Effects of hip replacement combined with alendronate sodium on postoperative healing of osteoporotic femoral neck fracture and levels of CTX-1 and BALP in patients

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Abstract. This study aimed to explore the improvement of hip replacement combined with alendronate sodium on the condition of patients with osteoporotic femoral neck fracture and factors affecting the efficacy of patients. In total, 140 patients with femoral neck fracture from July 2015 to October 2017 in the Affiliated Xuzhou Hospital of Jiangsu University were collected. Of these, 61 patients were treated with hip replacement as the control group and 79 patients were treated with alendronate sodium as the observation group on the basis of the control group. ELISA was used to detect levels of carboxy-terminal opeptide of type I collagen (CTX-I) and bone alkaline phosphatase (BALP) in serum of patients before and after treatment. Harris score was used to compare the clinical efficacy of patients after treatment. Changes in the expression of CTX-I and BALP before and after treatment were compared between the two groups, and the correlation between CTX-I and BALP levels and Harris score was analyzed. According to the clinical efficacy of patients, the two groups were divided into the significant effect group and poor effect group. Risk factors affecting the efficacy of patients were analyzed, and the ROC of subjects with risk factors was drawn. After treatment, the expression of BALP in serum increased significantly compared with that before treatment, and the expression of CTX-I decreased significantly. After treatment, the expression of BALP in serum in the observation group was significantly higher than that in the control group ($P<0.05$). Multivariate analysis revealed that age, time of operation, CTX-I after treatment and BALP after treatment were independent risk factors affecting the efficacy of patients. In conclusion, hip replacement combined with alendronate sodium can effectively improve the clinical efficacy of patients, and age, time of operation, CTX-I after treatment and BALP after treatment are found to be independent risk factors affecting the postoperative efficacy of patients.

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Introduction

Osteoporosis is a common orthopedic disease clinically, which is closely related to the age and sex of patients (1). According to the investigation and study by Wong and McGirt (2), it was found that the incidence rate of osteoporosis is on the increase annually. Osteoporosis treatment constitutes an increasing financial burden. Osteoporosis is a disease caused by a variety of reasons. The pathological characteristics of patients' bone tissue are bone mass reduction and bone tissue degeneration (3). Femoral neck fracture is the most common part of osteoporotic fracture clinically. Due to the decrease of bone mineral density and the degeneration of bone tissue, patients are prone to fracture under mild impact (4). At present, the elderly population in China is continuously increasing, and statistics show that the number of elderly >65 years of age in China has reached 138 million (5). The increasing number of the elderly leads to an increase in the number of patients with osteoporosis, which not only brings great pain to the patients after fracture, but also increases the economic burden (6). Therefore, a good treatment plan is the key to improve the patients' condition.

Since the clinical onset characteristics of osteoporosis are not obvious and are relatively hidden, most patients are diagnosed with osteoporosis only after fracture (7). The study found that patients who do not receive timely treatment will affect the prognosis and even endanger the lives of patients (8). At present, the clinical treatment plan for osteoporotic femoral neck fracture patients is mainly total hip replacement, which relieves pain by changing the joint structure of the patients, thus achieving the effect of improving the prognosis and quality of life of the patients (9). However, recent findings have shown that some patients suffer from bone loss and osteolysis due to osteoporosis after surgery, which has an impact on

the stability of the prosthesis after replacement, shortens the service life of the prosthesis, and leads to the failure of clinical treatment to meet expectations (10). Alendronate sodium, as a bone metabolism regulator, can inhibit bone absorption and improve bone mineral density, and it is widely used in clinical practice (11). There are few reports on the combined use of alendronate sodium and hip replacement in the treatment of osteoporotic femoral neck fracture. During metabolism, osteoblasts secrete bone alkaline phosphatase (BALP), which regulates the hydrolysis of phosphate and pyrophosphate and promotes bone formation and bone mineralization (12); human type I collagen C-terminal peptide (CTX-1) can specifically reflect the decomposition of type I collagen in bone tissue (13). Previous studies have shown that CTX-1 and BALP are involved in the process of osteoporosis (14).

Therefore, this study explores the improvement of hip replacement combined with alendronate sodium on the condition of patients and the risk factors affecting the efficacy of patients, providing references for clinicians' treatment.

Materials and methods

Clinical data of patients. From July 2015 to October 2017, in Affiliated Xuzhou Hospital of Jiangsu University (Jiangsu, China), 140 patients who underwent hip replacement due to femoral neck fracture were collected, of which 61 patients were treated with hip replacement as the control group and 79 patients were treated with hip replacement combined with alendronate sodium as the observation group. This study was approved by the Medical Ethics Committee of Affiliated Xuzhou Hospital of Jiangsu University. Inclusion criteria were as follows: Garden index can be used for evaluation with a grade ≥III, Singh index can be used for evaluation with a Singh index between IV and VI. Patients were diagnosed as femoral neck bone fracture through imaging examination. The clinical data were complete and signed written informed consents were obtained from the patients and/or guardians. Patients were admitted to hospital for treatment within 24 h after injury with indications for hip replacement surgery. Exclusion criteria were as follows: Patients combined with tumor, cognitive dysfunction of patients could not be evaluated. In addition, patients with congenital heart, liver and kidney defects, patients with surgical contraindications, patients who were allergic to this drug therapy.

Main reagents and drugs. CTX-I, BALP, ELISA kit (China Shanghai Enzyme-Linked Organisms, ml028171, ml058531), alendronate sodium tablets (Yangzijiang Pharmaceutical Group Shanghai Heini Pharmaceutical Co., Ltd.; SFDA approval no. H20065637), calcitriol pills [Roche Pharma (Switzerland) Ltd.], SFDA approval no. J20150011), Caltrate D tablet (Wyeth Pharmaceutical Co., Ltd.; SFDA approval no. H10950029).

Treatment plan. Patients from both groups received total hip replacement surgery (12). After the surgery, patients from both groups were treated with conventional drugs as follows: Caltrate D tablets were chewed after meals, 1 day/time, 1 tablet/time; calcitriol pills were taken orally on an empty stomach 30 min before eating in the morning, 1 day/time, 2 tablets/time. On this basis, patients in the control group took alendronate sodium tablets 1 day/time, 10 mg/time, 30 min before eating in the morning. Patients took the medicine continuously for 3 months.

Detection of CTX-I and BALP expressions. Peripheral venous blood (5 ml) of patients before and 3 months after treatment was collected, kept still for 30 min, and centrifuged at 2,680 x g for 10 min, at 4˚C. Serum was collected, and the expression of CTX-I and BALP was detected by ELISA kit. The detection methods were as follows: Bank wells, standard wells and sample wells to be detected were respectively arranged. Standard substance (50 μl) was accurately added to the enzyme-labeled coating plate, 40 μl of sample diluent was added to the sample well to be tested, and then 10 μl of sample to be tested was added. The sample was added to the bottom of the well of the enzyme-labeled plate without touching the wall of the well, and it was gently agitated and mixed. After sealing the plate with sealing plate membrane, it was incubated at 37˚C for 30 min. The sealing film was removed, the liquid was discarded, and then it was spin-dried. Each well was filled with washing liquid, left to stand for 30 sec, and then discarded. The process was repeated five times, and then it was patted dry. Enzyme-labeled reagent (50 μl) was added to each well, except for blank wells. After sealing the plate with sealing plate membrane, it was incubated at 37˚C for 30 min. The sealing film was removed, the liquid was discarded and spin-dried. Each well was filled with washing liquid, left to stand for 30 sec, and then discarded. Again the process was repeated five times, and then it was patted dry. Firstly, 50 μl of developer A was added to each well. Then, 50 μl of developer B was added to each well. They were mixed with gentle shaking and developed color at 37˚C in the dark for 15 min. Then, 50 μl of stop solution was added to each well to stop the reaction. The absorbance (OD value) of each well was measured in sequence at zero and 450 nm wavelength of blank wells. The determination was carried out within 15 min after the termination liquid was added.

Observation indicators. Main observation indicators were as follows: Harris score was used to compare the clinical efficacy of patients after treatment. Harris score (15) had a total score of 100 points. The higher the score was, the more significant the improvement of hip joint function was. The score of 100-90 was considered as excellent, 89-80 was considered as good, 79-70 was considered as general and <70 was considered as poor. Excellent rate = (excellent+good)/total number x 100%.

Secondary observation indicators were as follows: The expression changes of CTX-I and BALP before and after treatment in the two groups were compared, and the correlation between CTX-I, BALP and Harris score was analyzed. According to the clinical efficacy of the patients, they were divided into the significant effect group and poor effect group, and the risk factors affecting the efficacy of the patients were analyzed, and the receiver operating curve (ROC) of risk factors for efficacy diagnosis was drawn.

Statistical methods. SPSS 20.0 software was used to analyze the collected data in this study, GraphPad Prism 7 software was used to draw relevant images, K-S was used to analyze the data distribution, and the measurement data were expressed

Table I. Clinical data of patients [n%].

Factor	Observation group (n=79)	Control group (n=61)	χ^2/t value	P-value
Sex			0.464	0.496
Male	33 (41.77)	29 (47.54)		
Female	46 (58.23)	32 (52.46)		
Age (years)	64.8±4.90	65.8±6.25	1.221	0.224
Admission time (h)	4.51±1.35	4.77±1.69	1.012	0.313
BMI (kg/m^2)	21.74±1.77	21.97±1.61	0.793	0.429
Previous medical history				
Hypertension	40 (50.63)	27 (44.26)	0.560	0.454
Diabetes	25 (31.65)	16 (26.23)	0.488	0.485
Smoking history			0.329	0.566
Yes	35 (44.30)	30 (49.18)		
No	44 (55.70)	31 (50.82)		
History of alcoholism			0.271	0.603
Yes	10 (12.66)	6 (9.84)		
No	69 (87.34)	55 (90.16)		
Place of residence			0.800	0.371
City	50 (63.29)	43 (70.49)		
Countryside	29 (36.71)	18 (29.51)		

BMI, body mass index.

Table II. Clinical efficacy of patients [n(%)].

Group	Excellent	Good	General	Poor	Excellent rate	Z value	P-value
Control group (n=61)	15 (24.59)	18 (29.51)	18 (29.51)	10 (16.39)	33 (54.10)	-2.015	0.044
Observation group (n=79)	25 (31.65)	35 (44.30)	10 (12.66)	9 (11.39)	60 (75.95)		
χ^2 value	0.840	3.203	6.108	0.734	7.370		
P-value	0.360	0.074	0.014	0.392	0.007		

by usage rate (%). Chi-square test was used, expressed as χ^2. Non-parametric test was used for grade data, expressed as Z. Means ± SD was used for measurement data, and t-test was used for data conforming to normal distribution. Paired t-test was used for intra-group comparison before and after treatment, independent sample t-test was used for inter-group comparison, expressed by t. Rank sum test was used for data that did not conform to the positive distribution, expressed by z. Multi-factor logsitic regression was used for analysis of risk factors affecting the efficacy of patients. ROC curve was used for analysis of clinical value of significant risk factors. Spearman's correlation test was used for analysis of correlation between CTX-I, BALP and Harris score after treatment. And when P<0.05, there were statistical differences.

Results

Clinical data of patients. The comparison of clinical data of patients from the two groups showed that there was no statistical difference in factors including sex, age, admission time, BMI, previous medical history, smoking history, history of alcoholism, and place of residence of patients in the control group (P>0.05) (Table I).

Clinical efficacy of patients. Comparing the clinical efficacy of patients from the two groups after treatment, it was found that the control group had 15 excellent cases, 18 good cases, 18 general cases, and 10 poor cases. The observation group had 25 excellent cases, 35 good cases, 10 general cases, and 9 poor cases. In terms of the single clinical efficacy, there was no difference in the other efficacy grades except for good (P>0.05). The rank sum test analysis showed that there were significant differences in the clinical efficacy of the two groups (P<0.05). Comparing the excellent and good rates of patients from the two groups, it was found that the excellent and good rates of the observation group were significantly higher than those of the control group (P<0.05), as shown in Table II.

Table III. Changes of CTX-I of patients before and after treatment.

Group	CTX-I (μg/ml)		t value	P-value	Variation difference
	Before treatment	After treatment			
Control group (n=61)	0.53±0.21	0.35±0.12	5.902	<0.001	0.18±0.14
Observation group (n=79)	0.54±0.22	0.24±0.08	12.192	<0.001	0.30±0.20
t value	0.288	6.339			3.990
P-value	0.774	<0.001			<0.001

CTX-I, carboxy-terminal opeptide of type I collagen

Table IV Changes of BALP of patients before and after treatment.

Group	BALP (U/l)		t value	P-value	Variation difference
	Before treatment	After treatment			
Control group (n=61)	36.04±1.87	50.57±1.68	-46.728	<0.001	-14.53±2.43
Observation group (n=79)	36.27±1.71	60.70±1.90	-83.230	<0.001	-24.43±2.61
t value	0.751	32.928			22.928
P-value	0.454	<0.001			<0.001

BALP, bone alkaline phosphatase.

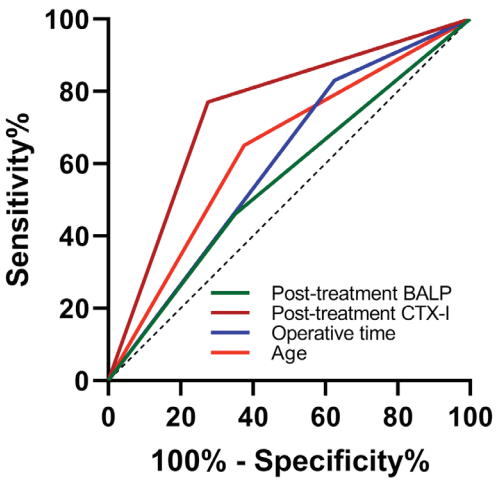

Figure 1. Curve area of each index of risk factors. When age and area under CTX-I curve after treatment compared with 0.5, P<0.05, which had clinical significance. CTX-I, carboxy-terminal opeptide of type I collagen.

Changes of CTX-I and BALP of patients before and after treatment. Comparing expressions of CTX-I and BALP in serum of patients from the two groups before and after treatment, it was found that there was no difference in expressions of CTX-I and BALP between the two groups before treatment (P>0.05). After treatment, the expression of BALP in serum of patients from the observation group was obviously higher than that from the control group, and the expression of CTX-I was lower than that of the control group. Differences in expressions of CTX-I and BALP in the observation group were obviously greater than those in the control group (P<0.05). More details are shown in Tables III and IV and Fig. 1.

Relationship of expressions of CTX-I and BALP with clinical efficacy of patients after treatment. The Spearman correlation test was used to analyze the relationship between the CTX-I and BALP expressions in serum of patients from the two groups after treatment and the clinical efficacy of the patients. It was found that the CTX-I expression was negatively correlated with the clinical efficacy of the patients after treatment, that is, the expression gradually decreased with the improvement of the clinical efficacy; while the BALP expression was positively correlated with the clinical efficacy of patients after treatment, that is, the expression gradually increased with the good clinical efficacy (rCTX-I=-0.801, PCTX-I<0.001; rBALP=0.563, PBALP<0.001) (data not shown).

Analysis of risk factors affecting efficacy. According to the clinical efficacy of patients after treatment, patients with excellent efficacy were divided into groups with significant efficacy, patients with good efficacy, general efficacy and poor efficacy were divided into groups with poor efficacy. Single factor analysis of the collected clinical data of patients showed that there were differences between the two groups (P<0.05) in age, time of operation, CTX-I after treatment and BALP after treatment that were risk factors affecting the prognosis of patients, while the other indexes had no differences (P>0.05), and the indexes with differences were assigned. Furthermore, multi-factor logstic regression was used and LR method was selected for analysis. It was found that age, time of operation, CTX-I after treatment and BALP after treatment were

Table V. Single factor analysis of clinical data.

Factor	Significantly effective group (n=40)	Less effective group (n=100)	χ^2/t value	P-value
Sex			2.605	0.107
Male	22 (55.00)	40 (40.00)		
Female	18 (45.00)	60 (60.00)		
Age (years)			8.823	0.003
≥65	15 (37.50)	65 (65.00)		
<65	25 (62.50)	35 (35.00)		
Admission time (h)	4.15±1.44	4.65±1.71	1.631	0.105
BMI (kg/m^2)	21.54±1.57	21.80±1.88	0.773	0.441
Previous medical history				
Hypertension	20 (50.00)	47 (47.00)	0.320	0.572
Diabetes	8 (20.00)	33 (33.00)	2.332	0.127
Smoking history			1.795	0.180
Yes	15 (37.50)	50 (50.00)		
No	25 (62.50)	50 (50.00)		
History of alcoholism			0.706	0.401
Yes	6 (15.00)	10 (10.00)		
No	34 (85.00)	90 (90.00)		
Place of residence			0.388	0.534
City	25 (62.50)	68 (68.00)		
Countryside	15 (37.50)	32 (32.00)		
Time of operation (min)	40.13±7.10	54.36±9.92	8.258	<0.001
Intraoperative hemorrhage (ml)	301.54±66.88	310.55±101.70	0.517	0.606
CTX-I (μg/ml) after treatment	0.20±0.11	0.33±0.11	6.317	<0.001
BALP (U/l) after treatment	58.57±5.16	55.38±5.18	3.301	0.001

CTX-I, carboxy-terminal opeptide of type I collagen; BALP, bone alkaline phosphatase.

Table VI. Assignment table.

Factor	Assignment
Age	≥65 =1, <65 =0
Time of operation	≥45 min=1, <45 min=0
CTX-I after treatment	≥0.20 μg/ml=1, <0.20 μg/ml=0
BALP after treatment	≥55.00 U/l=1, <55.00 U/l=0
Clinical efficacy (y)	Good, general, poor=1, excellent=0

CTX-I, carboxy-terminal opeptide of type I collagen; BALP, bone alkaline phosphatase.

independent risk factors affecting the efficacy of patients. ROC curve analysis showed that age, time of operation, CTX-I after treatment, and area under BALP curve after treatment were 0.638, 0.603, 0.748, 0.555, among which there was no difference between time of operation and area under BALP curve after treatment and 0.5 (P>0.05), while there were significant differences between age and CTX-I after treatment and 0.5 (P<0.05) (detailed in Tables V-VIII).

Discussion

With the continuous development of society, people's living standards and quality of life have been continuously improved, and most developed countries are prone to population aging (16). Some surveys and statistics show that 12% of the world's population are >60 years old, and the metabolism and immune function of people gradually decline with age (17,18). Hip fracture is a kind of femoral neck fracture which is more common clinically, in which the incidence rate of the elderly is significantly higher than that of the young, and the elderly are prone to fracture when falling and twisting due to physical mobility inconvenience (19,20). At present, there are reduction and internal fixation and total hip replacement for the treatment of femoral neck fracture clinically. Compared with reduction and internal fixation, total hip replacement, although the time of operation is long and the trauma is relatively large, can carry out weight-bearing training and corresponding recovery exercise in early postoperative patients, which can rapidly improve the quality of life of patients (21). However, recent findings have shown that patients are prone to bone loss and osteolysis after total hip replacement, which leads to prosthesis loosening

Table VII. Univariate analysis.

Factor	B	S. E	Wals	Sig.	Exp (B)	95% CI
Age	1.492	0.484	9.512	0.002	4.444	1.722-11.466
Time of operation	-1.392	0.537	6.728	0.009	0.249	0.087-0.712
CTX-I after treatment	2.432	0.487	24.938	0.000	11.382	4.382-29.563
BALP after treatment	-1.081	0.501	4.658	0.031	0.339	0.127-0.905

CTX-I, carboxy-terminal opeptide of type I collagen; BALP, bone alkaline phosphatase.

Table VIII. ROC parameters of each index of risk factors.

Parameter	Age	Time of operation	CTX-I after treatment	BALP after treatment
AUC	0.638	0.603	0.748	0.555
95% CI	0.535-0.740	0.494-0.711	0.654-0.841	0.450-0.660
Standard deviation	0.053	0.055	0.048	0.053
P-value	0.011	0.059	<0.001	0.310
Specificity	62.50%	37.50%	72.50%	65.00%
Sensitivity	65.00%	83.00%	77.00%	46.00%
Youden index	27.50%	21.00%	49.50%	11.00%
Cut-off	≥65 years old	<45 min	≥0.20 μg/ml	<55.00 U/l

CTX-I, carboxy-terminal opeptide of type I collagen; BALP, bone alkaline phosphatase.

and affects the postoperative quality of life of patients to some extent (19). For this reason, some scholars said that patients after total hip replacement can combine drug intervention to improve this phenomenon.

Caltrate D tablets and calcitriol pills are commonly used clinically as basic anti-osteoporosis drugs (22). In this study, we added alendronate sodium tablets on the basis of patients' basic drugs. Alendronate sodium tablets are the third generation of anti-osteoporosis diphosphate drugs widely used clinically, are potent osteoclast inhibitors, have high affinity with bone surface, and have little effect on bone mineralization (23). Previous studies have shown that alendronate tablets can improve bone morphology and clinical vertebral body fractures, and can also reduce the recurrence rate of fractures (24). Through combined treatment, we found that the clinical efficacy of patients in the observation group was significantly improved compared with that in the control group, and the excellent and good rate of patients in the observation group was significantly higher than that in the control group, which suggested that the addition of alendronate sodium tablets on the basis of conventional treatment could further improve the clinical efficacy of patients. At present, the clinical evaluation indexes of the efficacy after hip replacement are mainly judged according to Harris and Charnley scores (25). Although the accuracy of these scores has been verified clinically, subjective bias still exists to some extent, while the serological index results are relatively objective. In this study, we also detected CTX-I and BALP in serum of patients. CTX-I and BALP are markers of reactive bone metabolism, in which BALP changes through the secretion of bone cells, which can reflect the maturation and activity of osteoblasts, and the expression will obviously increase when bone diseases occur, while the differential expression of CTX-I can reflect bone loss (26). We found that the CTX-I and BALP expressions of patients in the control group and the observation group had obvious changes after treatment. The CTX-I expression of patients in the observation group was significantly lower than that of patients in the control group, while the BALP expression was opposite to that of patients in the observation group. This shows that the combined alendronate sodium tablets can promote the maturation of osteoblasts of patients and inhibit the generation of osteoclasts, thus achieving the effect of accelerating the postoperative recovery of patients. In the study of Zhang *et al* (27), it was found that the high level of CTX-I was one of the risk factors for hip fracture in patients. However, this study significantly reduced the expression of CTX-I in patients after treatment, possibly by inhibiting the formation of osteoclasts. Furthermore, we further analyzed the correlation between CTX-I and BALP and the clinical efficacy of patients, and found that the expression of CTX-I was negatively correlated with the clinical efficacy after treatment, while the expression of BALP was positively correlated with the clinical efficacy, which suggested that we could become an evaluation index of the efficacy of patients by observing expressions of CTX-I and BALP after treatment.

At the end of the study, we analyzed the factors that affect the efficacy of patients. We found that age, time of operation, CTX-I after treatment and BALP after treatment were independent risk factors that affect the efficacy of patients.

Furthermore, we found that age and CTX-I after treatment had certain predictive value for the clinical efficacy of patients through ROC curve analysis. Due to the improvement of quality of life and the gradual increase of the elderly population, the study found that China has entered an aging society initially, and the elderly have reduced their tolerance to surgery due to the reduction of their metabolism, thus affecting the clinical efficacy of patients (28). CTX-I, as a marker of osteoclast formation, its increased expression indicates the increase of osteoclasts. The increase of osteoclasts is easy to cause bone loss and osteolysis in patients, which is not conducive to the improvement of patients' condition (29). Therefore, patients should choose treatment according to their own conditions before surgery, pay close attention to the expression of CTX-I in patients after surgery, and take drugs in time, so as to accelerate the recovery of patients after surgery.

However, there are still some limitations in this study. Firstly, in this study, we only carried out the death of patients after 3 months of clinical efficacy, and did not carry out long-term follow-up and detection. Secondly, in this study, we only detected the expressions of CTX-I and BALP, and did not detect other bone metabolism indicators. Whether there are better prognostic observation indicators is unclear. Therefore, we will increase our follow-up time and detection index in future researches to supplement our research results.

In conclusion, hip replacement combined with alendronate sodium can effectively improve the clinical efficacy of patients, and age, time of operation, CTX-I after treatment and BALP after treatment are found to be independent risk factors affecting the postoperative efficacy of patients.

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Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Authors' contributions

XO and YZD wrote the manuscript and were also involved in the conception of the study. LY and FX interpreted and analyzed the patient data. XY, PS and SMT designed the study and performed the experiment. QC and YQX were responsible for the analysis and discussion of the data. XO wrote the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the Affiliated Xuzhou Hospital of Jiangsu University (Jiangsu, China). Patients who participated in this research had complete clinical data. Signed written informed consents were obtained from the patients and/or guardians.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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