The Efficacy and Safety of Two Low-Dose Peri-Operative Dexamethasone in Total Hip Arthroplasty: A Single-Center Randomized Controlled Trial

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Research article

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Abstract

Objective To evaluate the efficacy and safety of two low-dose dexamethasone in the perioperative period of total hip arthroplasty (THA) with a single-center randomized controlled trial.

Method 98 patients who underwent THA received two low-dose (10 mg) IV-dexamethasone (group dexa) or IV- isotonic saline group (The placebo).The post-operative day 24 h,48 h,72 h c reactive protein (CRP) and interleukin-6(IL-6), the pain VAS scores at rest and mobilization, the incidence of postoperative nausea and vomiting (PONV), nausea VAS score, postoperative fatigue rating and analgesia and antiemetic, the postoperative lengh of stay (PLOS), wound problems and complications were recorded and compared.

Results The inflammatory markers (CRP, IL - 6) level postoperative 24,48,72 hours in dexa group of was lower than the placebo group (P<0.05).The 24 hours of rest and dynamic pain VAS score in dexa group was lower than those in blank group (P<0.05).The incidence of PONV, nausea VAS score, fatigue ICFS score in dexa group was lower than the blank group (P<0.05) and the dosage of analgesic and antiemetic were decreased significantly (P<0.05).In addition, the PLOS of dexa group was shorter than the blank group (P< 0.05).There was no significant difference in perioperative complications between the two groups (P> 0.05).

Conclusion The application of two low-dose dexamethasone in the perioperative period of THA can effectively reduce the postoperative CRP and IL-6 levels, reduce pain, nausea, postoperative fatigue and the use of opioid analgesics, shorten the PLOS, without increasing the risk of incision infection or gastrointestinal hemorrhage.

Introduction

Total hip arthroplasty (THA) is one of the most effective treatment for the end-stage hip diseases, which can greatly improve the mobility and quality of life of patients[1].However, surgical trauma often causes severe postoperative inflammation during THA, which may lead to increased postoperative pain and fatigue, increased incidence of postoperative nausea and vomiting (PONV), prolonged hospital stays, and slowed down early recovery speed.As a consequence, that may indirectly reduce patient satisfaction[2].Therefore, it is of great significance to actively control perioperative inflammation of THA, reduce pain, fatigue, nausea and vomiting.Glucocorticoids, a class of steroid hormones with considerable anti-inflammatory effects, have been widely used in many surgical fields including THA[3, 4].But the use of dexamethasone during the perioperative period of THA has slowed the pace due to concerns about adverse reactions.In recent years, some studies have reported that glucocorticoids can reduce PONV and fatigue, and are also recommended as part of THA multi-mode analgesia programs[5-7]. However, due to clinical heterogeneity, the optimal time, mode and dose of glucocorticoids in THA has not been determined, which may lead to significant differences in clinical outcomes.Although side effects are relatively low, most regiments are still given in a single low-dose intravenous administration[8, 9].

According to the results of the studies, the perioperative anti-inflammatory effect of patients cannot be satisfied[8, 10].Therefore, this prospective randomized controlled trial aims to explore the efficacy and safety of two low-dose (10mg-IV) dexamethasone (Dexa) during perioperative THA.

Materials And Methods

This trial is approved by the institutional review Board, approved by the institutional Ethics Committee, and registered at the International Clinical Trials Registry (ChiCTR2000039487).From April 2020 to September 2020, all subjects signed written informed consent prior to surgery.

Inclusion criteria :(1) patients received unilateral THA; (2) Understand and sign the informed consent.

Exclusion criteria :(1) allergy to Dexa;(2) Age ≤18 years or ≥75 years;(3) any glucocorticoids within 3 months before surgery or any strong opioids within 1 week;(4) history of severe heart disease (NYHA≥3), liver and kidney failure, systemic rheumatic diseases (rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus);(5) ipilateral hip surgery history;(6) without normal cognitive function and sensation;(7) lost to follow-up.

According to the principle of admission sequence, a random allocation sequence concealed in opaque sealed envelopes only opened before surgery.Eligible patients (n=98) were divided into dexa group or blank group.The dexa group (n=50) was given IV-dexamethasone 10mg (2ml) and the placebo group (n=48) was given IV-isotonic saline (2ml).The first dose was given just after the anesthetic was done, and the second was given three hours later.

Surgical steps

All THAs are operated in the same laminar flow hundred-stage operating room by an experienced joint surgeon.Anterolateral approach and bio-type prosthesis were adopted. Some anesthesiologists chose general anesthesia, and the blood pressure was controlled within 90-110mmhg / 60-70mmhg during the whole process.

Postoperative nursing plan

Upon return to the ward, patients were underwent functional training, including active muscle strength training, under the supervision and assistance of a specialist nurse.One day before surgery, oral analgesics (Celecoxib, 10mg, bid) were used for preventive analgesia. When the pain VAS scores were reported greater than 4, oxycodone (10mg) was given orally. Intramuscular injection of Tramadol was given if the patient claims severe pain greater than 6. Intramuscular metoclopramide (10 mg) was selected as the first-line rescue option if the patient had two or more PONV or had severe nausea (VAS>4), and Ondarsetron was added if the vomiting could not be resolved after 30 minutes.

All patients began subcutaneous injection of LMWH (4000 IU 0.4ml) 6 h postoperatively as the drug prophylaxis for DVT, and the patient was instructed to exercise with ankle pump and given air pressure to

prevent thrombosis.In addition, patients were instructed to take Xarelto (Bayer, Germany)10mg orally every day until 35 days after surgery as a preventive measure after discharge.

We recorded all the patients C-reactive protein (CRP) and interleukin–6(IL-6) after 24 h, 48 h and 72 h,the pain VAS scores at rest and activity, the incidence of PONV, nausea VAS score, postoperative fatigue ICFS ratings, analgesia and antiemetic drug use, PLOS. Besides, perioperative complications such as wound problems and gastrointestinal hemorrhage. Within 3 hours of returning to the ward, the level of nausea was assessed using the VAS(0 for non-nausea and 10 for severe imaginable nausea).Fatigue was assessed by fatigue scale (ICFS) before and 24h after surgery. Within one month after discharge, the patients were followed up for complications such as incision infection, poor wound healing (wound drainage, redness and swelling around the wound, fat liquefaction) and gastrointestinal hemorrhage.

Statistical methods

Sample size calculations were performed using PASS 2011(NCSS, LLC. Kaysville, Utah, USA) software on the basis of a two-sample t-test. With a power of 0.90 and the significant level of 0.05, 40 patients per arm were needed.

If a 10% exclusion rate was expected, the minimum sample size was 45 in each group. All data analysis was performed by SPSS version 24 (SPSSInc. USA). Student's t test or Wilcoxon Mann-Whiney U test was used to analyze quantitative data and Pearson Chi-square test or Fisher exact test was used to analyze qualitative comparative data. Statistical significance was defined as $P<0.05$.

Results

Baseline data

Data of 112 patients recruited from July 2020 to October 2020 were scheduled to receive unilateral, primary THA in our hospital. Of these patients, seven patients did not qualify and five denied participation. Thus, the trial was completed in 98 patients. Among them,fifty patients were randomly assigned to the dexa group and the rest were randomly assigned to the placebo group (figure 1). Baseline characteristics of the two groups were comparable (Table1).

Table 1 Demographic data of the patients receiving THA

	Group placebo	DEXA	P Value
N	48	50	-
Age（y）	64.19±5.84	64.36±5.64	0.88
Gender（M/F）	21/27	21/29	0.86
Height（m）	1.60±0.08	1.63±0.09	0.13
Weight（kg）	63.82±8.92	65.50±7.01	0.30
BMI（kg/m^2）	24.82±3.20	24.73±3.05	0.89
Hypertension（Y/N）	10/38	11/39	0.89
Diabetes（Y/N）	2/46	3/47	0.68
Etiology （ONFH/OA/DDH）	25/14/9	24/16/10	0.74
Preoperative CRP	7.86±2.72	7.57±2.78	0.55
Preoperative IL-6	2.36±1.39	2.66±1.62	0.32
Preoperative rest VAS	5.46±0.87	5.38±1.10	0.70
Preoperative walking VAS	7.96±0.87	8.08±0.88	0.49
Preoperative ICFS score	61.88±5.96	63.26±4.65	0.20

BMI: body mass index; ONFH: Osteonecrosis of the Femoral Head;OA: osteoarthritis;DDH: development displasia hip.CRP: C-reactive protein;IL-6: interleukin-6;VAS: visual analogue scale; ICFS:Identity-Consequence-Fatigue-Scale.

Correlation of inflammatory markers

CRP and IL-6, as acute inflammatory factors, were rapidly increased in all patients after surgery. CRP reached its peak at 48 hours after surgery in both groups, and the mean serum level of the placebo group at 24, 48, and 72 hours after surgery was significantly higher than that of the dexa group (P_1<0.001, P_2<0.001,P_3<0.001).The mean serum IL-6 concentration in the blank group reached its peak at 24 h after surgery, while that in the Dexa group reached its peak at 48h.At 24, 48, and 72 hours postoperatively, IL-6 levels in the dexa group were lower than those in the placebo group and the difference was statistically significant (P_1 < 0.001, P_2 < 0.001, P_3 < 0.001)(Figure 2 and 3) .

POD: Postoperative day; CRP: C-reactive protein; IL-6: interleukin-6;*:P<0.05

Pain related conditions

Compared to the preoperative, the postoperative pain during rest and activity was significantly reduced. The pain VAS score of dexa group at 24 hours of rest and walking was lower than that of the placebo group, and the difference was statistically significant (P_1=0.002), but there was no significant difference between the rest and dynamic VAS at 48 and 72 hours after surgery (P>0.05) (Figure 3 and 4).

POD: Postoperative day;*:P<0.05

Analgesic drugs

Compared to the placebo group, the number of patients received Tramadol in Dexa group were significantly reduced (P=0.03), and consumption of Tramadol as a whole was also less, with statistically significant difference (P=0.005).The number and total dosage of the dexa group requiring paracetamol oxycodone were small, but there was no significant difference between the two groups (P_1=0.11,P_2=0.24) （Table 2）.

Table 2 The requirement of rescue treatment between the two groups

	Group placebo	Group dexa	*P* Value
Oxycodone			
N	36/48	32/50	0.11
Total dose（mg）	710	540	0.24
Tramadol			
N	19/48	10/50	0.03
Total dose（mg）	3500	1200	0.005
Metoclopramide			
N	12/48	4/50	0.02
Total dose（mg）	180	40	0.007
Ondansetron			
N	3/48	2/50	0.62
Total dose（mg）	15	10	0.62

PONV related information

The incidence of PONV in the dexa group was 4.00% (2/50) and 25% (12/48) in the control group and the difference between the two groups was statistically significant (P=0.003). The VAS nausea was (1.94±1.82) in the dexa group and (1.14±1.18) in the placebo group, which was statistically significant

differences between the two groups (P=0.01) (Table5).In terms of postoperative antiemetic drugs, the dexa group required less metoclopramide in number and total dose than the placebo group (P_1= 0.02, P_2=0.007), which was statistically significant difference.While there was no statistically significant difference in total number and dose of ondansetron between the two groups (P1=0.62, P2=0.62)(Table 5).

Fatigue and PLOS related conditions

Postoperative ICFS score of dexa group was (69.38±8.65), which was significantly lower than that of the placebo group [(78.94±10.34)], and the difference was statistically significant (P=0.00).The PLOS of dexa group was (5.00±0.50) d, which was significantly lower than the placebo group [(5.58±0.82) d], and the difference was statistically significant (P=0.00) (Table5).

Complications related information

The incidence of poor wound healing was 6.0% (3/50) in the dexa group and 8.33% (4/48) in the placebo group, and there was no statistically significant difference (P=0.66).No serious complications such as incision infection and gastrointestinal hemorrhage were found in all patients of the two groups (Table5).

Table 3 The clinical effect and complications

	Group placebo	Group dexa	*P* Value
PONV	12/48	2/50	0.003
VAS-nausea	1.94±1.82	1.14±1.18	0.01
Post-ICFS	78.94±10.34	69.38±8.65	0.00
PLOS（d）	5.58±0.82	5.00±0.50	0.00
Wound problems	4/48	3/50	0.66
Incision infection	0/48	0/50	-
Gastrointestinal hemorrhage	0/48	0/50	-

PONV: Postoperative nausea and vomiting; VAS: visual analogue scale;ICFS: Identity-Consequence-Fatigue-Scale;PLOS: postoperative length of stay.

Discussion

Dexamethasone is the highly efficient, high bioavailability of long-term glucocorticoid and the organization half-life is about 3 hours [3, 11], which is the study of the causes of interval again for three hours.The dose method and the time can be varied according to the actual conditions, including veins and local, large doses and small doses, preoperative, intraoperative, or after surgery[12, 13].However, there is still no consensus on the optimal dose, method or safety of THA administration in perioperative period.

At present, some studies have shown that local and systemic inflammatory responses after surgery are closely related to early recovery and postoperative pain[14, 15]. 110 patients were randomly divided into dexa group and the placebo group by Pei, etc.[16].The dexa group was given two doses IV-dexamethasone(10 mg,once), and the walking VAS pain score at postoperative 24 hours was lower than the placebo group and the difference was statistically significant (P<0.05),which was consistent with our findings. However, there was no difference between the two groups at 24 hours of rest VAS score, which was not consistent with our study at this point. Zheng et al.[17] conducted a meta-analysis on a total of 127 patients in three studies. The visual analogue scale (VAS) scores at 24 hours (P<0.001) and 48 hours (P=0.04) in the dexamethasone group were lower than those in the placebo group, and the dosage of opioids was significantly lower than that in the placebo group (P<0.001), which could effectively reduce postoperative pain and opioid use at 48 hours after surgery. In our study, through two low-dose IV-dexamethasone (10mg,once), we can effectively reduce the dynamic and rest pain 24 hours after THA and reduce the dosage of tramadol, which is basically consistent with the results of the former study. However, there were no statistically significant differences between the dexa group and the placebo group at rest for 48h and 72h (P_1=0.07, P_2=0.08) or dynamic VAS pain score (P_1=0.08,P_2=0.15).This result suggests that whether the dosage of dexamethasone can be increased to further reduce the postoperative pain after THA. Of course, we should always pay much attention to the risk of side effects caused by dexamethasone [18].In addition, Sculco etc. studied that [19] 27 patients were randomly divided into trial group (13 cases) and control group (14 cases).The experimental group was received 20 mg oral prednisone and two-dose intravenous hydrocortisone, every 8 hours. The experimental group was significantly lower than the control group at serum levels of IL- 6 after 6 hours and 24 hours, which was agreement with the results of our study.

Postoperative fatigue of THA is a common clinical symptom, which often leads to early recovery delay and affects patients' initiative in rehabilitation [20].Through Meta analysis of the relationship among pain, sleep and fatigue, Whibley, et al.[21] pointed out that the three factors influenced each other and interacted with each other. It can be a virtuous circle established to promote early recovery of patients and improve hospitalization satisfaction if each factor is positively controlled. In this study, ICFS was used to assess fatigue. The results showed that the postoperative ICFS score of dexa group was (69.38±8.65), and was significantly lower than that of the placebo group [(78.94±10.34)], and the difference was statistically significant between the two groups (P=0.00), which was consistent with the findings of McGonagle [20]and Whibley[21].In addition, Lei et al.[5] also supported our results.

Dexamethasone is as an antiemetic agent by inhibiting prostaglandin synthesis or the release of endogenous opioids [3].Some studies have reported that intravenous administration of low-dose glucocorticoids can effectively play an antiemetic role [8, 19].Wakamiya et al. [22] enrolled 100 adolescent patients with scoliosis to be operated and were randomly divided into dexamethasone group and the control group. The dexamethasone group received intravenous application of 0.15mg/kg, and the results showed that the incidence of PONV at 72 hours in dexamethasone group was significantly lower than that in the control group[(62.5% VS 84.0%),CI0.58, RR0.74, 95% to 0.96, P=0.02)].The dexamethasone

group received fewer emergency antiemetics during the first and second 24 hour postoperatively, and there was no increase in adverse reactions, which was confirmed the safety and efficacy of low-dose dexamethasone in adolescents. Seki et al.[23] also reached the same conclusion. In our study, two low-dose(10mg,once) IV-dexamethasone was received in dexa group respectively.It can obviously reduce the incidence of PONV (P=0.003), and the nausea VAS score in dexa group was (1.14± 1.18), which was significantly decreased in the placebo group [(1.94±1.82)], and there was statistically significant differences (P=0.01) between the two group. In addition, it could also statistically reduce the number and total dose of the use of metoclopramide (P_1 = 0.02, P_2 = 0.007).

The economy is always one of the greatest concerns for patients, especially since the "2019-new Coronavirus" outbreak this year. That has made hospitalization more straitened and prolonged hospitalization has brought more expensive medical expenses. Kelly, etc. [24] retrospectively analyzed 376 patients underwent THA. Through one-way analysis of variance,164 patients were received dexamethasone therapy and the other were not as a comparison. The results showed that LOS of dexamethasone therapy of patients were significantly shortened (29.40 hours vs 35.26 hours) without dexamethasone, and there was statistically significant difference (P< 0.001).In our study, the PLOS of dexa group patients were (5.00±0.50) d, and it was significantly reduced compared to the placebo group [(5.58±0.82) d] (P=0.00).It also means that the same conditions indirectly reduced the hospitalization costs of patients. In our study, further analysis found that postoperative pain, nausea and fatigue may further increase patients' fear of discharge. Thus, it may prolong the hospital stay, which is consistent with the results of PEI et al.[16] and McGonagle et al. [20], and it also indirectly confirms the systematic review of Whibley et al.[21].

The perioperative application of glucocorticoids in THA has many benefits, but its complications are also issues that we must pay much attention. Among various complications, infection and gastrointestinal hemorrhage are more likely to attract the attention of orthopedic surgeons, which may increase morbidity and mortality. At present, the safety of dexamethasone in the perioperative period of THA has not been fully clarified, which also delays the application of dexamethasone in the perioperative period of joint replacement [8].Arumugam etc.[25] studied 3194 patients who underwent hip knee replacement.The experimental group was received 8 mg dexamethasone intravenous injection,and control group was 4 mg. The result showed that not only could statistically reduce the incidence of PONV（P＜0.05）, but serious complications, such as hyperglycemia, periprosthetic joint infection（PJI）and gastrointestinal hemorrhage had no significant difference compared to the other, and there was no statistical difference（P＞0.05）.They confirmed the application of dexamethasone in the perioperative period of THA was safe and effective, at the same time, suggested that there should be further promoted its application in joint replacement. In our study, the incidence of poor wound healing was 6.0% (3/50) in the dexa group and 8.33% (4/48) in the placebo group, and there was no statistically significant difference (P=0.66).No serious complications such as incision infection or gastrointestinal hemorrhage were found in all patients, which also confirmed the safety of two low-dose dexamethasone applications in the perioperative period of THA, and that was consistent with the results of previous studies [4, 10, 16].However, it should be pointed out that some

scholars are concerned about the safety of dexamethasone in the perioperative period of THA, especially for patients with diabetes[26-28], which should attract our extensive attention.

There are some limitations to be noted in our study: 1)This study solely focused on a short follow-up period, and it could be short on statistical power to sufficiently assess the linical effect and safety; 2) No comparison about the dosage was shown in our study, further studies may need to determine the minimum effective dose; 3) The second dose was administered within the first post-operative three hours, and if it is necessary and safe to give an additive dose of dexamethasone within 24 or even 48 hours following THA is still unknown.

In this study, we believe that dexamethasone can effectively relieve the pain and nausea during the perioperative period of THA, reduce postoperative fatigue, and effectively shorten the hospital stay after THA without increasing the serious complications such as infection and gastrointestinal hemorrhage. However, it should be pointed out that the optimal dose and safety of dexamethasone in the perioperative period of THA need to be further confirmed through more center and large sample studies.

Declarations

Clinical trial registration

Clinical trial was registered in the International Clinical Trial Registry (ChiCTR-IOR-16008865).

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Statement

We confirmed that all experimental protocols were approved by Guangxi zhuang autonomous region people's hospital and all methods were carried out in accordance with relevant guidelines and regulations in the manuscript.

Authors' contributions

Fulin-Li performed the data collection and analysis and participated in

manuscript writing.Yu Huang,Xiao Huang,Wenwen-Huang performed the database setup and statistical analysis.Dong Yin performed the operations and participated in the study design and coordination and helped to draft the manuscript. All of the authors have read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable as no identifying personal information is being published in

this manuscript.

Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee (Guangxi zhuang autonomous region people's hospital) and an exemption from informed

consent was obtained from our responsible Investigational Ethics Review

Board.

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Figures

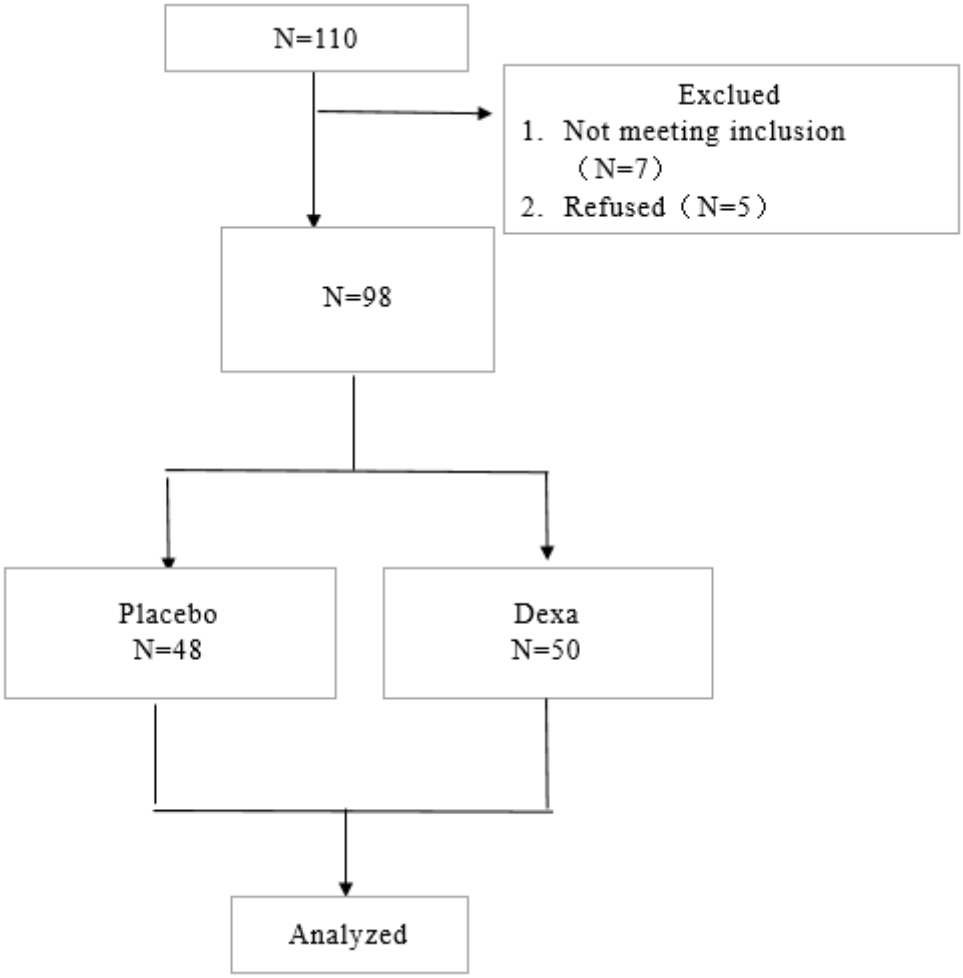

Figure 1

Schematic diagram of the patient study process

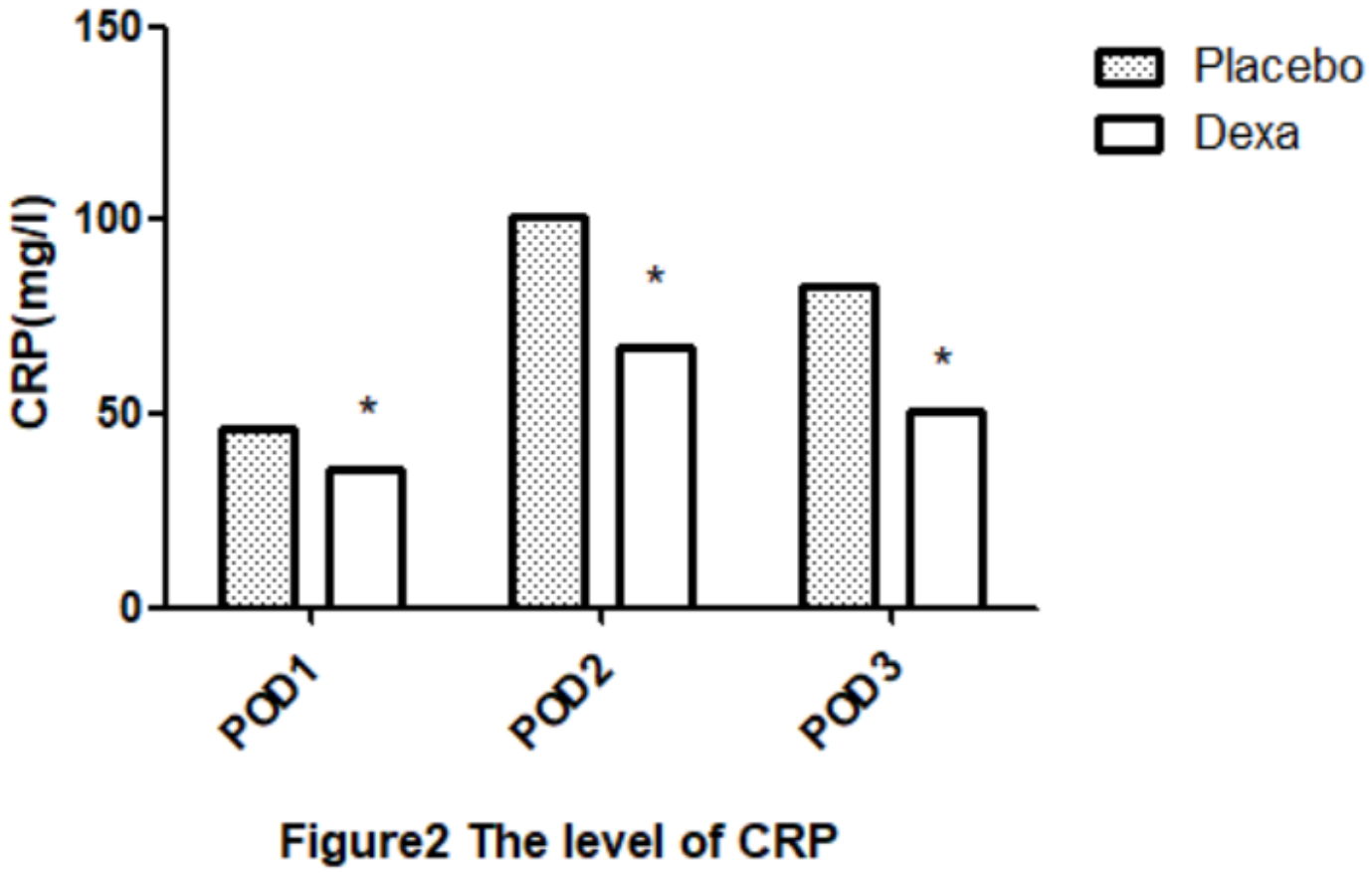

Figure 2

shows the comparison of CRP between the two groups on POD1,2 and 3.The Student's t test was performed to detect the difference between the groups.* means $P<0.05$.

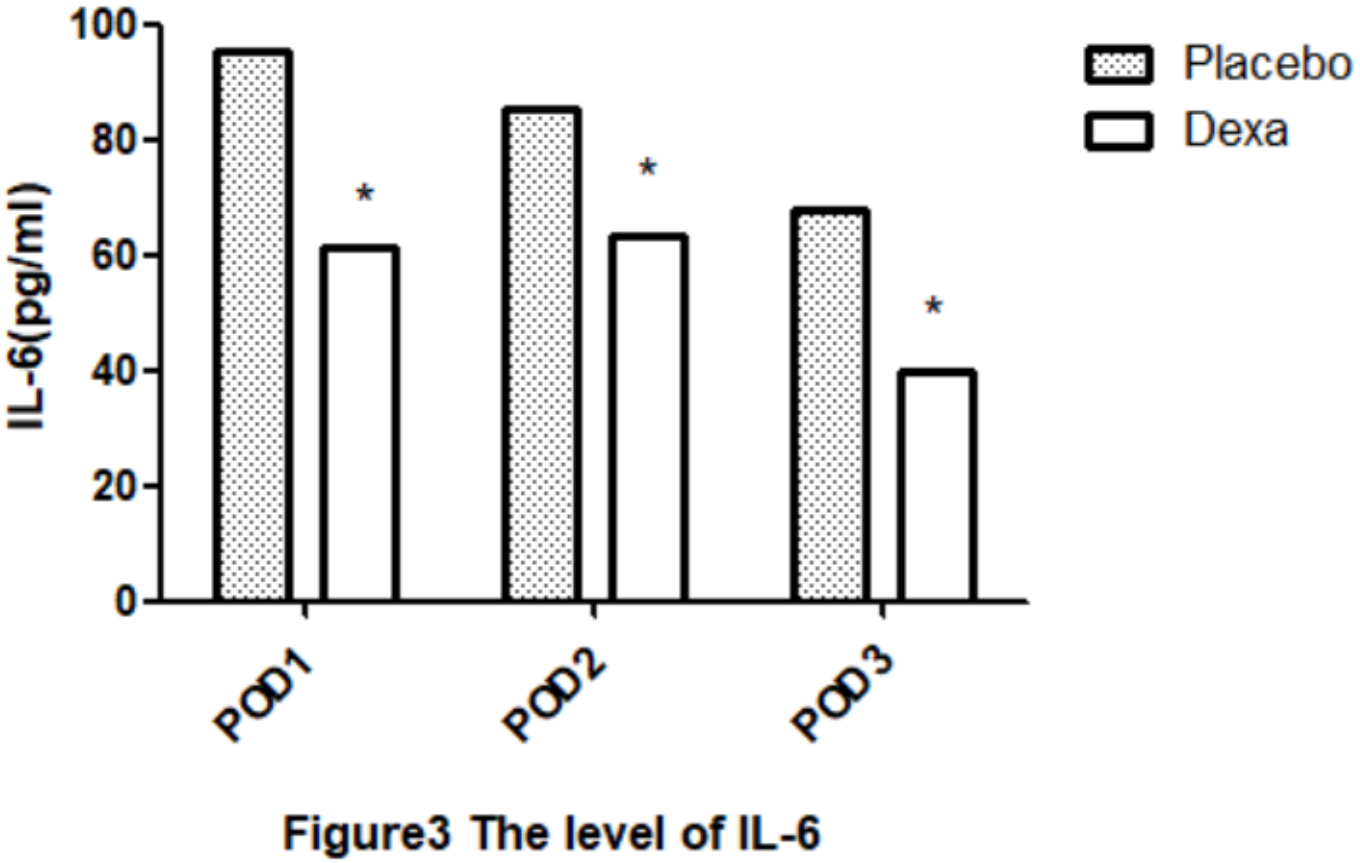

Figure3 The level of IL-6

Figure 3

shows the comparison of IL-6 between the two groups on POD1,2 and 3.The Student's t test was performed to detect the difference between the groups.* means $P<0.05$.

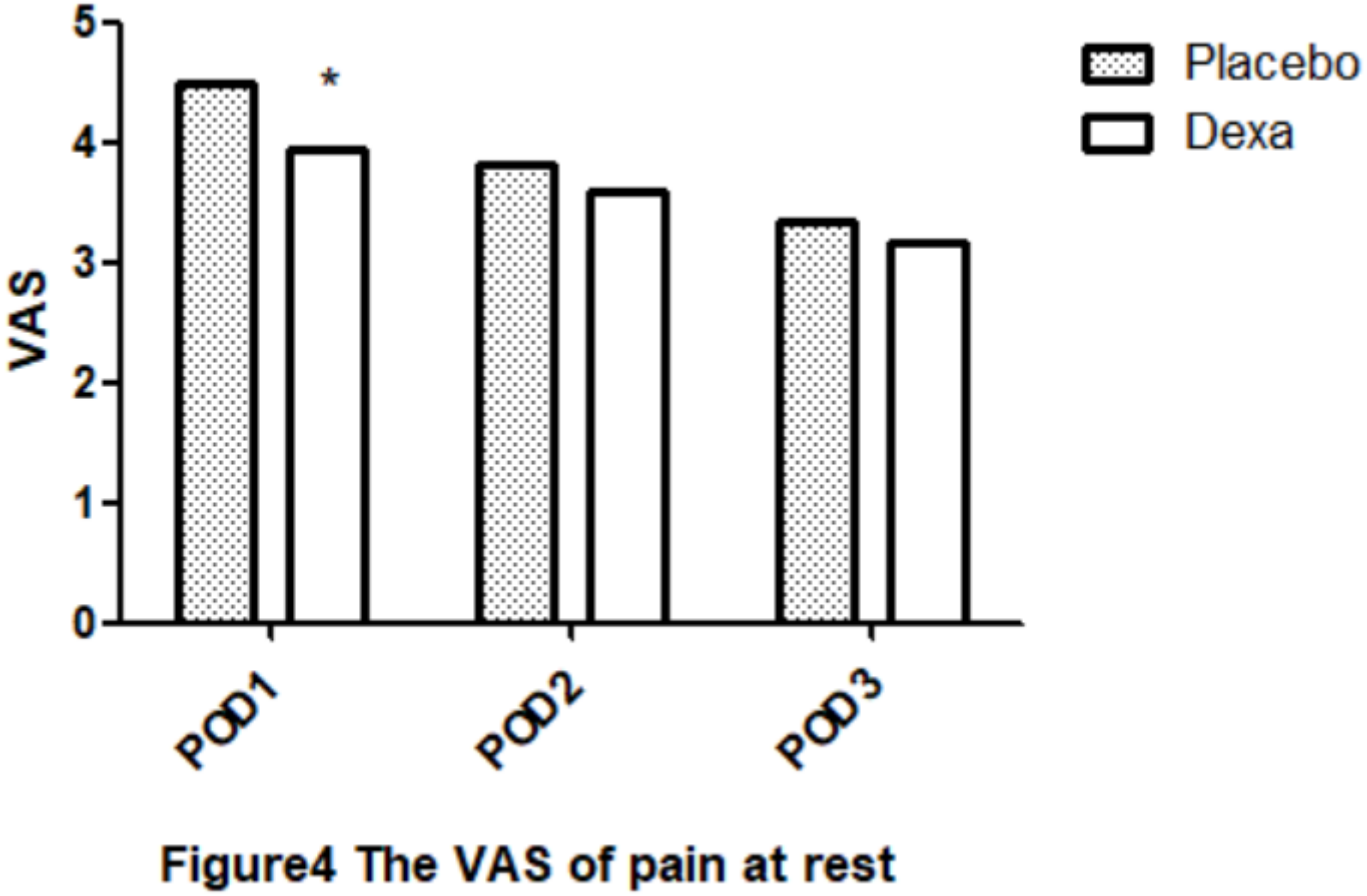

Figure4 The VAS of pain at rest

Figure 4

shows the comparison of VAS of pain at rest between the two groups on POD1,2 and 3.The Student's t test was performed to detect the difference between the groups.* means P<0.05.

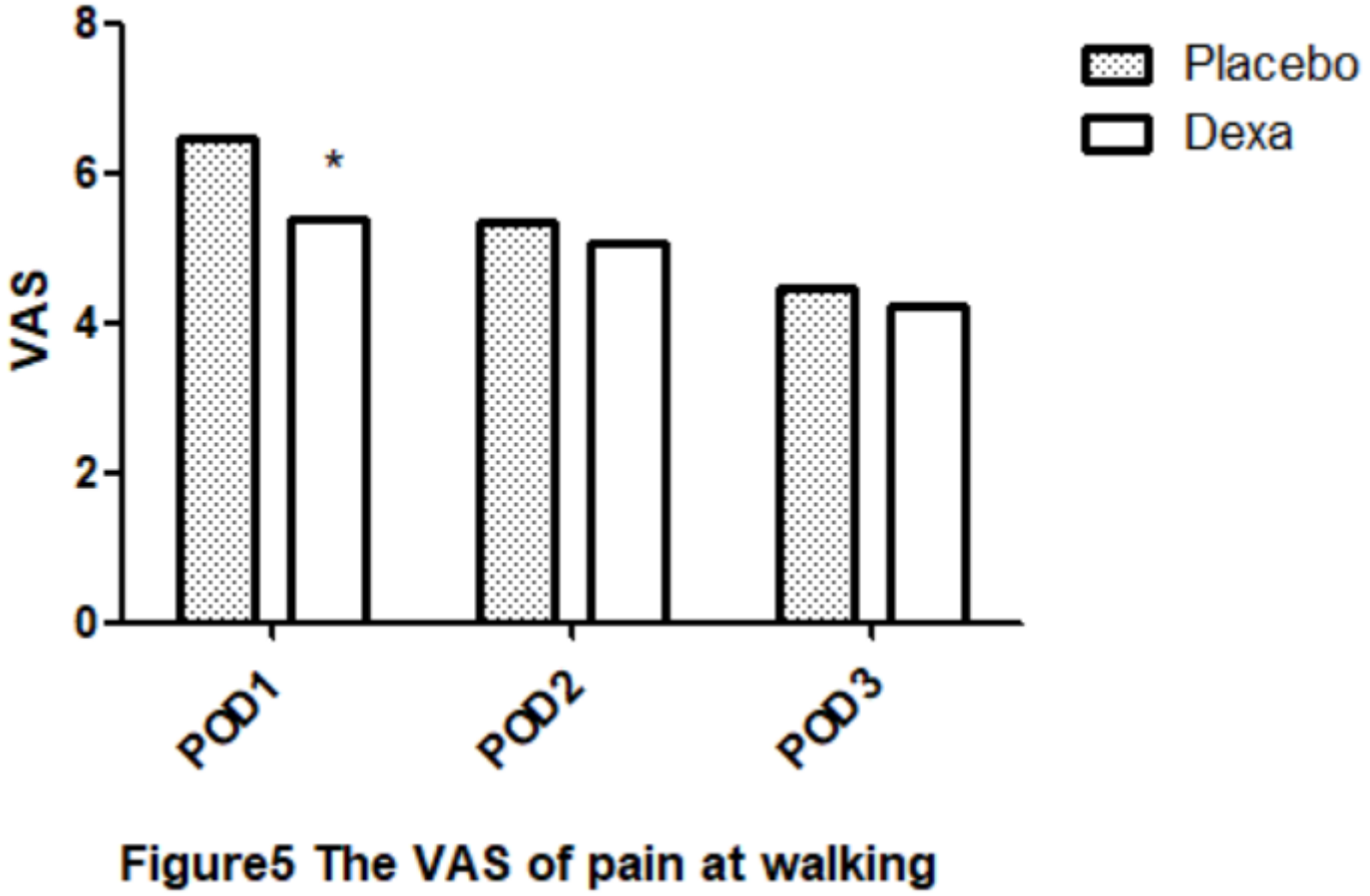

Figure5 The VAS of pain at walking

Figure 5

shows the comparison of VAS of pain at walking between the two groups on POD1,2 and 3.The Student's t test was performed to detect the difference between the groups.* means $P<0.05$.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORT2010Checklist.doc