

Retroperitoneoscopic debridement and internal fixation for the treatment of lumbar tuberculosis

Yong Tang, MD, PhD^a, Jichao Ye, MD, PhD^a, Xumin Hu, MD, PhD^a, Wei Yang, MS^{b,*}

Abstract

To describe the retroperitoneoscopic debridement technique and evaluate the clinical outcome of internal fixation for the treatment of lumbar tuberculosis.

Twenty-eight patients were performed conventional laparoendoscopic technique (n=17) or laparoendoscopic single-site technique (n=11). Antituberculosis chemotherapy and thoracolumbosacral orthosis were given to all patients. The clinical outcomes were evaluated with preoperative and postoperative Visual Analog Scale, and radiographs with respect to sagittal angle and fusion status.

Average time of the 28 procedures was 220.6 ± 50.9 min (180–365 min). The average intraoperative blood loss was 108.6 ± 95.3 mL (50–400 mL). All patients showed significant improvement of their Visual Analog Scale back pain score at follow-up and were classified as having a radiographic fusion in this study. The mean sagittal angle was $11.2 \pm 3.6^\circ$ before operation, significantly improved to $3.7 \pm 2.4^\circ$ after operation. There were no recurrent infections during the follow-up period. Complications included loosening of anterior fixation and temporary deficit of the sympathetic nerve.

Retroperitoneal laparoscopic approach with CO₂ insufflation technique is a challenging but safe and effective procedure for lumbar spine tuberculosis. Retroperitoneal laparoendoscopic single-site can be used for anterior lumbar spine surgery, offer exposure for L1 through L5.

Abbreviations: ASIA = American Spinal Injury Association, BG = bone graft, LESS = laparoendoscopic single-site, PM = psoas muscle, VAS = Visual Analog Scale.

Keywords: laparoendoscopic single-site, lumbar spine, retroperitoneoscopic, tuberculosis

1. Introduction

Modern laparoscopic surgery began in the 1980s. The latest development of laparoscopic surgery includes the application of retroperitoneal approach. In 1992, Gaur^[1] reported the first use of balloon technology for dissection of the retroperitoneum, and it was successfully used in many retroperitoneal laparoscopic operations. Later on, spine surgeons extended the use of retroperitoneal laparoscopic exposures to the anterior lumbar

spine. McAfee et al^[2] reported on an anterior laparoscopic retroperitoneal approach for the anterior lumbar interbody fusion without CO₂ insufflation during the entire operative procedure. Olinger et al^[3] described a technique that allows anterior fusion of fractures of the thoracolumbar junction and the lumbar spine by a laparoscopic retroperitoneal approach using CO₂ insufflation. The significant advantages of retroperitoneal endoscopic spine surgery include not requiring entrance into the peritoneal cavity, and avoiding dissection near the large vessels and the hypogastric plexus.

In China, there is still a high incidence of spine tuberculosis. Recent studies have shown successful use of implants either anteriorly or posteriorly after debridement of necrotic tissues with no recurrence,^[4–6] but the ideal surgical procedure for spine tuberculosis (anterior, posterior, or combined techniques) remains a matter of debate. In our experience, it seems that anterior debridement is superior because it allows a safe decompression, radical removal of all affected tissue and direct visualization of the load-bearing anterior column for exact placement of the anterior graft. However, standard open retroperitoneal approaches to the lumbar spine are associated with substantial surgical morbidity.^[7] Therefore, minimally invasive techniques can be used for anterior debridement and subsequent reconstruction with bone graft. The present study was to clarify whether laparoscopic retroperitoneal approach using CO₂ insufflation coupled with anterior or posterior internal fixation are a feasible strategy for the treatment of lumbar spine tuberculosis. Furthermore, the study described a laparoendoscopic single-site (LESS) technique for exposures to the anterior lumbar spine.

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The authors have no conflicts of interest to disclose.

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

^a Center of Minimal Invasive Spine Surgery, Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangzhou, China, ^b Office of Drug Clinical Trial Institution, First Affiliated Hospital of Jinan University, Guangzhou, China.

* Correspondence: Wei Yang, Office of Drug Clinical Trial Institution, First Affiliated Hospital of Jinan University, Huangpu Avenue West 613, Guangzhou 510630, China, (e-mail: weiyang@jnu.edu.cn).

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2. Materials and methods

2.1. Subjects

This retrospective study was approved by our institutional review board. Twenty-eight endoscopic retroperitoneal procedures on the lumbar spine tuberculosis were performed at our institution between October 2009 and October 2015. There were 10 female and 18 male patients with a mean age of 47.3 years (22–78 years) (Table 1). The pathogenic levels involved 2 intervertebral space in 3 patients, 1 in 25 patients. Neurological assessments were made according to the scoring system of the American Spinal Injury Association (ASIA).^[8] Twenty patients were neurologically normal (ASIA E), 5 was ASIA D, and 3 was ASIA C. A definitive diagnosis was made by histological examination of diseased tissue. The standard 4-drug therapy of isoniazid (5 mg/kg), rifampicin (10 mg/kg), pyrazinamide (25 mg/kg) and streptomycin (15 mg/kg) was administered 2 weeks before operation, continued for 2 months and followed by rifampicin/isoniazid for 9 months (medicine treatment programs were designed and audited by Wei Yang). Patients were supported by a thoracolumbosacral orthosis for 3 months after operation. Patients were then followed up for 12 to 48 (29.2±12.1) months. Two endoscopic retroperitoneal techniques were performed, which included conventional laparoendoscopic technique and LESS technique. Conventional laparoendoscopic technique was performed in 17 patients who underwent anterior debridement, spinal-cord decompression and iliac bone graft with 1-stage posterior instrumentation. LESS technique was performed in 9

patients who underwent single-level fusion with 1-stage anterior debridement, bone graft and single rod anterior instrumentation, and 2 patients who underwent 2-level fusion. Endoscopic procedure was performed with left approach in 18 patients and right approach in 10 patients.

2.2. Conventional laparoendoscopic technique

The operation was divided into 2 parts. The first step was to fix the spine with pedicle screws by open or percutaneous approach. The second step was endoscopic examination via retroperitoneal approach, including anterior debridement and iliac crest bone block implantation. For the endoscopic procedure, the patient was placed in the lateral decubitus position. The operating table was tilted up 15° to increase the distance between the lower edge of the chest and the iliac crest. In order to relax psoas major muscle, the first 1.5 cm incision (Fig. 1A) was made at the lesion of axillary midline. Under direct observation, the abdominal muscle layer was separated in sequence by blunt dissection until peritoneal fat was found (Fig. 2A). The self-made balloon (ethics committee approval number: SYSMH 2007-12, approval date: September 1, 2007) was put into the retroperitoneal cavity, 400 mL air was injected, and the balloon was kept dilated for 3 to 5 minutes (Fig. 2B). Then a 10 mm air-tight trocar replaced the balloon (Fig. 2C) and the cavity was filled with carbon dioxide at a pressure of 13 mm Hg. Once the cavity was established, a 30°-endoscope was introduced, two 10 mm trocar trocars were placed in the anterior axillary line of the lower rib under (Fig. 1B) and the

Table 1
Patient demographics and clinical characteristics.

Sex	Age (yr)	ASIA	Level	Technique	Approach	Follow-up (months)	Operative time (min)	Blood loss (mL)	Fusion	VAS					Sagittal angle (degree)		
										Preop	2wk	3mo	6mo	Final	Preop	2wk	Final
F	40	C	L4/5	LESS	L	30	190	100	PF	10	5	3	2	2	6	5	5
F	22	E	L2/3	C	L	42	220	50	DF	4	2	0	1	0	12	5	5
F	45	E	L2/3	C	R	18	210	50	DF	6	2	0	1	2	16	5	5
M	34	E	L1/2, 2/3	LESS	R	18	305	260	PF	9	4	3	2	2	7	0	0
F	56	D	L1/2	LESS	L	48	250	50	DF	10	6	4	2	2	9	2	2
F	60	E	L3/4	LESS	L	48	190	50	DF	3	1	0	0	0	8	0	0
M	50	E	L3/4	LESS	L	42	200	80	DF	10	4	3	2	0	6	3	3
M	43	D	L3/4	C	R	46	180	50	DF	9	3	2	2	2	10	3	3
F	32	D	L2/3	LESS	R	24	200	55	PF	10	6	4	3	3	8	0	3
F	53	E	L1/2	C	R	24	200	100	DF	9	3	2	2	2	13	5	5
M	38	E	L5/S1	LESS	L	12	200	135	DF	9	3	2	2	2	6	0	3
M	68	E	L3/4, 4/5	LESS	L	18	180	120	DF	9	2	1	1	0	8	0	0
M	56	E	L4/5	C	L	12	310	400	DF	10	6	4	3	3	15	5	5
M	47	E	L3/4	C	L	30	190	100	DF	9	2	1	1	2	11	3	3
M	45	E	L4/5	C	R	36	180	55	PF	9	2	1	1	3	12	5	5
M	78	E	L2/3, 3/4	C	R	12	365	300	D	10	6	4	3	3	18	8	9
M	45	D	L2/3	C	L	30	200	115	DF	9	2	1	1	2	12	5	5
F	26	E	L1/2	C	L	36	180	60	DF	4	1	0	1	0	15	5	5
M	36	C	L3/4	C	R	36	240	70	DF	3	1	0	1	2	15	5	5
F	39	E	L3/4	C	L	26	200	95	DF	10	4	3	2	2	12	5	5
M	47	E	L4/5	LESS	R	30	255	140	PF	4	1	0	1	0	6	3	3
M	48	E	L1/2	C	L	42	260	100	DF	10	4	3	2	2	11	3	3
M	52	C	L1/2	C	L	18	240	100	DF	4	1	1	1	2	13	5	5
M	51	E	L2/3	LESS	L	26	185	60	PF	9	2	1	0	0	14	5	5
M	56	E	L2/3	C	L	42	185	70	DF	5	1	1	1	0	11	5	5
M	58	E	L1/2	C	R	12	216	60	PF	4	1	1	1	3	17	3	3
F	65	D	L2/3	C	L	30	245	70	DF	10	3	1	1	0	16	5	10
M	33	E	L4/5	LESS	L	30	200	145	DF	4	1	1	1	1	6	5	5

Technique: C (Conventional laparoendoscopic technique). D = Death, DF = definitive fusion, L = left, LESS = laparoendoscopic single-site, PF = probable fusion, R = right, VAS = Visual Analog Scale.



Figure 1. Conventional laparoendoscopic technique. The first trocar was inserted at the diseased level in the mid-axillary line (A). The second trocar (B) was placed at the subcostal anterior axillary line, and the third trocar was placed at anterior axillary line of the iliac crest (C).

anterior axillary line of the iliac crest (Fig. 1C), respectively. From this position, under visual control, the retroperitoneal space was enlarged by ultrasonic scalpel, the psoas muscle overlying the lumbar spine was mobilized dorsally, and the segmental vessels were divided (Fig. 2D). The tuberculosis lesion, including abscesses, affected vertebrae and discs, was debrided until healthy bleeding margins were obtained. In cases of large paravertebral abscesses, the abscess was drained and debridement was performed directly through the transpsoas approach. The supporting bone graft was then inserted into this position and a trocar was temporarily removed in order to bring the bone graft into the retroperitoneal cavity.

2.3. LESS technique

The patient was placed in the lateral decubitus position after induction of general anesthesia. Before the patient was prepared for surgery and prior to skin incision, the diseased vertebra was marked on the skin under fluoroscopic control. A single transverse incision of about 3 to 4 cm starting from the mid-axillary line was made in projection to the lesion (Fig. 3A). A balloon dissector was placed into the initial retroperitoneal space,

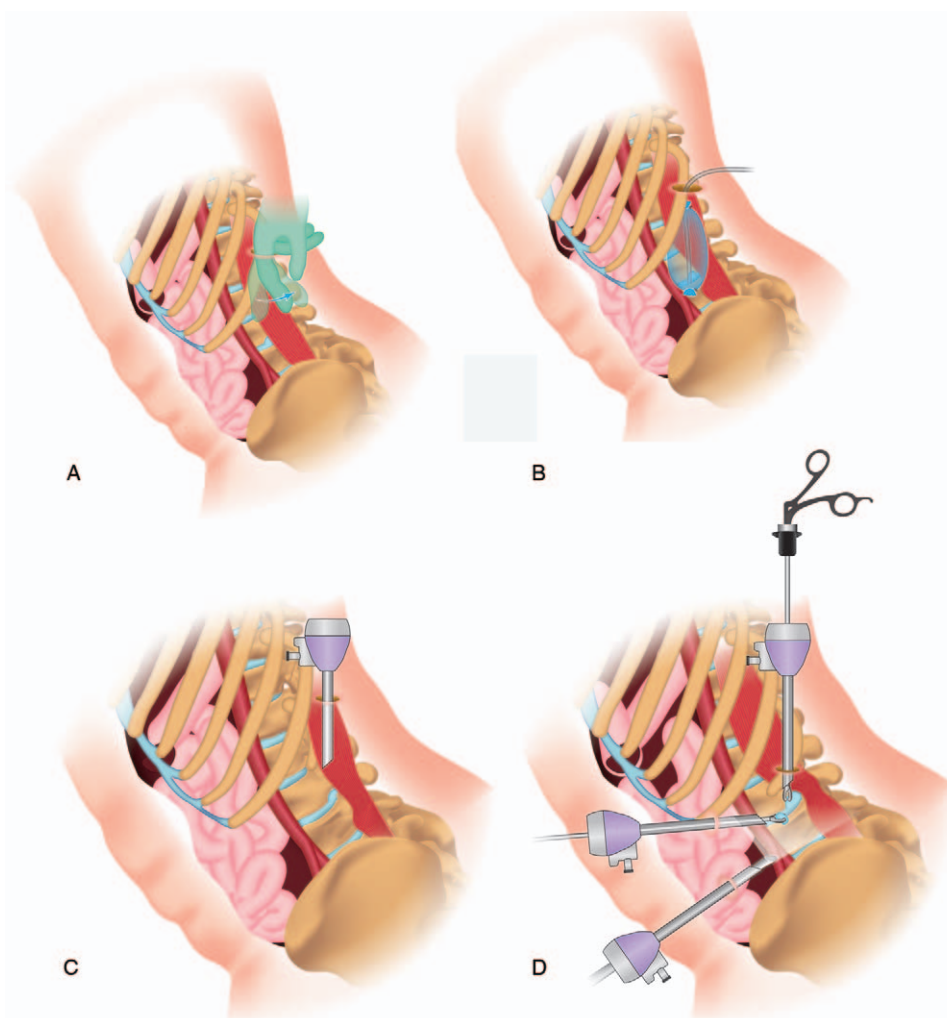


Figure 2. Procedure of conventional laparoendoscopic technique. Blunt dissection of the peritoneal fat (A). The self-made balloon was inserted into the retroperitoneal cavity, 400mL air was injected and kept for 3 to 5 minutes (B). A 10mm air-tight trocar replaced the balloon (C). Debridement and bone graft transplantation was performed under visual control (D).

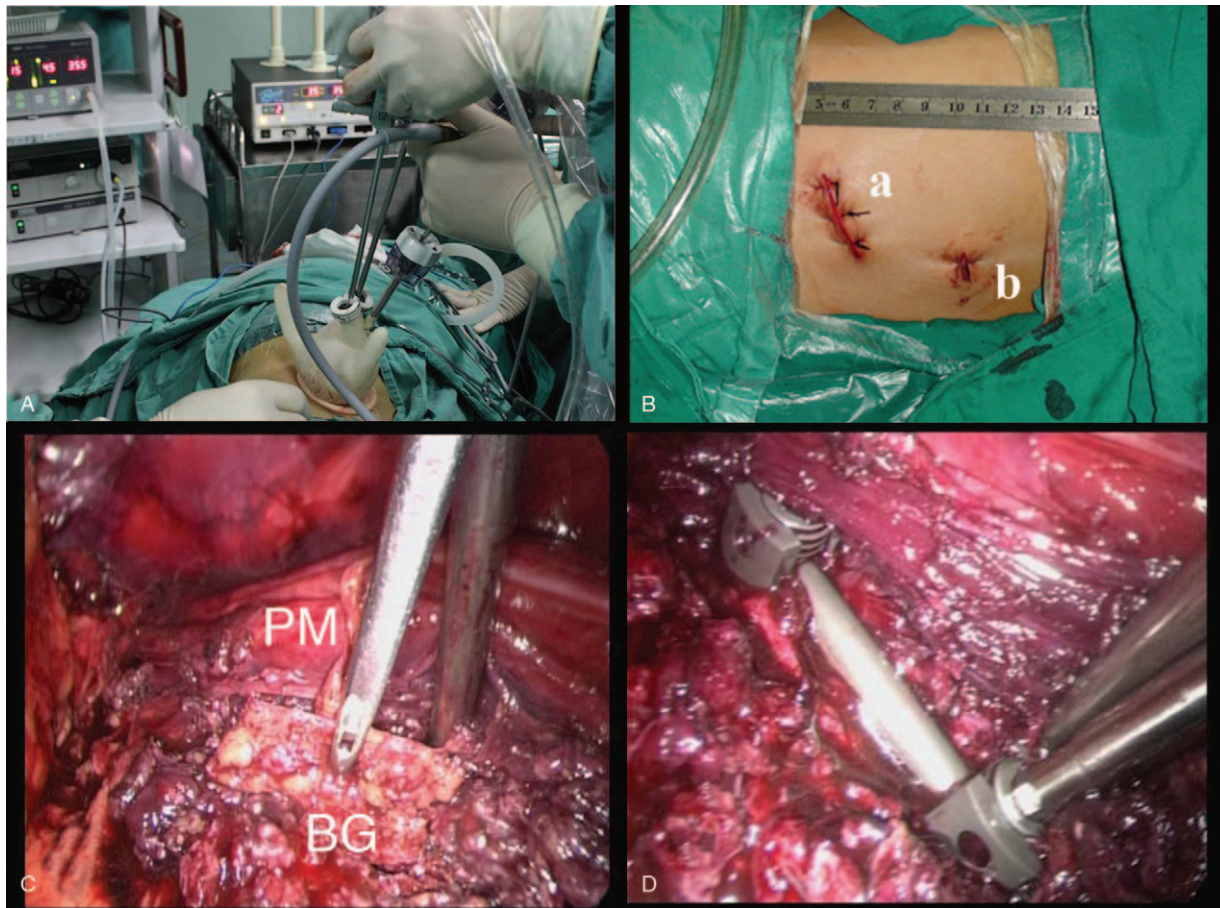


Figure 3. LESS technique. (A, B) An approximately 3 to 4 cm transverse single incision was made in projection to the lesion. The procedure was done through a homemade multichannel single-port access device. (C) A supporting bone graft was inserted into the position. (D) The rod was fixed with 2 screws drilled into the neighboring vertebral bodies. BG = bone graft, PM = psoas muscle.

and filled with 400 ml of air to enlarge the retroperitoneum. A self-made multichannel single-port device was inserted to establish the channel. This self-made surgical device was provided by urology department, which has been approved for regular use in this hospital, and the paper has been published.^[9] This device was made from 2 stretchable rings and a surgical glove with trocars and valves attached to its fingers. The bigger ring had a diameter of 7 cm, the smaller ring had a diameter of 5 cm that was fixed at the middle part of the glove. The wrist part of the glove was turned over, the smaller ring was inserted into the retroperitoneal cavity; the bigger ring was left outside and was fixed to the margin of the glove. Three 10-mm trocars were fixed to the glove fingers, followed by insufflations of the retroperitoneal cavity with CO₂ to 13 mm Hg. The tuberculosis lesion was debrided, and the bone graft was brought into the retroperitoneal cavity via multichannel single-port (Fig. 3C). The preselected vertebral screws and rod (Weigao Orthopaedic Devices CO. LTD, China) were introduced into the retroperitoneal cavity in the same manner and brought into position above the graft. The rod was fixed with 2 screws drilled into the neighboring vertebral bodies (Fig. 3D). When 2-level fusion with single rod instrumentation was performed, 1 more 12-mm trocar was placed in the mid-axillary line in projection to the distal vertebral body (Fig. 3B). The screw was drilled into the distal vertebral body via this trocar and fixed with the rod.

2.4. Clinical assessment

X-rayed, erythrocyte sedimentation rate, C-reactive protein, routine blood tests, hepatic function were measured before and after the operation (at 2 weeks, 3 months, 6 months, and then every other year), and 3-D CT scan was performed at the final follow-up. Sagittal angle was measured by intersecting the angle between parallel lines from the upper endplate of the upper vertebra and lower endplate of the lower vertebra. Fusion assessment was determined by plain X-ray according to the criteria by Lee et al.^[10] Definitive fusion or probable fusion that met Lee's criteria was classified as spinal fusion. Visual Analog Scale (VAS) from 0 to 10 was used to assess the patient's pain severity (0 for absence of pain, 10 for maximum pain).^[11]

2.5. Statistical analysis

Statistical analysis of the data was performed using SPSS 17.0 software (SPSS Inc., Chicago, IL). The change of kyphosis angle and VAS were compared using a 2-sample *t* test. Probability values of less than .05 were considered to be significant.

3. Results

3.1. Summary of patients

The operative time needed for the procedure reflects the learning curve. The average time for the endoscopic approach

was 6 hours for the first case and 3 hours for the last. The average time of the 28 procedures was 220.6 ± 50.9 minutes (180–365 minutes). There was no conversion to open. All patients were extubated at the end of the operation. The average intraoperative blood loss was 108.6 ± 95.3 mL (50–400 mL), including the blood loss from the iliac crest wound and the loss due to concomitant injuries. Assessment of ASIA grade revealed that patients with neurological deficit made good recovery (ASIA E).

3.2. Severity of pain

All patients showed significant improvement of their VAS back pain score at follow-up. The mean VAS pain score was 7.6 ± 2.5 before operation, improved to 2.8 ± 1.8 ($P < .05$) 2 weeks after operation, 1.7 ± 1.5 ($P < .01$) 3 months after operation, 1.5 ± 0.8 ($P < .01$) 6 months after operation and 1.5 ± 1.1 ($P < .01$) at the final follow-up. There was no significant difference observed between VAS pain score after operation.

3.3. Radiographic fusion

At final follow-up, all patients had plain X-ray films and CT scan. According to the criteria by Lin et al,^[9] 20 patients showed definitive fusion and 7 patients probable fusion. One patient (male, 78 years) died of abdominal aortic aneurysm 1 year after operation. Twenty-seven patients (27/28, 96.4%) were classified as having a radiographic fusion in this study (Fig. 4).

3.4. Sagittal angle

The mean sagittal angle was $11.2 \pm 3.6^\circ$ before operation, 2 weeks after operation the mean sagittal angle significantly improved to $3.7 \pm 2.4^\circ$ ($P < .01$). At the final follow-up, the mean sagittal angle was $4.1 \pm 2.2^\circ$ ($P < .01$), the sagittal angle was well corrected. One patient with osteoporosis exhibited loss of 5° by the final follow-up. There was no significant difference observed between sagittal angles after operation.

3.5. Complications

There were no recurrent infections during the follow-up period. One patient of anterior instrumentation (1/11, 9.1%) who underwent single-level fusion was found to be loose after falling down 3 months postoperatively. Removing anterior instrumentation and posterior stabilization of the spine with pedicle screws were performed for revision, and the patient had an uneventful postoperative recovery. Two patients (2/28, 7.14%) developed a temporary deficit of the lumbar sympathetic nerve whose temperature of affected leg increased. The symptom disappeared 1 month after operation.

4. Discussion

Among the 22 countries with the highest TB burden in the world, China ranks third. There are about 1 million cases of tuberculosis every year in China.^[12] Chemotherapy, adequate rest and

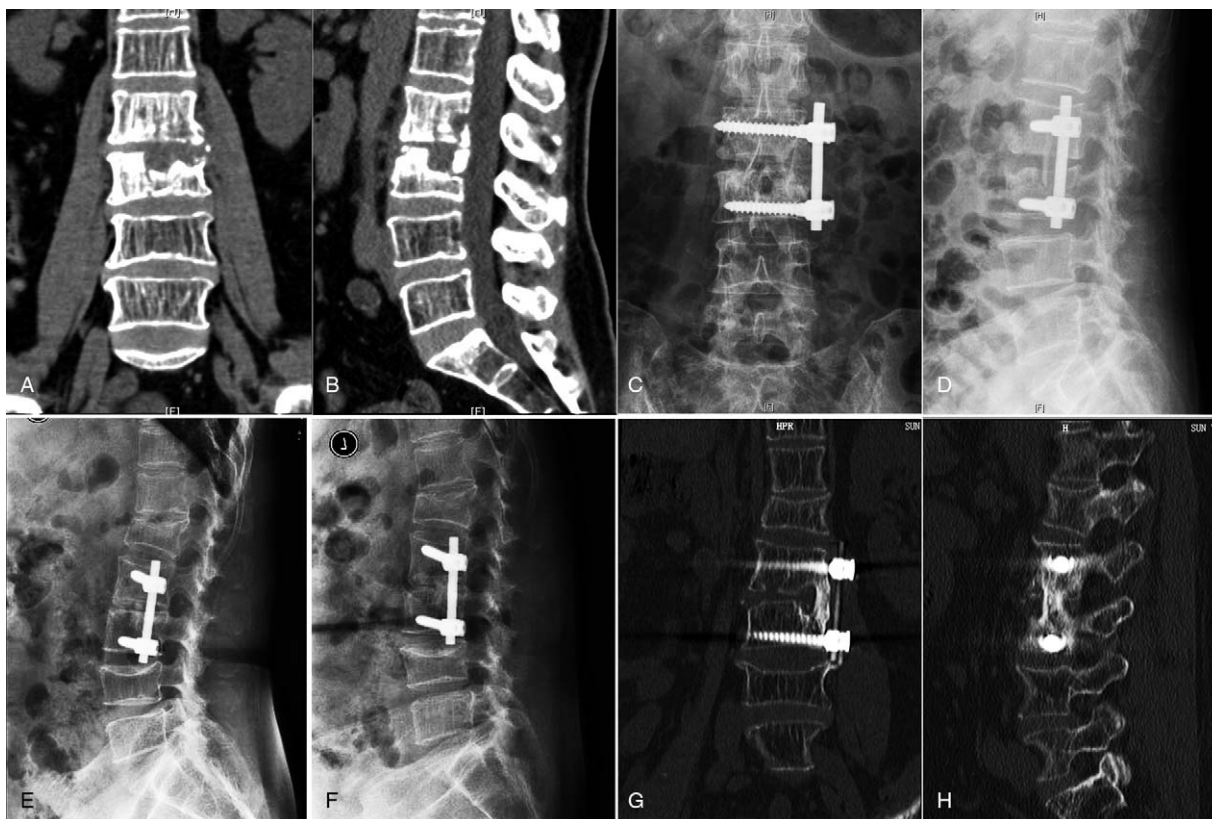


Figure 4. A 55 years old female, (A, B) coronal and sagittal CT scan showed marked destruction of L2, L3 vertebral bodies, the remaining part of the vertebral body was more than 50% of the original. (C, D) Postoperative X-rays illustrated the position of bone graft and implants. (E, F) Eighteen-month follow-up flexion-extension radiography showed definitive fusion, (G, H) coronal and sagittal CT scan showed solid bony fusion of bone graft and adjacent vertebral body. CT = computed tomography.

nutrition are the mainstream of therapy for spinal tuberculosis. There is a controversy in the literature about the necessity of additional surgical intervention to spinal tuberculosis.^[13] However, there are always demands of short hospitalization, and rapid return to work in China. Laparoscopic spine surgery could be designed for the patients who are motivated to return to a higher quality of life, and reserved for diagnostic biopsy, spinal instability, severe deformity, myelopathy, severe sepsis, significant abscesses, and open draining sinuses.^[14]

Since the report of Hodgson et al in 1960,^[15] anterior approach has been advocated as the treatment of choice for spine tuberculosis by using strut graft to fill the defect created and to reconstruct the anterior column with anterior or posterior internal fixation after drainage and debridement of the cold abscess.^[16,17] Potential benefits of surgery were less kyphosis, immediate relief of compressed neural tissue, quicker relief of pain, higher percentage of bony fusion, quicker bony fusion, less relapse, less bone loss, earlier return to previous activities, and shorter hospitalization of patients.^[14,18] Retroperitoneal laparoscopy was used for the diagnosis of anterior sacroiliac joint tuberculous arthritis previously.^[19] With the help of urological surgeons, we can consider extending the advantages of retroperitoneal laparoscopic exposures to the anterior lumbar spine, and performing complex procedure more than biopsy without extended invasion.

We described 2 endoscopic retroperitoneal techniques, which included conventional laparoendoscopic technique and LESS technique. The indications for conventional laparoendoscopic technique include a sagittal angle over 10°, L1 or S1 vertebral body is involved, and the remaining part of the vertebral body is less than 50% of the original. A mild kyphosis can be successfully corrected by the anterior approach alone, but for kyphosis of more than 10° the conventional laparoendoscopic technique by itself provides only limited correction. In cases of L1 or S1 vertebral body is involved, anterior fixation of L1 or S1 vertebral body need entrance into the thoracic or peritoneal cavity. If the remaining part of the vertebral body is less than 50% of the original, anterior fixation of next healthy vertebra will be need. In these situations, we chose to perform 1-stage posterior fixation.

In the present study, we developed a retroperitoneal LESS technique with homemade single port and conventional laparoscopic instruments. LESS technique can reduce the multiple-trocar related parietal trauma. To our knowledge, there is no report of retroperitoneal LESS technique for anterior lumbar spine surgery previously. LESS technique was performed in patients who needed limited debridement, and the remaining part of the vertebral body is more than 50% of the original. The incision of LESS technique is in projection to the lesion, and allows instruments to be operated directly over diseased vertebral body. Through the working port, abscess of contralateral side can be drained through the intervertebral space. The bone graft, screws, and rod can be brought into the retroperitoneal cavity via single-port directly, and screws can be drilled into the vertebral bodies parallel to the end plate. When 2-level fusion with anterior single rod instrumentation was performed, 1 more 12-mm trocar needed to be placed in the mid-axillary line in projection to the distal vertebral body so that the screw can be drilled into the vertebral bodies parallel to the end plate. However, lack of instrument triangulation, dissection through a single port is more difficult than conventional multi-port laparoscopy.

Single rod system was selected for anterior fixation which adapted to the laparoscopic procedure. Significant drawback of single rod anterior instrumentation is possible inadequate

fixation. With this concern in mind, the patients were recommended to have a thoracolumbosacral orthosis for 3 months after operation, all patients were classified as having a radiographic fusion by the final follow-up in this study. However, the anterior instrumentation of 1 patient (1/11, 9.1%) was found to be failed due to falling down and revision with posterior fixation was performed. We sought to remedy the anterior fixation instability by selecting a dual-rod or low-profile plate system.

In fact, minimally invasive anterolateral approaches to the lumbar spine are also concerned, especially lateral approach for anterior lumbar interbody fusion.^[20–22] These approaches use a modification of the retroperitoneal approach to the lumbar spine assisted by an expansible channel system. This type of approaches gradually separates the muscle fiber after the blunt separation of muscle bundle, and the visual field is set up through a tubular retractor, so extensive stripping of paraspinous soft tissue can be avoided. The overall design concept of these tubular system is in line with the surgeon's operating habits, allowing surgeon to perform surgical operations such as intervertebral discectomy, nerve root decompression, and interbody fusion under the direct view. However, when compared with tubular system to the lumbar spine in the surgery of lumbar tuberculosis, we consider that retroperitoneal laparoendoscopic technique not only basically includes those advantages above, but also has at least 2 important advantages over tubular system according to our clinical experience. On the one hand, tubular system obtains smaller visual field than the retroperitoneal laparoendoscopic technique, hence it is not conducive to the situation which the scope of the disease is large. On the other hand, it is also the most important thing that in the event of a segmental artery bleeding during the surgery, the laparoendoscopic technique can easier to perform a hemostasis operation, which will greatly reduce the risk.

Two patients (2/28, 7.14%) developed an injury of the lumbar sympathetic nerve. The psoas is mobilized from the spine and retracted posteriorly in this series. The paravertebral sympathetic chain medial to the psoas muscle need to be identified and retracted in a medial direction. The key to avoid damaging sympathetic chain is to avoid transverse cuts until all the prevertebral tissue has been elevated. In cases of large paravertebral abscess or big psoas muscle covers almost the whole lateral aspect of the vertebra, a psoas splitting approach could be used. Problems with the psoas splitting technique include difficult exposure, the possibility of inducing neuropathia in the psoas muscle and geniofemoral nerve injury.^[23]

After 12 to 48 months' follow-up, the results of these 2 endoscopic retroperitoneal techniques described above were proven. Especially we prove that retroperitoneal LESS technique for anterior lumbar spine surgery can be considered safe and effective. Nevertheless, we still tend to choose conventional laparoendoscopic technique in the treatment of lumbar tuberculosis for its several advantages over LESS technique. Firstly, as for LESS technique, because all the operating instruments are entered through a single channel, the operating space is narrow and the instruments may cross interfere with each other, while incisions of conventional laparoscopic surgical have certain distances and they are relatively independent, which can avoid the conflict between the instruments during the operation. Secondly, because the instruments of LESS technique are often in the same parallel line with the lens, they are also easy to cover the lens. Sometimes, in order to give consideration to the operation of the apparatus, the lens may need to make the proper concession to obtain the

best visual field. But in turns of conventional laparoendoscopic technique, since the instruments can be operated in a relatively independent space, a larger field of vision will be obtained, and the scope of operation is more flexible. Moreover, LESS technique has a theoretical risk of the attachment of Mycobacterium tuberculosis due to the demand of placing internal fixations in the focus area, however, internal fixation is relatively isolated from the focus if using the conventional laparoendoscopic technique, so this risk can also be avoided. Finally, based on the reasons above, conventional laparoendoscopic technique is easier to perform, which makes the operation time shorter.

Our results show that retroperitoneal laparoscopic approach is a safe procedure for lumbar spine tuberculosis without serious complications. The laparoscopic system provides direct optical illumination and magnifying images are more conducive to the evaluation of the operative segment of the spine. The exposure and observation of spine make the anterior debridement of lumbar in 1 stage bone grafting and internal fixation be possible. Retroperitoneal laparoscopic approach with CO₂ insufflation technique can offer exposure for L1 through L5 that well observation can be obtained. LESS technique was performed in patients who needed limited debridement with 1-stage anterior surgery.

However, there are still several limitations. Due to high requirements of laparoscopic operation skills and three-dimensional thinking, the learning curve for laparoscopic spine surgery is steep and remains technically challenging, laboratory training and laparoscopic surgeons' assistant are recommended thus. Furthermore, larger studies should be implemented to better understand the risk/reward ratio.

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None.

Author contributions

Conception and design: Yong Tang, Wei Yang. Acquisition of data: Yong Tang, Jichao Ye, Xumin Hu. Analysis and interpretation of data: all authors. Drafting the article: Yong Tang, Wei Yang. Critically revising the article: Yong Tang, Wei Yang. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Yong Tang. Statistical analysis: Yong Tang, Wei Yang. Study supervision: Wei Yang.

Investigation: Jichao Ye, Xumin Hu.

Methodology: Yong Tang, Wei Yang.

Resources: Jichao Ye, Xumin Hu.

Supervision: Wei Yang.

Writing – original draft: Yong Tang.

Writing – review & editing: Yong Tang.

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