was indicated no statistical significance. ($P > 0.05$).

**Table 2.** The FICI distribution of *G. chinensis* against thirty strains of carbapenem-resistant E. coli when combined with meropenem or levofloxacin

| Drug combination | FICI ≤ 0.5 | 0.5 < FICI ≤ 1.0 | 1.0 < FICI ≤ 2.0 | FICI > 2.0 |
|---|---|---|---|---|
| *G. chinensis*+Meropenem | 26(86.7%) | 4(13.3%) | 0(0%) | 0(0%) |
| *G. chinensis*+Levofloxacin | 20(66.7%) | 10(33.3%) | 0(0%) | 0(0%) |

## 4. Discussion

*Galla chinensis*, a nontoxic Chinese herbal medicine, is naturally formed when Rhus chinensis Mill is parasitized by *Melaphis chinensis* Bell. *G. chinensis* is considered to be a potential antibacterial agent. The main active ingredient of *G. chinensis* is *G. chinensis* tannin, which is formed by the condensation of 7 to 9 molecules of gallic acid and 1 molecule of glucose. The content is about 60% to 70%, even up to 80%; *G. chinensis* tannin can be made into nearly 100 kinds of fine chemical products by purification and synthesis. It has been widely used in medicine, chemical industry and food, and has become a research hotspot in the research field[7]. *G. chinensis* not only has the effect of clearing away heat and detoxification, but also has a significant broad-spectrum antibacterial effect. In the early studies, the MIC rsults of *G. chinensis* ethanol extract against 140 strains of Enterococcus showed that the MIC90 of *G. Chinensi* against *Enterococcus. faecalis*, *Enterococcus faecium* and other Enterococcus was 0.315mg/mL, 0.63mg/mL and 0.63 mg/mL, respectively, which suggesting that *G. chinensis* ethanol extract has strong antibacterial activity against Enterococcus[9]. Li Kaixuan et al. also found that *G. chinensis* has effective antibacterial activity by detecting the antibacterial activity of Chinese herbal extracts against multi-drug resistant Acinetobacter baumannii[6]. In this study, the bacteriostatic activity of *G. chinensis* against carbapenem-resistant *E.coli* was tested


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to show that the MIC value of 80~5120μg/mL has certain effective antibacterial activity.

In recent years, the detection rate of carbapenem-resistant *E.coli* in the clinic has gradually increased, which has brought great challenges to clinicians' anti-infective treatment. Faced with the increasingly severe drug resistance situation and the slow development of new effective antibacterial drugs, it is of great significance to carry out the deep excavation of traditional Chinese medicines and the combination of antibacterial drugs for anti-infective treatments[10,11]. Both meropenem and levofloxacin are commonly used antibacterial drugs in the clinic and as drug use increases, there is more drug resistance. Therefore, finding synergistic antibacterial drugs for anti-infective treatment plays an important role in the rational and effective use of clinical antibacterial drugs. In this study, the results indicated that *G. chinensis* has a certain combined effect when used in combination with meropenem or levofloxacin. When *G. chinensis* was combined with meropenem, the MIC50 and MIC90 of the two antibacterial drugs were significant declined. The MIC50 and MIC90 of *G. chinensis* were 1/4 of that when the drug was used alone, and the MIC50 and MIC90 of meropenem were 1/32 and 1/4 of that of the drug was used alone; When *G. chinensis* was combined with levofloxacin, the MIC50 and MIC90 of *G. chinensis* were 1/4 of that when the drug was used alone, and the MIC50 and MIC90 of levofloxacin were 1/8 and 1/64 of that of the drug was used alone. In addition, when *G. chinensis* was combined with meropenem, the synergistic effect was 86.7%, the additive effect was 13.3%, and the irrelevance and antagonism were 0; When *G. chinensis* was used in combination with levofloxacin, the synergistic effect was 66.7%, the additive effect was 33.3%, and the irrelevance and antagonism also were 0. These also indicated that the combination of *G. chinensis* and the above two antibacterial drugs has a certain combined effect. The results are different from those reported by Zhang Haiyue et al.[12] and Wang Lingjing[13], which may be related to the difference of strains.[14] In this study, the clinically isolated carbapenem-resistant E. coli were selected. Zhang Haiyue et al. used bovine levofloxacin-resistant E. coli, and Wang Lingjing et al. chosed multidrug resistant *Pseudomonas aeruginosa*. The mechanism of bacterial resistance is complex, and it can be resistant to antibiotics by producing β-lactamase, change in cell membrane permeability, active efflux pumps, change in drug targets, and biofilm formation[15]. Wang Lingjing et al. showed that *G. chinensis* alone or in combination with ciprofloxacin can promote the expression of multiple drug-resistant *Pseudomonas aeruginosa* (MDR-PA) efflux pump genes to different extents, suggesting that Chinese medicine passes promote efflux pump gene expression to play an antagonistic role in antibiotics. It is suggested that there may be different types of bacteria, and the mechanism of resistance is also different, resulting in differences in experimental results[16,17].

## 5. Conclusion

In summary, this study found that *G. chinensis* combined with meropenem or levofloxacin has a certain combined antibacterial effect on anti-infective treatment of carbapenem-resistant *E.coli*, and this treatment can be considered for anti-infective treatment in clinical practice. However, this study also has defects such as the small number of research strains and the small number of antibacterial drugs, and we will further study them in future research.

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REVIEW

# Brief Talking about the Development of Medical Device Industry in China

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ABSTRACT

With the continuous development of China's economy and the improvement of Chinese' living standards, people's awareness of health care has gradually increased, so the demand for medical devices products is also strengthen. In addition, China is gradually entering an aging society and policy support for the medical device industry. China's medical device industry is developing rapidly.

## 1. Introduction

In recent years, whether the State Council promulgated the "Healthy China 2030" Program Outline or "China-Made 2025", the trend of promoting biomedicine and high-performance medical devices in China is obvious. With the remarkable improvement of people's living standard, people pay more attention to the health field. With the support of policy dividend and market dividend, China's medical device industry has developed rapidly.

## 2. Text

According to the "China's medical device industry competition pattern and leading enterprises analysis report" released by perspective industry research institute, statistical data show that the market scale of China's medical device industry reached 212 billion yuan in 2013, and broke through 300 billion yuan in 2015, up to 2017, t By 2017, the market size of China's medical device industry has grown to 445 billion yuan, with a year-on-year growth of 23.3%.. In 2018, the market size of China's medical device industry exceeded 500 billion yuan, reaching 525 billion yuan, an 18% increase over the previous year. The compound growth rate was 20% in 2013-2018.[1] From 2011 to 2017, the scale of China's medical device market has been expanding at a rate more than twice the world level, but there is still much space for

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development compared with the world level. Although we expanded capacity in the market for medical device industry speed, but because of the relevant basic science and manufacturing technology, medical device industry is relatively backward, leading to domestic enterprises engaged in medical equipment industry is relatively low in the link, medical device products are still concentrated in low and middle-end varieties, and the competition pattern is diversified. China's medical equipment industry mainly relies on imports of high-end products. Although there are more than 2000 export-certified enterprises in China, most of them have relatively weak competitiveness in terms of scale and brand, and lack of core technology. OEM is the main form of export, lacking of their own brand, it is at a disadvantage in the international market competition. At present, the basic composition of China's medical device market is 25% of high-end products, 75% of low-end products; while in the international medical device market, the basic composition of medical device products is 55% of high-end products, 45% of low-end products. In addition, 70% of the high-end products market, which accounts for 25% of China's medical devices, is occupied by foreign capital. These 70% of foreign enterprises occupy more than 80% of the market in areas with high technical barriers, such as medical imaging equipment and in vitro diagnosis, while Chinese medical devices enterprises mainly produce low-end products.[2]

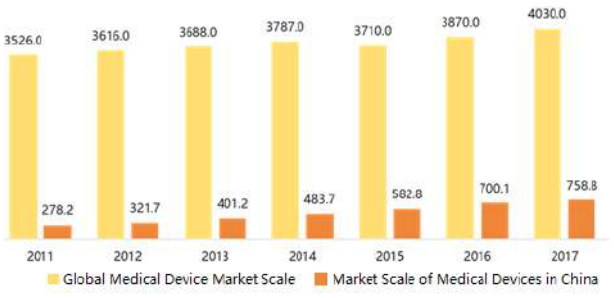


**Figure 1.** Contrast the Scale of Medical Device Market between China and the World from 2011-2017 ($100 million)

In terms of the product structure of China's medical device market in 2018, medical imaging, in vitro diagnosis and low-value consumables account for a relatively high share in the domestic medical device market, accounting for 16%, 14% and 13% of the market share respectively. and the top seven subdivisions including cardiovascular equipment, accounted for 68% of the market share.[1]

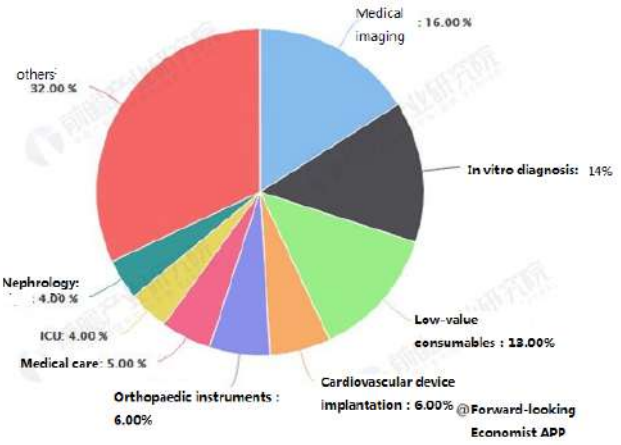


**Figure 2.** Statistics on the Product Structure of China's Medical Devices Market in 2018

From the perspective of consumption structure of medical devices, medical imaging, in vitro diagnosis and consumables (including low and high value) account for the highest proportion, while high-value consumables such as cardiovascular and orthopaedics are in a relatively high growth stage. Overall, CT, nuclear resonance and ultrasound occupy 16% of the market share in the field of medical imaging. Domestic enterprises mainly focus on low-end products, with market share between 10% and 20%. In the field of in vitro diagnosis, foreign enterprises still occupy the country because of their technical advantages and closed system strategy of "equipment + reagent", medium and high-end markets for in vitro and in vivo diagnostics.

Since March 2014 and January 2017, CFDA has opened a special review channel for innovative medical devices and a priority approval channel for medical devices. By the end of May 2018, 161 projects had been selected into the special approval procedure for innovative medical devices, 15 projects had been selected into the priority approval procedure for medical devices, and a total of more than 30 varieties of devices had been approved.[3] With the accumulation of technology and the acceleration of approval over the years, a series of domestic high-end equipment products were released, and domestic enterprises gradually have the conditions to import and replace them in high-end hospitals.

In 2019, the market scale of the whole industry not only focuses on breakthroughs in quantity, but also on the research and development of innovative devices and high-end devices. China is accelerating the import substitution and independent innovation of medical devices. In order to accelerate the development of medical device science and technology industry, the Office of the Minis-

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try of Science and Technology formulated and issued the "13th Five-Year Plan for Scientific and Technological Innovation of Medical Devices" (hereinafter referred to as the "Plan"). According to the framework and content of the "Plan", the new strategic opportunities and objectives facing the development of medical device industry were defined, and the medical device was put forward. Focus on the development of cutting-edge technology and major products. The specific development goals pointed out in the Plan include: breaking through 1-3 original innovative technologies, 10-20 frontier key technologies and forming more than 300 core patents; developing 10-20 frontier innovative products, leading screening and early warning, early diagnosis, micro/non-invasive treatment, individualized diagnosis and treatment, artificial intelligence diagnosis, intraoperative precise imaging, medical wisdom. The development of new medical products and health service technologies such as medical treatment and preventive treatment of diseases by traditional Chinese medicine; Focus on cultivating 8-10 large-scale medical device enterprise groups with strong competitiveness in domestic and international markets, establishing 8-10 medical device science and technology industry clusters, 80-100 furniture with independent core intellectual property rights and a certain scale of innovative high-tech enterprises.[4]

From the content of the above plan, we can see that the government has made great efforts to promote innovative equipment and advanced products, and paid more attention to the development of diagnostic screening, intelligent medical treatment, home rehabilitation equipment and surgical equipment. In a good economic, social, technological and policy environment, China's medical device industry continues to develop. Many medical device enterprises have been recognized by capital. Intelligent household medical equipment has become a new direction for China's medical devices.

In 2017, there were only four companies with revenue exceeding 5 billion yuan, including Merry Medical, Weigao Stock, Xinhua Medical and Dean Diagnosis. In 2017, Top10 accounted for only 12.58% of the total sales revenue of the medical device industry, while Top50 accounted for 31.71% of the total sales revenue of the medical device industry. Compared with Top10 sales revenue of the global medical device industry, 37.55% still has a lot of space to improve.[5]

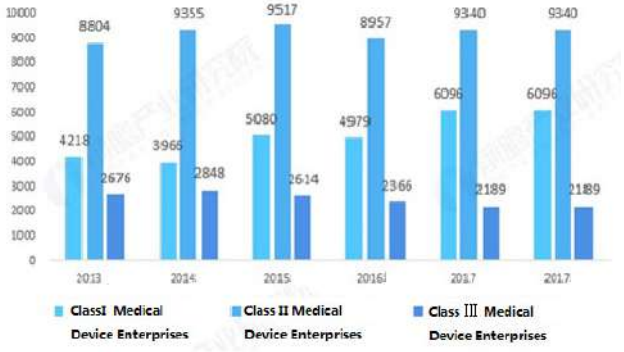


**Figure 3.** Number of Manufacturing Enterprises of Medical Devices in China from 2013 to 2017

In recent years, many reports showed that in medical imaging, medical informatization, in vitro diagnostic, consumables, patient care, health care equipment and so on six big niche, in China's medical equipment market share rising. In advanced medical equipment, there are a lot of high-tech products such as: multiple row helical CT, DSA system, digital color B ultrasonic and high intensity focus ultrasonic therapeutic apparatus, digital X-ray machine, auxiliary body parts, repair and replacement products and materials, electrical control prosthetic limbs, and other products,[6] (prospective net the economist in 2018, the China medical equipment industry technology development trend analysis focus on high-end medical equipment technology) Production of the products effectively increased with independent intellectual property rights innovation, make the medical equipment industry in our country have more new products and new economic growth point.

Taking yuwell medical for example, based on the high performance base completed in the first half of 2017, the company maintained a performance growth of nearly 20% from January to June 2018.[7] (yuwell medical first three quarters' performance report of 2018) The enterprise continuously increased the speed and intensity of new product promotion, consolidated the market share of old products, and continued optimization of core elements such as brand, marketing network and product structure, strengthened the integration and sharing of merger resources, and constantly increased comprehensive competitiveness.

Jiuan medical is a high-tech enterprise focusing on the development and production of health electronic products and intelligent hardware. Its products cover personal health wearable devices in the fields of blood pressure, blood sugar, blood oxygen, ecg, heart rate, weight, body fat, sleep, sports and other fields. In recent years enterprises to "Internet + medical field transformation, establish a mobile Internet" smart hardware + mobile + cloud service



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"personal health management cloud platform of mobile medical service innovation management model has basic forming, and explore new retail offline mode in France, and access to Xiaomi $25 million strategic investment in science and technology, as Xiaomi cooperation partner.

For another example Mindray medical, is a large company with annual revenue of more than 5 billion yuan. Its main business covers three fields: life information and support, in vitro diagnosis and medical imaging. The advantage is that, through cutting-edge technological innovation, we can provide more perfect product solutions, such as integrated first-aid solutions, perioperative integrated solutions, and integrated solutions for severe diseases. By using intelligent medical concepts, innovative products, integrated information mode, high-quality first-aid and efficient information interconnection, we can improve the efficiency of diagnosis and treatment.

Large enterprises have a complete development system, specific product direction, and sufficient experience. For small and medium-sized enterprises, on the one hand, they have to resist the pressure from foreign medical device companies and domestic large enterprises; on the other hand, they have to deal with the policy changes brought by medical reform. In the rapidly developing medical industry, how could they survive and develop?

According to the CFDA, most of the companies are small, with more than 90 percent being small and medium-sized enterprises. Nanjing runfengyuan medical device technology co., ltd. is a small enterprise, which was established in 2014 due to the introduction of nanjing government. It focuses on the research, development and production of rehabilitation medical devices, focusing on the medical anti-bedsore pad and medical temperature controller. Improve traditional mattress to clinical application in the process of research and development, such as sound, vibration, interfere with sleep problems, has developed the first use of the water cycle through the tiny vibration and water can make patients comfortable warm effect 24 hours of continuous use, has now been extended to the major national hospital feedback effect is good. Such small enterprises exert their advantages in the team of Chinese medical device enterprises, and devote themselves to solving patients' pain, innovating medical device products, and finding their own way of survival.

China's medical device industry has a weak foundation for development, medical device supervision started late, and the phenomenon of small, large, scattered and low-level competition of medical device enterprises has not been fundamentally changed, so it has become a top priority to accelerate the improvement of China's medical device industry's technological innovation ability, and strengthen the joint production, study and research of medical device research and development.

At the beginning of the enterprise development, small and medium sized medical equipment enterprises should according to their own characteristics, opening up new road, can put the energies on the following goals:

Focus on low-value consumables: choose primary hospitals, which have a large number, wide distribution, insufficient procurement funds and are sensitive to price, so they purchase and use many domestic medical devices, especially low-value consumables. But the basic-level hospitals use less, influence is small, only depend on the basic-level hospitals enterprises difficult to become bigger and stronger.

Attention to private hospitals: at present, there are 15,000 private hospitals in China, and the annual purchase amount of medical equipment reaches more than 300 billion yuan.[8] (electronic audiophiles network medical electronics) the private hospital market is relatively easy to achieve profits, because compared with public hospitals, private hospitals do not need bidding for equipment procurement, procurement time is short, cost is relatively low, and in the later stage, mass procurement can be formed.

Establishment of independent brand: if an enterprise wants to develop continuously in the long run, it must take the road of independent research and development and establishment of independent brand. In the market, we should stand at the height of being a brand, integrate dealer resources and expand influence with the help of academic activities. Branding is a long-term process that requires enterprises to spend a lot of time, energy and investment. To increase sales volume, we can cooperate with distributors to explore county-level hospitals, quickly achieve sales and realize payment collection, and lay a good foundation for the subsequent development of the enterprise.

Emerging technologies such as mobile medicine, telemedicine, surgical robot and gene sequencing make miniaturized and intelligent medical devices the future development direction. Foreign markets may be put off by protectionist and patent policies for a while, but it is only a matter of time before cost-effective Chinese manufacturing challenges big international brands on a global scale. The bottleneck limiting the development of medical devices in China may be the gap in clinical research, new materials and technologies and other basic subjects.

Driven by national policies, no matter large or small enterprises, the scale of China's medical device market will continue to expand at a rate more than twice that of the world level. During the 13th five-year plan period, China's medical device industry will focus on five areas,

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including digital diagnosis and treatment equipment, tissue repair and renewable materials, molecular diagnostic instruments and reagents, artificial organs and life support equipment, and health monitoring equipment. [8] under the guidance of national policies and the upgrading demand of equipment in domestic medical and health institutions, medical devices will have a huge domestic consumer market.

Market is huge, but China's medical device companies can seize the market and dividend policies, whether on domestic consumer market and is very good to complete the import substitution, must be in the product technology research and development, originality, core technology, team construction, key components procurement, quality system, and constantly improve and perfect the company's operations. Some traditional enterprises are in urgent need of transformation and upgrading. Many provinces and cities have also made important arrangements for the transformation, upgrading and development of medical device enterprises in their respective regions in "made in China 2025", and put forward their own development goals of domestic devices in 2020 and 2025. Therefore, while the industrial scale is growing rapidly, the proportion of domestic devices, especially in county hospitals, will be greatly improved.

## 3. Conclusion

"Idle boast the strong pass is a wall of iron, with firm strides we are crossing its summit". Looking to the future, domestic import substitution is an inevitable trend for the domestic market, and domestic policies are also supporting the big health industry. At the same time, the trust of domestic medical institutions to national brands is steadily improving, and the market outlook continues to be good. Our enterprises should grasp the policy trend, enhance their awareness of the importance of the rule of law, set up the height of the national brand of confidence, actively break industry deeply, reform of power supply side, increase the supply quality, and the effect of medical treatment service, satisfy the people's growing health care needs.

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REVIEW

# Exploration and Discussion on Drug Management in the Operating Room

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ABSTRACT

Operating room drug management work directly related to the safety of medication and the scientific nature of medication, the most important content of operating room drug management is to ensure the rational and safe use of drugs, to avoid drug abuse and misuse. This paper mainly explores the problems existing in the current operating room drug management process, points out the specific drug management model, and hopes to give full play to the role of drug management to ensure that drugs can be applied scientifically.

## 1. Introduction

The work of the hospital is relatively complicated, and there are many kinds of drugs to be used in the operation process, especially narcotic drugs. In order to ensure the smooth and safe completion of anesthesia and surgery, it is necessary to strengthen the management of the operating room drugs, identify the problems that may exist in the drug management process, and take targeted measures to solve them, which enables the drug management to be process-oriented, institutionalized and standardized.

## 2. Main Types of Drugs in the Operating Room

### 2.1 Narcotic Drugs

Narcotic drugs are an important part of operating room drugs. Commonly used operating room anesthetics include muscle relaxants, general anesthetics, local anesthetics, partial anesthetic antagonists, and analgesics, which mainly includes propofol, succinylcholine chloride, lidocaine hydrochloride, neostigmine mesylate, flumazenil and other drugs.[1]

### 2.2 Psychotropic Drugs and Toxic & Narcotic Drugs

Psychotropic drugs and toxic & narcotic drugs are special drugs in surgical drugs, which regulate the systematic processes and systems for special drug management, and are also an important part of drug management in medical institutions. As an important use place for psychotropic drugs and toxic & narcotic drugs, it is necessary to pay attention to the classification methods and management

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methods of psychotropic drugs and narcotics when conducting drug management in the operating room. At present, the common toxic & narcotic drugs in the operating room mainly include the pre-anesthetic induction drugs Mida Tenglun analgesic drugs, remifentanil and dizocine, sedative drugs, and small surgery anesthetics and vasopressors.[2]

### 2.3 Rescue Drugs and Other Drugs Commonly Used in the Operating Room

Common rescue drugs and commonly used drugs in the operating room include adrenaline, atropine, dopamine, dexamethasone, furosemide, and tonofolamine.[3]

## 3. Main Drug Management Requirements in the Operating Room

The operating room is responsible for the treatment of departmental surgery and intraoperative rescue. Unlike other specialist wards, the operating room drugs have certain particularity. The consumption of drugs is relatively large, and the types are relatively complicated, mainly based on narcotic drugs and rescue drugs. During the operation, the drug management and placement are required to meet the safety and convenience characteristics. The operating room is usually a fully enclosed modern operating room. In order to facilitate the timely use of drugs during the operation, it is necessary to rationally design and install the drugs according to the layout of the operating room, and improve the quality of drug use and the efficiency of drug use. Because hospital surgery is relatively complicated, the types are quite diverse, therefore, it is often necessary to use a variety of rescue drugs, design drugs in the vicinity of the operating room, to ensure that the drug can be accurate and rapid, to win sufficient time for the rescue of the disease. The drugs commonly used in the course of surgery mainly include balance solution, Ringer's solution, glucose solution, sodium chloride solution, glucose, mannitol and low molecular weight dextran. Anesthesiology in the anesthesia department set up a number of anesthesia adjuvant drugs including atropine, adrenaline, ephedrine, dexamethasone and other drugs. At the same time, it is necessary to set up an ambulance in the anesthesia recovery room. The ambulance should contain all kinds of rescue items and rescue medications to avoid accidents.[4]

The operating room needs to be set up in a general operating room, a specialist operating room, and an ambulance according to its own working characteristics. In general, the operating room needs to be equipped with medicine car, medicine cabinet and commonly used drugs. After the surgery, the roving nurse will hand over all the prescriptions to the foreman nurses, and the foreman nurses will timely supplement and record the drugs, which will facilitate the drug management and post-operative medication. In order to facilitate rapid drug use during the operation, it is necessary to properly set up the drug car and the medicine cabinet to ambulance, and position it and lock it reasonably, improve the success rate of rescue and the efficiency of drug use, and save time in medicine. The emergency vehicle needs to be prepared according to the relevant standards of the hospital, and the professional medical staff is responsible for establishing the drug specification card for the rescue drug, checking the use record of the rescue drug and supplementing the drug in time. After the use of the drug in the ambulance, it is necessary to sign the licensee to observe the period of use of the drug in the drug vehicle, and to change the drug three months before the drug expires. The ambulance is divided into four layers, each of which is equipped with various injections, various first-aid injections, various rescue kits, and rescue drugs.[5]

## 4. Existing Problems in the Management Process of Operating Room Drugs

### 4.1 Strong Randomness of Drug Storage

Judging from the current status of drug management in the operating room, there is a widespread randomness of drug storage, and there is no problem of sample placement in strict accordance with relevant regulations. Many hospitals do not have professional pharmacists in the operating room for drug management. Drug management and inventory are usually carried out by medical staff and nurses. Many high-risk drugs such as insulin, digitalis and muscle relaxants are mixed with common drugs, which may cause dangerous use of drugs. Secondly, there are still phenomena such as unclear validity period of the drug, unclear batch number and label disagreement in the drug management, which increases the difficulty of drug check-up by medical personnel, and is likely to cause medical troubles in which the drug is used in disorder. For some drugs that need to be preserved under special conditions such as temperature and humidity, they are not preserved according to relevant regulations, which may cause drug failure or even adverse drug reactions. For example, oxytocin and heparin sodium used in clinical practice require cryopreservation, but from the perspective of actual drug management, drugs are not stored in strict accordance with relevant regulations. Adrenalin drugs do not have light-shielding measures, which will inevitably lead to a decrease in the therapeutic effect of the drug, a decrease in



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activity, and even cause drug failure and serious toxic side effects of the drug, which may threaten the life and health of the patient.[6]

### 4.2 Unplanned Drug Requisition in the Operating Room

Under normal circumstances, the hospital will set strict standards for the management and control of drugs in the operating room, however, many hospitals do not follow the actual situation of operating room surgery and the needs of drug management during the process of drug management in the operating room, only the technical management of psychotropic drugs and narcotic drugs is not restricted and regulated according to the dosage of the drugs required by the daily patients and the specifications of the drugs, but simply settles with the pharmacy according to the amount of the amount, however, there are large price differences between different specifications of different drugs, which will cause repeated redundant drugs to be returned to the pharmacy, which will not only cause economic losses for patients, but also lead to repeated balance work, which will increase the workload of the pharmacy, thereby affecting the efficiency of the hospital.[7]

### 4.3 Special Drug Abuse

The operating room has a relatively large amount of special drugs, and it is usually impossible to determine the amount of special drugs during the operation before surgery. Therefore, many hospitals do not impose strict regulations and restrictions on the collection of special drugs. In the process of actual surgery, due to imperfect prescription management, unscientific and special drugs not registered in time, it is easy to cause the loss of special drugs and drug abuse problems, affecting the smooth and safe development of surgical activities.

### 4.4 Other Common Problems during Surgery

The drugs in the operating room mainly include three types of drugs, and the three types of drugs can be divided into a plurality of relatively small types. The same drug can be divided into a variety of different specifications, requiring pharmacy personnel and medical personnel who apply drugs during the surgery to conduct systematic scientific research on the drug, to clarify the main role played by the drug and the specific traits of the drug. However, the staff of medical staff and pharmacies often lack scientific and reliable communication and communication, and cannot grasp the real-time supply information of drugs, which may cause problems of drug shortage or drug breakage, and cause drug use danger. In many hospitals, there are problems in the process of rescuing the vehicle during the operation of the rescue vehicle. Sometimes the pharmacy setting is far away from the operating room setting, and the medicine cannot be replenished in time and quickly equipped, which may cause disturbance and damage of the surgical process.

## 5. Countermeasures for Drug Management in the Operating Room

### 5.1 Develop an Effective Drug Management System

Formulating a scientific and sound drug management system is a prerequisite for ensuring the smooth and scientific development of drug management. Generally speaking, the amount of drugs used should be determined according to the number of operations and the size of the surgery. Therefore, it is necessary to count the doses and types of drugs used in the operation during the daily operation, fix the bases of some commonly used rescue drugs and narcotic drugs, prevent the abuse of drugs, and be responsible for the use of drugs by special personnel to ensure that the supply of medicines is timely and avoid the loss of medicines. Secondly, it is also necessary to check the drugs regularly, clean the small pharmacies in a timely manner, periodically check the drugs, and do a good job in the drug budget, so that the drug can be collected in a uniform and orderly manner, and the drug's shelf life is checked monthly, and the drug that is about to deteriorate or expire is replaced. Drug administrators need to take up their own responsibilities and strictly follow the relevant standards and procedures to complete the management and use of drugs. Special drugs such as psychotropic drugs, highly toxic drugs and narcotic drugs are required to be kept by special counters, especially for highly toxic drugs, it needs to be locked and managed. In addition, there is also a need to develop an effective check system. With the continuous development of the modern medical system and the gradual improvement of the medical level, the drugs used in the surgical process are becoming more and more complex and advanced, in order to ensure the safety of medication and prevent allergic reactions, it is necessary to carefully check the antibiotics used to prevent wound infection during the operation, check the dosage, name and results of the skin test, and do a good job of shifting between nurses. Anesthesiologists and roving nurses need to communicate and communicate to ensure that the drug is correct before it can be applied to the patient. At the same time, it is necessary to do a good job of sorting and placing medicines. The types of medicines used in the operation process and the reaction of medicines are com-

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plicated. In order to facilitate the timely use of medicines and avoid the occurrence of drug errors, samples need to be classified. At present, the medicines in the operating room are mainly placed in five categories, including narcotic drugs, internal medicines, topical medicines, toxic medicines and biological preparations, it is necessary to separately place and mark them, strictly distinguish high-risk drugs from other drugs, cryopreservation of biological preparations, and protect certain special drugs such as adrenaline from light.

### 5.2 Strengthen the Study and Training of Operating Room Medical Staff on Drug-Related Knowledge

With the continuous development of modern medical technology and the advancement of medical science, the variety of various drugs has increased, which has also brought great pressure on the work of medical staff in the operating room. In order to strengthen the understanding of surgical medications by medical staff in the operating room and reduce the occurrence of erroneous medication, it is necessary to strengthen the training of the medical knowledge of the operating staff in the operating room, which allows the medical staff in the operating room to identify the usual doses, pharmacological effects, adverse reactions, routes of administration, and contraindications for drug formulation of various drugs. Learn about pharmacological knowledge at regular intervals every month. After the periodic cleaning, the spare time is used to carry out the rescue and coordination training work and the rapid selection of medicines for medical staff is practiced to avoid the panic phenomenon in the face of the rescue problem and the time for the rescue due to the failure.

### 5.3 Strengthen the Process of Drug Operation

After formulating an effective drug management system, it is necessary to strengthen the allocation of drug storage personnel to ensure the normal operation of drugs and reduce the loss of drugs. It is required that during the operation, the anesthesiologist and the roving nurse work together to register the medication, and after the surgery is finished, the type of medication, the dose of the medication, and the medication are input into the computer system. The daily nurse on duty receives the relevant drugs from the pharmacy according to the computer records. After checking the correct drugs, the drugs are sorted into the medicine cabinet and checked against the base of the medicine in the medicine cabinet. Secondly, the relevant medical personnel of the anesthesiology department need to lock the special counters, keep the prescription drugs for anesthesia, and carry out statistics and input according to the relevant procedures after use. The nurses on duty receive the anesthesia prescription according to the computer records, and hand it to the anesthesiologist on duty to lock and keep. When receiving intravenous fluids and consumable drugs, it is necessary to check the dosage, batch number, quantity and name of the drug in time, and sign and review it with the issuer after checking the error, to avoid the phenomenon of drug mis-distribution and omission, and to ensure that the operating room is fully equipped.

### 5.4 Improve Drug Management Methods

The management of the operating room, as well as the collection and distribution, are the responsibility of the surgical pharmacy. Usually, except for the drugs that are commonly used during part of the surgery and during the rescue process, the drugs are distributed according to the number of operations. It is necessary to properly manage and distribute narcotic drugs, prepare a special anesthesia box for each anesthesiologist, determine the daily use of the medicine, and get the anesthetic medicine to go to work. After the shift, the pharmacy is responsible for recovering the anesthetic drugs. Do a good job in the standardization and process management of drugs, and do a good job of recording, so that the use and collection of drugs can be ruled. For the management of the drug application during the operation, it is necessary for the medical staff to send the information about the drug used to the drug delivery room one day in advance. The pharmacy should first complete the surgical drugs according to the doctor's advice, and send the drugs to the operating room on the day of surgery. The nurses in the operating room are responsible for receiving these drugs and checking the drugs. After the operation, the pharmacy is responsible for recovering the remaining medicines. For some special operations, a special medical box is needed to facilitate the use of the shoelaces and emergency use. At the same time, it is necessary to regularly check the use of developing drugs and do a good job in drug management and supplementation.

## 6. Conclusion

In summary, the operation of the drug management in the operating room is directly related to the safety and reliability of the operation. Judging from the current situation of drug management in the operating room, there are various problems such as unclear management processes, unclear management responsibilities, and abuse of special drugs, which seriously affect the safety and scientificity of



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drug use. Therefore, it is necessary to strengthen research on drug management in operating rooms, clarify the methods of scientific drug use, and set up special personnel to carry out drug management in the operating room, improve the concept of drug management, ensure the normal operation of surgical drugs, and improve the working level of the overall operating room.

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All articles should include a cover letter as a separate document.

The cover letter should include:

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The corresponding author should be identified.

Eg. Department, University, Province/City/State, Postal Code, Country

- A brief description of the novelty and importance of the findings detailed in the paper

Declaration

v Conflict of Interest

Examples of conflicts of interest include (but are not limited to):

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- Honoria
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- Author’s position on advisory boards or board of directors/management relationships
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This section confirms that written consent was obtained from all participants prior to the study.

- Ethical Approval

Eg. The paper received the ethical approval of XXX Ethics Committee.

- Trial Registration

Eg. Name of Trial Registry: Trial Registration Number

- Contributorship

The role(s) that each author undertook should be reflected in this section. This section affirms that each credited author has had a significant contribution to the article.

1. Main Manuscript
2. Reference List
3. Supplementary Data/Information

Supplementary figures, small tables, text etc.

As supplementary data/information is not copyedited/proofread, kindly ensure that the section is free from errors, and is presented clearly.

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A general introduction to the research topic of the paper should be provided, along with a brief summary of its main results and implications. Kindly ensure the abstract is self-contained and remains readable to a wider audience. The abstract should also be kept to a maximum of 200 words.

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Abstract and keywords should be reflected as font size 14.

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Section headings, sub-headings, and sub-subheadings should be differentiated by font size.

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This section offers closure for the paper. An effective conclusion will need to sum up the principal findings of the papers, and its implications for further research.

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Graphs, figures and tables should be labelled closely below it and aligned to the center. Each data presentation type should be labelled as Graph, Figure, or Table, and its sequence should be in running order, separate from each other.

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