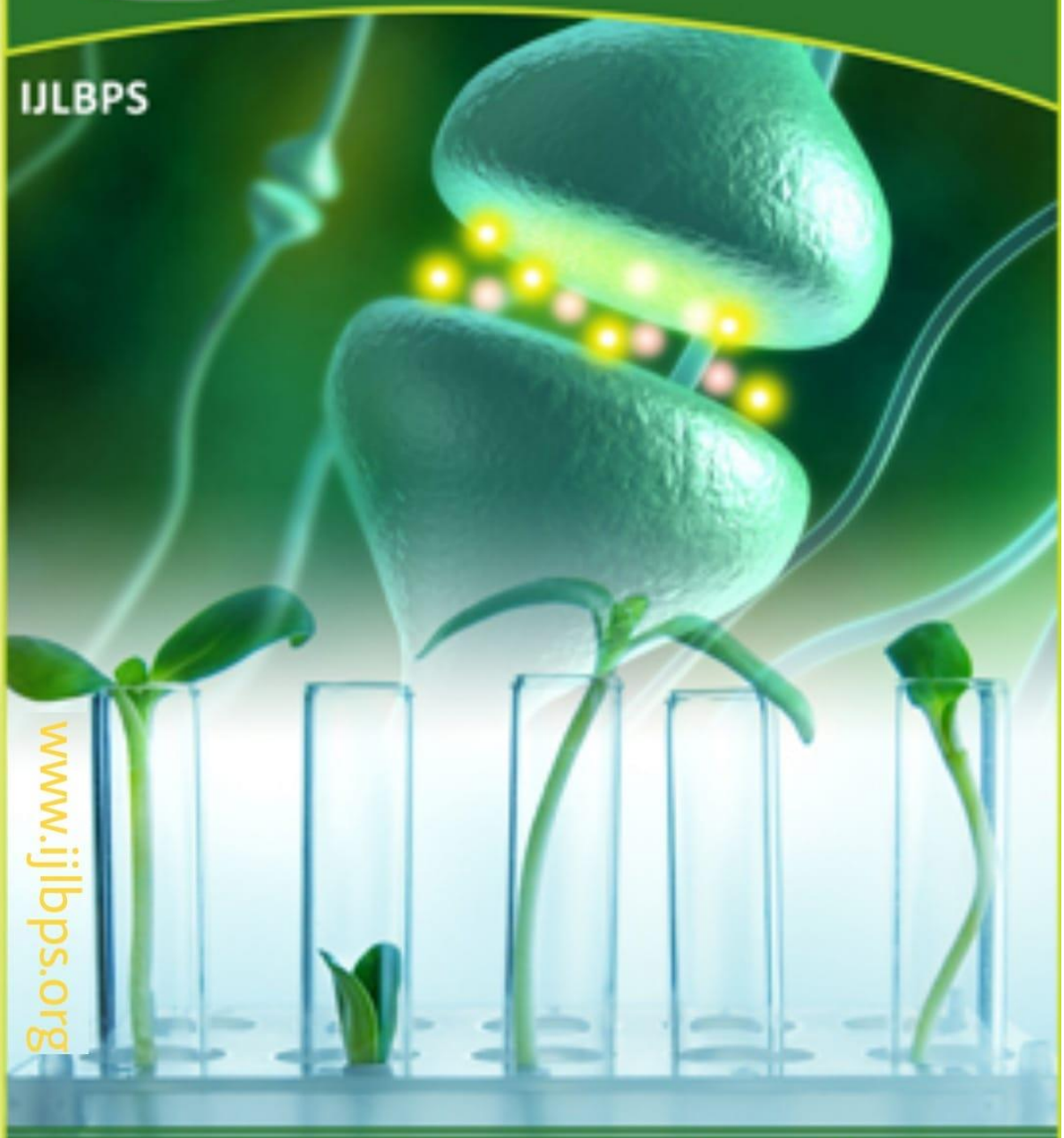
ISSN 2395-650X

International Journal of Life Sciences Biotechnology Pharma Sciences



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International Journal of Life Sciences Biotechnology Pharma Sciences

ISSN2395-650X

Volume 8 Issue3, July 2020

Impact of amoxicillin sodium/clavulanate potassium and cefazolin sodium on inflammatory factor expression, discomfort, and postoperative infection in patients having orthopedic surgery

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Abstract

The goal is to compare the effectiveness of two antibacterial therapies in orthopedic surgery.
Techniques: Based on the postoperative antibiotics used to prevent infection, 96 patients who had orthopedic surgery from January 2021 to December 2022 in the Suzhou Hospital of Integrated Traditional Chinese and Western Medicine, Suzhou, China, were retrospectively analyzed and split equally into two groups. Cefazolin sodium was administered to the study group and amoxicillin sodium/clavulanate potassium was given to the control group. A comparison was made between the two groups for the incidence of postoperative infection, pain score, inflammatory variables, and quality of life.
Findings: Compared to the control group, the study group saw a decreased incidence of postoperative infection ($p < 0.05$). The visual analogue scale (VAS) scores of the two groups were identical ($p > 0.05$) before to the intervention, but they substantially reduced ($p < 0.05$) after it, with the former group's score being lower than the latter ($p < 0.05$). The levels of inflammatory factors in both groups were the same before the intervention ($p > 0.05$); after the intervention, the levels substantially decreased in both groups ($p < 0.05$), with the study group's levels being lower than those in the control group ($p < 0.05$). Following the intervention, the quality of life ratings increased for both groups ($p < 0.05$), with the study group scoring higher than the control group ($p < 0.05$).
In summary: After orthopedic surgery, cefazolin sodium is superior than amoxicillin sodium/clavulanate potassium in avoiding infection in orthopedic patients. To verify these results, however, this therapy approach must be expanded to more clinical settings.
Keywords: Orthopedic surgery, quality of life, inflammatory variables, amoxicillin sodium/clavulanate potassium, cefazolin sodium, and antibacterial infection

INTRODUCTION

As a result of economic and social advances, the number of patients with orthopedic diseases has been rising in recent years [1]. Compared with other types of operations, orthopedic surgery is more complicated and are of longer duration. Patients are prone to incision infection after surgery due to extensive intraoperative bleeding and decreased body immunity [2]. Postoperative incision infection in orthopedic patients may cause bone defects or non-union, affecting treatment efficacy as well as prognosis of patients. Hence, it is necessary to actively prevent postoperative infection in orthopedic surgery [3]. Currently, antibacterial drug prophylaxis is mainly given half an hour before or after orthopedic surgery in clinical practice [4]. Cefazolin sodium has a wide antibacterial spectrum, and effectively inhibits staphylococci, *Streptococcus pneumoniae*, Klebsiella, *Enterobacter aerogenes* as well as *Escherichia coli*. Moreover, the drug has a long half-life [5]. Amoxicillin sodium/clavulanate potassium, also a common antibacterial drug, is a compound preparation composed of clavulanic acid and amoxicillin, and is effective against infections caused by enzyme-producing resistant bacteria [6]. The aim of this study was to determine the comparative prophylactic effect of two antibacterial therapies in orthopedic surgery.

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International Journal of Life Sciences Biotechnology Pharma Sciences

ISSN2395-650X

Volume 8 Issue3, July 2020

METHODS

General patient profile

A total of 96 patients with orthopedic surgery admitted to Suzhou Hospital of Integrated Traditional Chinese and Western Medicine before surgery from January 2021 to December 2022 were retrospectively analyzed and divided into two groups based on their postoperative medication to prevent infection. Control group (n = 48) received amoxicillin sodium/clavulanate potassium, while the study group (n = 48) administered cefazolin sodium for postoperative infection prevention. Patient profile (including gender, age, fracture location, cause of fracture, etc) of both groups are shown in Table 1, and it indicates that there was no statistical difference between the profiles of the two groups ($p < 0.05$).

Ethical approval

All procedures involving human participants were approved by the Ethics Committee of Suzhou Hospital of Integrated Traditional Chinese and Western Medicine (approval no. 2021-004) and followed the guidelines of the 1964 Helsinki Declaration and its later amendments for ethical research involving human subjects [7].

Inclusion criteria

(1) Met the criteria for orthopedic surgery; (2) patients aged 18 years or older; (3) patients were fully informed and agreed and signed to participate in the study.

Exclusion criteria

(1) A previous history of allergy to the study drug; (2) Have related lesions affecting heart, liver, lung and kidney function; (3) Shows ectopic function in coagulation mechanism; (4) Pregnant and lactating women; (5) Presence of tumors; (6) deficiency in mental and communication functions.

Treatments

For the control group, 0.5 – 1.0 g of Amoxicillin sodium/clavulanate potassium (State medical permit no. H20056310; Harbin Pharmaceutical Group General Pharmaceutical Factory, Harbin, Heilongjiang, China) was mixed with 100 ml normal saline half an hour before surgery and administered intravenously. After surgery, the treatment was repeated, and subsequently, twice daily for 4 days.

For the study group, 0.5 – 1.0 g of cefazolin sodium (State medical permit no. H23020945), produced by Harbin Pharmaceutical Group General Pharmaceutical Factory (Harbin, Heilongjiang, China) was mixed with 100 ml normal saline half an hour before surgery and administered intravenously. The treatment was repeated after surgery, and then twice daily for 2 days.

Evaluation of parameters/indices

Postoperative infection

The incidence of postoperative infection was recorded and compared between both groups.

Pain

Visual analogue scale (VAS) was applied to evaluate the pain symptoms of the patients, and the score ranged from 0 to10. A higher score indicated more severe pain in the patients.

Inflammatory factors

Fasting venous blood samples (10-mL) were collected from the patients before treatment and in the morning after treatment. The samples were centrifuged in a medical centrifuge (Changsha Weierkang Xiangying Centrifuge Co. Ltd, TDZ4-WS type) at a speed of 3000 r/min for 10 min at a radius of 10 cm. The serum (upper layer) was collected and divided into two tubes (tubes A and B) and stored in a − 60 °C refrigerator.

Table 1: Comparison of general patient profile for the two groups

Variable		Study group (n=48)	Control group (n=48)	Statistical value	*P*-value
Mean age (years)		37.92±2.12	38.02±2.11	0.232	0.817
Mean weight (kg)		75.23±5.11	74.98±5.08	0.240	0.811
Education level (n, %)	*Junior high school and below*	16, 33.33	17, 35.42	0.050	0.975
	High school	26, 54.17	25, 52.08		
	High school or above	6, 12.50	6, 12.50		
Gender (n, %)	*Male*	28, 58.33	27, 56.25	0.043	0.837
	Female	20, 41.67	21, 43.75		
Cause of injury (n, %)	*Traffic accident*	24, 50.00	23, 47.92	0.235	0.972
	High-altitude fall	12, 25.00	11, 22.92		
	Heavy object injury	8, 16.67	9, 18.75		
	Others	4, 8.33	5, 10.42		
Fracture location (n, %)	*Upper limb*	22, 45.83	20, 41.67	0.169	0.681
	Lower limb	26, 54.17	28, 58.33		
Smoking history (n, %)	*Yes*	28, 58.33	29, 60.42	0.043	0.835
	No	20, 41.67	19, 39.58		
Alcohol history (n, %)	*Yes*	14, 29.17	15, 31.25	0.049	0.824
	No	34, 70.83	33, 68.75		
Surgical History (n, %)	*Yes*	12, 25.00	13, 27.08	0.054	0.816
	No	36, 75.00	35, 72.92		
Census register (n, %)	*Non-local*	1, 2.08	2, 4.17	0.344	0.558

Tube A was employed for the determination of inflammatory factors, while C-reactive protein (CRP), tumor necrosis factor-α (TNF-α), and interleukin-6 (IL-6) were determined by enzyme-linked immunosorbent assay (ELISA).

Quality of life

Using Generic Quality of Life Inventory 74 (QOLI-74) [8], the quality of life of both groups was evaluated before and after treatment. The scale includes emotional function, psychological status, physical function and social function. Each item was scored from 0 to 100 points; the higher the score, the better the quality of life of the patients.

Statistical analysis

Data were statistically processed using SPSS 23.0. Enumeration data (postoperative infection) were expressed as n and %, while Chi square ($\chi 2$) test was applied for comparison between the groups.

International Journal of Life Sciences Biotechnology Pharma Sciences

ISSN2395-650X

Volume 8 Issue3, July 2020

Measurement data (VAS score, inflammatory factors, quality of life score) were expressed as mean ± SD, whereas t-test was used for comparison of data. $P < 0.05$ was considered statistically significant.

RESULTS

Postoperative infection

In the study group, 1 patient had postoperative infection, i.e., an infection rate of 2.08 % (1/48), while in the control group, 10 patients had postoperative infection, i.e., an infection rate of 12.50% (6/48). Thus, the incidence of postoperative infection in the study group was significantly lower than in control group ($\chi 2 = 3.8523$, $p = 0.0497$).

Pain

Before intervention, VAS scores were similar for the two groups ($p > 0.05$) but decreased significantly in both groups after intervention ($p < 0.05$); however, the score for the study group was lower than for the control group ($p < 0.05$, Table 2).

Table 2: Comparison of pain symptoms between both groups (point, mean ± SD, n = 48)

Group	1 h before surgery	3 h after surgery
Study	5.40±0.49	2.19±0.49*
Control	5.42±0.50	3.92±0.50*
χ^2-value	0.198	17.121
P-value	0.844	<0.001

*Statistically significant compared with value at 1 h before surgery ($p < 0.05$)

Inflammatory factors

Prior to intervention, the inflammatory factor levels in both groups were similar ($p > 0.05$), but the levels in both groups after intervention were lower ($p < 0.05$); the levels significantly lower in the study group than in the control group ($p < 0.05$, Table 3).

Quality of life

Prior to intervention, the quality of life scores for both groups ($p > 0.05$) were identical, but the scores for both groups increased significantly after intervention ($p < 0.05$); however, the score for the study group was significantly higher than for the control group ($p < 0.05$, Table 4).

DISCUSSION

Most orthopedic diseases are caused by accidents, and surgical therapy is mainly adopted in clinical practice [9]. However, orthopedic surgery has some levels of complexity and is longer in duration than most other surgical procedures. The application of various instruments during surgery also causes inevitable damage to local tissues; thus, incision infection is likely to occur after surgery [10]. Patients with mild incision infection after orthopedic surgery are relatively simple to treat, but the incision healing time and hospital stay will be prolonged, resulting in increased treatment costs for patients [11].

Table 3: Comparison of inflammatory factors between both groups (mean ± SD, n = 48)

Group	CRP (mg/L)		TNF-α (pg/mL)		IL-6 (pg/mL)	
	1 h before surgery	*3 h after surgery*	*1 h before surgery*	*3 h after surgery*	*1 h before surgery*	*3 h after surgery*
Study	3.83±0.12	0.66±0.06*	39.66±7.21	23.21±2.21*	29.16±3.15	17.52±3.02*
Control	3.84±0.10	1.92±0.21*	38.70±7.14	31.23±2.34*	29.20±3.17	23.04±3.13*
χ^2-	0.444	39.970	0.655	17.263	0.062	8.793
P-	0.658	<0.001	0.514	<0.001	0.951	<0.001

*Statistically significant compared with value at 1 h before surgery ($p < 0.05$)

Table 4: Comparison of quality of life between both groups (mean ± SD, n = 48)

Group	Affective function		Psychological state		Physical function		Social function	
	1 h before surgery	*3 h after surgery*	*1 h before surgery*	*3 h after surgery*	*1 h before surgery*	*3 h after surgery*	*1 h before surgery*	*3 h after surgery*
Study	47.12±8.10	59.55±6.02*	45.77±7.31	56.49±6.66*	46.44±7.41	56.51±6.30*	46.88±6.66	57.12±6.02*
Control	47.20±8.11	53.48±6.31*	44.30±7.11	50.27±6.41*	45.91±7.50	50.51±6.22*	47.41±6.81	52.33±6.11*
t value	0.048	4.822	0.999	4.662	0.348	4.695	0.385	3.869
P-value	0.962	<0.001	0.321	<0.001	0.728	<0.001	0.701	<0.001

*Statistically significant compared with value at 1 h before surgery ($p < 0.05$)

Patients with more severe infections may have fatal and disabling conditions, posing a threat to their lives and safety. Therefore, for patients undergoing orthopedic surgery, it is necessary to strengthen the prevention of postoperative infection in clinical practice [12]. Previous reports have confirmed that the bacteria causing postoperative incision infection are mainly Gram-positive bacteria, such as *Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa*. Therefore, the selection of antibacterial drugs warrants a wide antibacterial spectrum and high safety characteristics [13]. Amoxicillin sodium/clavulanate potassium is a compound preparation composed of clavulanic acid and amoxicillin, with the latter being a β-lactamase inhibitor that represses β-lactamase derived from resistant bacteria. In combination with amoxicillin, clavulanic acid ensures that amoxicillin does not lose its activity due to β-lactamase [14]. Amoxicillin sodium/clavulanate potassium is frequently used in clinical practice for lower respiratory tract infections, otitis media, sinusitis, skin tissue infections, and

urinary tract infections, induced by sensitive bacteria. Furthermore, it is also used to treat urinary tract infections triggered by *Enterobacter* species [15]. Cefazolin sodium is a first-generation cephalosporin antibacterial drug in clinical practice, with a wide antibacterial spectrum, which greatly suppresses streptococci other than Gram-positive bacteria, staphylococci, and enterococci, especially against Gram-positive bacteria and has stronger antibacterial activity [16]. In the present study, the two drug regimens were applied in preventing postoperative infection in patients undergoing orthopedic surgery. The results revealed that the incidence of postoperative infection in the study group was lower than in the control. This implied that cefazolin sodium had greater effect in infection prevention than amoxicillin sodium/clavulanate potassium combination. The findings suggest that cefazolin sodium has a broader antibacterial spectrum than amoxicillin sodium/clavulanate potassium, and also has a longer drug half-life in plasma. Therefore, it has a more sustained antibacterial effect than amoxicillin sodium/clavulanate potassium [17]. Moreover, cefazolin sodium is rapidly distributed in parts of the body, except the head, after entering the body, and the anti-infective effect is striking [18,19].

Due to soft tissue injury in orthopedic surgery patients, numerous related immune cells release inflammatory factors during the immune response, resulting in a significant increase in TNF-α, CRP, IL-6, and other inflammatory factors which interact with each other [19]. The massive production of inflammatory factors leads to the stimulation of synoviocytes, chondrocytes, etc, which produce prostaglandin E2, protein polysaccharide, and collagenase, thereby damaging the cartilage matrix of the patients and giving rise to increased risk of infection [20]. The findings of the present study indicate that the inflammatory factor levels in the two groups before the intervention were similar. However, cefazolin sodium was considerably more effective in reducing inflammatory factors than amoxicillin sodium/clavulanate potassium. The results revealed that cefazolin sodium was superior to amoxicillin sodium/clavulanate potassium in relieving pain symptoms. Furthermore, it was considered that cefazolin sodium relieved the pain while reducing the risk of infection by repressing inflammatory response. Based on the results, the improvement in patients' quality of life correlates with the recovery of their physical and mental state. Thus, overall, cefazolin sodium was superior to amoxicillin sodium/clavulanate potassium in relieving pain, preventing infection, has better recovery prognosis, and substantially improves the quality of life of patients.

CONCLUSION

The findings of this study show that, compared with amoxicillin sodium/clavulanate potassium, cefazolin sodium is better at relieving postoperative pain, reducing inflammatory factors and enhancing quality of life, as well as lowering the risk of infection in patients undergoing orthopedic surgery. Therefore, this single drug regimen should be preferred to the combination regimen in minimizing orthopedic surgery infections, but these findings need to be validated in further clinical trials.

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