

Outcomes of a retrospective study on sustained release betamethasone for transient radicular symptoms in patients after Transforaminal Lumbar Interbody Fusion operation

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Abstract

Background: Transforaminal lumbar interbody fusion (TLIF) operation is a commonly treatment for Lumbar disc herniation (LDH). but some patients had transient radicular symptoms after surgery. At present, some studies believes that the application of steroids is effective in radiculopathy caused by LDH. **Method:** The patients who with single-level LDH underwent TLIF operation were retrospectively analyzed from March 2017 to July 2019. Patients were divided into observation group—a gelatin sponge with a mixture of 1 ml betamethasone injection + 2 ml 2% lidocaine placed around the spinal nerve roots after decompression—and control group 1—1 ml betamethasone injection + 2ml 2% lidocaine placed around the spinal nerve roots after decompression—group 2—a gelatin sponge with 3 ml normal saline placed around the spinal nerve roots after decompression—group 3—no anything was placed—. Clinical data such as lasegue sign, postoperative hospital stays, VAS score of leg pain, ODI index, Effective standard and therapeutic effect were collected. **Results:** A total of 186 patients were finally included, the observation group 46 cases, control group 1: 53 cases, group 2: 45 cases, and group 3: 42 cases. VAS score of postoperative legs pain in the observation group at the postoperative 1-5 day were significantly lower than those in the control groups ($P < 0.05$). The recovery of Lasegue sign in the observation group were significantly better than the control groups ($P < 0.05$). The average of postoperative hospital stay in the observation was significantly shorter than the control groups. In addition, the unmeration of leukocyte in the four groups postoperative were significantly higher than before operation ($P < 0.05$). the rate of complications in observation group and control groups has no significant difference. The patients in the four groups had basically the same satisfaction with the final efficacy ($> 90\%$). **Conclusion—**the use of gelatin sponge sustained-release steroids and other mixed solutions can significantly relieve transient radicular symptoms after TLIF operation, and does not influence the occurrence of postoperative complications.

Background

LDH patients have increased by years due to the aging of the population and the wrong lifestyle. TLIF is still a commonly treatment for LDH. But some patients had transient radicular symptoms after surgery, which generally lasted for 2–4 days, and some even more than 10 days. Seriously affected the patient's medical experience and hospital bed turnover efficiency. For such patients, intravenous glucocorticoids and dehydration drugs can significantly relieve symptoms, but there are also clear side effects, including induced aggravation of infection and peptic ulcer, mood disorders, rebound phenomenon and so on [1]. The use of dehydrated drugs can increase the strain on the kidneys. At present, there are studies [2–5] believes that the application of steroids for local epidural blockade of lumbar vertebrae is effective in radiculopathy caused by LDH, It can increase the concentration of local drugs meanwhile reducing the dose of drugs, so as to avoid systemic side effects of drugs. Moreover, the adsorption effect of gelatin sponge, extended the drug release cycles, theoretically can override a postoperative symptoms of radicular, reduce the related side effect. therefore, we hope to use the gelatin sponge adsorb steroid drugs in local place around nerve root in the TLIF operation to alleviate transient radicular symptoms of

postoperative early. However, there are no relevant clinical studies to support this view. we conducted a retrospective randomized, single-blind case-control study to further understand the clinical efficacy and complications of the method. Provide theoretical basis and provide clinical data support for further basic research and development of controlled-release formulation.

Methods

Participation information

This study was approved by the ethics committee of the hospital, and patients gave informed consent and signed it. A total of 186 patients with LDH who underwent TLIF operation in Ningbo No.6 Hospital from March 2017 to July 2019 were included.. CT + 3D reconstruction and MRI examination were performed before operation.

Inclusion criteria: age < 75 years; (2) clinical physical examination and imaging examination confirmed lumbar disc herniation, (3) nerve root symptoms clear, straight leg elevation positive; (4) after conservative treatment no obvious improvement in 3 months, the existence of surgical indications; (5) comply with the principle of informed consent; (6) can accurately express, communication barrier-free.

Exclusion criteria: (1) previous lumbar surgery history; (2) patients with diabetes, active peptic ulcer, malignant tumors, serious liver and kidney dysfunction and diseases of the blood system; (3) acute inflammation, vertebral infection, severe osteoporosis, lumbar congenital deformity and other surgical contraindications.

Preoperative lumbar spine positive lateral position, dynamic position X-ray film, 3D-CT, MRI examination, clear diagnosis, exclusion of root symptoms caused by other factors, followed up for 3 months. There were no significant differences in demographic characteristics and other conditions between the groups ($P > 0.05$), which were comparable (Table 1).

Table 1
Detail baseline characteristics of all patients

Parameter	Observation group	Control group 1	Control group 2	Control group 3	P value
No.of patients	46	53	45	42	
Age(year)	55.6 ± 7.2	53.4 ± 6.9	55.4 ± 6.8	54.5 ± 8.4	.334
Male/Females	32/14	33/20	29/16	23/19	.547
Symptom duration(months)	7.3 ± 4.0	7.9 ± 4.4	6.8 ± 3.1	7.0 ± 3.6	.524
Herniation level					
L3/L4	6	5	3	3	.413
L4/L5	26	30	22	17	
L5/S1	14	18	20	22	
Surgical time (min)	118 ± 13.0	116 ± 10.7	113 ± 11.1	121 ± 11.1	.501
Blood loss (ml)	206 ± 34.5	200 ± 37.0	193 ± 34.9	202 ± 47.1	.326
Half/Complete laminectomy,n	35/11	44/9	39/6	31/11	.397
NOL(*10 ⁹ /L)	7.3 ± 1.2	7.1 ± 0.9	7.4 ± 1.2	6.9 ± 1.5	.220
PBG(mmol/L)	5.9 ± .6	6.1 ± .7	6.2 ± .7	6.1 ± .7	.435
Stay post operation (day)	5.7 ± 1.4	6.6 ± 1.4	6.6 ± 1.9	6.7 ± 1.7	.002
blood glucose(mmol/L)	5.9 ± .69	6.1 ± .74	6.3 ± .71	6.1 ± .77	.131
Lasegue sign(°)	44.3 ± 11.0	43.0 ± 10.6	40.5 ± 9.6	42.6 ± 9.9	.298
Numeration of leukocyte(*10 ⁹ /L)	6.6 ± .92	6.3 ± 1.13	6.4 ± .85	6.2 ± 1.02	.317
NOL:Numeration of leukocyte PBG:Postprandial blood glucose					

Surgical Procedure

The patient was placed in a prone position with shoulders and bilateral flaps raised. After general anesthesia, routine skin preparation and draping, centered on the body surface projection of the responsible section, cut the skin, subcutaneous soft tissue, muscle, deep fascia by layers, carefully stop bleeding during surgery, place THE PEDICLE screw after expose the vertebral plate and facet joints and fluoroscopy to ensure the position of the screw is correct, the laminectomy is performed, released the adherent nerve root, and the intervertebral cage with the autologous bone is inserted into the intervertebral

space after the nucleus pulposus is removed. The gap was filled with gelatin sponge to stop bleeding (Fig. 1). After fluoroscopy ensure its position was accurate, the nail rod system was installed and restoration the spondylolysis, and the intertransverse bone graft was performed. The diluted iodine and saline were alternately washed and the incision was placed and drained. The tube was fixed and the observation group placed a gelatin sponge with a mixture of 1 ml betamethasone injection + 2 ml 2% lidocaine on the nerve root of the spinal cord (Fig. 2). In the control group 1, 1 ml betamethasone injection + 2 ml 2% lidocaine was placed, and in the control group 2, a gelatin sponge with 3 ml normal saline was placed around the spinal nerve roots after decompression, and the control group 3 no anything were placed. Finally, vancomycin was applied to the wound, and the incision was closed by layers suture, and the drainage tube was opened.

Postoperative Treatment

Four groups of patients were given oxygen routinely, ECG(Electrocardiogram) monitoring, and skin oxygen monitoring for 12 hours. attention was paid to the movement and sensation of legs, and wound drainage, etc. Removed drainage tube when the daily drainage volume was less than 50 ml.The patients who wear a lumbar support can get out of bed when the pain was significantly reduced. Postoperative blood reexamination of blood routine, biochemical, timely review of CT(Computed Tomography) or MRI(Magnetic Resonance Imaging) after extubation,the patients discharge from hospital when the vas score below 2 and the incision healed well. regular follow-up, to avoid large waist activity within 3 months.

Measurements

Before operation and 3 months after operation, Lasegue sign, numeration of leukocyte and blood glucose of the four groups before and after the operation were recorded, including the postoperative hospital stay, wound healing and infection. Clinical efficacy was evaluated by using the modified Macnab criteria at discharge. VAS and ODI were used to assess the pain and functional recovery of the four groups before and after surgery, 1–5 days, 1 month, 2 months, and 3 months after surgery.

Statistical Methods

SPSS 18.0 statistical software was used for data analysis. The measurement data were expressed as mean \pm standard deviation ($\bar{x} \pm s$). The comparison between groups was performed by single factor ANOVA test or independent sample t test. The count data were compared by χ^2 test, expressed as $P < 0.05$. The difference was statistically significant.

Result

In the study, 186 patients were finally included. All patients had good intraoperative screws and cages, and no blood transfusion was found. No cases were found in which the screws were placed in the spinal canal and the cage was loose. Among them, the observation group included 46 cases, control group 1:53 cases, control group 2:45 cases, and control group 3:42 cases. The average age of the observation group was 55.6 ± 7.2 y, the average disease duration was 7.3 ± 4.0 m, the prominent segment L3/4:6cases, L4/5:26cases, L5/S1 :14cases, the average operation time was 118 ± 13.0 min, the average blood loss was 156 ± 34.5 ml, the average preoperative blood glucose was $5.9 \pm .69$ mmol/L, and the average preoperative numeration of leukocyte was $6.6 \pm .92 \times 10^9$ /L (Table 1). VAS score of postoperative legs pain at the postoperative 1–5 day were significantly lower than those in the control groups ($P < 0.05$), and rebound pain was lower than the control groups (Table 2, Fig. 3). The recovery of Lasegue sign as also better than the control groups ($P < 0.05$). The average of postoperative hospital stay was 5.7 ± 1.4 days, which was significantly shorter than the control groups. At 2–3 months, there was no significant difference in VAS and ODI between the four groups ($P > 0.05$). There was no statistically significant difference in blood glucose before and after operation in the observation group ($P > 0.05$) (Table 3), numeration of leukocyte postoperative was significantly higher than preoperative in each group ($P < 0.05$), but there was no statistically significant difference between groups ($P > 0.05$) (Table 1). The patients in the four groups had the similar satisfaction with the final efficacy ($> 90\%$) (Table 4). In addition, 5cases(10.8%), 5cases (9.4%), 6cases(13.3%) and 4cases (9.5%) in the observation group and control group 1, 2, 3 had postoperative nausea, vomiting, leakage of cerebrospinal fluid and other complications (Table 5).

Table 2
VAS score of legs pain from pre-operation to postoperative month 3

Parameter	Observation group	Control group 1	Control group 2	Control group 3	P value
Pre-operation	6.5 ± 1.3	6.1 ± 1.3	6.2 ± 1.4	6.1 ± 1.2	.320
Day 1	2.5 ± 0.8	2.8 ± 0.9	2.9 ± 0.9	3.1 ± 0.9	.001
Day 2	2.4 ± 0.8	2.8 ± 1.1	2.9 ± 1.1	2.9 ± 0.9	.021
Day 3	2.6 ± 1.0	3.2 ± 1.2	3.3 ± 1.1	3.4 ± 1.2	.001
Day 4	2.4 ± 1.0	3.1 ± 1.4	3.2 ± 1.4	3.3 ± 1.5	.001
Day 5	1.9 ± 0.9	2.3 ± 1.4	2.5 ± 1.1	2.5 ± 1.2	.013
Month 1	1.4 ± 0.7	1.5 ± 0.8	1.6 ± 0.9	1.6 ± 0.8	.445
Month 2	1.0 ± 0.5	0.9 ± 0.5	1.0 ± 0.7	0.9 ± 0.6	.880
Month 3	0.7 ± 0.5	0.6 ± 0.5	0.6 ± 0.5	0.7 ± 0.5	.842
DAY 1:postoperation 1 day month 1:postoperation 1month					

Table 3

The D-VALUE BETWEEN pre-operation and postoperation 3 days of Lasegue sign ;blood glucose;Numeration of leukocyten

The D-VALUE BETWEEN Pre-operation and Postoperation 3 days					
Parameter	Observation group	Control group 1	Control group 2	Control group 3	P value
Lasegue sign(°)	14.1 ± 5.6	8.6 ± 4.7	7.7 ± 4.9	7.1 ± 4.7	.000
blood glucose(mmol/L)	-.05 ± .63	-.09 ± .72	.16 ± .68	.05 ± .46	.160
Numeration of leukocyte(*10 ⁹ /L)	-4.6 ± 1.8	-4.1 ± 1.9	4.9 ± 1.8	-4.1 ± 1.7	.110

Table 4

Effective standard postoperation 3 months

Effective standard in four groups(n)				
Parameter	Observation group	Control group 1	Control group 2	Control group 3
excellent	13	15	11	10
good	29	33	31	28
better	2	4	3	2
poor	2	1	0	2
Rate of excellent and good	91.3%	90.5%	93.3%	90.4%

Table 5

Complication after TLIF operation

Complication(n)				
Parameter	Observation group	Control group 1	Control group 2	Control group 3
Infection	0	0	0	1
Locf	1	0	1	1
Ponv	4	5	5	3
Total	5(10.8%)	5(9.4%)	6(13.3%)	4(9.5%)
Ponv: post operation nausea and vomiting; locf leakage of cerebrospinal fluid				
The patient who infection in control group 3 is one of the patients in Locf				

Discussion

The mechanisms of symptoms

Although TLIF surgery's curative effect is exact, but patients always complain that pain relief is not complete. After removed drainage tube, the pain worse, Some patients appear even "rebounding pain". By review the literature [2, 7–11], we found that the possible mechanisms of transient radicular symptoms after TLIF was as follows:1.Long-term pressure inflammatory stimulation caused adhesion and edema around nerve roots, which reduced its tolerance to mechanical effects, increased the sensitivity of pain, and produced sensitization of central pain sensation;2.The intraoperative dural membrane floating increases the tension of nerve roots, aggravating the intraoperative strain injury and causing postoperative rebound pain;3.Aseptic inflammation occurs in damaged tissues cause a large number of inflammatory mediators include phospholipase A2, arachidonic acid and its metabolites TNF-2, IL-2, prostaglandins,etc., which imbalance the pro-inflammatory and anti-inflammatory factors.In addition, due to less blood supply around the disc and nerve roots, the clearance of inflammatory factors is slow, so that postoperative pain relief is not complete. 4. Blood oozed inside the incision after extubation, which caused postoperative hematoma to become organized and scar hyperplasia, and increased the stimulation and pulling of nerve roots; 5.The spinal cord and nerve roots are in a state of long-term compression and ischemia, reperfusion injury caused by the release of compression causes postoperative nerve root pain.

Steroid hormones have strong anti-inflammatory effects, reduce inflammatory exudation, and improve local microcirculation, reduce tissue edema, directly act on nerve roots and surrounding tissues, inhibit hyperplasia of nerve roots and surrounding connective tissue, thereby reducing accumulation of local acidic substances and desensitization.[12]It is widely used for epidural steroid injection (ESI) treatment, However, there are risks such as increased infection, cardiovascular failure, glucose metabolism disorder[13, 14].the use on clinical is still controversial[2, 15].Although the standard operation of injection can reduce the occurrence of complications, but the kambin triangle is still unable to avoid spinal cord vascular injury compared with the nerve. In addition, granule steroids strayed into the blood vessels cause complications such as spinal cord infarction and paraplegia [4, 16]. Although clinical treatment of postoperative lower extremity root symptoms can be achieved by oral, intravenous steroids, mannitol, etc., it takes a certain dose and time to achieve effective concentration locally,lead to the increase of complications [17], the existing contraindication of patients, such as liver and kidney dysfunction, femoral head necrosis, diabetes, etc.) will increase viscera burden lead to failure. So we used betamethasone, which has a relatively small molecular weight, and we did a statistical analysis of the possible adverse reactions.

Drug Selection

Some literatures[3, 5] have pointed out that local anesthetics combined with steroids have better efficacy than local anesthetics alone. In this study, lidocaine belongs to amide local anesthetics, which can continuously relieve neuralgia after local anesthesia block [18], while steroids can reduce the permeability of nerve root vessels of spinal cord and prolong the action time of local anesthetics. In addition, the efficacy of 8 ml volume for epidural block with the same dose of steroids was significantly better than 4 ml [19], but the optimal volume and drug concentration were not reported yet. Considering that the oozing blood of the surgical wound has a certain expansion effect on the drug, we have not expanded the volume of the mixed solution, and adopted a gelatin sponge with better histocompatibility as the carrier of the above-mentioned drug, and using its adsorption function of slow-release function, and because of its soft, won't cause secondary to nerve compression. In order to eliminate the difference between groups, all the four groups were operated by the same operator. Nerve monitoring was used throughout the operation to determine whether postoperative lower limb dysfunction was caused by local anesthetic or intraoperative nerve injury. By observing Fig. 3 and Table 2, we found that the VAS scores of legs' pain in the four groups increased on the fourth day postoperation, reaching a peak in 4–5 days, suggesting that the extubation after operation, intraoperative nerve root traction led to increased edema, hematoma compression. The same stimulus appeared, but the curve of the observation group became more stable, which enabled the patient to get out of bed earlier and increase functional rehabilitation. From Fig. 3–4, we found that the short-term efficacy of this method is exact. From Fig. 4, we found that the observation group had the most obvious decrease in ODI index during hospitalization, while the control group mainly focused on postoperative. Within 1 month, the patient's earlier bed-out activity was positively correlated with functional recovery, indicating the importance of early pain relief. In addition, the hospitalization time, efficacy satisfaction, and ODI index (within 5 days) of the observation group were superior to the control group, further indicating that the method has greater advantages in patient satisfaction and bed turnover. The literature reported that the complications of topical application of steroids (including the risk of hypotension, spinal cord infarction, meningitis) compared with the control groups, were not found in our study. Incision healing, infection rate, and blood glucose changes were not significantly different from the control groups, as reported by Bogduk [20], further confirming the safety of the method. Although Numeration of leukocyte of patients before and after surgery were significantly different, no differences were found between the groups. We considered that the increase in numeration of leukocyte count after surgery was a stress reaction caused by intraoperative trauma, and was not related to the use of steroids [21–23]. In the observation group, 4 patients had a postoperative nausea and vomiting rate of 8.6%, which was no significantly increased compared with the control groups, and was considered to be related to the use of intraoperative anesthetics. The control group 1 directly infiltrated the mixed solution, and the drug was easily lost under the suction of the negative pressure drainage tube, and could not play a role locally. Therefore, the role of the gelatin sponge could not be ignored. Some patients have a relatively long course of disease, high preoperative inflammation index, and there may be hyperalgesia. Secondly, hemostasis does not completely dilute the drug during the operation, resulting in serious drug loss. In addition, if the patient expects higher efficacy, VAS score will increase, we recommend strict hemostasis during surgery, appropriate delay of negative pressure drainage release time.

Matters Needed Attention

The dose of the drug in this study was determined based on the existing literature, not sure the minimum effective dose, the optimal drug ratio, and the effective time of the drug. In addition, the study object in this paper is single-center case and the sample size is small.

Conclusion

Through this study, the use of gelatin sponge sustained-release steroids and 2% lidocaine mixed solutions can significantly improve transient radicular symptoms after TLIF, shorten hospitalization time, help patients get out of bed early, improve clinical satisfaction, the effect is exact, and local small dose, it is safe and feasible to apply steroids in a short period of time, and the placement of gelatin sponge will not cause secondary compression. Has the advantages as follow: 1. Avoid the occurrence of similar puncture accidental complications 2. Instantly reach a certain concentration in the local, avoid systemic administration 3. Have a certain sustained release effect 4. Reduce the dilution and loss of the drug caused by drainage and oozing. Simple operation in direct vision environment 6. Make patients get out of bed early and accelerate recovery.

Abbreviations

TLIF - Transforaminal Lumbar Interbody Fusion

LDH - Lumbar Disc Herniation

VAS - Visual Analogue Scale

ODI - Oswesry Disability Index

Declarations

Ethics approval and consent to participate: This study was approved by the ethics committee of the Ningbo No.6 hospital, and patients gave informed consent and signed it.

Consent for publication: Not Applicable.

Availability of data and materials: The data and material are consented by patients to use in this clinical study.

Competing interests: No conflict of interest exists in the submission of this manuscript

Funding: We have no funding in this research.

Authors' contributions:

MW: conceived and designed the study, and is the Surgeon of all operation

WY,XD:performed the experiments

MW,LH: data analysis and write manuscript,reviewed and edited the manuscript

All authors have read and approved the manuscript

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Figures



Figure 1

Gap was filled with gelatin sponge to stop bleeding



Figure 2

The tube was fixed and the observation group placed a gelatin sponge with a mixture of 1 ml betamethasone injection + 2 ml 2% lidocaine on the nerve root of the spinal cord

Mean of VAS score from pre-operation to postoperation 3 months

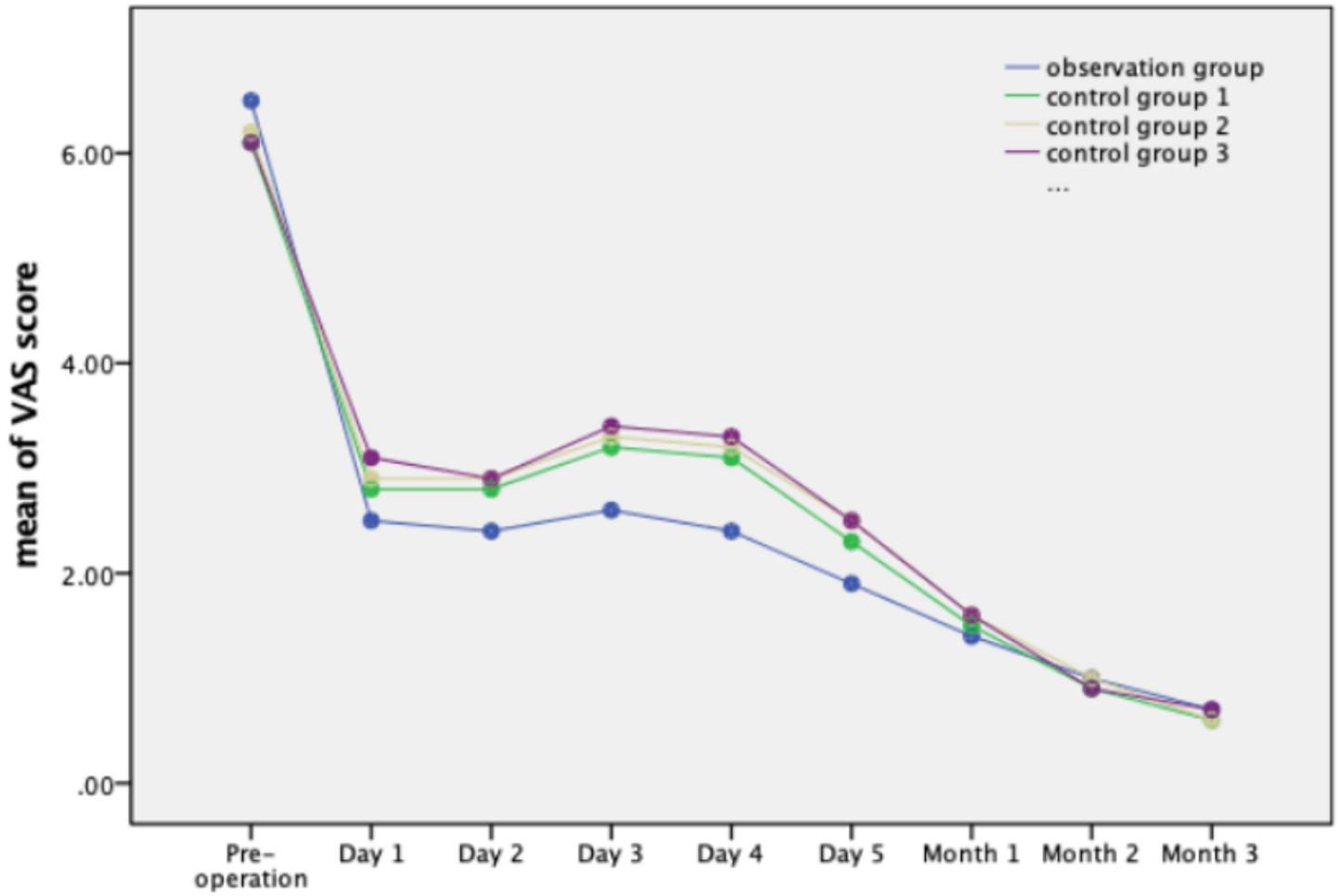


Figure 3

Mean of VAS score from pre-operation to postoperation 3 months

Mean of ODI score from Pre-operation to postoperation 3 month

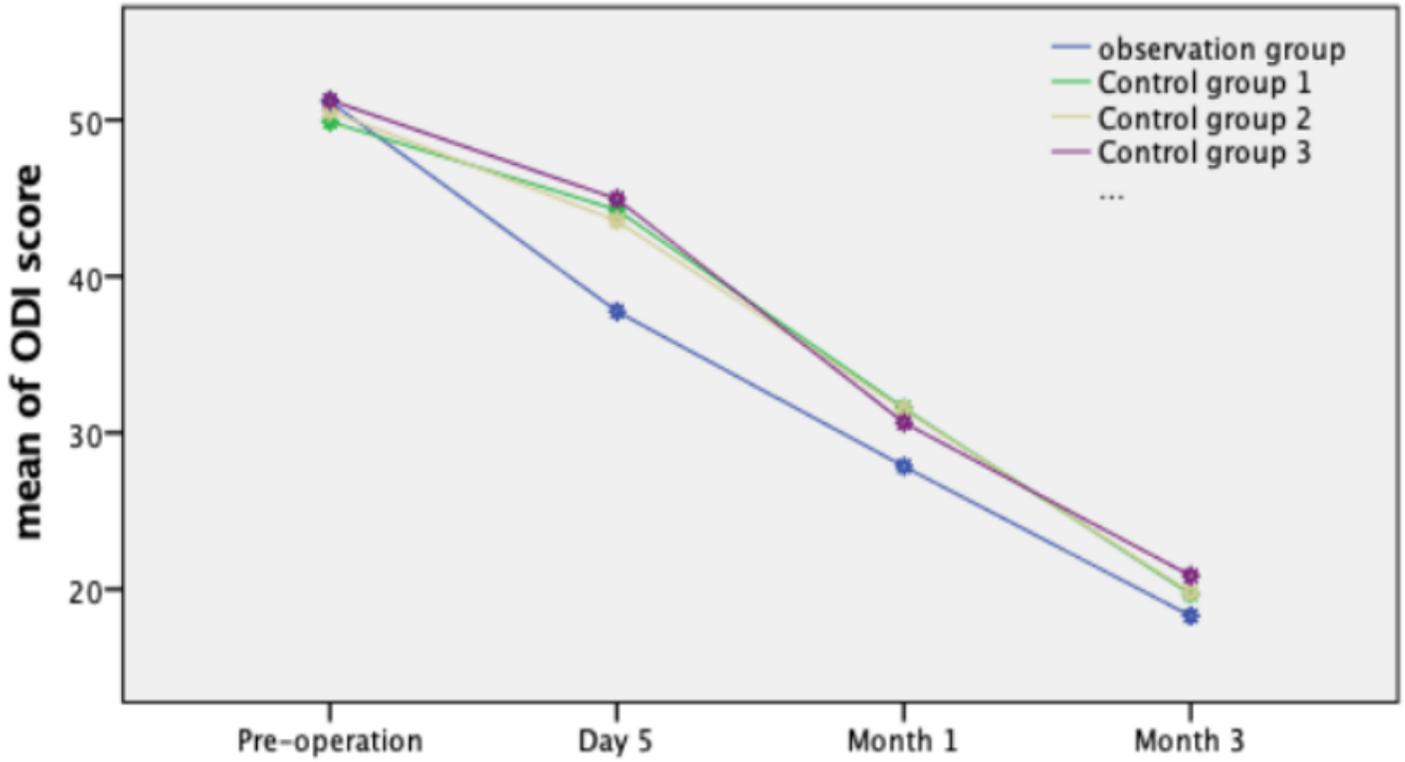


Figure 4

Mean of ODI score from Pre-operation to postoperation 3 months