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Robot-assisted versus fluoroscopy-assisted kyphoplasty in treatment of severe osteoporotic vertebral compression fractures in the old patients: a retrospective study



Robot-assisted in treatment of severe OVCF

Peng Liu¹, Jiang Hu¹, Wei Zhang¹, Fei Wang¹, Liuyi Tang¹, Weijun Zhou¹ and Shu Lin^{1*}

Abstract

Background Although percutaneous kyphoplasty (PKP) is used to treat severe osteoporotic vertebral compression fractures (OVCF), the unsatisfactory effect of bone cement reduction and leakage is a concern. In recent years, the application of surgical robots in the field of orthopaedics has shown promising prospects. Since 2017, our hospital has used surgical robot-assisted PKP to treat severe OVCF.

Methods One hundred and fifty-five old patients with severe OVCF who had undergone PKP were retrospectively analyzed and stratified into two groups: robot-assisted (n = 88) and fluoroscopy-assisted (n = 67). The surgical time, intraoperative radiation dose, surgical efficacy (analgesic effect and limb function), imaging evaluation (accuracy of puncture, distribution of bone cement, reduction of vertebral height, and rectification of Cobb angle), and leakage of bone cement were analyzed to evaluate the potential advantages of robot-assisted PKP in the treatment of severe OVCF.

Results There were significant differences in surgical time (P < 0.001), intraoperative radiation dose (P < 0.001), analgesic effect (P = 0.001), accuracy of puncture (P = 0.008), distribution (P = 0.013), and leakage of bone cement (P = 0.019) between the two groups. However, postoperative limb function (P = 0.612), reduction in vertebral height (P = 0.068), and rectification of the Cobb angle (P = 0.243) were similar in both groups.

Conclusions The application of robot-assisted PKP for treating severe OVCF (Genant Grade III) can slightly shorten surgery time and significantly reduce intraoperative total radiation exposure for both patients and clinicians. Additionally, it improves puncture accuracy and reduces the cement leakage rate, ultimately achieving satisfactory pain relief. However, in terms of functional recovery, no significant differences were observed between the two approaches.

Keywords Osteoporosis vertebral compression fractures, Percutaneous kyphoplasty, Bone cement leakage, Robotassisted

*Correspondence: Shu Lin linshu6650337@163.com

¹Department of Orthopedic Surgery, Sichuan Provincial People's Hospital, School of Medicine, University of Electronic Science and Technology of China, No. 32 West Second Section, First Ring Road, 610072 Chengdu, China

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Introduction

With the aging global population, osteoporosis continues to be an increasingly serious public health problem worldwide [1, 2], leading to disability and death [3–5]. Osteoporotic vertebral compression fractures (OVCF) are the most common complications of osteoporosis. In the US and Europe alone, more than 1,700,000 OVCFs occur every year [6], which constitutes a serious public health issue because of their direct and indirect effects on health-related quality of life and healthcare expenditure [7]. OVCF can lead to chronic back pain, limited activity, impaired neurological function, decreased quality of life, and increased mortality owing to related complications.

Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) have been widely used to treat OVCF owing to their efficacy and safety [6, 8–10]. However, in the early stages of the application of this technology, severe OVCF (vertebral compression of \geq 75%) [11] was considered a relative contraindication. OVCF is the most serious complication of osteoporosis and has a high disability and mortality rate [6]. Although there have been reports of the clinical application of this technique to treat severe OVCF, unsatisfactory reduction and leakage of bone cement are concerns [12, 13].

In recent years, the application of surgical robots in orthopaedics has shown promising prospects. Especially in percutaneous pedicle screw placement, the use of surgical robots significantly improves the accuracy of placement and reduces the number of fluoroscopies compared to the free-hand technique or the use of fluoroscopy [14–17]. Since 2017, our hospital has used surgical robot-assisted PKP to treat severe OVCF. Here, we review the clinical data of patients who underwent robot-assisted treatment and compare them with those of patients who underwent traditional fluoroscopy-assisted treatment to provide a feasible solution for severe OVCF.

Methods and patients

Patients

The medical records of 155 patients (48 men, 107 women; mean age: 72.15 years, age range, 60–92 years) with severe OVCF who had undergone PKP in Sichuan Provincial People's Hospital between October 2017 and December 2021 were retrospectively analyzed (Fig. 1). The patients were divided into two groups: robot-assisted (n=88) and fluoroscopy-assisted (n=67). Of the 155 patients, 75 had a clear history of trauma (all falls) and 64 had comorbid diseases such as diabetes, hypertension, cardiopathy, and cerebral infarction. The time from fracture to surgery was 1–40 days (mean: 9.4 days). In total, 146, 7, and 2 cases had one-, two-, and three-segment fractures, respectively. The lesion was located between T_7 and L_4 and all patients had varying degrees of osteoporosis. The main clinical symptom of the patient was

low back pain. General patient data were collected and analyzed to ensure comparability. Written informed consent was obtained from all patients, and the study was approved by the Ethics Committee of our hospital. All methods were performed in accordance with the relevant guidelines and regulations, including the Declaration of Helsinki.

Inclusion and exclusion criteria

Patients were included if they had (i) severe OVCF, belonging to Genant Grade III [18], (ii) intact posterior edge of the vertebral body without compression of the spinal cord or nerve root, and (iii) dual energy X-ray absorptiometry showing osteoporosis.

Patients were excluded if they had (i) secondary origins, including other pathological fractures (metastatic tumour, myeloma, or hemangioma) and/or infections; (ii) other associated conditions, such as lumbar disc protrusion, spondylolisthesis, spinal stenosis, and/or scoliosis; (iii) history-related factors, including old fractures and/or incomplete clinical data.

Preoperative preparation

All patients were diagnosed with severe OVCF by imaging examination, including digital radiography, computed tomography, magnetic resonance imaging, and bone mineral density test by dual energy X-ray absorptiometry. The skin was prepared (non-shaving) the night before surgery, and an iodine allergy skin test was performed. All patients were preoperatively fasted for 6–8 h. Blood pressure was controlled to <140 mmHg, and fasting blood glucose was regulated to <10 mg/dL if the patient had underlying hypertension or diabetes. The patient was informed before surgery that robot-assisted surgery would incur additional costs, and it was up to the patient to decide whether or not to use robotic assistance. The two groups of patients were treated by surgeons with the same surgical experience at one medical centre.

Surgery

Patients were placed in the prone position after general anesthesia. The unilateral puncture approach through the pedicle (if the lumbar vertebra) or outside the pedicle (if the thoracic vertebra) was used in all patients. *Fluoros-copy-assisted group*: The pedicle of the injured vertebrae was marked on the body surface under fluoroscopic guidance using the C-arm X-ray machine. A working sleeve with an inner core was used to penetrate the injured vertebra from the outside and upper part of the pedicle under fluoroscopy and pull out the inner core at a depth of approximately 1/3 vertebra. A bone tunnel was made with a bone drill, and a balloon containing a contrast agent was placed in the middle of the injured vertebra for expansion. The balloon was removed after the pressure



Fig. 1 The flow chart of this retrospective study; *: Belong to Genant Grade I-II (vertebral compression of < 75%); **: longer than 6 weeks and no change of high signal in MR images; ***: Lack of control in fluoroscopy-assisted group

in the capsule approached 200 kPa (upper limit), or the height of the vertebra was satisfactorily restored. Finally, bone cement was injected into the injured vertebrae using a push rod. The amount of bone cement injected was 1.5-3.5 mL (average: 2.6 mL), and the surgery was completed after the bone cement solidified. If leakage of bone cement occurred (including the intervertebral disc, paravertebral vessels, and spinal canal) during the operation, surgery was stopped immediately. Robot-assisted group: The "Tianji" 3rd generation orthopaedic robot of Beijing Tianzhihang Medical Technology Co., Ltd. was used as a guide; it comprised the manipulator, optical tracker, and surgical planning and navigation components. A tracer was installed on the spinous process of the upper vertebra after pasting the surgical film. A positioning ruler was installed on the back of the injured vertebra, and a C-arm X-ray machine scanned the three-dimensional structure of the punctured vertebra. The data obtained were transmitted to a robot workstation for puncture planning. Next, a command was issued to the manipulator-driven mechanical arm at a specified position. A small incision was made at the puncture point, the secondary sleeve was inserted until the bone surface, and the guide needle was implanted with an electric drill reaching a depth of 1/2 vertebra. Finally, the working cannula was placed through the needle, and the remaining protocol was identical to that of the fluoroscopy-assisted group (Fig. 2).

Postoperative protocol

Computed tomography (CT) and radiography were performed within 48 h of surgery. Bisphosphonates were injected for subsequent anti-osteoporosis treatment, and analgesics were administered if necessary. The patients could get out of bed for walking activity with a brace 24 h after surgery and were discharged 2 days later.

Follow-up and efficacy evaluation

All patients were required to be followed up for at least one year after surgery. (i) Surgical time: The time from the first incision to completion of surgery was recorded. (ii) Intraoperative radiation dose: the dose of continuous scanning when patients' information registration and single fluoroscopy when surgical manipulation were included in the robot-assisted group. The single fluoroscopy dose was directly measured using a C-arm X-ray machine (ARCADIS Orbic 3D System; Siemens, Germany). (iii) Surgical efficacy: Preoperative and postoperative changes of Visual Analog Scale (VAS; Pain is divided into 10 points, 0 points corresponded to no pain and 10 points corresponded to unbearable pain) and Oswestry Disability Index (ODI; The questionnaire is composed of 10 aspects including pain, self-care, extraction, walking, sitting, standing, sleeping, sexual life, social life and tourism and 0-5 points for each item. Scores=total points / 50×100%, 0% scores corresponding to normal function and 100% scores corresponding to severe dysfunction) were used to assess pain relief and limb function recovery, respectively. (iv) Imaging evaluation: The



Fig. 2 A: The robot arm performs continuous scanning during registration. B: Place the secondary sleeve under the navigation of the robot. C: Percutaneous implantation of Kirschner wire. D: Insert the sleeve along the Kirschner wire. E: Place a balloon to dilate the injured vertebra. F: Push the bone cement



Fig. 3 A-D: Class A, Class B, Class C and Class D of bone cement distribution, respectively. E-H: Grade A, Grade B, Grade C and Grade D of Gertzbein-Robbins (puncture deviation), respectively

Table 1	Demographic data of	patients with severe c	steoporotic vertebral of	compression fractures

Variable	Robot-assisted group (n = 88)	Fluoroscopy-assisted group (n=67)	Chi-square/F	<i>p</i> -Value
Sex (male/female)	26/62	22/45	0.193	0.661
Age, years [mean±SD]	71.90 ± 6.46	72.49±6.37	0.325	0.569
Follow-up, months [mean±SD]	13.14±2.13	13.80±2.27	3.408	0.067
Bone mineral density (O/S)	28/60	22/45	0.018	0.893
Segment (One-Level/Two-Level/ Three-Level)	85/3/0	61/4/2	3.304	0.192
Site (T ₇ -L ₄)	7/8/5/4/10/17/15/9/7/6	7/5/2/8/13/14/7/4/4/3	7.944	0.540
Time of injury	8.71±7.20	10.39±8.06	1.858	0.175

O/S: Osteoporosis (-3.0 < T \leq -2.5)/Severe osteoporosis (T \leq -3.0)

results of CT scan were used to evaluate the accuracy of puncture and distribution of bone cement according to the Gertzbein–Robbins [19] grading standard (Grade A: no deviation, Grade B: deviation < 2 mm, Grade C: 2 mm < deviation < 4 mm, Grade D: deviation > 4 mm) and bone cement dispersion (Class A: unfilled unilateral distribution no crossing the midline of the vertebra, Class B: filled unilateral distribution reaching the midline of the vertebra, Class C: unfilled bilateral distribution crossing the midline of the vertebra, Class D: filled bilateral distribution crossing the midline and more than 3/5 of the vertebra) (Fig. 3). (v) Reduction of vertebral body: postoperative vertebral midline height and Cobb angle (intersection of the vertical line of the upper and lower vertebral bodies). (vi) Surgical safety: bone cement leakage.

Statistical analyses

Measurement data are expressed as mean±standard deviation. The Quantile-Quantile (Q-Q) plot and the Kolmogorov-Smirnov test were used to assess the normality of the data distribution. The differences in means between groups were statistically evaluated using oneway analysis of variance. The comparison of counting data between groups was statistically evaluated using the chi-square test. All analyses were performed using Statistical Product and Service Solutions software, version 16.0 (SPSS UK, Ltd., Woking, United Kingdom), and statistical significance was set at P < 0.05.

Results

General demographic data and surgery procedure

All patients were followed up for 10–20 months, with an average of 13.4 months. There was no significant difference between the two groups with respect to age, sex, fracture segment, or bone mineral

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Variable		Robot-assisted group (n = 88)	Fluoroscopy-assisted group (n=67)	F	<i>p</i> -value
Surgery time (min)		26.69±4.02	30.26±6.16	18.976	0.000 *
Radiation dosage (cGycr	n²)	215.28±44.13	605.16±86.71	1328.112	0.000 *
Puncture angle (degree)		23.99 ± 2.73	21.18±4.07	26.435	0.000 *
Vertebral height (mm)	Preoperative	7.09 ± 2.54	7.55 ± 2.26	1.389	0.240
	Postoperative	9.17±2.86	9.94±2.13	3.387	0.068
Cobb angle (degree)	Preoperative	31.20±10.06	29.38 ± 8.57	1.404	0.238
	Postoperative	14.46±5.87	15.54±5.38	1.371	0.243
VAS score	Preoperative	6.53±0.84	6.50 ± 0.98	0.055	0.814
	Postoperative	2.42 ± 1.03	2.29 ± 1.24	0.454	0.501
	Last follow-up	2.02 ± 0.85	2.59±1.28	1328.112 26.435 1.389 3.387 1.404 1.371 0.055 0.454 11.066 1.570 0.121 0.258	0.001 *
ODI score	Preoperative	42.85 ± 2.93	43.45 ± 2.93	1.570	0.212
	Postoperative	24.89 ± 9.06	25.39±8.73	0.121	0.729
	Last follow-up	24.09 ± 8.27	24.77±8.22	0.258	0.612

Table 2 The surgical and orthopaedic parameters, VAS and ODI scores of patients with severe osteoporotic vertebral compression fractures

* Indicate significant difference at P<0.05; VAS indicates visual analogue scale; ODI indicates Oswestry disability index

Table 3 The postoperative radiographic evaluation of patients with severe osteoporotic vertebral compression fractures

Variable		Robot-assisted group (n = 88)	Fluoroscopy-assisted group (n=67)	F	<i>p</i> -value
Deviation of puncture	Grade A	Grade A 40	24	11.916	0.008*
	Grade B	36	21		
	Grade C	11	19		
	Grade D	4	11		
Distribution of bone cement	Class A	7	15	10.817	0.013*
	Class B	15	21		
	Class C	38	22		
	Class D	31	17		
Leakage of bone cement		20	29	5.504	0.019*

* Indicates significant difference at P<0.05

density (P>0.05) (Table 1). The mean time of surgery time was 26.69±4.02 min in the robot-assisted group and 30.26±6.16 min in the fluoroscopy-assisted group (P<0.001). The mean fluoroscopy dose was 215.28±44.13 cGycm² in the robot-assisted group and 605.16±86.71 cGycm² in the fluoroscopy-assisted group (P<0.001) (Table 2).

Surgery efficacy

Vertebral height and Cobb angle increased and decreased to 9.17 ± 2.86 mm and 14.46 ± 5.87 degrees in the robotassisted group and 9.94 ± 2.13 mm and 15.54 ± 5.38 degrees in the fluoroscopy-assisted group, respectively (P = 0.068 and P = 0.243). The VAS scores decreased to 2.02 ± 0.85 in the robot-assisted group and 2.59 ± 1.28 in the fluoroscopy-assisted group, respectively (P = 0.001), the ODI decreased to 24.09 ± 8.27 points in the robotassisted group and 24.77 ± 8.22 points in the fluoroscopy-assisted group (P = 0.612), one year after surgery (Table 2). The accuracy of puncture and distribution of bone cement between the robot-assisted and fluoroscopy-assisted groups showed significant differences (P = 0.008 and P = 0.013, respectively) (Table 3).

Complications

Bone cement leakage occurred in 29 (38.67%) vertebral segments in the fluoroscopy-assisted group: intervertebral disc leakage (n = 10), paravertebral or prevertebral soft tissue leakage (n = 8), needle-channel leakage (n = 6), paravertebral vein leakage (n = 3), and posterior longitudinal ligament leakage (n = 2). The robot-assisted group had 20 (21.98%) vertebral segments with bone cement leakage: intervertebral disc leakage (n = 6), paravertebral or prevertebral soft tissue leakage (n = 6), needle channel leakage (n = 4), paravertebral vein leakage (n = 2), and posterior longitudinal ligament leakage (n = 2). The differences between groups were statistically significant (P = 0.006).

Discussion

PKP for OVCF

Vertebral compression fractures often induce severe lumbar pain in elderly patients. Vertebral fracture leads to fracture fretting caused by secondary trabecular fracture, and pain is transmitted by the nerves that dominate the vertebral body and its periosteum. Vertebral fracture deformation leads to traction and tension of the posterior branch of the spinal nerves, resulting in low back pain

of the posterior branch. The movement of pseudarthrosis around the spine leads to forward movement of the centre of gravity of the upper trunk, increasing the load on muscle groups around the spine. Peripheral muscles contract and spasm for a long time, resulting in fatigue, muscle hypoxia, metabolic disorders, and accumulation of metabolic substances. PKP is a practical technology for treating this type of disease with minimal invasiveness, quick effects, and low cost. Solidification by bone cement can reduce vertebral fractures and stabilize the spine, thus reducing spinal nerve traction caused by sliding between vertebral bodies. Moreover, the fever and toxicity of bone cement during solidification can play a role in the denervation of the vertebral body to achieve analgesia. In short, the patient's back pain is greatly relieved, and they can even directly perform outof-bed activities, such as walking soon after surgery. In clinical practice, the bone cement for treating OVCF, namely poly (methyl methacrylate), is rapidly solidified after being injected into human bone tissue, and a small amount of bone cement can restore the stiffness of injured vertebrae to normal. The stiffness of the injured vertebrae increased by > 50% with 30% bone-cement filling [20]. However, the stiffness of the unilateral distribution of bone cement was weaker than that of the bilateral distribution. Some researchers believe that symmetrical distribution of bone cement may have better biomechanical effects [20, 21]. In patients with severe OVCF, unilateral puncture and bilateral diffusion could further reduce the surgical and anesthesia time. Nevertheless, for novice users of PKP to treat severe OVCF, it is not easy to master the accurate puncture angle and place the balloon in an ideal site because the small space in the sagittal position and inclination angle (horizontal position) should be simultaneously taken into account. Under these conditions, robot-assisted navigation can be used to accurately and safely complete surgery. In addition, we recommend that the pressure of the balloon should be in the range of 80-100 kPa for severe OVCF because excessive pressure often causes the end plate to split, which may lead to bone cement leakage to the intervertebral disc. Furthermore, the reduction of vertebral fractures and distribution of bone cement are more ideal when the balloon is repeatedly expended in multiple positions of the injured vertebra.

Robot-assisted PKP for severe OVCF

In our study, the number of intraoperative bone cement leakages and bone cement crossing the spinal midline in the robot-assisted group was lower and higher than that in the fluoroscopy-assisted group, respectively. There were 29 cases of bone cement leakage in the fluoroscopy-assisted group and the proportion of paravertebral leakage was the highest. Repeated adjustment of the puncture angle by manual percutaneous puncture using a C-arm X-ray machine destroys the bone integrity of the pedicle site. In addition, the space of the injured vertebra of severe OVCF is narrower than that of common OVCF; therefore, greater pressure is encountered during cement infusion. Taken together, these factors increase the possibility of paravertebral leakage of bone cement. Although it is relatively safe for patients through the lateral pedicle puncture approach if cement leakage occurs in the posterior vertebral body, there still exists a potential risk of nerve injury due to heating during cement solidification. The distribution of bone cement across the midline of the vertebral body can strengthen the structural units of the bilateral vertebral bodies simultaneously and restore the biomechanical structure of the spine to the greatest extent. The puncture angle of the robot-assisted group was significantly larger than that of the fluoroscopyassisted group, which is a challenge for manual operation because a very large puncture angle may cause the puncture needle to enter the spinal canal, leading to spinal cord injury. A robot-assisted guide will undoubtedly increase the confidence of operators.

The recovery of vertebral body height in both groups was not ideal. It is difficult to achieve anatomical reduction by balloon inflation alone; however, patients in the two groups received a good analgesic effect. This shows that sagittal balance and stability of the spine in elderly patients with severe OVCF seems more valid for postoperative functional recovery than anatomical reduction. There was no statistically significant difference in the analgesic effect between the two groups in the early postoperative period. However, with continued follow-up, the trend of pain relief in the robot-assisted group was better than that in the fluoroscopy-assisted group. This is related to the destruction of the painful nerve of the vertebral body by fever during the solidification of bone cement and the larger contact and anchoring area of the symmetrically distributed bone cement [21]. Of course, a statistical difference does not necessarily mean that it has clinical significance. Although the pain difference was approximately 0.57 points on the VAS between the two groups and the difference was significant, the usual minimum clinically important difference for a 10-point scale was approximately 2 points. We did not find a significant difference in the ODI between the two groups at either the early or late follow-up. This finding suggests that the quality of life of elderly patients after surgery is affected by many factors besides pain, such as comorbid diseases, cardiopulmonary function, and daily living habits. Therefore, these two approaches are equivalent in terms of their long-term therapeutic effects.

Advantages of robot-assisted PKP

In recent times, there have been many reports about robot-assisted screw placement [22-24], but there are few reports about robot-assisted PKP and fewer reports about robot-assisted PKP in the treatment of severe OVCF. Traditional PKP for treating severe OVCF is dependent on doctors' operating experience; it is a challenging technique to perform, and bone cement leakage, the most common and major complication associated with this technique, are known to occur often. Cement leakage includes extra-vertebral leakage, epidural leakage, and vascular leakage. This can lead to adverse events such as nerve damage, spinal instability, infection risk, and vascular embolism. Although the literature reports a low mortality rate from pulmonary embolism caused by cement leakage [25], accurate statistical data is still lacking. Currently, most clinical robotic systems are equipped with computer-aided navigation, which not only ensures the accuracy of surgery and effectively reduces leakage but also minimizes radiation exposure to doctors [14, 26-28]. Robot-assisted spinal surgery is associated with fewer complications, lower revision rates, and shorter hospital stays than the traditional fluoroscopic-based approach [16, 29]. At the early stage, the surgery time of PKP with robot assistance is roughly the same as that for manual fluoroscopy; this is mainly the time spent on omnidirectional scanning of the spine and the design of the puncture scheme before robot navigation. However, the surgery time of the robot-assisted group was significantly shorter than that of the fluoroscopy group with an increasing number of surgical cases. This is also consistent with literature reports on the learning curve associated with orthopaedic robots [30, 31]. In our study on a limited number of multi-segmental severe OVCFs, the surgery time and fluoroscopy dose were adjusted by dividing them by the number of segments to reflect single-segment records. Additionally, there was no significant difference in the distribution of fracture segments between the two groups, ensuring their comparability.

Limitations and prospects

One of the main limitations of our study is the relatively short follow-up period, which restricts our ability to assess long-term outcomes following robot-assisted percutaneous kyphoplasty. Although the immediate postoperative benefits such as reduced surgical time, lower intraoperative radiation exposure, and improved analgesic effects are promising, longer-term studies are needed to evaluate the durability of these results and overall efficacy. Additionally, retrospective studies may be subject to inherent biases. Future research, particularly prospective study with extended follow-up periods to assess long-term outcomes including functional recovery will be essential to confirm the sustained benefits and safety of this technique.

Conclusion

The application of robot-assisted PKP for treating severe OVCF (Genant Grade III) can slightly shorten surgery time and significantly reduce intraoperative total radiation exposure for both patients and clinicians. Additionally, it improves puncture accuracy and reduces the cement leakage rate, ultimately achieving satisfactory pain relief. However, in terms of functional recovery, no significant differences were observed between the two approaches.

Abbreviations

- PKP Percutaneous kyphoplasty
- OVCF Osteoporotic vertebral compression fractures
- PVP Percutaneous vertebroplasty
- VAS Visual analogue scale
- ODI Oswestry Disability Index
- CT Computed tomography

Author contributions

Peng Liu: Conceptualization, Writing– Original Draft. Jiang Hu: Supervision. Wei Zhang: Formal analysis. Fei Wang: Investigation. Liuyi Tang: Validation. Weijun Zhou: Writing– Review & Editing. Shu Lin: Conceptualization.

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Data availability

The data used and/or analyzed in this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol was approved by our Institutional Review Board (IRB) at Sichuan Provincial People's Hospital, School of Medicine, University of Electronic Science and Technology of China (grant number: 2019–298). Written informed consent was obtained from all patients for the publication of this study. All methods were performed in accordance with the relevant guidelines and regulations, including the Declaration of Helsinki.

Consent for publication

Not applicable.

Conflict of interest

Peng Liu, Jiang Hu, Wei Zhang, Fei Wang, Liuyi Tang, Weijun Zhou and Shu Lin declare that they have no conflict of interest.

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