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Gram-negative rods are associated with prolonged treatment in patients with thoracolumbar pyogenic spondylitis after minimally invasive posterior fixation compared with gram-positive cocci: a multicenter retrospective cohort study

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Abstract

Background This study compared patient characteristics, clinical outcomes, and antibiotic durations between patients undergoing posterior fixation for gram-negative rods (GNR) or gram-positive cocci (GPC) thoracolumbar pyogenic spondylitis.

Methods In this multicenter retrospective cohort study, 53 patients who underwent minimally invasive posterior fixation for thoracolumbar pyogenic spondylitis were categorized into a GPC or GNR group based on the identified causative organisms. Patient characteristics, surgical outcomes, and postoperative infection control were compared between the two groups to identify factors affecting antibiotic duration.

Results The patients in the GNR group ($n=14$) were older (77.2 years versus 70.1 years; $p=0.008$), had a higher incidence of a history of abdominal-pelvic infections (4 versus 0; $p=0.003$), required longer preoperative antibiotics (5.9 weeks versus 3.0 weeks; $p=0.035$), and had more unplanned additional surgeries due to poor infection control ($n=4$ versus $n=1$; $p=0.014$) than those in the GPC group ($n=39$). Furthermore, GNR infection independently predicted longer preoperative antibiotic duration ($p=0.002$, $\beta=0.43$).

Conclusions Pyogenic spondylitis with GNR is associated with the need for prolonged antibiotic treatment and higher rates of unplanned additional surgeries due to poor infection control as compared to GPC-associated pyogenic spondylitis. Older age and a history of abdominal-pelvic infections tend to complicate the management

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in these patients; therefore, tailored treatment strategies are required to optimize treatment duration and minimize complications.

Clinical trial number Not applicable.

Keywords Pyogenic spondylitis, Posterior fixation, Gram-negative rods, Gram-positive cocci, Multicenter study

Background

The prevalence of pyogenic spondylitis is increasing worldwide as we move toward an aging society [1]. Causative organisms can be identified in approximately 80% of patients, with methicillin-susceptible *Staphylococcus aureus* (MSSA) being the most common pathogen [2, 3]. Although identifying organisms enables the use of targeted antibiotics, this does not always translate to improving patient outcomes, that is, patients with positive blood cultures often require prolonged treatment, and resistant organisms, such as methicillin-resistant *Staphylococcus aureus* (MRSA), are associated with worse outcomes [4–6]. While treating gram-negative rods (GNR) is particularly challenging, often leading to extended hospital stays [7], MSSA is also linked to poor survival, highlighting the variability in outcomes by pathogen type [8].

Over the years, there has been a dramatic shift toward surgical intervention for pyogenic spondylitis as it has improved the prognosis and reduced treatment failures [9]. In particular, minimally invasive posterior fixation with percutaneous pedicle screws (PPS) is favored for its low invasiveness, fewer complications, and safety [10]. In our practice, we use this approach to achieve early infection control, shorter treatment duration, and spinal stability in a single procedure for patients resistant to conservative treatment.

Certain pathogen types are linked to poor outcomes; however, the impact of specific organisms on the treatment duration and clinical results following surgery is still unclear [4–8]. There is limited pathogen-wise data for postoperative antibiotic duration and outcomes in patients with pyogenic spondylitis. Therefore, this study aimed to compare demographic characteristics, clinical outcomes, and antibiotic durations in patients who underwent posterior fixation for conservative treatment-resistant thoracolumbar pyogenic spondylitis caused by GNR versus gram-positive cocci (GPC). We hypothesized that patients with pyogenic spondylitis caused by GNR require longer treatment durations and experience more perioperative complications than those with GPC as the causative organism.

Methods

Study design and participants

This multicenter retrospective cohort study included 86 consecutive patients with thoracolumbar pyogenic spondylitis (T1/2–L5/S1) treated with minimally invasive posterior fixation at nine affiliated facilities from January 2014 to December 2023, with postoperative follow-up for at least six months [4]. The study was approved by the Institutional Review Board of each participating facility.

The inclusion criteria were:

1. Patients who underwent minimally invasive fixation only via the posterior approach, that is, those who did not receive direct intervention on the infected intervertebral spaces through debridement or bone grafting from either the anterior or posterior approach [4].
2. Patients in whom the causative organism (specifically GPC or GNR) was identified [11].

Patients with unidentified causative organisms and those in whom the identified causative organisms included anaerobic bacteria or tuberculosis, were excluded [12].

Patients were classified into a GPC or GNR group based on the causative organisms identified; drug-resistant organisms were included in the appropriate group [11].

Data collection

The following data were collected for all patients:

1. Clinicodemographic data on admission: age, sex, location of infection (thoracic and thoracolumbar [T1/2–T12/L1] or lumbar and lumbosacral [L1/2–L5/S1]), number of infected levels (multi- or single-level), comorbidity (diabetes mellitus, cancer), history of infectious diseases and type of infection, extravertebral abscesses (epidural, iliopsoas, empyema), and blood data (white blood cells [WBC] count, C-reactive protein [CRP] levels).
2. Causative organism and antibiotics: the presence of blood cultures and local sample cultures, causative organisms and their types, the duration of intravenous antibiotics (total, preoperative, postoperative), and whether oral antibiotics were used after intravenous antibiotics.
3. Surgical data and postoperative outcomes: operation time, blood loss, range of fixation, postoperative follow-up period, occurrences of unplanned additional surgeries and their reasons (particularly for surgical site infection, implant failure, and

poor infection control), along with any infection recurrence.

Blood cultures were collected in 2–3 sets before antibiotic administration, whereas local cultures were obtained either before antibiotic administration or 3 days after cessation of antibiotics. History of infectious disease was defined as a previous infection treated with antibiotics weeks or months before pyogenic spondylitis was diagnosed and was a potential source of hematogenous spread leading to pyogenic spondylitis [11].

Surgical procedures

Surgery was indicated in cases with neurological deficits, progressive bone destruction, persistent or enlarged abscess, instability, and failure of conservative treatment. The timing of surgery was determined individually at each facility [9, 12].

The surgical technique followed prior studies [4, 12]. Briefly, all surgeries were performed under general anesthesia with the patient in the prone position. PPS were inserted above and below the infected vertebrae, typically at least two or three levels, depending on the patient's age and bone quality. The decision to insert screws into the infected vertebrae was made at each facility's discretion [12]. No corrective measures were perfomed for vertebral destruction or deformity, nor were posterior decortication, bone grafting, or direct debridement of the infected discs performed. Bilateral rods were inserted in situ to complete the surgery. In patients with an epidural or iliopsoas abscess secondary to pyogenic spondylitis, drainage was typically not performed. Instead, minimally invasive posterior fixation was conducted to address the underlying cause, i.e., pyogenic spondylitis [13, 14].

Pre- and postoperative antibiotic protocol

Physicians at each facility monitored the clinical progress and made the final decisions on antibiotic types and treatment durations. Intravenous antibiotics were typically given for six weeks, combining both preoperative and postoperative phases [15]. Selective antibiotics were administered based on the culture results. Intravenous antibiotic administration was discontinued when the abscess reduced in size and the CRP levels normalized to preinfection values [4, 16]. The decision to continue oral antibiotics was taken by the treating physician at each facility, considering certain factors, such as the type of causative organism [15]. For evaluating postoperative abscess reduction, magnetic resonance imaging (MRI) was taken in approximately half of the patients 14–30 days after posterior fixation; due to local healthcare insurance limitations, the remaining patients were primarily assessed using computed tomography.

Clinical outcomes

The primary outcome was the duration until infection control, specifically the duration of preoperative and postoperative antibiotics between the GPC and the GNR groups [4, 17]. The secondary outcomes involved postoperative clinical outcomes, including infection recurrence and frequency and reasons for unplanned additional surgeries due to complications [4, 12, 17].

Statistical analysis

Continuous variables were reported as mean ± standard deviation. The two groups (GPC and GNR) were compared in terms of demographic data, clinical data, and operative outcomes. Continuous variables were analyzed using Welch's t-test, while nominal variables were assessed using Fisher's exact test. Multiple regression analysis was used to compare the duration of pre and postoperative antibiotics using the antibiotic duration (in weeks) as the dependent variable. Explanatory variables included eight factors identifiable on admission [4, 6, 12, 14]: sex, age, multiple/single-level intervertebral infections, diabetes mellitus, cancer, iliopsoas abscess, CRP levels, and whether the causative organism was GNR or GPC. Continuous variables were dichotomized, with age divided into <65 and ≥ 65 years, and CRP divided into <10 mg/dL and ≥ 10 mg/dL [4, 14].

A p-value of <0.05 was considered statistically significant. All analyses were performed using JMP 10 software (SAS Inc., Cary, NC, USA).

Results

Patient characteristics

Of the 86 patients, 26 were excluded because the causative organism could not be identified, two had tuberculosis, and five had anaerobic bacteria as the causative organism; hence, 53 patients (GPC: $n=39$; GNR: $n=14$; mean age = 72.0 ± 11.2 years) were included in the final analysis (Fig. 1). The mean preoperative intravenous antibiotic duration of the study cohort was 3.8 ± 3.5 weeks.

The GNR group patients were significantly older (77.2 ± 6.5 years versus 70.1 ± 12.0 years; $p=0.008$), had a higher incidence of a history of abdominal-pelvic infections ($n=4$ versus 0; $p=0.003$), and a longer duration of preoperative intravenous antibiotics (5.9 ± 4.4 weeks versus 3.0 ± 2.8 weeks, $p=0.035$) than the GPC group patients, respectively (Table 1).

While blood cultures were obtained from all patients, local samples were collected from 20 out of the 39 patients in the GPC group and from five of the 14 patients in the GNR group ($p=0.36$). Local samples could not be collected from 28 patients owing to the following reasons: 8 had suspected sepsis and received antibiotics promptly after blood cultures without local sampling, 11 had thoracic spine involvement which made local

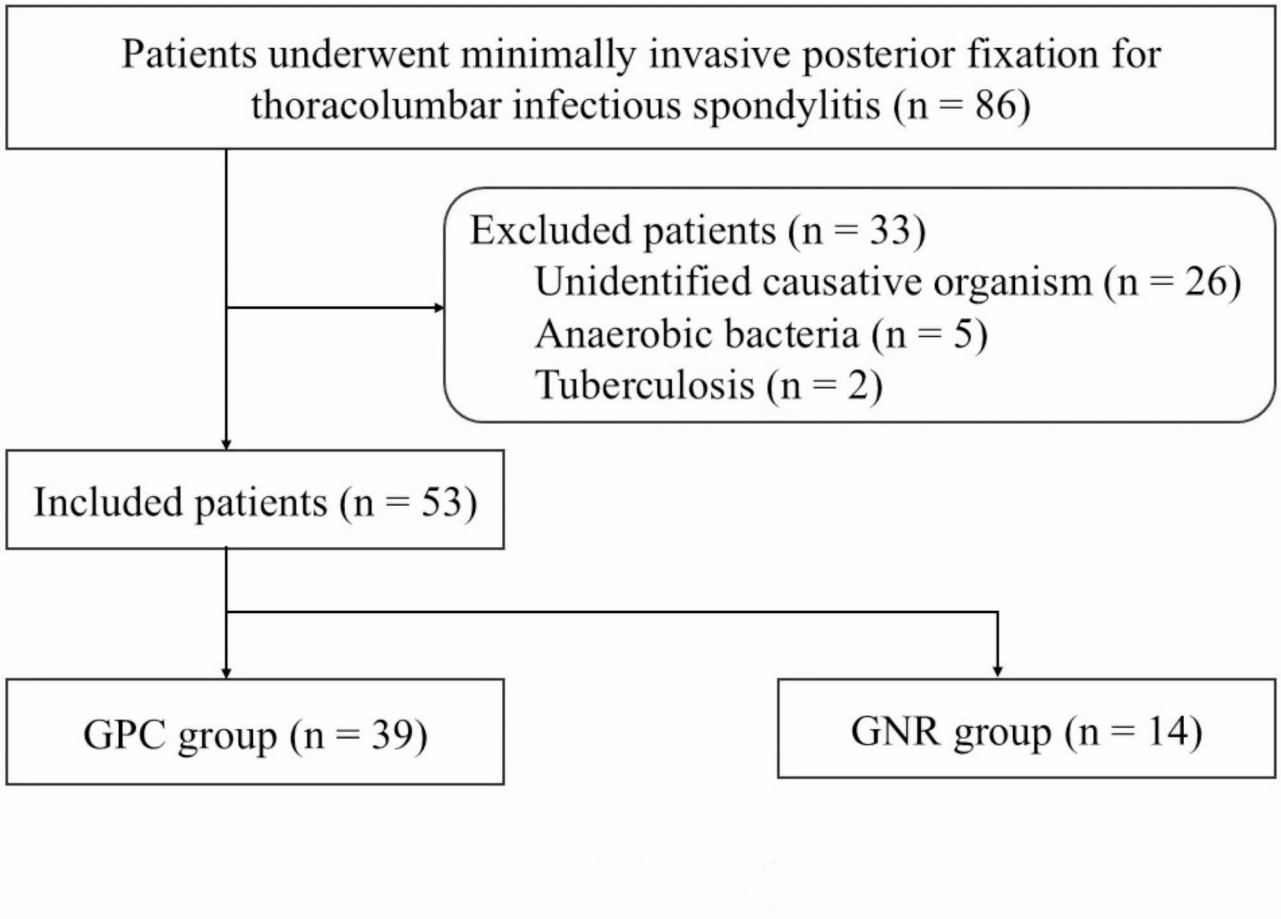

Fig. 1 Inclusion and exclusion criteria of the study patients
GPC: Gram-positive cocci, GNR: Gram-negative rods

sampling difficult, 4 had a history of infection with an already identified causative organism, and 5 were on antiplatelet or anticoagulant therapy and local sampling was considered a bleeding risk for them. Blood cultures were positive in 33 patients, local samples in 14, and both in six. The most frequent organism in the GPC group was *Streptococcus*, while *Escherichia coli* was most common in the GNR group (Table 2). Three patients with drug-resistant organisms were identified in the GPC group (one each of MRSA, methicillin-resistant *Staphylococcus epidermidis*, and methicillin-resistant coagulase-negative *Staphylococci*).

Surgical data and postoperative outcomes

There were no significant differences between the two groups in terms of operation time, blood loss, or range of fixation (Table 3). The mean overall postoperative follow-up period was 25.4 ± 17.0 months. The mean postoperative and total intravenous antibiotic duration was 4.1 ± 2.0 weeks and 7.9 ± 3.8 weeks, respectively. After discontinuing intravenous antibiotics, 45 patients received oral antibiotics, whereas 8 patients did not. The duration of postoperative intravenous antibiotics did not differ significantly between the two groups (GNR: 4.9 ± 2.4 weeks, GPC: 3.8 ± 1.8 weeks; $p = 0.14$); however, the mean total intravenous antibiotic duration was significantly longer in the GNR group (10.8 ± 4.5 weeks versus 6.8 ± 2.9 weeks; $p = 0.0072$).

None of the patients experienced infection recurrence during follow-up. Thirteen unplanned additional surgeries were performed after minimally invasive posterior fixation (GPC: $n = 8$; GNR: $n = 5$). Unplanned surgery because of poor infection control was more commonly seen in the GNR group (4 versus 1; $p = 0.014$). Among the five patients with poor infection control, two underwent drainage for residual abscesses after posterior fixation as postoperative imaging showed no reduction in abscess size, necessitating additional surgery. The other three patients underwent anterior debridement and bone grafting as their blood test results indicated no improvement even 2 weeks after posterior fixation, indicating insufficient infection control and the need for additional surgery. Antibiotic change was required in two of these five patients with poor infection control.

Table 1 Preoperative characteristics of patients in the GPC and GNR groups (*N* = 53)

	GPC group (*n* = 39)	GNR group (*n* = 14)	*p*
Sex			0.75[a]
Male	27	9	
Female	12	5	
Age (years)	70.1 ± 12.0	77.2 ± 6.5	0.0089[b]
≥ 65	28	14	0.026[a]
< 65	11	0	
Location			0.51[a]
Thoracic (including thoracolumbar: T1/2–T12/L1)	12	6	
Lumbar (including lumbosacral: L1/2–L5/S1)	27	8	
Multi- or single-level intervertebral infection			0.71[a]
Multi-level	9	2	
Single-level	30	12	
Comorbidity (including duplicated)			
Diabetes mellitus	13	5	1.00[a]
Cancer	9	2	0.71[a]
History of infectious diseases	5	5	0.11[a]
Abdominal-pelvic infection	0	4	0.0034[a]
Urinary tract infection	2	1	1.00[a]
Skin infection	2	0	1.00[a]
Infection due to an artificial device (implanted defibrillators)	1	0	1.00[a]
Extravertebral abscess (including duplicated)	26	12	0.30[a]
Epidural abscess	20	9	0.54[a]
Iliopsoas abscess	17	9	0.22[a]
Empyema	2	1	1.00[a]
Blood data at admission			
White blood cells (/μL)	12,885 ± 6089	12,278 ± 8502	0.81[b]
CRP (mg/dL)	14.0 ± 10.8	15.1 ± 9.9	0.74[b]
< 10 mg/dL	19	6	0.76[a]
≥ 10 mg/dL	20	8	
Duration of preoperative intravenous antibiotics (weeks)	3.0 ± 2.8	5.9 ± 4.4	0.035[b]

a: Fisher's exact test, b: Welch's t-test. Values are in mean ± standard deviation

GPC: gram-positive cocci, GNR: gram-negative rods, CRP: C-reactive protein

Table 2 Causative organisms identified in the blood and local sample cultures of the study patients (*N* = 53)

Organism	Total	Blood culture (+)	Local sample culture (+)	Both cultures (+)
Total	53	33	14	6
GPC (%)	39 (74%)	23	12	4
Streptococcus species	22	15	7	0
MSSA	13	7	2	4
MRSA	1	0	1	0
MSSE	1	1	0	0
MRSE	1	0	1	0
MRCNS	1	0	1	0
GNR (%)	14 (26%)	10	2	2
Escherichia coli	10	7	2	1
Klebsiella pneumoniae	4	3	0	1

GPC: gram-positive cocci, MSSA: methicillin-susceptible *Staphylococcus aureus*, MRSA: methicillin-resistant *Staphylococcus aureus*, MSSE: methicillin-susceptible *Staphylococcus epidermidis*, MRSE: methicillin-resistant *Staphylococcus epidermidis*, MRCNS: methicillin-resistant coagulase-negative *Staphylococci*, GNR: gram-negative rods

Table 3 Group-wise surgical data and postoperative outcomes for the study patients ($N=53$)

	GPC group ($n=39$)	GNR group ($n=14$)	*p*
Surgical data			
Operation time (min)	154 ± 79	161 ± 92	0.81[a]
Blood loss (g)	181 ± 299	80 ± 94	0.069[a]
Range of fixation (number of fixed vertebrae)	6.1 ± 2.2	6.7 ± 1.6	0.30[a]
Postoperative period of follow-up (months)	24.8 ± 16.5	27.0 ± 18.7	0.71[a]
Duration of intravenous antibiotics (weeks)			
Postoperative	3.8 ± 1.8	4.9 ± 2.4	0.14[a]
Total	6.8 ± 2.9	10.8 ± 4.5	0.0072[a]
Recurrence of pyogenic spondylitis	0	0	1.00[b]
Unplanned additional surgeries	8	5	0.29[b]
Poor infection control	1	4	0.014[b]
Anterior debridement and bone grafting	1	2	
Drainage of the residual abscess	0	2	
Surgical site infection	3	0	0.56[b]
Implant failure	2	1	1.00[b]
Adjacent segment disease	1	0	1.00[b]
Postoperative neurological disorders	1	0	1.00[b]

a: Welch's t-test, b: Fisher's exact test. Values are in mean ± standard deviation

GPC: gram-positive cocci, GNR: gram-negative rods

Table 4 Results of the multiple regression analysis for factors affecting the duration of preoperative intravenous antibiotics

	As reference	Partial regression coefficient	Standard error	t value	*p*	β
(Intercept)		6.67	0.96	6.95	< 0.0001	0
Age: ≥65	< 65	−0.35	0.58	−0.61	0.54	−0.082
Sex: Female	Male	0.34	0.47	0.71	0.48	0.090
Multilevel	Single-level	1.38	0.59	2.36	0.023	0.32
Diabetes mellitus (+)	(−)	0.46	0.49	0.93	0.36	0.13
Cancer (+)	(−)	1.34	0.56	2.4	0.021	0.31
Iliopsoas abscess (+)	(−)	0.37	0.45	0.83	0.41	0.11
CRP at admission:						
≥ 10 mg/dL	< 10	−0.39	0.46	−0.85	0.40	−0.11
GNR	GPC	1.69	0.53	3.18	0.0027	0.43

CRP: C-reactive protein, GNR: gram-negative rods, GPC: gram-positive cocci,

β: Standardized partial regression coefficient

Factors associated with the duration of pre and postoperative intravenous antibiotics

The duration of preoperative intravenous antibiotics was associated with several factors: multilevel intervertebral infections ($p=0.023$, β: 0.32), the presence of cancer ($p=0.021$, β: 0.31), and GNR being the causative organism ($p=0.002$, β: 0.43) (Table 4).

No significant factors were associated with the duration of postoperative intravenous antibiotic administration; in particular, there was no significant difference based on whether the causative organism was GNR or GPC ($p=0.29$, β: 0.15) (Table 5).

Discussion

This study yielded the following key results:

1. Patients with GNR-associated pyogenic spondylitis undergoing minimally invasive posterior fixation were older, had a higher incidence of a history of abdominal-pelvic infections, and required longer durations of preoperative and total intravenous antibiotics and more unplanned additional surgeries due to poor infection control compared with the GPC-associated pyogenic spondyliti.
2. The presence of multilevel intervertebral infections, cancer, and infection with GNR was associated with prolonged durations of preoperative intravenous antibiotics.

Numerous studies have examined patient characteristics and clinical outcomes by organism type in pyogenic

Table 5 Results of the multiple regression analysis for factors affecting the duration of postoperative intravenous antibiotics

	As reference	Partial regression coefficient	Standard error	t value	*p*	β
(Intercept)		3.56	0.59	6.06	< 0.0001	0
Age: ≥65	< 65	0.45	0.35	1.28	0.21	0.18
Sex: Female	Male	−0.16	0.29	−0.54	0.59	−0.073
Multilevel	Single-level	−0.57	0.36	−1.59	0.12	−0.23
Diabetes mellitus (+)	(−)	−0.60	0.30	−1.99	0.053	−0.29
Cancer (+)	(−)	0.28	0.34	0.83	0.41	0.12
Iliopsoas abscess (+)	(−)	0.16	0.28	0.57	0.57	0.079
CRP at admission:						
≥ 10 mg/dL	< 10	0.49	0.28	1.74	0.088	0.25
GNR	GPC	0.35	0.33	1.07	0.29	0.15

CRP: C-reactive protein, GNR: gram-negative rods, GPC: gram-positive cocci,

β: Standardized partial regression coefficient

spondylitis [7]. The findings of patients in the GNR group being older and having a higher incidence of a history of abdominal-pelvic infections are consistent with previous research [12, 17, 18]. Additionally, reports suggest that shorter antibiotic courses for GNR are linked to higher infection recurrence rates, which may explain the overall longer duration of antibiotics used in this study [18]. Previous studies have identified several factors influencing antibiotic duration, which include positive blood cultures, abscesses, multilevel intervertebral infections, elevated CRP levels, and resistant organisms, such as MRSA [4–6, 14]. We also observed that the presence of multilevel intervertebral infections was associated with longer preoperative antibiotic treatment durations. While it is well known that GNR can complicate treatment, only a few studies have compared treatment durations among different causative organisms [19].

This study focused on two major organism groups responsible for causing pyogenic spondylitis, GNR and GPC, and observed two major findings.

1. The GNR group required prolonged preoperative and total antibiotics than the GPC group.

   As observed in previous studies, patients with GNR often have a higher incidence of a history of infections, such as abdominal and urinary tract infections, which require initial treatment [11, 17, 18]. Additionally, older age, a factor that was confirmed in our study, may be linked to decreased immune function and physical capability, leading to more cautious surgical indications and a preference for conservative treatment with bracing and antibiotics [20]. In contrast, MSSA is a GPC organism that is frequently associated with extravertebral abscesses in pyogenic spondylitis; this may prompt earlier surgical interventions, such as abscess drainage, due to neurological symptoms, resulting in shorter preoperative antibiotic durations [21].

   Furthermore, the multiple regression analysis suggests that once GNR is confirmed as the causative organism in pyogenic spondylitis, treatment is likely to be prolonged, highlighting the importance of careful planning. Since there was no difference in the duration of postoperative antibiotics between the GPC and GNR groups, earlier surgical intervention may help reduce treatment durations, even in GNR patients [9, 14, 16].

2. The GNR group experienced a higher rate of unplanned additional surgeries due to poor infection control than the GPC group.

   Surgical interventions for pyogenic spondylitis, including anterior, posterior, and combined approaches, each having their advantages and disadvantages [9, 10]. The rate of additional surgeries following posterior fixation for pyogenic spondylitis ranges from 2 to 17% [4, 22, 23] and may be linked to factors such as significant vertebral destruction, large abscesses, identification of causative organisms, and advanced age [4, 22, 23]. As mentioned above, the GNR group patients were older than the GPC group, which predisposed them to malnutrition and poor bone quality, thereby increasing the risk of complications and the need for additional surgeries after posterior fixation [4, 24]. Additionally, *Klebsiella pneumoniae*, the second most common organism in the GNR group, is known for its hypervirulent strains in pyogenic spondylitis [25]. Together these factors likely contributed to the poor infection

control observed in the GNR group; this also rendered posterior fixation alone insufficient to achieve segmental stability and warranted close monitoring to determine if additional surgery is needed.

As a multicenter study, this research includes a range of facilities, from university hospitals and urban medical centers to rural hospitals, suggesting that the findings may be generalized. However, there are several limitations to this study. Although it was a multicenter study conducted using strict patient selection criteria, the variability in antibiotic administration and surgical decisions across different facilities may have affected the results. Moreover, because of regional healthcare insurance limitations, we could not perform postoperative MRI scan for all patients, making it impossible to directly confirm complete abscess resolution in all patients and thereby limiting the applicability of our results. Furthermore, because of the retrospective design and the stringent selection criteria, the final sample consisted of 53 patients, of which only 14 patients belonged to the GNR group. Typically, clinical outcomes based on the causative organisms are reported with similar sample sizes [7, 11]. Hence, the small size of the GNR group limits the reliability of the finding. Lastly, we only included patients with GPC and GNR infections and excluded patients infected with anaerobic bacteria, tuberculosis, or unidentified organisms [11]. Previous studies have classified patients with drug-resistant bacteria, which are linked to worse clinical outcomes, into the GPC group [6, 11]. Although drug-resistant bacteria could confound the results, they represented a small fraction of our GPC group ($n = 3$). Recent reports have suggested that there is a trend toward a decrease in drug-resistant bacteria and tuberculous spondylitis and an increase in oral commensal organisms causing pyogenic spondylitis [26]. Therefore, it is essential to consider possible biases in patient backgrounds when interpreting the results of this study. Future research using larger sample sizes, prospective study designs, and standardized treatment protocols is required to improve reliability.

Conclusions

Patients with thoracolumbar pyogenic spondylitis caused by GNR are prone to poor infection control, experience extended antibiotic courses (both preoperative and overall), and require more unplanned additional surgeries when undergoing minimally invasive posterior fixation as compared to those with GPC as the causative organism. As the GNR group patients were older and had a higher incidence of a history of abdominal-pelvic infections, and the presence of GNR was found to be independently associated with longer preoperative intravenous antibiotics, it is essential to devise careful treatment strategies in these patients to prevent prolonged antibiotic use and treatment duration.

Abbreviations

MSSA	Methicillin-susceptible Staphylococcus aureus
MRSA	Methicillin-resistant Staphylococcus aureus
GNR	Gram-Negative Rods
PPS	Percutaneous Pedicle Screws
GPC	Gram-Positive Cocci
WBC	White Blood Cells
CRP	C-Reactive Protein
MRI	Magnetic Resonance Imaging

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Author contributions

HG, TF, KF, and MK conceived and designed the study. HG, KF, YO, YS, TN, TS, KS, SO, KO, YS, HK, KN, YT, MT, IS, and MU gathered and analyzed the data for the study. HG, TF, and KF drafted the manuscript which was then significantly revised by MK. All authors approved the current version of the manuscript submitted for publication.

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Data availability

The datasets generated during and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The institutional review board of Ibaraki Western Medical Center (protocol code No. 21 – 07, approved on January 27, 2022) approved all procedures, including the review of patient records. All procedures were performed in accordance with the Declaration of Helsinki. All patients provided written informed consent. The IRB approved the procedures outlined for obtaining consent for this study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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