https://doi.org/10.31925/farmacia.2022.6.21 **ORIGINAL ARTICLE**

ANALYSIS OF ADVERSE REACTIONS RELATED TO PROPHYLACTIC ANTIBIOTHERAPY IN PATIENTS WITH CLASS I ORTHOPAEDIC INCISION

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Manuscript received: October 2022

Abstract

This study was developed to analyse the effect of prophylactic use of antibiotics on postoperative infection and adverse reactions in patients with class I orthopaedic incisions. A total of 120 orthopaedic incision patients undergoing elective surgery were divided into a control group (44 cases, routine antibacterial treatment) and an intervention group (76 cases, preoperative prophylactic antibiotics). The time of using antibiotics, types of drugs, combination drugs, the rate of additional antimicrobial requests, length of hospital stay, cost of antibiotics and adverse reaction rate were compared between the two groups. Compared with the control group, the use rate of antibiotics in the intervention group increased within 0.5 h before the operation, 0.5 - 2 h and 2 h after the operation and within 24 h after the operation, the use rate of class I cephalosporin antibiotics increased, the use rate of antibiotics alone increased, the rate of additional antimicrobial request for patients with an operation time exceeding 3 h decreased and the average cost of antibiotics decreased. Compared with the control group, the intervention group had a drastically lower adverse reaction rate and postoperative infection rate. In conclusion, the preoperative administration of reasonable and standardized prophylactic antibiotics can effectively reduce the incidence of postoperative infection and adverse reactions in patients with class I orthopaedic incisions and reduce the cost of treatment.

Rezumat

Acest studiu a evaluat efectul utilizarea profilactică a antibioticelor asupra infecției postoperatorii și a reacțiilor adverse la pacienții cu incizii ortopedice de clasa I. Un total de 120 de pacienți cu incizie ortopedică supuși unei intervenții chirurgicale elective au fost împărțiți într-un grup de control (44 de cazuri, tratament antibacterian de rutină) și un grup de intervenție (76 de cazuri, antibiotice profilactice preoperatorii). Durata tratamentului, tipurile de antibiotice și combinațiile acestora, rata solicitărilor suplimentare de antimicrobiene, durata spitalizării, costul antibioticelor și incidența reacțiilor adverse au fost comparate între cele două grupuri. Comparativ cu grupul de control, rata de utilizare a antibioticelor în grupul de intervenție a crescut cu 0,5 ore înainte de operație, 0,5 - 2 ore după operație și 2 ore în 24 ore după operație, iar rata cererii suplimentare de antimicrobiene pentru pacienții cu o durată de operație mai mare de 3 ore a scăzut, precum și costul mediu al antibioticelor. Comparativ cu grupul de control, în grupul de intervenție frecvența reacțiilor adverse și a infecțiilor postoperatorii a fost semnificativ mai mică. În concluzie, administrarea profilactică preoperatorie a antibioticelor poate reduce eficient incidența infecțiilor postoperatorii și a reacțiilor adverse la pacienții cu incizii ortopedice de clasa I și poate diminua costul tratamentului.

Keywords: class I orthopaedic incision, antibacterial drugs, preventive use, postoperative infection, adverse reactions

Introduction

Reasonable application of antibacterial drugs in the perioperative period of orthopaedic surgery patients can drastically reduce the infection rate of surgical sites and promote the recovery speed of patients [1]. However, the unreasonable and nonstandard use of antibacterial drugs will not only affect the surgical effect of patients, but also increase the infection rate of drug-resistant bacteria after surgery, which increases the difficulty of treatment [2, 3]. The blood supply ability of bone tissue in patients undergoing class I incision surgery in orthopaedics is relatively weak, and long-term bed rest is required after surgery, which reduces the immune ability of such patients, further increases the probability of incision infection, and even leads to serious complications such as osteomyelitis in severe cases [4, 5]. According to the Chinese Ministry of Health, the probability of prophylactic use of antibiotics in patients with class I incisions in orthopaedics during the perioperative period is less than 30%, and the duration is shorter than 24 hours [6]. However, the actual situation of prophylactic application of antimicrobial drugs in clinical practice does not meet the requirements, and there are problems such as inappropriate drug selection and long treatment times.

Therefore, the effects of prophylactic use of antimicrobial agents on the incidence of postoperative infection and adverse reactions in patients with class I orthopaedic incisions were analysed. This study aimed to provide a reference for reducing the incidence of postoperative infection and adverse reactions in

patients with class I incisions in orthopaedics and to promote the rehabilitation of patients.

Materials and Methods

General patients information

From January 2021 to December 2021, the data of 120 patients who underwent elective surgery through class I incisions in the Department of Arthroplasty, Jincheng General Hospital, Jincheng Shanxi, China were collected. The patients were divided into a control group (n = 44) and an intervention group (n = 76) according to the perioperative application of prophylactic antibiotics, and the control group did not receive prophylactic antibiotics before surgery. There were 29 males and 15 females in the control group. The age ranged from 39 to 73 years old (54.18 ± 6.09). The body mass index was 18 - 25 (22.02 ± 1.24) kg/m^2. There were 19 cases of general fracture reduction, 15 cases of benign bone tumour resection, and 10 cases of scoliosis fixation and correction. The operation time ranged from 16 to 200 (92.16 ± 11.49) min. There were 53 males and 23 females in the intervention group. The age ranged from 37 to 75 (55.01 ± 6.32) years old. Their body mass index was 18 - 24 (22.17 ± 1.55) kg/m^2. There were 31 cases of general fracture reduction, 28 cases of benign bone tumour resection and 17 cases of scoliosis fixation and correction. The operation time ranged from 15 to 200 (95.01 ± 10.38) min.

Inclusion criteria: patients undergoing elective surgery through orthopaedic class I incision; patients with no infection before operation; patients with no mental illness or cognitive impairment.

Exclusion criteria: patients undergoing orthopaedic incision class II or III; patients with coagulopathy or immune system diseases; patients complicated with serious organic diseases such as heart, liver and kidney; patients with systemic severe infectious diseases; patients with incomplete clinical data. There was no substantial difference in baseline data between the control group and the intervention group ($P > 0.05$). The study was approved by the Medical Ethics Committee of the Jincheng General Hospital, Jincheng, China, and the included patients signed informed consent forms.

Intervention methods

Patients in the control group were treated with antibiotics according to their actual conditions. None of the patients received prophylactic antibiotics before surgery. During the operation, antibiotics were given according to the actual situation. After the operation, antibiotics were given according to the patient's infection, microbial test results and drug sensitivity test results. When the patient's symptoms of infection disappeared, the drug was discontinued. Patients in the intervention group received prophylactic antimicrobial therapy. Before surgery, patients should choose economical, efficient and safe antibiotics according to the characteristics of orthopaedic surgery and the actual situation of patients. According to the type of surgery and surgical site, appropriate antibiotics were given 30 min before surgery. If the operation time was more than 3 h, such patients needed to use additional drugs during the operation. After surgery, antibiotics should be given according to the rules of rational use of antibiotics in the perioperative period of orthopaedic surgery.

According to the relevant documents issued by the Ministry of Health and the management regulations of perioperative prophylactic use of antibiotics in our hospital, the rationality evaluation criteria of prophylactic use of antibiotics in clean surgery were formulated, including the indication of prophylactic use, preoperative administration time and intraoperative use and postoperative use of antibiotics. The standard of drug selection and drug combination was referred to in the Table of Antibiotics for Common Surgical Prophylaxis attached to Document 38 of the General Office of the Ministry of Health.

Observation indicators and evaluation criteria

The observation indicators recorded were: timing of receiving antibiotics during the perioperative period, types of antibiotics used during the perioperative period, the combination of antibiotics, the addition of antibiotics to the standard treatment, the average length of hospital stay, the *per* capita cost of antibiotics, the incidence of perioperative toxic reactions, allergic reactions, nausea and vomiting, postoperative infection and other adverse reactions.

Statistical analysis

SPSS 22.0 (IBM, NY, USA) was employed for comparative analysis. Dichotomous variables were represented by n (%), and the chi-square test was applied. Continuity variables were expressed as the mean plus or minus standard deviation ($\bar{x} \pm s$), and an independent sample t test was used. A value of $p < 0.05$ indicated that the difference between the two groups were statistically different.

Results and Discussion

Comparison of the timing of antibiotics in patients with class I incision in orthopaedics

The proportion of patients using antibiotics within 0.5 h, 0.5 - 2.0 h and 2.0 h before the operation in the intervention group was significantly increased compared with the control group, and the same trend was observed also for the proportion of patients using antibiotics within 24 h after the operation. The use of antibiotics in the control group was significantly increased in the intervention group 24 - 72 h and 72 h after the operation ($p < 0.05$) (Figure 1).

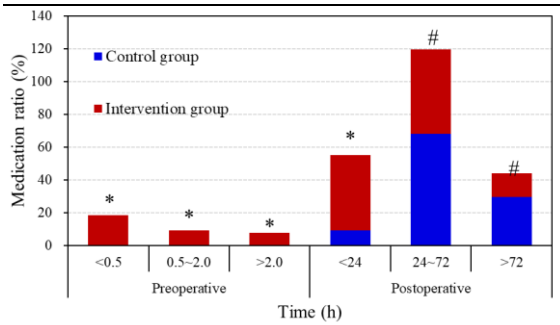

Figure 1.
Comparison of the proportion of perioperative antibiotics used between the two groups
(*p < 0.05 compared with the control group; # p < 0.05 compared with the intervention group)

Comparison of the use of antibiotics in patients with class I incisions in orthopaedics during the perioperative period

The proportion of perioperative use of generation I cephalosporins in the intervention group was significantly increased compared with the control group (p < 0.05). The proportion of perioperative use of cephalosporin II and cephalosporin III was significantly increased in the control group than in the intervention group (p < 0.05) (Figure 2).

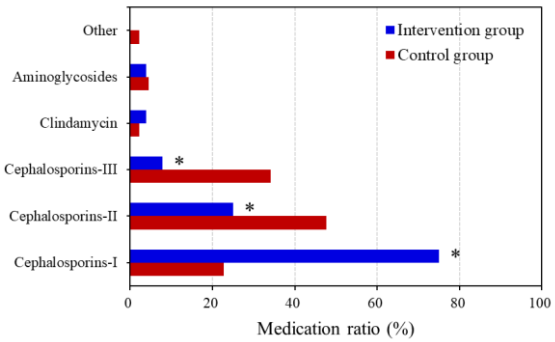

Figure 2.
Comparison of the types of antibiotics used between the two groups during the perioperative period
(*p < 0.05 compared with the control group)

The proportion of perioperative antibiotic monotherapy in the intervention group was significantly increased compared with the control group (p < 0.05). The proportion of patients in the control group who used antibacterial double drugs combination, triple drugs combination and midway dressing change during the perioperative period was significantly increased compared with the intervention group (p < 0.05) (Figure 3).

Additional antimicrobial request in patients with class I incision in orthopaedics

The operation time of more than 3 hours and the proportion of additional antibiotics were analysed and compared between the control group and the intervention group. There were 12 cases (27.3%) in the control group and 23 cases (30.3%) in the intervention group with an operation time of more than 3 hours (p > 0.05). The proportion of additional antibiotics in the control group was 100.0%, which was drastically higher than that in the intervention group (78.3%) (p < 0.05) (Figure 4).

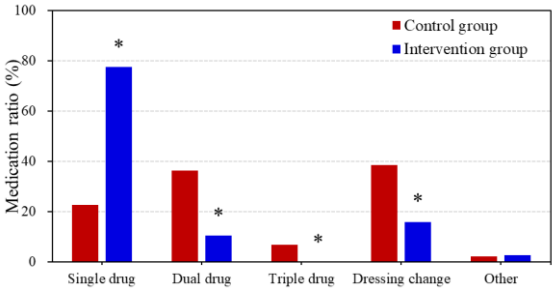

Figure 3.
Comparison of perioperative antibacterial drug combinations between the two groups
(* p < 0.05 compared with the control group)

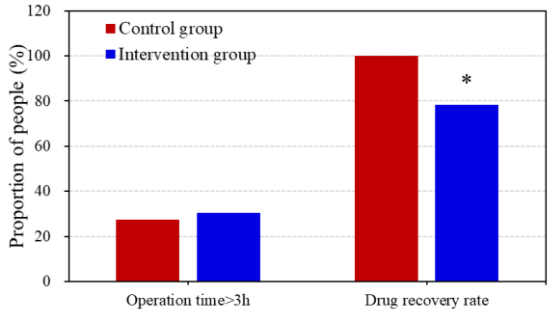

Figure 4.
Comparison of the use of additional antibiotics between the two groups during the perioperative period and the duration of the operation
(* p < 0.05 compared with the control group)

Comparison of hospital stay and antimicrobial cost in patients with class I incision in orthopaedics

The average length of hospital stay in the control group was 22.41 ± 5.66 days, and the average length of hospital stay in the intervention group was 21.21 ± 6.03 days, with no significant difference between the two groups (p > 0.05) (Figure 5).

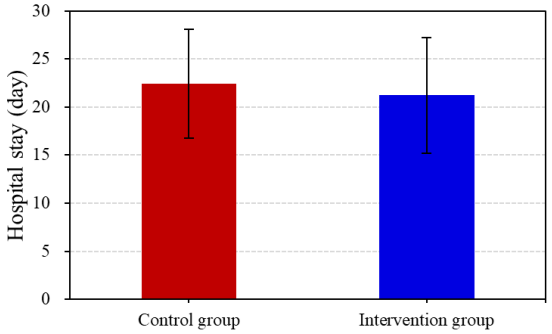

Figure 5.
Comparison of the mean length of hospital stay between the two groups

The average cost of antibiotics in the control group was significantly increased (815.75 ± 109.57 yuan) compared with the average cost of antibiotics in the intervention group (183.42 ± 110.51 yuan) ($p < 0.05$) (Figure 6).

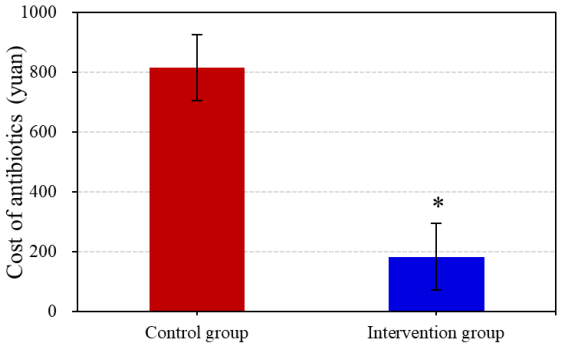

Figure 6.
Comparison of the average cost of antimicrobial therapy between the two groups
(* $p < 0.05$ compared with the control group)

Comparison of postoperative infection and adverse reactions in patients with class I orthopaedic incision

In the control group, nausea occurred in 4 cases (9.1%), vomiting in 3 cases (6.8%), upper abdominal discomfort in 1 case (2.3%), toxic reactions in 6 cases (13.6%) and allergic reactions in 4 cases (9.1%), with total adverse reactions in 10 cases (22.7%) and postoperative infection in 13 cases (29.5%). In the intervention group, nausea occurred in 2 cases (2.6%), vomiting in 2 cases (2.6%), upper abdominal discomfort in 0 cases (0.0%), toxic reactions in 4 cases (5.3%) and allergic reactions in 1 case (1.3%), with total adverse reactions in 5 cases (6.6%) and postoperative infection in 1 case (1.3%). The rates of postoperative infection and perioperative adverse reactions in the control group were significantly increased compared with the intervention group ($p < 0.05$) (Figure 7).

Among surgical incisions, class I incisions are also clean incisions, which mainly refer to those that do not enter the infected and inflammatory areas or those that do not enter the respiratory tract, digestive tract, urogenital tract and oropharynx [7-9]. Closed fracture internal fixation and spinal stenosis in orthopaedic surgery belong to class I orthopaedic incision surgery [10, 11]. Prophylactic application of antimicrobial agents is very important for the prevention of incision infection in orthopaedic patients undergoing class I incision surgery. However, current clinical data show that the advanced use of antimicrobial drugs, excessive use time, the excessive proportion of drugs and excessive types of combined drugs are all irrational drug use, which are the main factors leading to the increase in bacterial resistance [12, 13]. Patients with class I incisions in orthopaedics need to stay in bed for a long time after surgery, which reduces the resistance of patients and increases the incidence of postoperative complications such as infection, which is not conducive to the postoperative rehabilitation and mental health of patients [14]. Therefore, it is very important to actively use reasonable and standardized antimicrobial agents for the prevention of postoperative infection and promotion of rehabilitation in patients with class I incisions in orthopaedics. Therefore, patients undergoing elective surgery through class I incision in orthopaedics were included in this study, and the effects of prophylactic antibiotics on adverse reactions and postoperative infection were analysed.

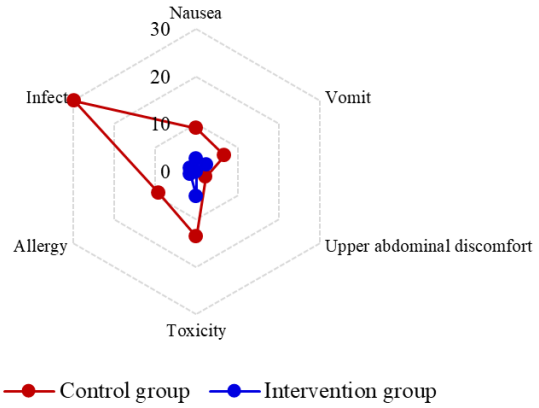

Figure 7.
Comparison of postoperative infection and adverse reactions between the two groups

With the rational and standardized use of antibiotics, only a few cases used antibiotics for more than 2 hours before surgery [15]. The results showed that prophylactic use of antibiotics in patients with orthopaedic class I incisions increased the proportion of antibiotics used within 0.5 h before surgery, 0.5 - 2 h, 2 h outside the surgery and within 24 h after surgery, while the postoperative infection rate was drastically reduced. This shows that prophylactic use of antibiotics and detailed management during the perioperative period can effectively grasp the timing of drug use and reduce the postoperative infection rate [16, 17]. This study found that prophylactic use of antibiotics in orthopaedic incision patients with class I cephalosporins was drastically increased in the proportion of patients treated with the generation I cephalosporins and a single use of antibiotics, and the probability of perioperative nausea, vomiting, upper abdominal discomfort, toxic reactions and allergic reactions were drastically reduced. These results indicated that the single use of antimicrobial agents can effectively prevent the incidence of adverse reactions in patients with class I orthopaedic incisions. However, patients with class I incision in orthopaedics are mostly treated with drugs of generation I cephalosporin, generation II cephalosporin and generation III cephalosporin for antimicrobial treatment, which is in line with the results of Zhou *et al*. [18]. This is because aminoglycosides have too many side effects

to be suitable for routine prophylactic antimicrobial intervention [19, 20]. Second, this study found that the rate of patients with operation times longer than 3 hours using antibiotics was drastically lower. This is due to factors such as active control of exogenous pollution during the perioperative period [21]. The principles of prophylactic use of antibiotics are excellent effect, wide coverage of common strains, high safety, easy use and relatively low price [22-25]. The results showed that the average cost of antimicrobial therapy was drastically reduced in patients with class I orthopaedic incisions who received prophylactic antimicrobial therapy. This finding indicated that the rational use of prophylactic antibiotics can reduce postoperative infection and adverse reactions but also reduce the treatment costs of patients and reduce their economic pressure, which is consistent with the results of O'Toole *et al*. [26].

Conclusions

In conclusion, rational and standardized use of prophylactic antibiotics in patients with class I clean surgical incisions in orthopaedics can reduce the incidence of postoperative infection and adverse reactions. However, it is still necessary to pay attention to the rational and standardized use of all types of antibacterial drugs in clinical practice. It is necessary to reduce the types of antibacterial drugs and strengthen medication management, which is conducive to reducing the resistance of infected bacteria and promoting the recovery of patients.

Conflict of interest

The authors declare no conflict of interest.

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