

Two Weeks of Imipenem as Initial Induction Therapy for Disseminated Rapidly Growing Nontuberculous Mycobacterium Infections: A single Arm, Open-Label, Comparative Study with Historical Control 4-week Imipenem Therapy

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Background: Disseminated non tuberculous mycobacterium (NTM) infection is a recently emerging problem worldwide, particularly in Asian countries. It is a difficult to treat the infections and there are limited options of antibiotic therapy. Currently, there is no guideline available for treatment of disseminated NTM infection, particularly from rapidly growing nontuberculous mycobacteria (RPGM). The common antibiotic regimen usually begins with imipenem intravenously for 2 to 4 weeks, followed by only oral regimen with macrolide and quinolone combination. Relapses of clinical symptoms occur frequently. Some experts thought it was related to the duration of imipenem given and preferred prolonged imipenem infusion for 4 weeks, but had no supported evidence.

Objective: To compare the relapse rate of disseminated NTM with 2-week imipenem versus historical cohort data of 4-week imipenem as initial therapy.

Materials and Methods: A prospective open-label study was conducted at Srinagarind Hospital, Khon Kaen, Thailand between 1 January 2019 and 28 February 2021. The adult patients who had a diagnosis of disseminated NTM infection were screened. After inclusion and exclusion criteria were met, the patients were enrolled and received imipenem as an initial therapy. Imipenem was stopped after completion of a 2 weeks course. The patients who had imipenem continued was defined as treatment failure. The patients came for a 1-month follow-up for 3 months, and then a 3-month follow-up, and then they had regular visits according to routine care. The demographic data was collected and clinical relapse was recorded during the study period. Intent-to treat and as treated analysis were performed.

Results: A total of 26 cases of disseminated NTM infection were enrolled. The patients received a 2-week imipenem arm. There were 30 cases from a historical cohort who were treated with 4-weeks of imipenem. By intent-to-treat analysis, the relapse rate of 2-week imipenem therapy was not statistically different from the 4-week arm at 1 month (8.0% vs. 6.7%) ($p=0.89$) and at 3 months (53.8% vs. 33.3%) ($p=0.67$). By as-treated analysis, there was also no difference in the relapse rate between the 2-week arm and 4-week arm at 1 month (10% vs. 6.7%) ($p=0.72$) and 3 months (44.4% vs. 34.2%) ($p=0.69$) follow-up.

Conclusion: Initial treatment of disseminated NTM infection with imipenem for 2 weeks has no statistical difference in the relapse rate when compared with treatment of imipenem for 4 weeks.

Keywords: Disseminated rapidly growing nontuberculous mycobacterium; Nontuberculous mycobacteria; Imipenem

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Non tuberculous mycobacterium (NTM) is a group of *Mycobacterium* spp. Other than *M. tuberculosis* and *M. Leprae*, NTM can generally be found in the environment, such as soil or a natural water reservoir⁽¹⁾.

There are many reports that NTM can cause diseases, although it is less virulent and less severe than *M. tuberculosis*. Disseminated NTM infection is a recently emerging problem worldwide, particularly in Asian countries⁽¹⁾.

The common manifestation usually presents as lung, skin and lymph node involvement, but disseminated infection is uncommon. The incidence of NTM infection

has increased continuously over the years, but it is unclear as to the reason. This may be explained by the progress in laboratory techniques.

Disseminated NTM infections are common in Northeast of Thailand⁽²⁾, although it can be found in the other parts as well⁽³⁾. Initially the majority of cases were found to be caused by rapidly growing NTM such as *M. abscessus*, *M. chelonae*, and *M. fortuitum*, but later, also by the other mycobacteria spp. Most patients also have concomitant opportunistic infections such as Salmonella, fungi (*Cryptococcus neoformans*, *Histoplasma capsulatum*, *Talaromyces marneffei*, etc.) as well as the other mycobacteria⁽³⁻¹¹⁾. These NTM-infected patients commonly have reactive skin lesions such as Sweet syndrome, generalized erythematous pustulosis (AJEP) or erythema nodosum. Recently, it is found that certain immune defects might be an underlying cause, especially anti-interferon gamma autoantibodies⁽²⁻⁴⁾. Nowadays, this syndrome is named as adult onset immunodeficiency⁽⁴⁾.

There are many antibiotics have in vitro activity against rapidly growing NTM, particularly macrolides, fluoroquinolones, linezolid, clofazimine, imipenem, cefoxitin, and amikacin⁽¹²⁻¹⁵⁾. However, there is no clear guideline on how to treat disseminated rapidly growing NTM infections. Most patients usually receive macrolides and quinolones as combination therapy^(16,17). In cases of sepsis, extensive skin lesions or generalized lymphadenopathy, antibiotics such as imipenem, amikacin, and tigecycline are usually given intravenously to hasten clinical resolution⁽¹⁶⁻¹⁸⁾. Imipenem is most commonly used due to less side effects than the others, and is on the essential drug list of Thailand. However, the optimal duration of imipenem therapy is uncertain due to varying clinical experiences of users, commonly between 2 to 4 weeks. However, the clinical resolution is usually after 2 weeks of imipenem, but many physicians usually continue it for 4 weeks to reduce the likelihood of relapse. Many patients have clinical relapse during a follow-up. Some authorities suggest that a more prolonged duration of imipenem initially may prolong the time to relapse. However, there are no supported evidences of such a hypothesis.

Objective

Therefore, we conducted the present study to compare the effect of 2 weeks versus 4 weeks of imipenem from historical cohort upon the relapse rate of disseminated rapidly growing NTM infection.

Materials and Methods

Study design and participants

The present study was a single arm, open-label study of 2-week imipenem compared with historical control data

of a 4-week imipenem as initial induction therapy. This was conducted in Srinagarind Hospital, a tertiary teaching medical center in Khon Kaen, Thailand between 1 January 2019 and 28 February 2021.

The inclusion criteria were as follows; (1) male or female aged >18 years old, 2) culture confirmed disseminated rapidly growing NTM infection, 3) give informed consent. The exclusion criteria are as follows; 1) lactating or breastfeeding women, 2) allergies to imipenem or carbapenem, 3) have other intravenous therapy other than imipenem that may effect to treatment response. All eligible patients had to sign informed consent before entry into the present study.

Imipenem 500 mg every 6 hours intravenously were given for 2 weeks. After imipenem is discontinued, oral macrolides and fluoroquinolones will be given as oral long-term therapy. The patient will come for a follow-up every month for 3 months and then every 3 months afterwards. The demographic data, microbiological data, and clinical relapse will be collected.

For oral maintenance therapy after imipenem, there were many regimens but all of them received only one of macrolides (azithromycin, clarithromycin) and one of quinolones (ofloxacin, ciprofloxacin, levofloxacin, moxifloxacin) determined by primary physician preference.

For historical cohort data of the 4-week imipenem therapy, the medical records of disseminated rapidly growing NTM infection during 1 January 2018 and 31 December 2018 were reviewed. The data were collected only on cases that received imipenem for 4 weeks. Electronic and paper medical record review yielded subject demographics data. The oral maintenance therapy was the same as the current study.

Operational definitions

Relapse means evidences of new symptoms and signs of disseminated NTM infections which need treatment with imipenem therapy.

Treatment failure means prolonged treatment with imipenem more than 2 weeks in 2-week arm and more than 4 weeks in 4-week arm.

The relapse and treatment failure will be determined by primary physicians. For historical cohort data the relapse and treatment failure will be determined by investigators.

Outcome

The primary endpoint is the relapse rate of disseminated rapidly growing NTM infection after treatment with imipenem for 2 weeks versus 4 weeks within 1 month and 3 months of follow-up.

Statistical analysis

There was no previous data of the relapse rate of disseminated rapidly growing NTM after treatment with imipenem. Therefore, we did a 1-year retrospective review of our medical records during January 1, 2018 to December 31, 2018. There were 43 patients who were diagnosed with disseminated NTM infection and received imipenem therapy for 4 weeks. After 10 patients were excluded due to being lost to follow up and referred to another hospital, there were 28 patients left who had clinical relapse within 12 weeks and got imipenem therapy for 4 weeks again. Therefore, the 12-week relapse rate was 3.6%. In the non-inferiority design, the hypothesis is no difference in the relapse rate between 2-week and 4-week imipenem, and an accepted non-inferiority margin at 10% with an alpha of 0.05 and 80% power, the sample size was 43 patients in each group.

The patients' characteristic data was analyzed by descriptive statistics. Continuous variables were presented as mean and standard deviation (SD). Categorical variables were presented as numbers and percentage. All statistical analysis was performed by using STATA16.0 (StataCorp., College Station, TX, USA).

Ethical considerations

The study was designed by the authors and approved by the Human Research Ethics Committee of Khon Kaen University as per the Helsinki Declaration and the Good Clinical Practice Guidelines (HE631088).

Results

There were 32 patients who were diagnosed as disseminated rapidly growing NTM infection admitted in Srinagarind hospital during 1 January 2019 and 31 February 2021. Six patients were excluded due to admissions for other reasons. There were 26 cases who were enrolled and they received a 2-week imipenem therapy.

There were 92 cases of disseminated rapidly growing NTM who were admitted in the hospital during 2018. Only 30 cases received 4-weeks of imipenem and were used as comparative data.

Flowchart of study enrollment and data for study analysis was shown in Figure 1.

The demographic data is demonstrated in (Table 1).

Interferon-gamma autoantibody was determined in 54/56 (96.4%) cases and all were detected.

There were 16 cases received more than 2 weeks due to the decision of the primary physicians (Table 2).

By intent-treat analysis, there was no difference in the relapse rate at 1 and 3 months. For the as treated analysis, which included those 16 cases in the 4-week arm, there also was no difference in the relapse rate at 1 and 3 months (Table 3).

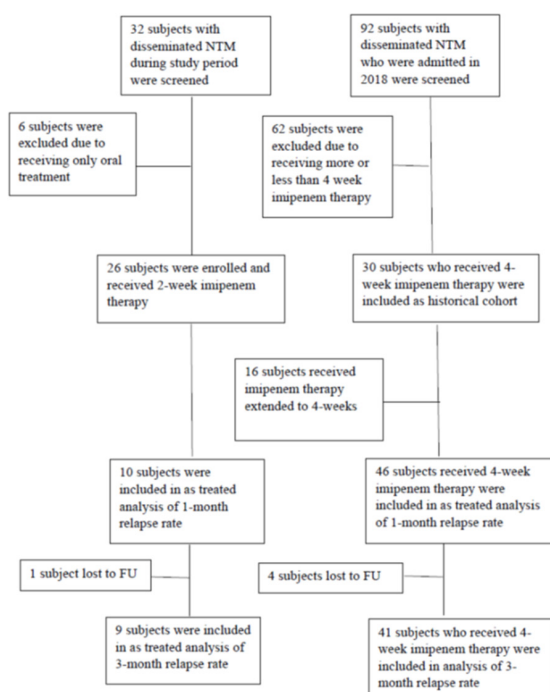


Figure 1. Flowchart of study.

Discussion

The present study shows that treatment of disseminated rapidly growing NTM infection with imipenem for 2 weeks versus 4 weeks does not have any difference in the relapse rate.

Disseminated NTM infection is an emerging clinical syndrome recently recognized and reported more worldwide, especially in Asian countries⁽¹⁾. The first large case series in Thailand was reported by Chetchotisakd et al.⁽²⁾, which showed a new clinical syndrome that presented with prolonged fever, multifocal lymphadenitis with positive culture for NTM, with or without reactive skin lesions and concomitant other infections, especially systemic fungi and salmonella. The term of disseminated rapidly growing NTM lymphadenitis was proposed because the majority of NTM were rapidly growing mycobacteria, especially *M. abscessus*, and the dominant feature was lymphadenitis. After that, more case series in Thailand were reported and they found that slow growing NTM can also cause this clinical syndrome^(3,4,6,7). The pathogenesis of this disease later found that it is associated with anti-interferon autoantibody^(4,5). Additionally, there was a broader spectrum of this disease, including opportunistic infections such as cryptococcosis, and histoplasmosis without NTM infection^(6,7,10). The term of adult onset acquired immunodeficiency was proposed and widely accepted⁽⁴⁾.

Although there is great progress in understanding the

Table 1. Baseline Demographic Characteristics and Laboratory Findings

Characteristic	Total (n=56)	4 weeks group (n=30)	2 weeks group (n=26)	p-value
Age, median (IQR), years	53 (35 to 66)	54 (37 to 66)	48 (35 to 62)	0.01
Male sex, n (%)	23 (41.1)	15 (50)	8 (33.8)	0.12
Agriculturist, n (%)	11 (33.3)	5 (35.7)	6 (31.6)	0.55
Underlying condition, n (%)				
Diabetes mellitus	11 (19.6)	7 (23.3)	4 (15.4)	0.34
Hypertension	8 (14.3)	4 (13.3)	4 (15.4)	0.57
NTM prior admission, n (%)				
M. abscessus	32 (57.1)	17 (56.7)	15 (57.7)	0.58
M. fortuitum	4 (7.1)	0 (0)	2 (7.7)	0.21
M. chelonae	1 (1.8)	0 (0)	1 (3.9)	0.46
M. marinum	1 (1.8)	0 (0)	1 (3.9)	0.46
M. tuberculosis	4 (7.1)	1 (3.3)	3 (11.5)	0.22
M. scrofulaceum	1 (1.8)	1 (3.3)	0 (0)	0.54
M. simiae	1 (1.8)	0 (0)	1 (3.9)	0.46
M. szulgai	1 (1.8)	1 (3.3)	0 (0)	0.54
NTM in current admission, n (%)				
M. abscessus	16 (28.6)	10 (33.3)	6 (23.1)	0.29
M. fortuitum	1 (1.8)	0 (0)	1 (3.9)	0.46
M. chelonae	1 (1.8)	1 (3.3)	0 (0)	0.54
M. intracellulare	1 (1.8)	0 (0)	1 (3.9)	0.46
Mycobacteria spp.	1 (1.8)	1 (3.3)	0 (0)	0.54
Co-infection, n (%)				
Salmonella spp.	6 (10.7)	2 (6.7)	4 (15.4)	0.29
Histoplasma capsulatum	4 (7.1)	2 (6.7)	2 (7.7)	0.64
Talaromyces marneffei	1 (1.8)	1 (3.3)	0 (0)	0.54
Herpes zoster virus	1 (1.8)	1 (3.3)	0 (0)	0.54
Herpes simplex virus	3 (5.4)	3 (10)	0 (0)	0.15
Clinical Presentation, n (%)				
Sweet's syndrome	17 (30.4)	8 (26.7)	9 (34.6)	0.36
AGEP	9 (16.1)	4 (13.3)	5 (19.2)	0.06
Lymphadenitis	55 (98.2)	30 (100)	25 (96.2)	0.46
Pneumonia	5 (8.9)	2 (6.7)	3 (11.5)	0.43
Osteomyelitis	4 (7.1)	1 (3.3)	3 (11.5)	0.25
Concurrent oral medication, n (%)				
Ofloxacin	18 (32.1)	11 (36.7)	7 (26.9)	0.31
Ciprofloxacin	16 (28.6)	9 (30)	7 (26.9)	0.52
Levofloxacin	21 (37.5)	10 (33.3)	11 (42.3)	0.34
Clarithromycin	35 (62.5)	23 (76.7)	12 (46.2)	0.02
Azithromycin	21 (37.5)	7 (23.3)	14 (53.6)	0.02
Clofazimine	19 (33.9)	13 (43.3)	6 (23.1)	0.09
Isoniazid	6 (10.7)	4 (13.3)	2 (7.7)	0.41
Rifampicin	6 (10.7)	5 (16.7)	1 (3.9)	0.13
Ethambutol	16 (28.6)	8 (26.7)	8 (30.8)	0.48
Pyrazinamide	1 (1.8)	0 (0)	1 (3.9)	0.46
Ethionamide	1 (1.8)	0 (0)	1 (3.9)	0.46
Cotrimoxazole	7 (12.5)	5 (16.7)	2 (7.7)	0.28
Doxycycline	1 (1.8)	1 (3.3)	0 (0)	0.54
Itraconazole	1 (1.8)	1 (3.3)	0 (0)	0.54

Table 1. Cont.

Characteristic	Total (n=56)	4 weeks group (n=30)	2 weeks group (n=26)	p-value
Linezolid	1 (1.8)	1 (3.3)	0 (0)	0.54
Laboratory				
WBC, median (IQR), cells/mL	20,110 (7,880 to 38,680)	17,695 (9,390 to 34,600)	20,410 (7,880 to 38,680)	0.67
ClCr, median (IQR), mL/min	64 (38 to 123)	55 (38 to 99)	75 (43 to 123)	0.03
ESR, median (IQR), mm/h	82 (11 to 114)	98 (58 to 114)	76.5 (11 to 105)	0.12
CRP, median (IQR), mg/L	61.2 (0.85 to 273.1)	54.9 (10 to 273.1)	51.5 (0.85 to 204.3)	0.83
Interferon gamma titer, n (%)				
<1: 5,000	1 (1.8)	0 (0)	1 (3.9)	0.48
>1: 5,000	53 (98.2)	28 (100)	25 (96.2)	

IQR=interquartile range; NTM=nontuberculous mycobacteria; AGEP=acute generalized exanthematous pustulosis; ClCr=creatinine clearance; ESR=erythrocyte sedimentation rate; CRP=C-reactive protein

Table 2. Number of subjects in each treatment arm

Duration of imipenem	n (%) n=56
4 weeks of imipenem	30 (53.6)
2 weeks of imipenem	26 (46.4)
Extended duration to 4 weeks of imipenem (treatment failure)	16 (28.6)

pathogenesis and clinical spectrum, there is still no well-established guideline for treatment of this disease, especially disseminated rapidly growing NTM infection. The in vitro susceptibility of rapidly growing NTM to commonly used antibiotics is variable and not satisfactory, especially rapidly growing mycobacteria⁽¹¹⁻¹⁴⁾. Initial intravenous therapy with imipenem is preferably initiated in therapy in patients who present with clinical sepsis or extensive lymphadenitis, with or without concomitant oral macrolides or quinolones combinations, which are used as oral long-term therapy^(15,16). The optimal regimen and duration of initial and long-term treatment is still unknown. In our institute, we usually give imipenem for 4 weeks as induction therapy and 1 to 3 years of oral treatment. However, there still has been relapse with clinical symptoms during follow-ups. The patients who had clinical relapse were admitted and retreated with intravenous imipenem for 4 weeks or until significant clinical improvement. Some patients had more than 2 relapses during their 2 to 3 years follow-ups and needed intermittent admission and 4-week imipenem therapy.

By our experience, we found that most of our patients had significant clinical resolution after 1 week of imipenem therapy. Imipenem is only intravenous formulary and there is no oral form, therefore the patients must be hospitalized. If the patients stay only 2 weeks in the hospital rather than 4 weeks, this will reduce cost of hospitalization and antibiotics.

In the present study, we had 56 cases of disseminated NTM enrolled during study period. There were 26 and 30 patients in the 2-week and 4-week imipenem treatment arms.

There were 16 cases in 2-week arm who had extension to 4-week imipenem therapy while no one in 4-week arm had extension more than 4 weeks.

By intent-to-treat analysis, the relapse rate of 2-week imipenem therapy was not statistically different from the 4-week arm at 1 month (8.0% vs. 6.7%) (p=0.89) and at 3 months (53.8% vs. 33.3%) (p=0.67). By as-treated analysis, there was also no difference in the relapse rate between the 2-week arm and 4-week arm at 1 month (10% vs. 6.7%) (p=0.72) and 3 months (44.4% vs. 34.2%) (p=0.69) follow-up.

Therefore, extending initial imipenem treatment from 2 weeks to 4 weeks for rapidly growing NTM treatment did not significantly reduce relapse rates, even though about 30% of patients in the 2-week group required extension to 4 weeks due to a partial response to therapy.

Although *M. abscessus* is susceptible to amikacin and clofazimine. But amikacin has high incidence of ototoxicity and nephrotoxicity in our experience, therefore in our center, we do not use amikacin in treatment of new NTM cases. Clofazimine was rarely used during study period due to a shortage of supply.

The strength of our study is the first report of clinical outcomes and relapse rates of disseminated rapidly growing NTM after treatment with imipenem therapy.

The present study has some limitations. First, the patients enrolled in this study did not reach the sample size calculated. Second, there was significant treatment failure in the 2-week arm because the primary physicians thought the patients should receive more imipenem therapy because they still had significant lymphadenopathy. The investigators did not intervene with their decision. Third, this is a single center study, there may be a differences in practices and preferences of primary physicians and specialists about the duration of imipenem therapy.

Conclusion

In conclusion, the 2-week therapy of imipenem for

Table 3. Primary outcome

Outcome*	n (%)	4 weeks	2 weeks	Odds ratio	p-value
ITT analysis					
Relapse in 1 month	4/56 (7.3)	2/30 (6.7)	2/26 (8.0)	1.15 (0.15, 8.77)	0.89
Relapse in 3 months	24/56 (48)	10/30 (33.3)	14/26 (53.8)	1.61 (0.61, 4.24)	0.17
As treated analysis					
Relapse in 1 month	4/56 (7.3)	3/46 (6.7)	1/10 (10.0)	1.53 (0.14,16.31)	0.72
Relapse in 3 months	18/50 (36)	14/41 (34.2)	4/9 (44.4)	1.30 (0.35, 4.89)	0.69

* There are some missing data, therefore the number of the determinant (n) is different

disseminated rapidly growing NTM had more relapse rate than the 4-week regimen but no statistically significance. A larger and more well-designed study is needed.

What is already known on this topic?

There is no clear guideline on how to treat disseminated rapidly growing NTM infections. Most patients usually receive imipenem therapy for 2 to 4 weeks followed by macrolides and quinolones as combination therapy. Relapse rate is still frequent.

What this study adds?

This study found that extending initial imipenem treatment from 2 weeks to 4 weeks for rapidly growing NTM treatment did not significantly reduce relapse rates, even though about 30% of patients in the 2-week group required extension to 4 weeks due to a partial response to therapy. This suggests that while a longer duration of imipenem might improve the initial outcome for some, it may not be sufficient to prevent relapse in all cases and could benefit from further research into longer or different combination therapies.

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Conflicts of interest

The authors declare no conflicts of interest.

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