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Matters of the heart: A scoping review toward better management of nontuberculous mycobacterial infections of cardiac devices

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ABSTRACT

Background: Implantable cardiac device-related (ICDR) nontuberculous mycobacteria (NTM) infections are increasingly reported in the literature, but guidelines for optimal management are lacking.
Methods: We searched Medline, Embase, and Scopus from inception to 1/20/2022 for cases of ICDR NTM infection. Cardiac devices include but are not limited to prosthetic valves, cardiovascular implantable device (CIED), and left ventricular-assist devices (LVAD). We categorized outcomes as death, failure, relapse, cure, and treatment complete.
Main results: A total of 81 articles met our inclusion criteria, representing 122 patients. Eleven different NTM species were reported, with rapidly growing mycobacteria (RGM) including *M. fortuitum, M. chelonae,* and *M. abscessus* comprising approximately 60 % of the identified organisms. Prosthetic heart valves (N = 61; 50 %) and CIED (N = 46; 38 %) were the most frequently associated cardiac devices. Favorable outcomes, defined as treatment complete and cure, were significantly associated with device removal after adjusting for age, gender, and device type (aOR 3.45, 95 %CI 1.30–9.14).
Conclusion: We found that patients who underwent device removal had better outcomes than those with retained devices. Device removal should be strongly considered when possible.

1. Background

Nontuberculous mycobacteria (NTM) are distributed worldwide and ubiquitous in the environment [1]. Implantable cardiac device-related (ICDR) (e.g., the cardiac implantable electronic device [CIED], prosthetic heart valve, left ventricular assist device [LVAD]) infections with NTM are rare, but with the increasing number of cardiac device implants in the past decade, the rate of ICDR-NTM infections has increased in parallel [2]. These infections are associated with significant morbidity and mortality, reaching 88 % mortality in some reports [2–7].

The approach to managing ICDR-NTM infections is not well described. There are no established diagnostic criteria and outcome definitions, and there is a scarcity and heterogeneity of the published literature, which is limited to case reports, series, and very few cohort studies. Biofilm formation, which protects organisms and impedes eradication, and a limited number of antimycobacterial agents, complicate therapy [1,8–10].

The treatment for ICDR-NTM infection generally entails a prolonged course of multiple antibiotics ranging from at least six months to years [9,11,12]. A further challenge includes the burden of potential device removal and uncertainties regarding the optimal re-implementation timing [2,4]. Despite the considerable expansion of knowledge about NTM disease, the optimal treatment approach for ICDR-NTM infection remains uncertain.

To address this knowledge gap, we conducted a scoping review to explore the evidence for the optimal management of ICDR-related infections in patients with NTM disease. Our primary objective was to investigate the association between device removal and clinical

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outcomes.

2. Methods

2.1. Review protocol

We conducted a scoping review of the literature that reports on treating ICDR-NTM infections and related outcomes. We aimed to identify and summarize the current body of literature and evaluate areas needing future study. Our approach to identify and select studies is detailed in a protocol that can be provided upon request. Our findings are presented here in accordance with guidance from information from the Joanna Briggs Institute (JBI) Scoping Review Network [13] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) [14].

2.2. Study eligibility criteria

We included reports of ICDR-NTM infections in patients who were treated with antibiotics. Given the rarity of ICDR-NTM infections, we included all study designs. We defined a cardiac device as any device placed in the body to replicate the heart's function and that meets the FDA definition of a high-risk medical device (Class III) [15].

2.3. Search methods

We identified potentially eligible studies through an electronic search of three bibliographic databases from their inception through January 2022 (Ovid Medline, Scopus, and Embase) (Appendix 1). Searches were devised in collaboration with the research librarian and the research team. We identified the following key themes to be integral to and reflective of our research question: 1) non-tuberculosis mycobacteria; and 2) implantable medical devices. Of note, we used a broader theme of implantable medical devices for our initial search, rather than a more specific theme of cardiac devices to avoid missing potentially relevant studies. Screening out of the studies of non-cardiac devices occurred during a title and abstract review. Then we used exploratory terms and keywords to generate sets for these themes. We used the Boolean operator "OR" to combine all the keywords for each different theme. Thereafter, we used the Boolean operator "AND" to find the intersection between these themes and yield the final search results. There was no language restriction applied in our approach. Any identified study in a foreign language was translated by using either google translate or by a research team member who was a native speaker of the language.

2.4. Study selection

The first phase of study screening involved each potential study's title and abstract. Titles and abstracts were screened by two independent reviewers using Rayyan screening software [16]. Each article was also reviewed by a second independent reviewer to check for discrepancies. If discrepancies arose, the reviewers discussed them until a consensus was reached about inclusion or exclusion. Studies that were identified as potentially meeting the criteria for use in the scoping review were then reviewed in their entirety for inclusion. Additionally, we manually reviewed those relevant studies' references to ensure a comprehensive look at our topic.

2.5. Data collection

Data was extracted utilizing a standardized data collection form in REDCap (Research Electronic Data Capture) hosted at Dartmouth Hitchcock Medical Center [17,18]. REDCap is a free, secure, web-based software platform that supports data capture for research studies.

Pairs of two independent infectious disease specialist physicians subsequently reviewed studies meeting inclusion criteria, and all relevant data were extracted. Each reviewer was blinded to the others' data extraction. To resolve discrepancies in the data collection process, when present, a third reviewer was brought in to assess the data in question independently and "break" the tie.

We collected demographic and clinical characteristics of the patients, device types, NTM species, diagnostic methods, treatment regimen, device removal, and outcomes.

2.6. Outcome definition

To our knowledge, there is no standardized framework to report the outcome of NTM infections. Therefore, for this scoping review, we adapted the tuberculosis (TB) outcome definition endorsed by the World Health Organization (WHO) [19]. The five possible outcomes for patients identified in our review are described in Table 1.

2.7. Data analysis

To assess the impact of device removal on health outcomes, we compared two groups of patients: those who underwent device removal and those who did not. We compared these groups in terms of patients' characteristics, study design, type of cardiac devices, NTM species, and whether the patient received a macrolide-based treatment regimen. Data were analyzed using chi-square for categorical variables and t-tests for continuous variables, with a two-sided p-value threshold of < 0.05 to determine statistical significance. Categorical data were presented as frequencies and percentages, while continuous data were expressed as means and standard deviations (SD). As the number of reported outcomes meeting the outcome definitions in our study was limited, we combined patients who met the definition of "treatment complete" and "cure" into a favorable outcome category for our analysis. Multivariate analysis was conducted utilizing logistic regression, which was adjusted for age, gender, and cardiac device type, as these variables were confounders that could influence the outcomes of our analysis. Statistical analyses were conducted using Stata (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP).

3. Results

We identified 2372 potentially eligible studies. After we removed duplicates, a total of 1567 studies were screened for titles and abstracts. Ninety-five studies were found to be potentially relevant and reviewed for full text. Sixty-six studies met our inclusion criteria, and an additional 15 were included after manually reviewing the relevant studies' references. A total of 81 studies were included in this review. The reasons for exclusion in the full-text review process are described in the flow diagram (Fig. 1).

Table 1
Outcome definitions.

Outcome	Definition*
Died	A patient who died during the follow-up period while on treatment or in the follow up period
Failure	A patient with persistent culture positivity while on treatment
Relapse	A patient with positive culture after completion of antibiotic therapy
Cured	A patient who was bacteriologically confirmed at the beginning of treatment, and there was no evidence of bacteriologic disease within 6 months of the end of therapy
Treatment completed	A patient who completed the treatment without follow-up culture

* Each outcome definition is mutually exclusive.

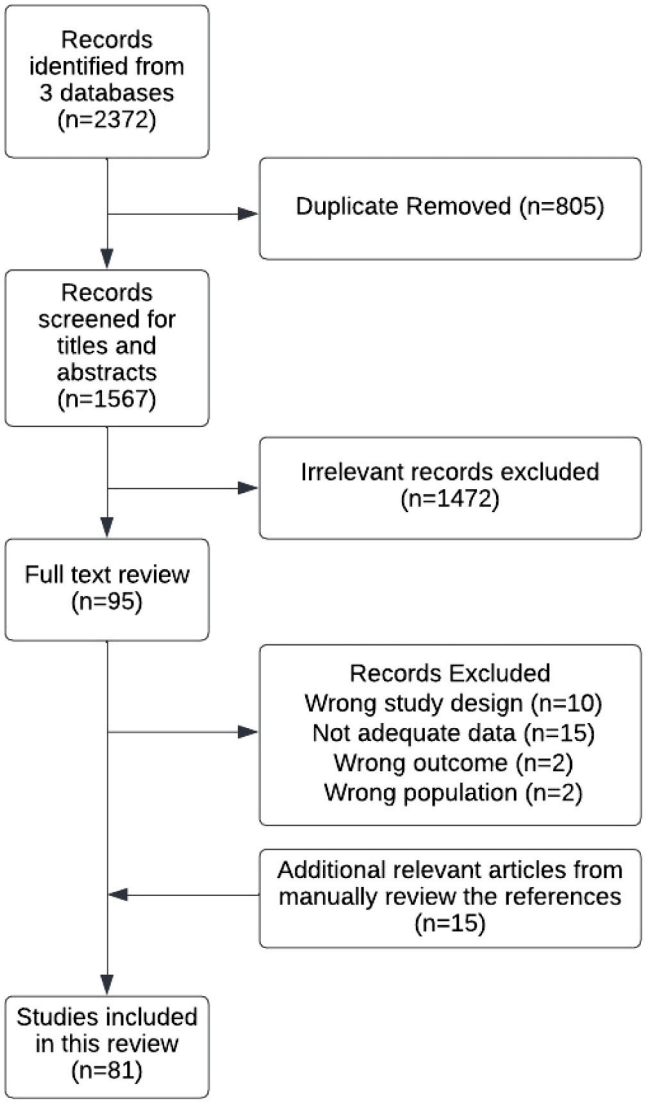

Fig. 1. PRISMA flow diagram.

3.1. Description of population

The 81 studies in this review represented a total of 122 patients (Appendix 2); 68 (56 %) were reported in case reports, 36 (30 %) in case series, and 14 (11 %) in cohort studies. The average age of patients was 60 years (range 15–86 years old, standard deviation [SD] = 16), and 65 % of patients were male (N = 79). Only 5 % of patients (N = 6) were documented to be moderate-to-severe immunocompromised per CDC's definition [20]. Of 122 patients with ICDR-NTM infections, 50 % (N = 61) involved prosthetic heart valves, 38 % (N = 46) involved an automatic implantable cardioverter-defibrillator (AICD) or pacemaker, 9 % (N = 11) an LVAD, and 3 % (N = 4) had infection of a coronary artery stent (Fig. 2).

3.2. NTM species and diagnosis

As shown in Table 2, the most common NTM species found in our review were *M. fortuitum* (24 %), *M. avium* complex (MAC; 21 %), *M. chelonae* (21 %), and *M. abscessus* species (15 %). There were 5 cases that were only reported as mycobacteria without identification.

The diagnosis of ICDR-NTM infection was made by culture for 55 % of patients (N = 68) and by 16S rRNA sequencing from tissues for 13 % (N = 16) of patients. Blood cultures were reported to be positive in 43 % (N = 52) of patients. Antimycobacterial susceptibility was reported for isolates from 52 % (N = 63) of patients in our review, with macrolide susceptibility in 48 % (N = 30) among those available reports.

3.3. Device type

3.3.1. Prosthetic valve

Our review identified 61 cases of ICDR-NTM infections associated with a prosthetic valve. The patients' average age was 58 years (range 17–84, SD = 17), and 61 % were male (N = 37). *M. chelonae* was the most common organism in this patient group (N = 21; 34 %), followed by *M. chimaera* (N = 18; 30 %). Of the patients who had blood cultures (n = 53), 66 % (N = 35) had positive cultures at the time of diagnosis. Thirty-six patients (59 %) underwent valvular replacement, and among those who had reported valve culture results, 61 % (N = 22) had positive cultures. The 16 s rRNA method was used for diagnosis in 28 % (N = 15) of patients. Outcomes were available for 53 patients, of whom 43 % died, 6 % were cured, and 45 % completed treatment without meeting the definition of cure.

3.3.2. CIED

We identified 46 patients with CIED infection (19 with AICD-related infection and 27 with pacemaker-related infection). The average age of these patients was 64 years old (range 15–86, SD = 15), and 60 % were male. *M. fortuitum* was the most common organism found in this group of patients (N = 21; 46 %). Pocket infections were commonly noted, with wound cultures positive in 32 patients (76 %). Only 24 % (N = 11) of patients in this group had a blood culture positive. 80 % (N = 37) underwent device removal and 63 % of patients (N = 22) underwent reimplant with a median time of 4.5 weeks after device removal. Among those with device removal, 51 % (N = 19) had a positive device culture.

3.3.3. LVAD

Six studies reported 11 patients with LVAD infection. The average age for LVAD patients was 63 years old (SD 16); all were male. *M. abscessus* was the most common organism found in this group of patients (N = 5; 45 %), but subspecies was not uniformly reported (e.g., *bolletii*, *abscessus* or *massiliense*). Only two patients had their LVAD removed. Six patients (67 %) died, including the two patients who had had their LVAD device removed.

3.4. Treatments

There were a substantial variety of antibiotic regimens in the included studies, likely tailored to the NTM species. Of 122 patients, 90 (74 %) received at least two antibiotics for target treatment; 52 (43 %) had macrolide in their regimens. Macrolides, including clarithromycin and azithromycin, were used in 45 % of patients with *M. fortuitum* (13 of 29), 88 % of those with MAC (22 of 25), and 56 % with *M. abscessus* (10 of 18). Only 12 % of the patients (3 of 25) with MAC infection were not treated with a macrolide-based regimen. Duration of therapy was reported in 69 % of patients (N = 84) and ranged from two weeks to lifelong, with a mean of 5.5 months (SD = 5.4).

3.5. Outcomes

Of 122 patients, 105 (86 %) had outcomes reported with sufficient information to be classified according to our definitions (Table 1). Among the 105 patients, 33 % (N = 35) died within the follow-up period, 7 % failed (N = 7), 4 % (N = 4) relapsed, 4 % (N = 4) were cured, and 53 % (N = 55) completed treatment but reports did not include evidence required for classification as cured.

3.6. Analysis of outcomes and device removal

Baseline characteristics of patients who did or did not undergo

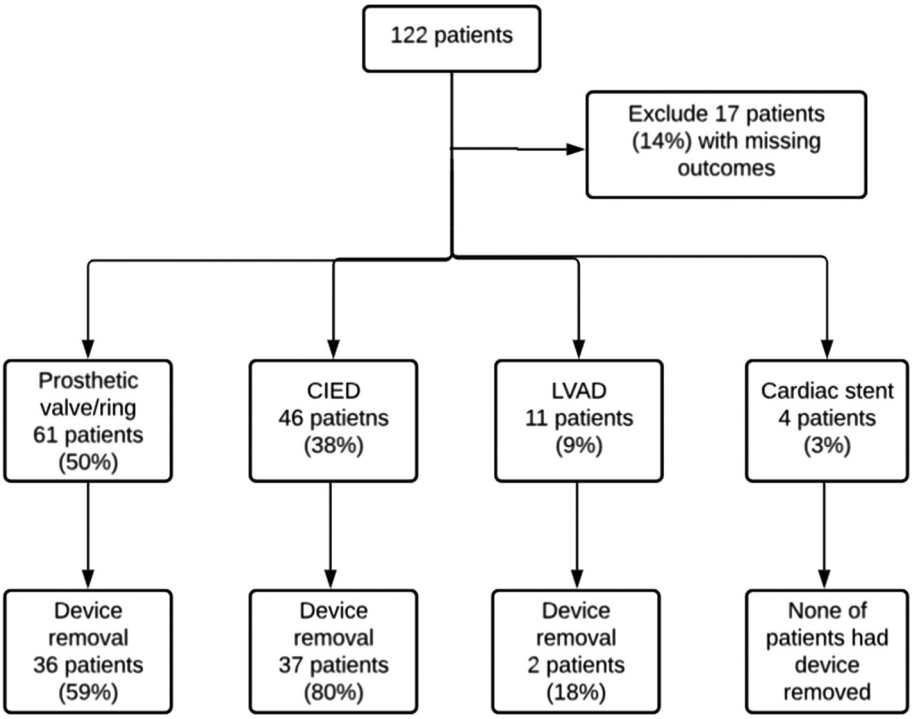

Fig. 2. Flow chart categorizing patients with reported outcomes, by device type and removal status.

Table 2
Reported NTM species among 122 patients with ICDR-NTM infections.

NTM species	Number of cases	Percentage (%)
M. fortuitum spp	29	23.77
MAC*	25	20.49
M. chelonae	25	20.49
M. absessus spp	18	14.75
M. goodii	6	4.95
Other*	19	15.57

*MAC (Mycobacterium avium complex): M. chimaera 22 cases and M. avium 3 cases.
*Other NTM includes M. mageritense (n = 3), M. neoaurum (n = 3), M. wolinskyi (n = 3), M. phlei (n = 1), M. gordonae (n = 1), M. peregrinum (N = 3) and non-speciation (n = 5).

device removal are shown in Table 3. Of 122 patients, 86 % (105) had reported outcomes and were included in the primary analysis to assess predictors associated with favorable outcomes (Table 4).

Patients who underwent device removal were statistically significantly more likely to have favorable outcomes when compared to patients who did not have their devices removed (70 % vs. 32 %, $p < 0.001$). After adjusting for age, gender, and device type, device removal was found to be significantly associated with favorable outcomes (aOR 3.45, 95 %CI 1.30–9.14, $p = 0.013$).

4. Discussion

Despite a considerable increase in knowledge about ICDR-NTM disease, the approach to diagnosis and therapy has yet to be standardized. Our scoping review identified and synthesized data from the entire available literature. We identified 81 studies with a total of 122 patients, making this the largest review of ICDR-NTM to date [4,6]. Almost half of patients with report outcomes had unfavorable outcomes with 33 % died, emphasized the high morbidity and mortality of NTM infections. Patients who underwent device removal had a higher probability of favorable than patients with retained devices. This was statistically significant after adjusting for age, gender, and device type.

Table 3
Characteristics of patients categorized by device removal.

Variable	Device removal N = 75 (61 %)	Retained device N = 47 (39 %)
Study type		
- Case report	45 (60 %)	23 (49 %)
- Case series	16 (21 %)	20 (43 %)
- Cohort	13 (17 %)	1 (2 %)
- Conference abstract	1 (1 %)	3 (6 %)
Age, mean (SD)	59 (17 %)	64 (14 %)
Male	45 (60 %)	34(72 %)
Immunocompromised	4 (6 %)	2 (4 %)
Cardiac Devices		
- Prosthetic valve	36 (48 %)	25 (53 %)
- CIED	37 (49 %)	9 (19 %)
- LVAD	2 (3 %)	9 (19 %)
- Coronary artery stents	0	4 (9 %)
NTM species		
- *M. fortuitum* spp.	21 (28 %)	8 (17 %)
- MAC	10 (13 %)	15 (32 %)
- *M. chelonae*	20 (27 %)	5 (11 %)
- *M. absessus* spp.	8 (11 %)	10 (21 %)
- *M. goodii*	6 (8 %)	0
- Other*	10 (13 %)	9 (19 %)
Macrolide-based regimen	27 (36 %)	25 (53 %)

CIED; Cardiac Implantable Electronic Device. LVAD; Left Ventricular Assist Device. MAC; *Mycobacterium avium* Complex.
*Other NTM includes *M. mageritense* (n = 3), *M. neoaurum* (n = 3), *M. wolinskyi* (n = 3), *M. phlei* (n = 1), *M. gordonae* (n = 1), *M.* peregrinum (N = 3) and non-speciation (n = 5).

This scoping review was based on the secondary data which innately has several limitations including lacking of full information about patients' comorbidities, diagnostic criteria, treatment course and outcomes which precluded us from evaluating the clear diagnosis, appropriateness of antibiotic regimens and their impact on the mortality attributed to ICDR-NTM infections.

We identified heterogeneity in the reported diagnostic criteria and the absence of a uniform treatment approach, which illustrates the need for evidence-based management guidelines, but also limits the

Table 4
Crude odds ratios (OR) and adjusted OR for having a favorable outcome (treatment complete or cure) compared to having less favorable outcome (died, failure, relapse).

Exposure	Crude OR	(95 % CI)	Adjusted OR*	(95 % CI)
Age	1	0.98; 1.03	1	0.98;1.04
Gender (female vs male)	1.87	0.82;4.25	1.53	0.6;3.91
Device type				
Prosthetic valve/ring	1		1	
CIED	2.89	1.18;7.07	2.02	0.76;5.34
LVAD	0.28	0.05;1.45	0.42	0.07;2.43
NTM species				
M. fortuitum spp.	1		N/A	N/A
MAC	0.5	0.15;1.68		
M. chelonae	1.71	0.54;5.4		
M. abscessus spp.	0.31	0.08;1.24		
Device removed vs retained.	5.09	2.15–12.05	3.45	1.30;9.14

*Adjusted for other variables except NTM species.

generalizability of our results.

Although we conducted comprehensive searches in multiple databases, we acknowledge that other applicable studies could have been missed. Additionally, the results of our review could have been affected by publication bias that may skew toward reporting patients who underwent device removal and were successfully treated.

The lack of a standardized outcome definition for ICDR-NTM infections challenges aggregating these cases. Unlike *M. tuberculosis* for which the WHO has established universal outcome definitions, there are no standardized outcome definitions in NTM infections. We are supportive of such efforts, one of which is ongoing at the Oregon Health & Science University, OR) to determine NTM outcomes.

5. Conclusion

Our scoping review found that among patients with ICDR-NTM infection, those who underwent device removal had better clinical outcomes than those with retained devices, even when adjusting for other factors, including the device type. Thus, device removal should be strongly considered when possible. Additionally, this review highlights the heterogeneity of the available literature and the need for standardized diagnostic criteria and outcome definition, which can help identify the optimal treatment approach. To facilitate a better understanding of these serious infections in future research, having standardized outcome definitions for all types of NTM-related infections is crucial. We advocate for NTM infections to become reportable by statute similar to other serious infectious diseases to efficiently identify optimal management.

6. Ethical statement

This scoping review does not require ethical approval.

7. Financial disclosure

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CRediT authorship contribution statement

Rattanaporn Mahatanan: Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Maria Alkozah:** Writing – review & editing, Formal analysis, Data curation. **Devin Lee:** Writing – original draft, Data curation. **Anais A. Ovalle:** Writing – original draft, Data curation. **Natalie B.V. Riblet:** Writing – review & editing, Writing – original draft, Validation, Supervision, Conceptualization. **Elizabeth A. Talbot:** Writing – review & editing, Writing – original draft, Supervision, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jctube.2025.100521.

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