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ORIGINAL STUDY

A comparative study of three approaches for the treatment of lumbosacral tuberculosis

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The posterior (P), antero-posterior (AP), and anterior approaches (A) with a new complex locking rod system (D-rod system) were performed on 64 patients with lumbosacral tuberculosis respectively and the efficacies of the three approaches were compared in our study. Related data were then collected and compared with an average of 27.0 months follow up. The lumbosacral angles, VAS, ODI, ESR, and Frankel Grade were significantly improved at the post-operation or final follow-up when compared to preoperative scores. The average surgical time, blood loss, and hospital stay following anterior and posterior approaches were markedly less than those following antero-posterior approach. Moreover, there was no tuberculosis recurrence in AP and A group. However, P group had a recurrence rate of 11.1% (2/18). None of the patients in P and A group developed intraoperative or postoperative complications, while two cases were found in AP group. Taken together, anterior approach with the D-rod system is an appropriate method for lumbosacral tuberculosis treatment.

Keywords : Tuberculosis, Lumbosacral spine, D-rod system, Approach

INTRODUCTION

Spinal tuberculosis is the most common form of extrapulmonary tuberculosis, accounting for approximately 50% of all cases of musculoskeletal tuberculosis and less than 1% of all cases of tuberculosis (10). Alarmingly, the morbidity rate of tuberculosis is rising, due in large part to the recent increase in drug-resistant (*12,8*).

One option for treating spinal tuberculosis is surgical management, with the main goal of eradicating the focus of tuberculosis, relieving spinal cord compression, restoring spine stability, and correcting deformities. Although a variety of surgical treatments have been performed on patients with lumbosacral tuberculosis (*3,11,18*), it is still a difficult therapy due to the specialized anatomical structure of the lumbosacral spine. Although there are still controversies in clinical decision-making, it is generally accepted that the anterior

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approach is superior to the posterior approach in lumbosacral tuberculose focus debridement. The anterior approach has achieved considerable success in tuberculosis management by allowing for the direct visualization of the tuberculose focus in both the anterior and middle columns. Moreover, it enables the restoration and maintenance of sagittal alignment of the lumbosacral junction following the correction of kyphosis (*6*). However, the lumbosacral region is also frequently associated with blood vessel injury, blockage of the ala ossis ilii, higher pseudarthrosistic rates, and limitations in the use of traditional anterior instruments, making all surgical approaches and techniques more complex than elsewhere (*13,19*). The recent and independent development of a new anterior, complex locking rod system (named as D-rod system according to the designer name zhenqi Ding) now allows for lumbosacral tuberculosis to be treated more easily via the anterior approach. Nevertheless, there is a lack of clinical studies comparing the single-stage posterior approach (P), the single-stage antero-posterior (AP) approach, and the single-stage anterior (A) approach with the new D-rod system. Therefore, this study sought to review and compare the therapeutic efficacies of these three approaches for the treatment of lumbosacral tuberculosis.

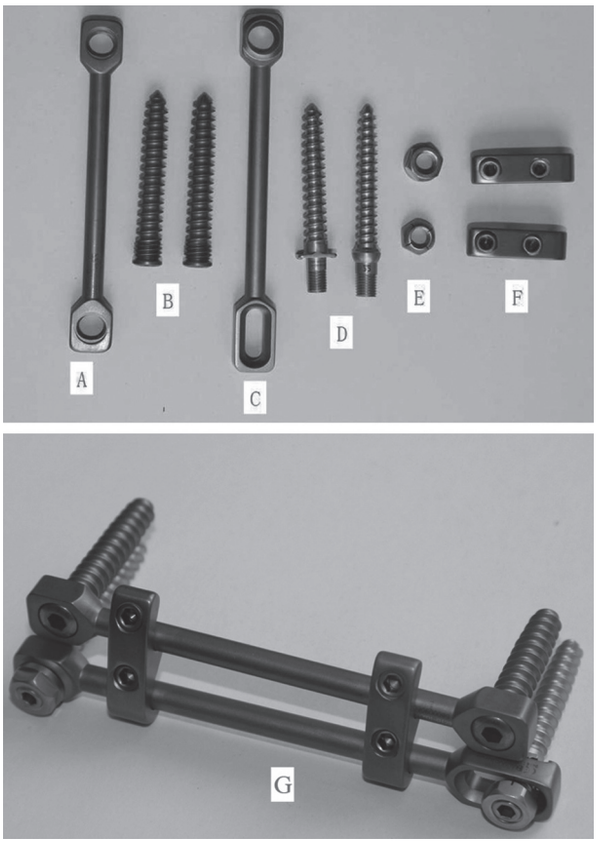

Fig. 1. **—** The components of the D-rod system. **(A)** Locking rod. **(B)** Locking screw (6mm in diameter). **(C)** Distraction/compression rod (60 to 130mm). **(D)** Bolts. **(E)** Nuts. **(F)** Adjustable transverse link bar. **(G)** Overall relation of the D-rod system.

METHODS

D-rod Instrumentation

The D-rod system features a separated body design that is comprised of an anterior locking rod, a posterior distraction/compression rod, two adjustable transverse link bars, and several other accessory instruments (Fig. 1). The implants are manufactured from a titanium-aluminum-vanadium alloy (Ti6Al4V, Double Engine Medical Material Ltd., Xiamen, China). Both the locking and distraction/compression rod are I-shaped in the configuration of "one body and two ends". Each end of the locking rod is flat with a locking screw hole. Two locking screws are fixed in the locking rod with the head below the surface of the hole, thereby providing a low profile. One of the distal ends of the distraction/compression rod forms a sliding groove, which can be distracted, compressed, and/or adapted to the fit the needs of different fixed-lengths. The other end of the distraction/compression rod features an adjustable angle bolt, which promotes fixation and can become more flexible. Two adjustable transverse link bars provide a solid connection between the anterior and posterior rods.

Clinical Data

This study was retrospective, clinical, and comparative and approved by the institutional review board. Written informed consent was obtained from all patients preoperatively. From February 2008 to December 2013, 64 cases of lumbosacral

tuberculosis received surgical treatment. Surgery was performed on patients with progressive tuberculosis spondylitis at L_4 and lower levels who had neurological functional impairment, kyphosis, huge abscesses, and who did not respond well to conventional treatments. Patients were excluded if they had previous lumbosacral surgery or trauma at L_4 and/or lower levels, a history of adolescent scoliosis or kyphosis, ankylosing spondylitis, and/or a failure to comply with standard postoperative chemotherapy. All patients were diagnosed by clinical symptom presentation, three-dimensional computer tomography (CT), and magnetic resonance imaging (MRI). CT-guided biopsy was used for preliminary diagnosis and postoperative pathological studies, the latter of which were performed to confirm the final diagnosis. Sixty-four patients received chemotherapy immediately after the diagnosis and were divided into three groups: 18 to the P group, 22 to the AP group, and 24 to the A group. Study participants were followed up at 1, 3, 6, 12, 24, and 36 months post-operatively for an average of 27 months. Detailed information for all the patients are shown in Table 1.

All the patients in the P group underwent debridement and a single stage, posterior pedicle-screw fixation. In the AP group, all patients underwent a single stage, posterior pedicle-screw fixation that combined anterior debridement with an autogenous iliac bone graft. The A group received a single-stage anterior debridement, autogenous iliac bone-graft fusion in combination with the D-rod system. Clinical and radiological assessments were performed preoperatively, postoperatively, and during regular follow-up, but were reviewed retrospectively for the purposes of the study. Clinical assessments included operative time, blood loss, visual analog scale (VAS), Oswestry Disability Index (ODI), erythrocyte sedimentation rate (ESR), and neurological deficits according to Frankel Grade. Radiographs, CT scans, and MRI images of the lumbosacral spine were obtained for all patients, while lumbosacral angle and bone fusion was used for radiological assessments.

Table 1. — Clinical parameters of the patients.

	Gender		Mean age	Level					Course of disease	Follow-up
	M	F	(years)	L_4	L_5	$L_{4\text{-}5}$	L_5-S_1	S_1	(months)	(months)
P group	9	9	39.6 ± 10.6	5	4	4	3	2	7.1 ± 2.5	27.0 ± 10.5
AP group	12	10	36.9 ± 10.3	4	5	4	3	3	7.9 ± 1.9	28.4 ± 8.7
A group	14	10	41.3 ± 10.8	7	5	5	5	2	6.8 ± 2.3	25.8 ± 10.2

Operative Approach

P group : the patient was placed in the prone position and a longitudinal, medial skin incision was made. After the spinous processes and vertebral laminae were exposed, pedicle screws (Medtronic, Inc. Minneapolis, MN USA) were inserted in the vertebral bodies at the involved levels. Then, a hemi-laminectomy or complete laminectomy and facetectomy were performed. Next, the abscess, infected disc and endplates, caseous necrosis and granulation tissues, and sequestrated bone within the vertebral body were removed. Tricortical structural autografts with matched size and additional cancellous autograft strips were harvested. Finally, a posterolateral fusion of the instrumented segments was then carried out using a cancellous bone graft.

AP group : first, the patient was placed in the prone position. The standard pedicle-screw (Medtronic) technique was used to affix the screws and an autogenous bone graft was inserted on the lamina and facet joints. The patient was then placed in the supine position. A paramedial incision and retroperitoneal approach were used to reach the diseased vertebrae. After radical debridement, the autogenous iliac bone or mesh with the autogenous iliac bone was tightly inserted into the bone groove.
A group: All patients were operated on with the standard anterolateral approach via a retroperitoneal flank incision in the lateral position. Typically, the approach was made from the more severely damaged side of the spine. To reduce the risk of thrombosis or tearing of the iliac veins through excessive retraction, segmental vessels emanating from the aorta and vena cava were divided to facilitate medial retraction of these vessels. Special attention was given to the iliolumbar or ascending vein, a large venous branch overlying the L_5 body and draining into the lateral common iliac vein. We generally dissected and completely ligated this vessel early in the procedure. The L_5 root often runs in close proximity to this branch and should thus be identified and avoided. After exposing the abscess,

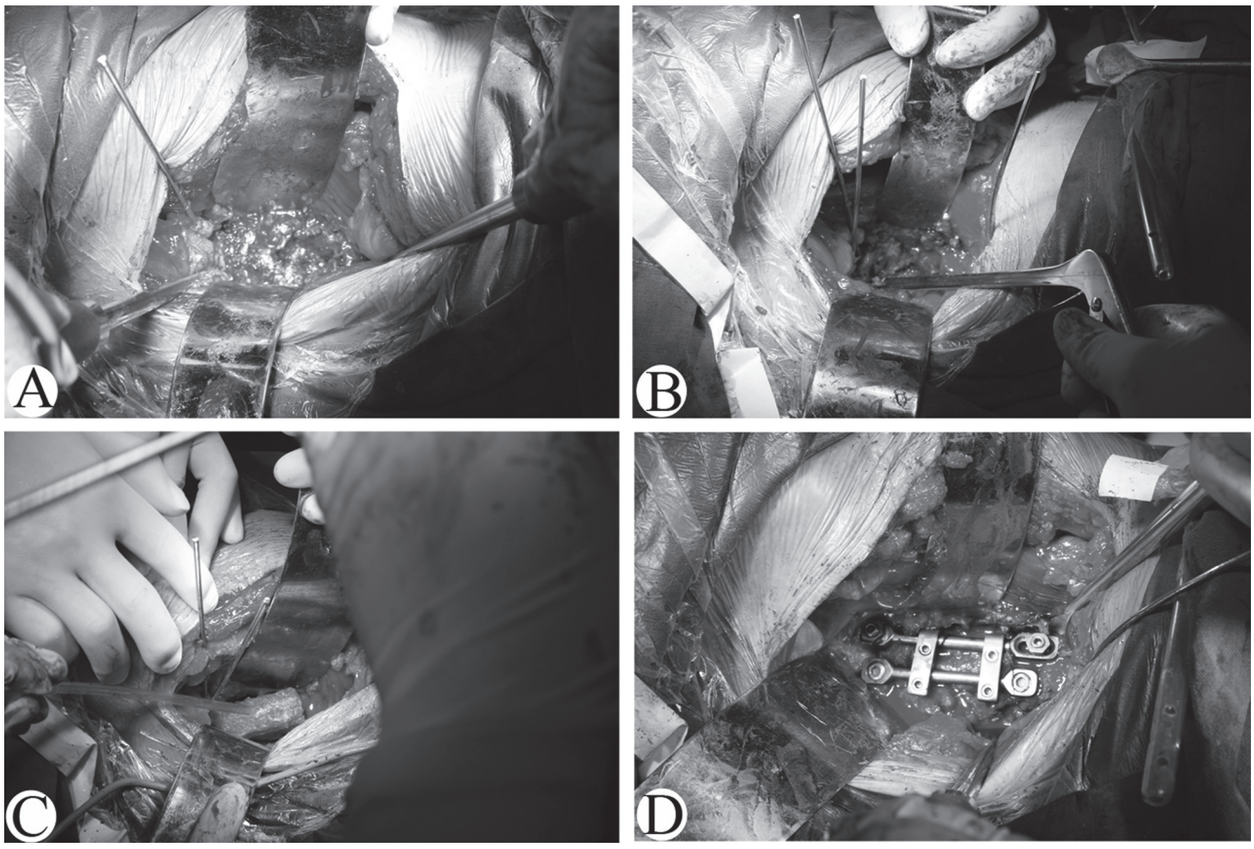

Fig. 2. — Surgical procedures of the anterior approach with the D-rod system. **(A)** Identification of the tuberculose focus. **(B)** Resection of the tuberculose focus and adjacent discs with conventional rongeurs. **(C)** Interbody autografting. **(D)** Installation and fixation of the D-rod system.

it was drained and any necrotic aterial within the body and the disc above and below the affected vertebral bodies were identified (Fig. 2A) and resected with conventional rongeurs and curettes down to the bleeding, normal bone (Fig. 2B). If the paravertebral abscess was large, drainage from a stab incision was necessary to identify the margin of the lesion foci. Slots were made in healthy, bleeding bone of the vertebral bodies above and/or below the affected vertebral bodies. After radical resection of the involved spine, distraction was performed between adjacent normal vertebrae to correct the kyphosis. The spinal defect was measured at this time. The resultant gap was repaired with bone grafts of suitable length that had been harvested from the iliac crest during the procedure (Fig. 2C). Finally, the D-rod system was inserted after interbody autografting (Fig. 2D).

Postoperative Treatment

Patients in the three groups were placed on strict bedrest for a minimum of two weeks. They were then allowed to walk with a lower lumbar orthosis, which was continued postoperatively for an average of six months. All patients received an antituberculosis chemotherapy regimen including isoniazid (5 mg/kg), rifampicin (10 mg/kg), pyrizinamide (25 mg/kg), and streptomycin (20 mg/kg) for three months, followed by rifampicin, isoniazid, and ethambutol for another three months, and finally rifampicin and isoniazid for half a year using the same dose.

Statistical Analysis

All data are presented as mean ± standard error of mean (SEM). Repeated analysis of variance

test, Least Significant Difference (LSD) t test and $\chi 2$-test were used for statistical analysis and satistical significance was determined using the SPSS17.0 program (SPSS Inc., Chicago, IL, USA). $p \leq 0.05$ was considered as significantly different.

RESULTS

Table 1 summarizes the patients' clinical parameters and disease characteristics. The nine men and nine women in the P group had a mean age of 39.6 ± 10.6 years and a mean duration of symptoms (before surgery) of 7.1 ± 2.5 months. There were 22 patients including 12 men and 10 women in AP group with a mean age of 36.9 ± 10.3 years and a mean duration of symptoms of 7.9 ± 1.9 months. Fourteen males and 10 females were enrolled in the A group. The mean age of patients was 41.3 ± 10.8 years and the course of the disease was 6.8 ± 2.3 months. The levels involved in the P group were L_4 (five cases), L_5 (four cases), $L_{4\text{-}5}$ (four cases), L_5-S_1 (three cases), and S_1 (two cases). In the AP group, the numbers of levels involved were four (L_4), five (L_5), three ($L_{4\text{-}5}$), six (L_5-S_1), and four (S_1). In the A group, the numbers of levels involved were seven (L_4), five (L_5), two ($L_{4\text{-}5}$), five (L_5-S_1), and five (S_1).

Table 2 summarizes the clinical assessment data. VAS, ODI, ESR and average hospital stay were compared within and amongst the three groups. Results indicated significant post-operative and final follow-up improvement of VAS, ODI and ESR at when compared with preoperative values. This improvement was observed for all three groups (all analyses, p = 0.000), which indicates that all three approaches were able to effectively treat lumbosacral tuberculosis. Moreover, the average hospital stay (in days) following the A and P approaches were markedly less than those following the AP approach (p = 0.000). Nevertheless, the average hospital stay between the P and A groups was not found to be statistically significant (p = 0.130). In the AP group, the mean duration of surgery was 197.7 ± 43.1 minutes, compared with 142.1 ± 17.8 minutes in the P group and 130.3 ± 21.9 minutes in the A group (p = 0.000). There was no difference in operation time between the A and P groups (p = 0.214). The mean blood loss volume during surgery was 380.6 ± 118.4 ml in the P group, 666.4. ± 165.4 ml in the AP group and 397.9 ± 118.2 ml in the A group. Statistical analysis revealed that there were significant differences in blood loss volume between the P and AP groups as well as the A and AP groups (p = 0.000). However, no statistical difference was found between the P and A groups (p = 0.684). There was no tuberculosis recurrence and no occurrence of tubercular peritonitis in the AP and A groups as compared with 11.1% (2/18) recurrence rate in the P group (not statistically significant, p = 0.093). The patients in AP group had a higher rate of complications when compared with those in the P and A groups, but this difference was not significant (p = 0.165). One case of iliac abscess occurred post-operatively in the AP group. The patient healed well after needle aspiration under Bmode ultrasound guidance, catheter flushing, and drainage. Another patient in the AP group had a minor bedsore. All patients in the P and A group had good recovery without erectile dysfunction, retrograde ejaculation, loosened or broken fixation, detached or subsided grafts, or other nerve root and/or spinal cord injuries.

The mean lumbosacral angle was significantly increased from the mean preoperative angle to the postoperative angle and remained stable until the final follow-up in all three groups (all analyses, p = 0.000). There was no difference in the lumbosacral angle in the postoperative (p = 0.099) and final

Table 2. — Summary of clinical assessment.

	P group	AP group	A group
VAS			
Preop	6.1 ± 1.1	6.6 ± 1.1	6.2 ± 1.2
Postop	2.9 ± 0.9	3.1 ± 0.7	2.6 ± 1.0
ODI (%)			
Preop	53.0 ± 12.0	58.6 ± 10.9	52.8 ± 13.9
Postop	29.6 ± 6.1	30.0 ± 6.7	33.4 ± 7.5
ESR(mm/h)			
Preop	67.4 ± 18.5	62.8 ± 16.5	61.7 ± 19.3
Postop	11.6 ± 3.8	9.6 ± 4.5	10.7 ± 5.2
Final	8.4 ± 3.9	6.6 ± 3.4	8.0 ± 4.3
Average stay (days)	11.7 ± 3.6	19.7 ± 3.6**##	6.2 ± 1.2
Operation time (mins)	142.1 ± 17.8	197.7 ± 43.1**##	130.3 ± 21.9
Blood Loss (ml)	380.6 ± 118.4	666.4 ± 165.4**##	397.9 ± 118.2
Recurrence (%)	11.1 (2/18)	0 (0/22)	0 (0/24)
Complication (%)	0 (0/18)	9.1 (2/22)	0 (0/24)

Compare with A group * p < 005, ** p < 0.01

Compare with A group * p < 005, ** p < 0.01

Table 3. — Summary of radiological assessment.

	Lumbosacral angles (°)			Bone fusion (months)
	Preop	Postop	Final	
P group	21.6 ± 1.4	28.5 ± 1.3$^{**\#\#}$	26.1 ± 1.2$^{**\#\#}$	7.2 ± 1.5
AP group	22.1 ± 1.3	29.2 ± 1.7$^{**\#\#}$	26.5 ± 2.1$^{**\#\#}$	7.0 ± 1.7
A group	21.4 ± 1.4	28.2 ± 1.5$^{**\#\#}$	26.8 ± 1.6$^{**\#\#}$	6.6 ± 1.2

Compare with pre operation in group * p < 005, ** p < 0.01
Compare with post operation in group * p < 005, ** p < 0.01

follow-up (p = 0.438) among the three groups. Bone fusion was evident at a mean of 7.2 ± 1.5, 7.0 ± 1.7, and 6.6 ± 1.2 months after surgery for the P, AP and A groups, respectively. No significant difference was observed amongst the three groups (p = 0.495) (Table 3).

Frankel Grade improved by 0 to 2 grades at the final follow-up. In the P group, seven patients with preoperative neurological deficits had complete recovery of neurological function. There were two patients with preoperative Frankel Grade B, only one of who recovered to Frankel Grade C. The second recovered to Frankel Grade D at the final follow-up. Two patients with preoperative Frankel Grade C recovered to Frankel Grade D at the final follow-up. In the AP group, eight patients with preoperative neurological deficits had complete recovery of neurological functioning, while one patient with preoperative Frankel Grade B was only able to recover to Frankel Grade C. One patient with preoperative Frankel Grade C had no recovery

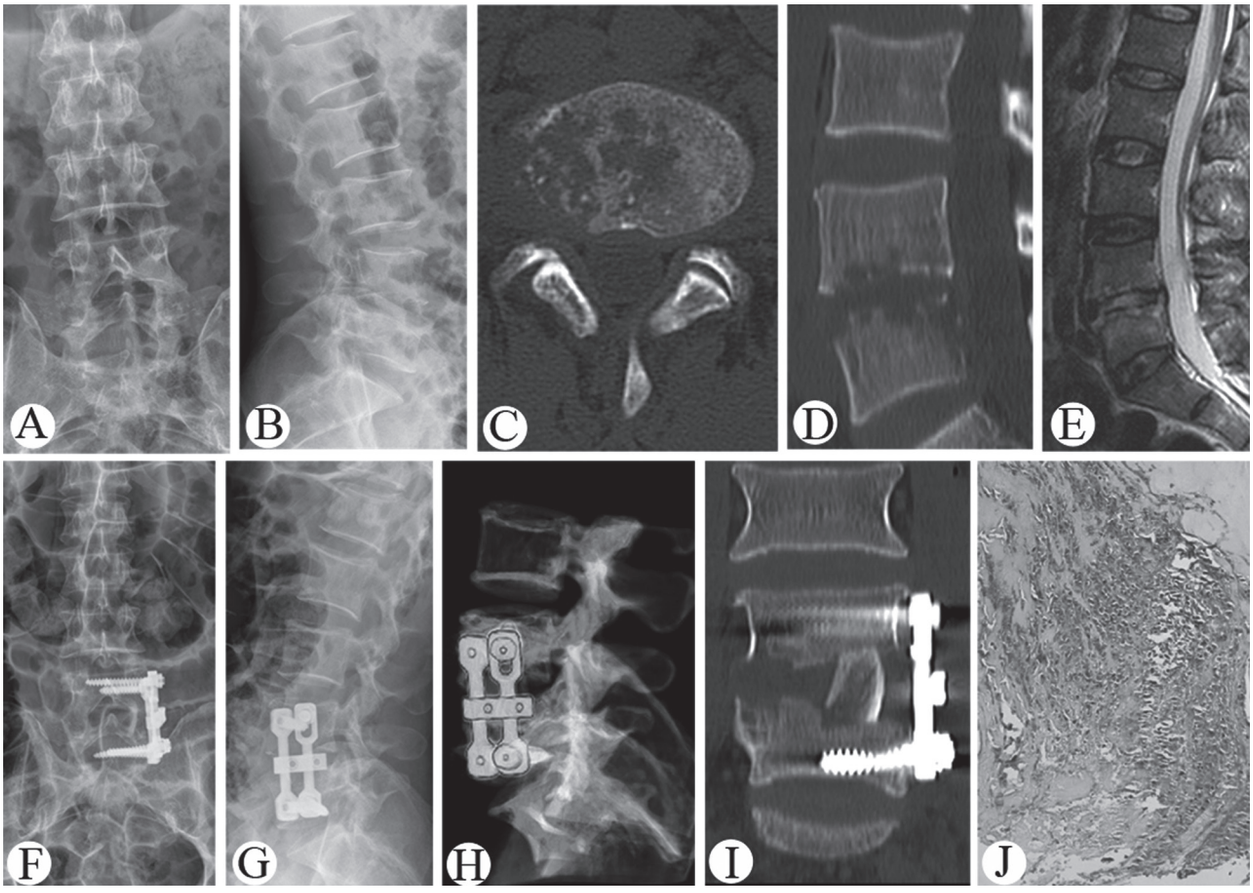

Fig. 3. — 51-year-old male patient with tuberculosis of $L_{4\text{-}5}$. **(A,B)** Preoperative antero-posterior (AP) and lateral X-rays showing damaged vertebral body of L_4 and L_5 and a narrowed disc space. **(C,D)** CT and 3D reconstruction showing vertebral body damage. **(E)** Preoperative MRI showing a change of vertebral body and intervertebral disc signals as a result of abscess formation. **(F,G,H,I)** Postoperative AP and lateral X -rays as well as CT showing lesions had been completely debrided and that the position of the D-rod system was accurate. **(J)** Postoperative pathological results confirming tuberculosis diagnosis.

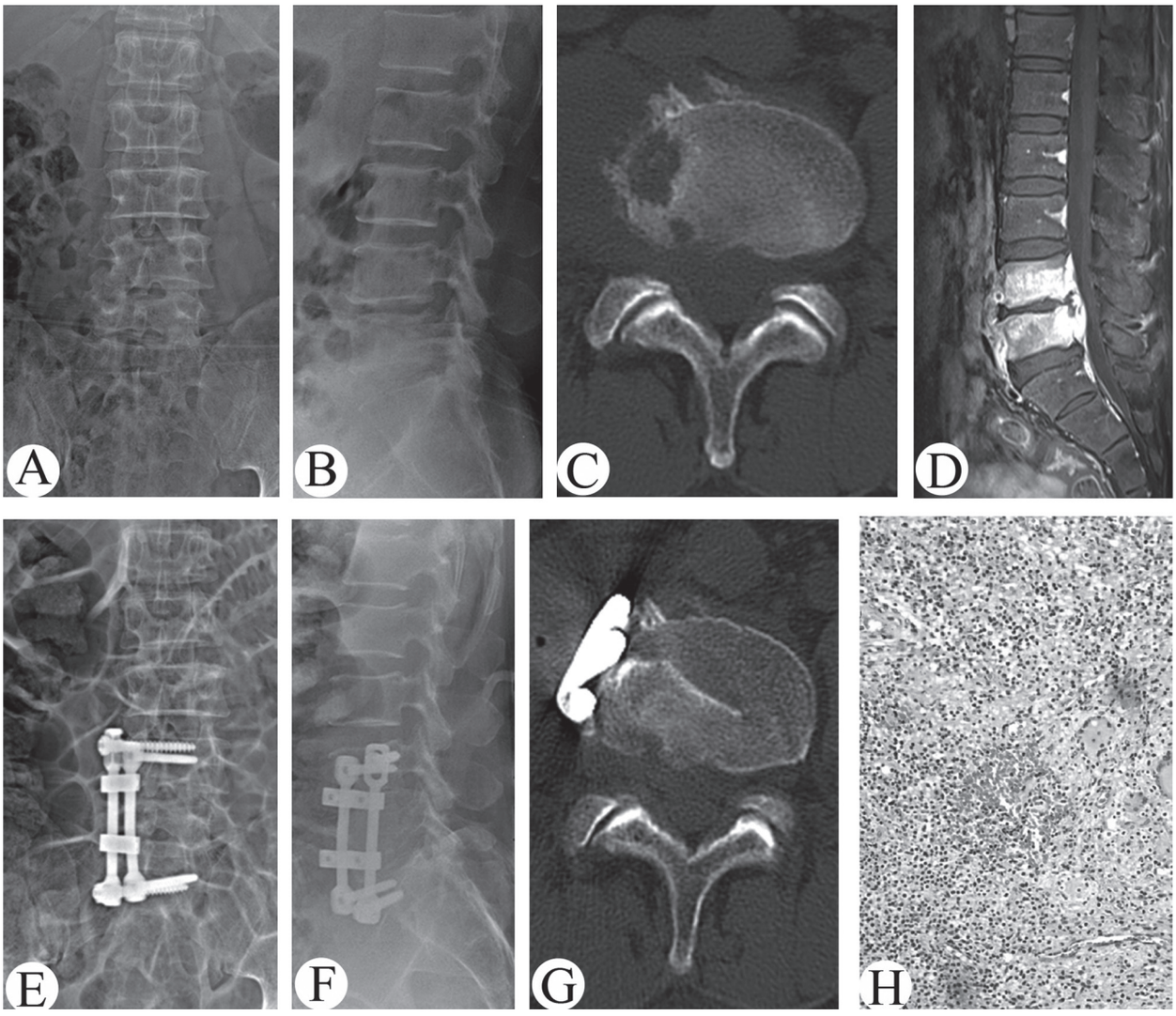

Fig. 4. — Radiographs from a 48-year-old patient who had $L_{4\text{-}5}$ tuberculosis. **(A,B,C,D)** Preoperative AP and lateral X-rays, CT, and MRI showing destruction of the vertebral body with abscesses. **(E,F,G)** Postoperative AP and lateral X-rays as well as CT showing the focus debridement, interbody autografting, and D-rod system. **(H)** Postoperative pathological outcome was consistent with preoperative diagnosis.

at the final follow-up. In the A group, complete neurological recovery was observed in 10 patients who presented with preoperative neurological deficits. Among the five patients with preoperative Frankel Grade C, two of them recovered to Frankel Grade D.

Typical cases in the A group are shown in Figs. 3 and 4.

DISCUSSION

Early diagnosis in combination with regular and adequate conservative antitubercular treatment can cure tuberculosis (*2*). Here, surgical treatment was only performed on patients with severe or progressive neurological functional impairment, an unstable spine, or severe spinal deformity.

Moreover, surgical treatment is also required for patients who do not respond well to conservative therapies, who have significant cold abscesses in their lumbo-sacral vertebrae, or cannot tolerate long-term immobilization.

Although chemotherapy can be effective for the treatment of spinal tuberculosis, residual back pain is relatively common because of kyphosis or hypolordosis of the lumbosacral junction (*17*). Indeed, external support may be required during chemotherapy if the associated back pain is severe and/or the duration of treatment is lengthy. Lordosis of the lumbar spine is associated with several biomechanical advantages and is essential for normal functioning (*9*). Hence, it is important to preserve normal curvature during treatment of spinal tuberculosis and minimize the chance of kyphosis. Compared to chemotherapy alone, surgical treatment of spinal tuberculosis results in rapid mobilization, spinal stabilization, and early fusion (*23,22,1,7,15*). Thus, we suggest that a combination of surgery and chemotherapy as the preferred treatment approach for tuberculosis of the lumbosacral segments with abscess formation and severe vertebral destruction (with or without neurological deficits).

Various surgical approaches have been described for the treatment of spinal tuberculosis. For instance, transpedicular drainage with posterior instrumentation may be effective for treating patients who receive an early diagnosis, but not as effective for those with major vertebral collapse and/or neurological deficits (*13*). Posterior debridement and instrumentation is another approach that has been widely used in the treatment of spinal tuberculosis (*7,20*). However, posterior instrumentation without anterior support may neither provide optimal spinal stability nor prevent the progression of kyphosis (*21*). A further approach is the use of anterior radical debridement accompanied by posterior instrumentation (*5*). Although this approach has been reported to be an effective means of treatment (*14*), the two-stage procedure is associated with increased operation time, prolonged anesthesia, increased blood loss, and an increased risk of complications when compared to one-stage procedures such as those previously described.

In the anterior approach, the tubercular focus can be thoroughly debrided using direct visual inspection. In addition, bony fusion is also relatively fast (*15*). In a long-term follow-up over an average of 20 years, of 26 cases of lumbosacral tuberculosis found that anterior debridement and bone graft fusion significantly reduced the incidence and degree of lumbosacral kyphosis when compared with conservative treatment (*16*). Furthermore, the anterior approach ensures that one position and one incision are needed during surgery, as debridement, fusion, and fixation can be completed simultaneously. As a result, operative time was greatly shortened (130.3 ± 21.9 min), blood loss was reduced (397.9 ± 118.2 ml), and hospital stay length was relatively short (6.2 ± 1.2 days). Additionally, patients that had undergone the anterior approach had improvements in their lumbosacral angles, VAS, ODI, ESR, and Frankel Grades at either postoperation or at the final follow up when compared with their preoperative condition. The rate of recurrence and complications has important implications for the evaluation of surgical treatment. There was no difference in rate of recurrence and complications among the three groups, which is likely due to the number of patients and follow-up time limitation. However, patients in treatment group A had promising results. Further studies with a larger sample size as well as longer outcome measures will help further clarify the validity of these findings. Collectively, these data support the hypothesis that the anterior approach is an effective method for lumbosacral tuberculosis treatment.

The anterior approach consisted of anterior and anterolateral approaches. Usually, a pach plate is used in the anterior approach. However, its use is limited by the site of vessel branch and cannot be applied when the tuberculosis focus is too large in L_5 because of the need for a large screw space. Superior hypogastric plexus spread in front of L_5 and damage to it can lead to regress gonobolia and aciesis in men and urinary incontinence in women (*4*). On the other hand, there is a lack of appropriate fixation in the anterolateral approach. Further, separate rod fixation is short of enough mechanics. In order to gain the advantages of anterior instrumentation

while minimizing the risk of vascular erosion, a novel anterior complex locking rod system (D-rod system) has been developed and was used in the present study. Mechanical tests have revealed that the D-rod system is strong enough and is safe for use in clinical populations, as there were no mechanical failures such as breakages and/or dislodgements. Since the locking screws are fixed in the anterior rod with the head below the surface of the rod, the fixation is strong and has a low profile. This orientation is particularly well-suited for anterior fixation since there are important organs and main blood vessels in front of the lumbosacral region. The D-rod system is inexpensive to produce and is relatively easy in its application. Importantly, the surgeon can contour the rod to arbitrary angle during operation to provide an individual fit that is patient-specific. The design of the separated body increases the fixed area of the D-rod system and enhances its mechanical stability. One end of the posterior rod is a sliding groove which permits distraction or compression depending on different fixed-lengths. The screw at the other end can flexible, thus increasing the angle effect.

SUMMARY

We summarize here our experience in treating lumbosacral segment tuberculosis with one-stage anterior decompression, bone grafting, and anterior instrumentation through the use of the D-rod system. Two important benefits of this surgical approach include (i) adequate removal of the infected material and (ii) early postoperative ambulation due to the firm internal fixation and correction of the spinal deformity. Furthermore, we found that one-stage anterior decompression, bone grafting, and anterior instrumentation were associated with dramatically reduced postoperative pain, deformity correction, and neurological recovery in patients with lumbosacral tuberculosis. Thus, this work demonstrates that one-stage anterolateral radical debridement, interbody fusion, and D-rod fixation can be an effective option for treating lumbosacral tuberculosis.

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