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Spinal Alignment/Deformity

Circumferential correction of spinal deformity and instability secondary to bacterial spondylodiscitis



Azeem A. Rehman, MD*, Ziev B. Moses, MD, Mazda K. Turel, MD, Ravi S. Nunna, MD, Mena G. Kerolus, MD, Samuel J. Meza, MD, Ricardo B.V. Fontes, MD, PhD

Department of Neurosurgery, Rush University Medical Center, Chicago, IL

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ABSTRACT

Background: Spinal deformity as a sequela of nontuberculous spondylodiscitis is a rarely discussed clinical entity. Sagittal plane deformity, segmental instability, and persistently active infection overlap in these patients resulting in severe restriction in activity and quality of life. The presence of multiple medical co-morbidities restricts surgical options but nonoperative care may be ineffective and result in persistent, refractory discitis for years. We describe our experience with vertebrectomy and long-segment fixation for patients with postinfectious thoracic or lumbar deformity.

Methods: A retrospective chart review of 23 consecutive patients who underwent vertebrectomy and long-segment fixation for thoracic or lumbar deformity secondary to nontuberculous bacterial spondylodiscitis was performed. Pre, peri- and postoperative data is compiled and analyzed with a focus on the perioperative management algorithm to safely perform an extensive reconstruction in this very sick patient population.

Results: Extremely low preoperative quality of life was evident with 87% (20/23) of patients bedridden primarily due to pain despite 70% (16/23) of patients being strong enough to ambulate (Frankel D or E). Most patients (87%) already had an identified infection under adequate treatment either through blood cultures, prior biopsy or decompressive surgery. A single-stage posterior-only was the primary surgical approach utilized in the majority (83%) of cases. Complications were present in 100% of patients, most commonly perioperative anemia and hypotension requiring vasopressor support and aggressive blood product replacement. One in-hospital mortality occurred secondarily to pulmonary embolism. Mean preoperative segmental angle was 18 ± 10 degrees of kyphosis which was corrected to 1 ± 9 degrees of lordosis (p=.001). The mean correction of the segmental angle was 19 degrees (standard deviation 23 degrees). Visual analogue scale scores improved from a preoperative value of 8.8 ± 0.9 to a postoperative value of 2.5 ± 1.4 (p<.001), which was obtained at the last outpatient follow-up (mean 631 days after surgery). Full self-care including ambulation was achieved in 18/23 (78%) patients, and the infection was successfully treated in 22/23 (96%) patients after long-term antibiotics.

Conclusions: Patients with refractory spondylodiscitis on appropriate care and antibiotics are typically considered extremely poor surgical candidates despite nonoperative care often being ineffective. Postinfectious deformity may also be so severe as to preclude a limited surgical treatment strategy. This study suggests that extensive circumferential reconstruction for deformity secondary to bacterial spondylodiscitis can be effective in restoring these extremely sick patients to self-care and ambulatory status.

Background

While the term "discitis" is frequently used to describe an infection of the intervertebral disc, this infection typically includes the adjacent vertebral endplate and vertebra. Thus, a more appropriate term may be

pyogenic vertebral discitis/osteomyelitis (PVDO). It has a very important place in spine history as one of the first pathologies successfully treated through surgery. In fact, popular surgical techniques for degenerative pathology such as anterior lumbar interbody fusion were initially developed to address spinal infections [1].

E-mail address: AzeemARehman@gmail.com (A.A. Rehman).

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^{*} Corresponding author. Azeem A. Rehman, MD, Department of Neurosurgery, Rush University Medical Center, 1520 West Harrison Street, 6th Floor, Chicago, IL 60607.

PVDO is a historically rare pathology, however the incidence is increasing with one United States epidemiological database analysis reporting an increase from 2.9 admissions per 100,000 to 5.4 admissions per 100,000 over a 15-year span [2]. A separate Japanese study noted an increase in PVDO from 5.3 admissions per 100,000 to 7.4 admissions per 100,000 over only a 3-year span [3]. Although the literature supports a low in-hospital mortality ranging from 2.2% [2] to 6% [3], there are published reports of mortality being as high as 15% [4]. A growing population of immunosuppressed patients and increasing rates of medical conditions that predispose to PVDO such as diabetes mellitus, chronic kidney disease, and intravenous drug use has contributed to its increasing incidence globally [2,3].

Clinical presentation is stereotypical with severe pain secondary to inflammatory and structural compromise. Classically, osseous destruction predominantly involves the anterior column. Epidural abscess or pathologic fracture may also lead to neural element compression. When the anterior column fails structurally, collapse and deformity may ensue typically in the form of kyphosis, although anteroposterior or lateral listhesis may also be present if posterior elements are compromised. Although postinfectious deformity is frequently neglected, Srinivasan et al. [5] found that 44% of those individuals with bacterial spinal infections developed a deformity primarily in the form of kyphosis.

The mainstay of treatment for PVDO is prolonged antibiotic therapy, with surgery usually reserved for symptomatic neural element compression or pathogen identification. Less commonly, osseous destruction may be so severe as to lead to clinically significant deformity, instability, or large cavities that themselves serve as infection reservoirs. These exceptionally severe cases are challenging to reconstruct due to failure of the anterior column and the frailty of these patients, not lending themselves well to posterior-only, short-segment fusions. There is compelling debate in the literature on what is the optimal management of these complex patients and while there have been algorithms proposed, there is no established consensus. We report our experience with aggressive surgical intervention utilizing deformity correction techniques for those PVDO cases in the extreme complex end of their spectrum.

Methods

This study is part of a comprehensive retrospective database of PVDO patients maintained by our department. This study was approved by the Institutional Review Board of our institution (#22041101-IRB01). During the period 09/2015-09/2021, our institution treated 262 patients with a diagnosis of PVDO, of which 23 required circumferential correction of thoracolumbar deformity secondary to PVDO by the senior author (8.8%). All patients had a preoperative diagnosis of PVDO either by prior local sampling, positive blood cultures, or highly suspected based on the presence on imaging of a disc-centered abscess with elevated inflammatory markers (CRP and ESR).

All patients had full thoracolumbar CT and MRI if possible; however, only a few patients could stand for full spine radiographs and even then, sagittal alignment parameters were unreliable due to pain. All patients had deformity or instability demonstrated by anterior column destruction and kyphosis on CT. The segmental deformity angle was measured 1 level above and below the collapsed vertebral body on these radiographs, with the caveat that supine positioning usually partially or completely corrects the deformity. If the segmental angle was kyphotic, a negative integer was ascribed. If the segmental angle was lordotic, a positive integer was ascribed. The postoperative segmental angle reflects the angle measured at the patient's last clinic follow-up, not the immediate postoperative angle.

Preoperative phase

Patient preoperative demographic and clinical data included comorbidities, ambulatory status, infectious history, preoperative VAS scores, and preoperative risk stratification scores (Table 1). The Charlson Co-morbidity Index (CCI) was used to describe the severity of their preoperative condition [6]. Our intensive care unit, internal medicine and infectious disease teams collaborate to optimize patients according to our institution's Neurosurgery Adult Spinal Deformity protocol. Deformity surgery was delayed until patients had at least 72 hours of antibiotics and were nonseptic. If patients required emergent spinal cord or cauda equina decompression before the 72 hours, a posterior decompressive operation was performed, and the patient stabilized until reconstruction would be feasible.

Surgical phase

Surgical data is summarized in Table 2. A variety of surgical techniques were employed but all cases involved aggressive debridement of necrotic tissue and reconstruction of the anterior column. Reconstruction was performed in a single-stage, posterior approach in 83% (19/23) of the cases, with 4 cases being performed in two stages. One of the 4 staged cases was an anterior-posterior fusion while the other 3 staged cases involved an initial debridement, decompression, and stabilization with the vertebrectomy portion of the case reserved for the second stage due to expected excessive intraoperative blood loss. Unplanned staging in 1 case was required for elevated blood loss in a patient with prior unilateral ischemic optic neuropathy, out of concern that the contralateral eye might suffer the same complication. Please see Fig. 1 and 2 for representative case examples.

Postoperative course

Postoperative physiological status was estimated with the SAPS II score. The SAPS II score is a metric to calculate the probability of hospital mortality using data obtained within 24 hours of admission to an intensive care unit without the need for an underlying diagnosis [7]. Postoperative care was performed initially in the intensive care unit, where our typical adult spinal deformity patients recover and are jointly managed by the intensive care unit and neurosurgery team. Postoperative clinical and imaging variables are summarized in Table 3.

Every patient was discharged to an acute rehabilitation or skilled nursing care facility for a minimum of 2 weeks. Antibiotic therapy was managed by the Infectious Diseases team and involved 6 to 12 weeks of intravenous therapy followed by oral suppressive therapy for a minimum of 2 years until at least fusion was demonstrated. Follow-up appointments were scheduled for 6 weeks, 12 weeks, 6 months, and 1 year with a detailed clinical evaluation and radiological surveillance with standing full-spine radiographs at each time points. Paired sample t-tests were performed to compare pre and postoperative changes in the visual analogue scale scores as well as the segmental angular changes across the deformity. The postoperative visual analogue scale score and the postoperative segmental angle reflect the most recent values at the patient's last clinical follow-up, not the values in the immediate postoperative period.

Results

Demographics

The mean age of the patients (11 male; 12 female) was 57 years (range, 32–70 years Extremely low preoperative quality of life was evident with 87% (20/23) of patients bedridden primarily due to pain despite 70% (16/23) of patients being strong enough to ambulate (Frankel D or E). Of note, one of the patients was paraplegic at baseline secondary to a prior spinal cord injury. Most of the patients (20/23, 87%) had a prior diagnosis of osteomyelitis/discitis with 26% (6/23) of the patients having undergone a previous surgery. Over half (14/23, 61%) of the patients presented with a neurologic deficit. All patients had either clinical, radiological, and laboratory data strongly suggesting PVDO. The mean

Table 1Preoperative demographic and clinical variables.

| Preoperative Characteristics | | Microbe | | Frank | el Score | Comorbidities | |
|--|---------------|--------------------------|----|-------|----------|------------------------------|----|
| Age (mean, range) | 57 (32–70) | MRSA | 3 | A | 3 | Diabetes mellitus | 12 |
| M:F | 11:12 | MSSA | 10 | В | 1 | IV drug use | 6 |
| Charlson Comorbidity Index (median, range) | 4 (1-9) | Strep pneumoniae | 1 | C | 3 | End stage renal disease | 6 |
| Ambulation | 3-23 | Salmonella | 1 | D | 6 | Rheumatologic disease | 1 |
| Known prior discitis | 20/23 | E. coli | 1 | E | 10 | Cancer | 1 |
| Prior surgery for discitis | 6-23 | Candida sp. | 1 | | | Cirrhosis | 2 |
| Neurologic deficit | 14/23 | Klebsiella | 1 | | | Traumatic paraplegia | 1 |
| VAS (mean ± 95% CI) | 8.8 ± 0.9 | Diptheroids, Pseudomonas | 1 | | | Prior elective spine surgery | 1 |
| Segmental Angle (mean ± 95% CI) | -18 ± 10 | Unknown | 4 | | | | |

Table 2Surgical variables.

| Surgery Characteristics | | Approach | | Blood product transfusion (median) | | |
|---|----------------------------------|---|---------|------------------------------------|----------|--|
| Duration (min, mean, range) Blood loss (cc, mean, range) | 503 (278–901) 2743 (750–8500) | Single-stage posterior Two-stage posterior | 19 3 | Packed RBC Fresh Frozen Plasma | 5 2.5 | |
| Levels fused (median) | 9 (7–16) | Two-stage anterior-posterior | 1 | Cryoprecipitate Platelets | 3 2.5 | |

Table 3 Postoperative clinical and radiographic variables.

| Postoperative Characteristics | | Complications | | | Frankel Score | | |
|-------------------------------------|---------------|--|---------------|----|---------------|---|--|
| Need for urgent decompression | 5–23 | Anemia | 1 | 11 | A | 2 | |
| SAPS II Score (median, range) | 24 (6-54) | Hypote | ension | 10 | В | 0 | |
| ICU stay (d, mean, range) | 6.0 (1-23) | Acute 1 | 3 | С | 0 | | |
| Hospital stay (d, mean, range) | 15.6 (6-35) | Pneum | Pneumonia | | | 6 | |
| Ambulation | 18/23 | Wound | 2 | E | 14 | | |
| Follow-up (d, mean, range) | 631 (40-2313) | Hardw | 2 | | | | |
| VAS (mean ± 95% CI) | 2.5 ± 1.4 | SVC th | 1 | | | | |
| Segmental Angle (mean \pm 95% CI) | 1 ± 9 | Atrial fibrillation Delirium Worsening deficit Recurrent discitis | | 1 | | | |
| | | | | 1 | | | |
| | | | | 1 | | | |
| | | | | 1 | | | |
| | | Mortality | | 1 | | | |
| | Preoperative | Postoperative | Paired T-test | | | | |
| VAS (mean ± 95% CI) | 8.8 ± 0.9 | 2.5 ± 1.4 | p<.001 | | | | |
| Segmental Angle (mean ± 95% CI) | -18 ± 10 | 1 ± 9 | p=.001 | | | | |
| Ambulation | 3-23 | 18/23 | = | | | | |

preoperative visual analogue scale was 8.8 ± 0.9 . The median Charlson Comorbidity Index (CCI) was 4 (range 1–9). One patient with severe liver cirrhosis and coagulopathy was at a hospice facility before being transferred to the hospital after surviving for 3 months. The presenting symptoms, diagnosis, co-morbidities and microbes are summarized in Table 1.

Surgery

All patients underwent a single or multilevel vertebral column resection (VCR) for correction of the deformity. The median number of fused levels was 9 (range 7–16). Most patients (83%, 19/23) had a single day, single stage procedure. In 4 patients the procedure was staged at a time interval of 1–2 weeks from the initial surgery. The average duration of surgery was 503 minutes (range 278–901 minutes). All patients were extubated the morning after surgery. The mean intraoperative estimated blood loss from surgery was 2743 cc (range 750–8500 cc). The median number of total blood products transfused during the hospital stay were: 5 packed red blood cells, 2.5 units of fresh frozen plasma (FFP), and 3 units of cryoprecipitate. Two patients required massive platelet transfusions of 19 and 17 units, respectively, during their hospital stay. A summary of the intraoperative findings are summarized in Table 2.

Postoperative complications

The median SAPS II score on the first postoperative day was 24 (range 6–54). The median postoperative intensive care unit and total hospital stay were 6.0 (range 1–23) and 15.6 (range 6–35) days respectively. The most common postoperative complications were hypotension requiring vasopressor support and anemia requiring blood product transfusion. Other complications included transient acute renal injury, pneumonia with acute respiratory failure, superior vena cava thrombus at the site of a hemodialysis catheter, atrial fibrillation, delirium, and worsening lower extremity weakness. All complications were transient and resolved with appropriate management. Two patients had a wound dehiscence within a month of surgery that required a wound wash out and re-closure. Details of complications are summarised in Table 3.

Follow-up

At the last follow-up, 15 out of 20 patients (75%) regained ambulation after surgical intervention. Of these, the majority resumed walking while in the hospital at an average of 8 days (range 3–17). One patient was paraplegic for several years before surgery and underwent surgery for an open posterior thoracic wound with 3 exposed vertebral segments, refractory to antibiotic treatment for more than 10 years and multiple attempts at superficial closure and flaps. There

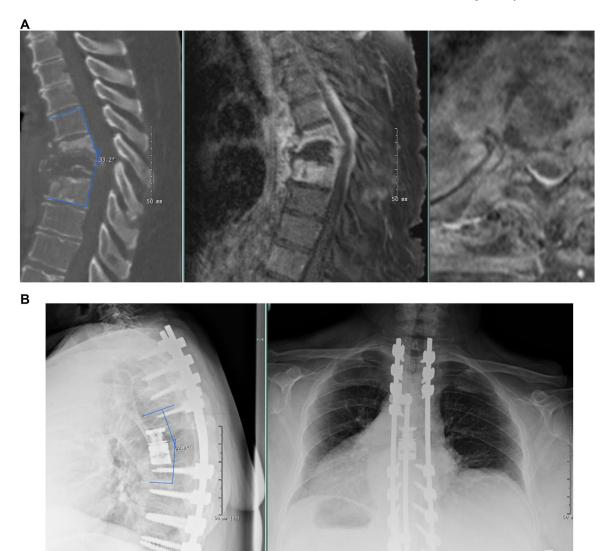


Fig. 1. A 65-year-old female presented with refractory back pain after being treated for T7–T8 osteomyelitis/discitis with intravenous antibiotics. She has a history of uncontrolled diabetes mellitus. She also has multiple skin lesions due to scratching secondary to pruritis from narcotic use. She was unable to ambulate due to a combination of pain and myelopathy. She underwent a T7 and T8 vertebrectomy, multilevel posterior column osteotomies, placement of a T6–T9 expandable intervertebral titanium spacer, and a T3-L2 posterolateral fusion. Following the surgery, she was able to ambulate and had significant improvement in her pain. (A) Preoperative computed tomography (lateral) and magnetic resonance imaging (T1-weighted sagittal and axial) demonstrates destruction of the T7 and T8 vertebral bodies, epidural abscess, and focal kyphosis measuring more than 30 degrees. (B) Follow-up AP and lateral radiographs demonstrate improvement in the focal segmental deformity.

was 1 perioperative mortality secondary to pulmonary embolism. There were two additional deaths more than a year after surgery unrelated to PVDO.

The mean postoperative visual analogue scale was 2.5 ± 1.4 (range 0–10), which was obtained at the last outpatient follow-up (mean 631 days after surgery). This finding was significantly lower than the preoperative VAS (p<.001). The mean duration of follow-up was 631 days (range, 40–2313 days) with all patients having a follow-up in the outpatient setting. The mean preoperative segmental angle measuring 18 ± 10 degrees of kyphosis was corrected to a mean of 1 ± 9 degrees of lordosis on follow-up radiographs. The mean correction of the segmental angle was 19 degrees (standard deviation 23 degrees). We found the postoperative segmental angle to be significantly improved compared with the preoperative angle (p=.001). All patients with Frankel grades less than E

had improvement of their preoperative grade except 1 patient who had a longstanding history of paraplegia prior to presentation (Table 3). All patients were placed on at least two years of antibiotic suppression. Recurrence of discitis after vertebral column resection was seen in only 1 patient who was noncompliant with oral suppression therapy, necessitating a re-do VCR 5 years after the index surgery.

Discussion

Bacterial spondylodiscitis is a heterogenous clinical entity that can be challenging in both diagnosis and treatment. A growing incidence has further increased its burden on the healthcare system, especially given reports that complications are as high as 31% for significant neurologic disability and 11% for death in the first year after diagnosis



Fig. 2. A 52-year-old female presented with acute right lower extremity weakness. She has a history of human immunodeficiency virus and intravenous drug abuse. She underwent an emergent lumbar laminectomy and decompression. Following the surgery, she had improvement in her right leg weakness, but was still unable to ambulate due to pain. She then underwent an L3 corpectomy, L4 vertebral column resection, L5–S1 transforaminal interbody fusion, placement of an expandable intervertebral titanium spacer, and a T12-pelvis posterior spinal fusion. Following the second surgery, she was able to ambulate and had significant improvement in her pain. (A) Preoperative computed tomography (lateral) and magnetic resonance imaging (T1-weighted sagittal and axial) demonstrates L3–L4 osteomyelitis/discitis with extensive osseous destruction and epidural abscess as well as L3–L4 spondylolisthesis. (B) Follow-up AP and lateral radiographs demonstrate improvement in the focal segmental deformity.

[8]. Moreover, advanced pathology more frequently results in bone destruction. Postinfectious kyphotic deformity has been reported in up to 44% of cases of PVDO patients prior to surgical intervention although the percentage of patients in whom this is clinically relevant is much lower [5].

Numerous proposed mechanisms have been hypothesized for the development of deformity in this population. Initially, hematogenous spread secondary to bacterenia allows for the dissemination of bacterial pathogens via either arterial supply to the vertebral metaphysis or less commonly venous supply through Batson's plexus [9,10]. This seeding may also inoculate the nearby intervertebral disc and ultimately result in deformity both through endplate and vertebral body destruction. Vascular dissemination increases the intraosseous pressure and impedes blood flow to the vertebral body and disc, resulting in ischemic necrosis

of these structures [11]. In addition, proteolytic enzyme products of the bacteria (especially *S. aureus*) also directly facilitate degradation and invasion of the disc [12].

This predictable pattern of progression is most localized to the anterior column. Consequently, loss of anterior column support remains the primary biomechanical factor leading to deformity in this population. Most cases with mild deformity due to disc space destruction and vertebral endplate violation can be reconstructed with interbody support only and avoidance of a vertebrectomy, relying on the remaining cortical walls of the vertebra to support a graft. In this series, the deformity was much more severe with complete destruction of at least 1 vertebral body and thus a full vertebral column resection with placement of an expandable cage was necessary. A prior retrospective study has described a posterior-only approach to vertebral column resection for a variety of

pathologies, including postinfectious kyphoscoliosis [13]. For all cases except 1, the vertebral column resection was performed through a posterior approach and involved the affected disc and adjacent vertebral bodies. This area corresponded to the apex of the deformity in every case.

Tsai et al. [14] reported a series of 43 patients with a mean preoperative segmental kyphosis of 11 degrees that underwent early surgical intervention dependent on surgeon's surgical preference. Given the degree of anterior column height loss and the subsequent severity of deformity (as evidenced by a mean preoperative kyphotic angle of 18±10 degrees) in this series, noncircumferential treatment was deemed inadequate to address such extreme malalignment. Noncircumferential treatment in these cases of extreme deformity may increase the risk of reoperation (secondary to implant failure or pseudarthrosis) and/or further instability. Klockner et al. [15] reported outcomes on a population in which only 5 patients with a mean preoperative kyphotic angle of 20 degrees underwent combined anterior-posterior debridement and spinal reconstruction for PVDO. A staggering 60% of the entire group went on to require re-operation for recurrent infection or implant failure.

The need for complete vertebrectomy must be compared to anticipated elevated blood loss and added physiological stress of this very invasive procedure. The degree of osseous destruction is the central question due to the correlation with the resultant kyphotic deformity. Cases with instability only or with limited destruction of the endplates can be appropriately stabilized and treated with thorough disc debridement and posterior instrumentation, with or without interbody support. Mohamed et al. [16] reported a series of 15 patients with PVDO that successfully underwent long-segment posterior fixation without debridement of infection. Of note, this population was largely healthier (average Charlson Comorbidity Index 2) and only a minority of these patients had failed intravenous antibiotic therapy.

On the other hand, if deformity is already present or more than 50% of the vertebral body is compromised, not only is thorough debridement necessary but also anterior column reconstruction and endplate support is warranted to stabilize and reduce the load on the posterior implants. In contrast to the Mohamed et al. [16] study, our population had greater rates of chronic disease (median Charleson Comorbidity Index 4), and nearly all had failed prolonged intravenous antibiotic therapy. Moreover, all patients had such advanced bone destruction that posterior fixation without anterior column reconstruction was deemed a futile intervention. Several of our cases had undergone posterior-only or limited anterior reconstructions with failed results, in 1 case as many as 6 prior fusions.

Our median Charleson Comorbidity Index of 4 and the ASA grade 4 categorization of all patients underscore how sick our patient population was. These scales, although very nonspecific, appear more predictive in spine surgery as compared to the Revised Cardiac Index (RCI). The RCI is widely known to underestimate the risk of major cardiac events in patients undergoing spine surgery, particularly large fusions [17]. SAPS II is a useful assessment although it can only be calculated after the first 24 hours following surgery [7]. In our patient cohort, the mean SAPS II was 24 which predicted a perioperative mortality of 6.5%. Of note, our rate of 4.3% (1 in 23 patients) was thus similar.

In addition to estimating the individual perioperative risk, these indexes illustrate the need for a specific protocol at the institutional level to muster resources and specialized professionals to ensure acceptable outcomes. This necessity aligns with the benefit of specialized perioperative protocols for adult spine deformity such as that present in our institution. Our experience was that the PVDO population stretched these resources to yet another level. As such, we recommend that these aggressive reconstructions be limited to centers used to the challenges of surgery for adult spinal deformity with appropriate care protocols in place and capabilities to address the complications.

In osteomyelitis-discitis, deformity occurs due to focal kyphosis secondary to anterior osseous destruction. Although this focal change may result in spinopelvic derangement, correction of the focal segmental angle should restore any disruption in spinopelvic balance that is secondary to the infection. For patients who had a preexisting global spinal balance, a large reconstructive surgery to address that issue was not pursued given the presence of infection, the increased morbidity, and the inability to obtain reliable preoperative spinopelvic measurements given that almost all patients were unable to obtain preoperative standing films.

The limitations of this study include a small number of patients secondary to the relative rarity of patients presenting with advanced stages of PVDO. Our PVDO database represents one of the largest repositories of information regarding this relatively infrequently entity. In addition, these patients underwent varying posterior-only approaches (sometimes with additional stages) secondary to differences in infected segments and deformity. Our own surgical technique evolved to understand that posterior vertebral column resection was more effective and easier than a combined approach in most cases. As such, the tailored nature of each surgical intervention imposes some inherent limitations on comparative analysis.

Another limitation is the lack of a healthcare cost analysis. This study was performed in a developed country where healthcare is considered a privilege and not a right. The resources and costs involved in this treatment paradigm are obviously massive. Not only is there an issue of reproducibility if these resources are not available to most spine surgeons around the world, but there is an economical and even ethical question in resource-poor universal health systems whether this sort of treatment should be even attempted. Further research is needed to answer this question. With that said, the incidence of PVDO is increasing in developing countries with chronically sick population subsets. As such, we see this protocol as more applicable to similar social and economic situations like the United States. Ultimately, the most cost-effective measure would be to prevent deformity with prompt investigation, diagnosis, and treatment of PVDO.

Conclusion

This is the first series of PVDO patients with significant deformity and medical co-morbidities undergoing extensive, predominantly posterior-only anterior column reconstruction utilizing deformity correction techniques. Most literature on this topic only focuses on the safety of spinal instrumentation in the setting of active infections, which has long been established. Historically, surgeons have been wary to offer such drastic surgical interventions to this patient population secondary to extensive medical co-morbidities and unclear ability to withstand intraoperative blood loss, metabolic derangements, and extended time in prone position under general anesthesia. In this series, most patients regained independence for self-care and unassisted ambulatory status. This study suggests that extensive circumferential reconstruction for deformity originating from PVDO, although a massive procedure, is effective in restoring these very sick patients to self-care and ambulatory status, with acceptable morbidity and mortality.

Declarations of competing interest

One or more authors declare potential competing financial interests or personal relationships as specified on required ICMJE-NASSJ Disclosure Forms.

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