

An insight into outbreak of atypical mycobacterial infection following percutaneous nephrolithotomy - Role of cleaning and sterilization techniques inspected



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ABSTRACT

Background: Atypical wound infections following minimal access surgery continue to affect smooth recovery. Percutaneous nephrolithotomy (PCNL) for renal stones involves various small-sized nephroscopes and accessories. Improper cleaning and disinfection of which may result in bacterial biofilms formation and infections. **Aims and Objectives:** We inspected an outbreak of atypical wound infection after PCNL to find the responsible factor. **Materials and Methods:** This retrospective observational study had three groups based on cleaning and sterilization methods. In group A, manual cleaning of instruments was done followed by high-level disinfection using glutaraldehyde 2% solution with 20 min submersion. In group B, manual cleaning was supplemented with multienzyme cleaning with 10 min submersion but disinfection method was same as in group A. In group C, manual and enzyme cleaning was combined with ethylene oxide (ETO) sterilization. The outcome was assessed as wound infection occurrence at 1-month follow-up. **Results:** The study had 81 participants with 61 male and 20 females. The mean age was 36 ± 16 years. Group A, B, and C had 32, 24, and 25 participants, respectively. Pre-operative parameters were comparable among the groups. Late wound infection (at 1-month follow-up) occurred in 11 cases from group A, but none from others ($P=0.004$). Culture-revealed atypical mycobacterial growth in four cases, while *Staphylococcus* in another. Rests were sterile. Six patients were relieved after clarithromycin course for 1–5 months. Three patients needed scar excision. **Conclusion:** Manual cleaning with high-level disinfection is not adequate against atypical mycobacterial infections. A combination of enzymatic cleaning and high-level disinfection with glutaraldehyde or ETO sterilization effectively minimizes these infections.

Key words: Outbreak; Atypical; Mycobacteria; Percutaneous nephrolithotomy; Cleaning; Enzyme; Infection

INTRODUCTION

Minimal access surgery (MAS) has now become the management of choice for surgically treatable disease with the benefits of early mobilization, quick recovery, less wound size, and lower infection rate as compared to open surgery.¹ This benefit is seen extending among the all variety of surgical fields including urology.² Percutaneous nephrolithotomy (PCNL) in urology is one such minimally

access surgery which deals with various sizes of renal stone disease effectively with miniaturization of external wound and tract size to around 4–10 mm.³ However, the shift to MAS does come with its unique challenges, especially while cleaning, sterilization, or high-level disinfection of small-sized endoscopes and its accessory instruments, in order to achieve a minimal infection rate.⁴ A rise in atypical bacterial infections or non-tuberculous mycobacteria (NTM) has been seen recently after various laparoscopic

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surgeries at port sites.⁵⁻⁷ Lack in adequacy at any level of reprocessing increases the possibility of these chronically resistant infections.⁸

Wound infection in PCNL is usually seen less frequently but is associated with long-term morbidity with seropurulent discharge, unsightly appearance, continuous discomfort, and taking months to get resolved ultimately.⁹ Many factors have been found to be associated with these infections include the presence of external catheter such as percutaneous nephrostomy (PCN), inadequate sterilization, or high-level disinfection of the nephroscope and its accessory instruments, especially with glutaraldehyde alone.⁹ PCNL procedure involves the use of an initial puncture needle, guide wires, facial dilators, nephroscope, and amplatz sheath etc., in order to reach inside the renal system accurately from flank. This dependency on multiple instruments makes it more prone to wound infections with shortage in cleaning or disinfection at any level.¹⁰ Availability of variety of cleaning, high-level disinfection, and sterilization methods with varying efficacy and lack of comparative data makes the equation even more sophisticated.

We retrospectively analyzed the wound infection rate in PCNL surgery with focus on the combinations of methods used for instrument cleaning, disinfection, and sterilization.

Aims and objectives

Our aim was to see that which factor is responsible for atypical wound infection following PCNL.

MATERIALS AND METHODS

Study population

This retrospective observational study was done in the department of urology, Medical College, India, between February 2022 and March 2023. All the patients undergoing PCNL surgery for renal stone disease were included. Patient demographics clinical features stone characteristics, surgery details, and stone-free rate were recorded. The patients not coming for timely follow-up were excluded. Informed consent from patient was taken and declarations of Helsinki and its amendments were followed.

Group details

Patients were divided into three groups based on the method of instrument cleaning and disinfection or sterilization used. In group A, manual cleaning of instrument and nephroscope was done and glutaraldehyde 2% solution with 20 min submersion time was used for achieving high-level disinfection. In group B, manual cleaning was combined with enzymatic cleaning (3M

Rapid Multi-Enzyme Cleaner, 3M India Ltd, India) with a submersion time of 10 min followed by high-level disinfection using glutaraldehyde solution 2% for 20 min. In group C, manual and enzymatic cleaning was same as in group B, but was followed by sterilization using an ethylene oxide (ETO) system (PurEto 135L, Sterile Safequip And Chemicals LLP, India).

Outcome and analysis

The primary outcome was assessed in form of appearance of wound infection over the surgical site within 3rd post-operative days and a follow-up period of 1 month. Clinical features of wound infection were recorded with exact symptom, duration, treatment given, and the time required for complete healing of the wound. Secondary outcomes assessed were other post-operative events as per the Clavien–Dindo classification system, with special emphasis on appearance of fever or sepsis and hospital stay days. SPSS software was used for statistical analysis. The P-value was kept below 0.05 and significance was set at 95%.

RESULTS

Baseline characteristics

A total of 81 cases were found suitable for the study as per inclusion and exclusion criteria's. Group A had 32 cases, whereas group B, and C had 24 and 25 cases, respectively. 61 cases were male and 20 were female. Mean age was 36 ± 16 years. Distribution of age, BMI, symptoms duration, pre-operative hemoglobin, serum creatinine, stone, and renal parameters were comparable among the groups (Table 1).

Primary outcome

Four out of 81 patients showed features of wound infection within 3 days of surgery. Three were from group A, whereas one was from group B ($P=0.263$). All cases had serous discharge from the surgical site. Wound discharge subsided completely in three patients with empirical therapy, whereas one patient continued to have on-and-off sero-purulent discharge for 2 months despite treatment. On analyzing the predisposing factors, only the presence of PCN tube was found as a risk factor for early wound infection ($P=0.047$), which was present in two out of four cases preoperatively.

Wound infection at 1-month follow-up was observed in 11 out of 81 cases. All cases were in group A patients ($P=0.004$). Ten patients presented with on and off sero-purulent discharge from wound site with discoloration of skin (Figure 1), whereas one case had only erythema c tenderness and induration around the wound (Table 2). Onset of symptom was between 2 and 5 weeks following

Table 1: Comparison of pre-operative clinical, renal, and stone parameters of group participants

Parameters	Group			P-value
	A (n=32)	B (n=24)	C (n=25)	
Sex				
Female	5	7	8	0.303
Male	27	17	17	
Comorbidities				
Alcoholic	1	0	0	0.152
CKD	4	1	1	
CKD, Hypertension	2	0	0	
Diabetes	2	0	0	
Hypertension	2	0	2	
Syndromic	0	2	0	
HIV	0	1	0	
HbsAg	0	1	0	
Stone side				
Right	13	12	14	0.503
Left	19	12	11	
Hydronephrosis				
Yes	23	14	18	0.489
No	9	10	7	
PCN tube <i>in situ</i>				
Yes	5	2	1	0.329
No	27	22	24	
Pre-operative culture				
Sterile	29	23	25	0.375
<i>Escherichia coli</i>	2	0	0	
<i>Klebsiella</i>	0	1	0	
Polymicrobial flora	1	0	0	
Stone number				
Single	12	10	12	0.727
Multiple	20	14	13	
Stone density				
<1000HU	12	6	9	0.583
>1000 HU	20	18	16	
Kidney anatomy				
Normal	26	20	21	0.640
Small	1	0	0	
Bifid pelvis	0	1	0	
Diverticulum	0	0	1	
Horseshoe kidney	0	0	1	
Hypermobility	1	1	0	
Malrotated	4	2	2	
	Mean±SD	Mean±SD	Mean±SD	
Age (years)	40±15	33±16	34±16	0.215
BMI	24.8±4.0	24.6±2.9	24.1±3.6	0.737
Symptom duration (months)	10.6±16.0	9.2±8.7	11.6±12.9	0.824
Pre-op Hb (g%)	12.4±2.1	12.5±1.9	12.0±1.8	0.638
Pre-op creatinine (mg%)	1.6±1.3	1.1±0.7	1.3±1.1	0.181
Largest stone size (mm)	21.9±9.5	24.6±10.8	24.8±9.2	0.458

CKD: Chronic kidney disease, BMI: Body mass index, PCN: Percutaneous nephrostomy

surgery. The average amount of discharge was between 2 and 5 mL in these patients. Gram staining and Zn staining of discharge were negative in all cases. Culture of discharge revealed growth of NTM growth in four cases and *Staphylococcus aureus* growth in one case. Sterile wound culture was obtained in the rest five cases. Complete resolution of infection was seen in six patients with 1–5 months of medication of clarithromycin (500 mg, BD, and oral); one patient required linezolid (600 mg, BD, and oral) for 1 month and another needed faropenem (200 mg, TDS, and oral) for 1 month. Three patients got relief

after scar excision at 2–4 months post-operative period (Figure 2). Apart from group variable, no other factors could be found significantly associated with these atypical infection occurrences.

Secondary outcome

Occurrence of post-operative complications as per the modified Clavien system was comparable among the study groups. Alteration in post-operative Hb% and serum creatinine was also found similar. However, group A patients stayed for more days in the hospital than in group B

Cases	Presentation	Pre-op culture	Onset of symptoms	Wound culture	Management	Time to resolution
1	Wound discharge	Sterile	4 weeks	Sterile	Clarithromycin	3 months
2	Wound discharge	Sterile	3 weeks	Sterile	Clarithromycin	2.5 months
3	Wound discharge	Sterile	3 weeks	Sterile	Clarithromycin; Scar excision	2 months
4	Wound discharge	Sterile	4 weeks	NTM* Species	Clarithromycin	2 months
5	Wound discharge	Sterile	5 weeks	Sterile	Clarithromycin; Scar excision	3.5 months
6	Wound discharge	Sterile	4 weeks	NTM*	Clarithromycin	3 months
7	Erythema, Induration	Sterile	2 weeks	-	Clarithromycin	1 month
8	Wound discharge	Sterile	2 weeks	<i>Staphylococcus aureus</i>	Faropenem	1 month
9	Wound discharge	Sterile	2 weeks	Sterile	Linezolid	1 month
10	Wound discharge	Sterile	4 weeks	NTM*	Clarithromycin; Local therapy	5 months
11	Wound discharge	Sterile	5 weeks	NTM*	Clarithromycin; Scar excision	4 months

*NTM: Non-tuberculous mycobacteria

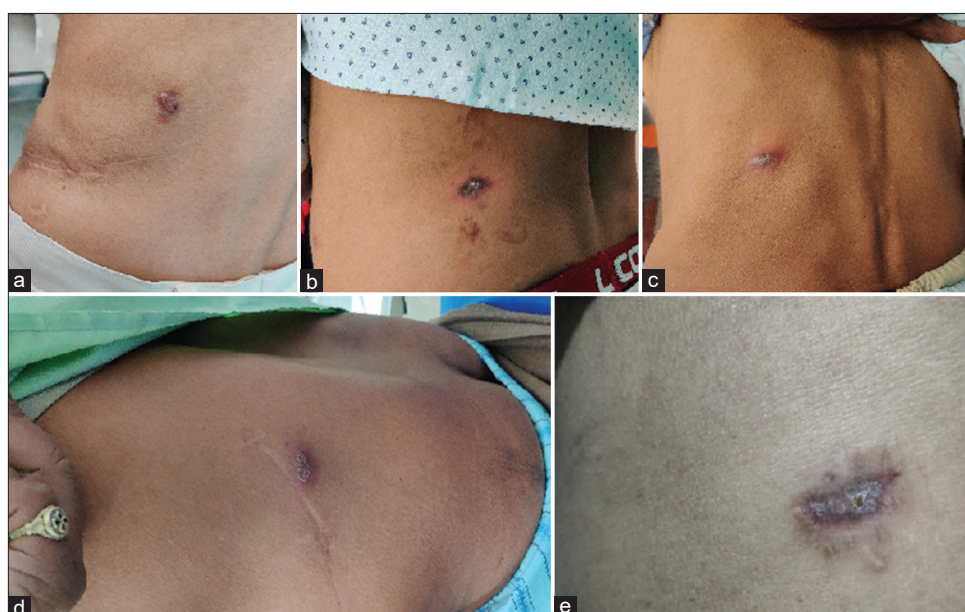


Figure 1: Post-operative wound infection images after 1-month interval with features of on and off sero-purulent discharge c-skin discoloration (a-e)

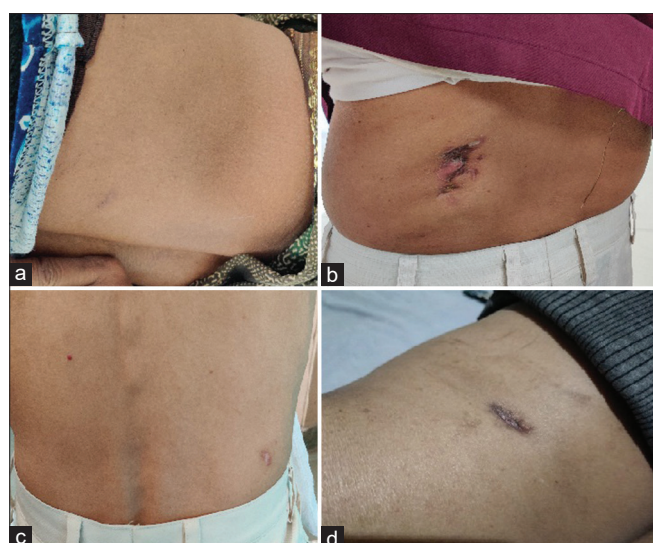


Figure 2: Images of healed wound in different scenarios (a) primary healed wound, (b) secondary healing after scar excision, (c) delayed healed wound, (d) delayed healed wound

and C (4.9 ± 2.0 vs. 3.4 ± 0.6 vs. 4.1 ± 1.6 days; $P=0.008$). On the contrary, patients in group B and C were more satisfied than in group A (satisfaction score 4.7 ± 0.4 vs. 4.4 ± 0.9 vs. 3.9 ± 0.9 ; $P=0.008$) (Table 3).

DISCUSSION

Wound infection following surgery creates an extra physical and psychological burden to an already recovering patient and delays overall regaining of daily activities of life. Long slender channels of endoscopes, nephroscopes and dilators, delicate instruments, complex manufacturing, heat-sensitive accessories, and combination of various materials, biofilm formation altogether make the process of cleaning and disinfection cumbersome.¹¹ Urological instruments usually fall into category of semi-critical items as per Spaulding classification and require high-level disinfection.¹² Many guidelines, training, and assessment

Table 3: Comparison of study outcome and post-operative parameters of study participants

Parameters	Group			P-value
	A (n=32)	B (n=24)	C (n=25)	
Wound on day 3				
Healthy	29	23	25	0.263
Leakage	3	1	0	
Wound at 1 month				
Discharge	10	0	0	0.004
Erythema	1	0	0	
Healed	21	24	25	
Post-operative events as per Modified Clavien scale				
Grade 1	6	0	4	0.411
Grade 2	5	2	3	
Grade 3	2	0	0	
Grade 4	0	0	0	
	Mean±SD	Mean±SD	Mean±SD	
Post-operative Hb change (g%)	-1.0±0.9	-0.6±0.7	-0.3±1.3	0.105
Post-operative creatinine change (mg%)	0.1±0.5	0.2±0.3	0.1±0.4	0.888
Hospital stay (days)	4.9±2.0	3.4±0.6	4.1±1.6	0.008
Patient satisfaction score (1–5)	3.9±0.9	4.7±0.4	4.4±0.9	0.008

programs have been proposed to ensure adequacy at each level of reprocessing.¹³⁻¹⁵ Despite these many outbreaks have been reported recently, especially in urology practice.¹⁶⁻¹⁸

In our study, the occurrence of wound infection in group A only highlights the importance of proper cleaning of endoscopes and accessories. Manual cleaning and rinsing may not be sufficient in removing all the blood, tissue stains, and debris.¹⁹ An extracellular polymeric substance (EPS) covers the bacterial biofilm and affects the cleaning and disinfection process significantly.²⁰ This EPS contains lipid, polysaccharide, DNA, and protein etc.²¹ This probably was the main reason for outbreak in group A and use of Glutaraldehyde alone in this scenario does not reduce the bacterial load to a desired level. Glutaraldehyde efficacy also comes down with increasing organic load. Hence a multienzyme solution helps in removal of this EPS and ensures efficient cleaning.²² Stiefel et al., proved the *in vitro* efficacy of a good enzyme cleaner in a 96-well-plate system with >99% reduction of CFU and biofilms.²³ Hutchisson and LeBlanc emphasized the use of fresh, properly diluted, immersed, and made as per manufacturer solution only, in order to achieve the best results.²² We could also minimize the infection rate in group B and C after the addition of multi-enzymatic cleaner.

Sterilization and disinfection methods used did not affect the wound infection rate in our study. Glutaraldehyde was also utilized in group B for high-level disinfection apart from use in group A, where all infections were seen. ETO sterilization system was used in group C. So use of combination of multi-enzymatic cleaning with Glutaraldehyde or ETO was found sufficient to arrest the infection outbreak. Zühlsdorf and Kampf also determined

in vitro efficacy of the enzymatic cleaner and Glutaraldehyde-based disinfectant for chemo thermal processing of flexible endoscopes in a washer disinfectant.²⁴ This is important for clinical practice in developed countries, where ETO or plasma sterilization systems are not available easily. Use of these portable solutions for instrument processing becomes cheaper and handy in remote areas.

An outbreak in our study was mainly due to NTM species, though they could be proved by culture in four cases only. Gupta et al., found six cases of mycobacterial infections over PCNL site with discharging wounds.⁹ Though they did not perform a culture analysis of discharge, patients improved after first-line ATT treatment. Causative factors identified were the sharing of the operation theater and disinfection tray with general surgery cases along with the use of 2% Glutaraldehyde solution alone for disinfection. Singh et al., in her series of four cases of NTM infections following laparoscopic cholecystectomy reported delayed onset of appearance of discharging sinuses with surrounding discoloration.²⁵ Long standing treatment using second-line ATT drugs was used for 4–10 months period. Author also highlighted role of high clinical suspicion to start treatment as cultures are often negative. Sasmal et al., in their review on port site infection (PSI) in laparoscopic surgery also emphasized complexity in managing NTM infections.²⁶ He divided infections into early and delayed PSI with different clinical and etiological factors. Our one infection with non-NTM bacteria had features similar to early PSI, whereas others were alike delayed PSI c NTM predominance. Ghosh et al., investigated an outbreak of 15 cases of PSI following laparoscopy and found NTM growth in 11 cases with similar clinical features as ours.²⁷ Further, workup revealed a disinfectant plastic tray responsible for infections. In our study, inadequate cleaning

of small-sized facial dilators (6–16 Fr), 18G initial puncture needle, and Amplatz sheath was probably the inciting factor for NTM outbreak. Author also recommended use of metal surface, autoclaving, or use of OPA over Glutaraldehyde to prevent infections. The last point was contrary to our finding where combination of Glutaraldehyde with enzymatic cleaning was also efficient to bring down the infection rate.

Treatment of NTM infections remains a challenge. A combination of clarithromycin, ciprofloxacin, and amikacin has been recommended for a long duration for infection clearance with variable response rate.²⁸ We utilized long-term clarithromycin alone with overall good response. Nie et al., analyzed species identification of NTM by 16S rRNA sequence analysis and drug sensitivity testing.²⁹ He found a correlation between clarithromycin to high prevalence of *erm* (41) genotype. This insight may provide further clue to a variable response or persistent of infection in patients. Further research is needed in this area. Surgical excision of scar is also well described for persistent wound infection.⁵ Our three patients also underwent same for complete resolution of symptoms.

Limitations of the study

Limitations are small sample size, retrospective in nature, lack of PCR, or liner probe array tests for genotype assessment of NTM species and separate drug sensitivity testing etc.

CONCLUSION

Atypical mycobacterial infection can occur with any level of fault in instrument processing. Wound cultures are often negative and long-term clarithromycin therapy with or without scar excision is required for complete healing. Manual cleaning with high-level disinfection is not sufficient to arrest the NTM growth and biofilm formation. Addition of multienzyme solution cleaning results in better removal of residual blood clots and tissue material especially inside the small instrument channels. It overall curtails the opportunity for bacteria to grow after high-level disinfection or sterilization.

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