TB/NTM Year in Review 2025

충북대학교병원
호흡기 내과
김선형

목차 – 일단 결핵부터

Treatments

Rifampicin-susceptible pulmonary tuberculosis

Tuberculous Meningitis

MDR/RR TB

Prevention

BCG revaccination

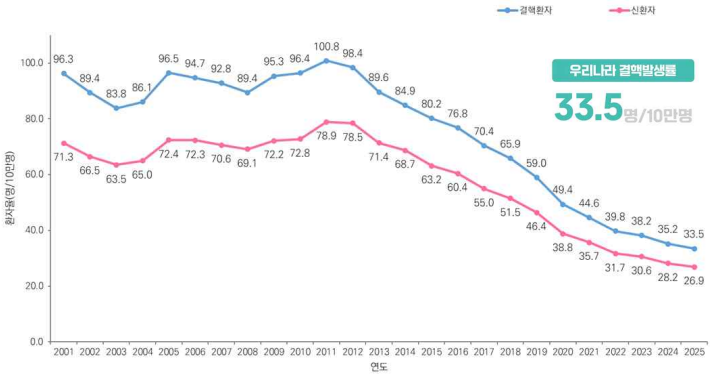
MDR/RR TB

Drugs

Linezolid **:** Dose, 대체제 (Sutezolid, Delpazolid)

Fluoroquinolone

2025 결핵 환자 신고 현황



[그림 1] 결핵 (신)환자율 2001–2025

Efficacy and safety of 8-week regimens for the treatment of rifampicin-susceptible pulmonary tuberculosis (TRUNCATE-TB): a prespecified exploratory analysis of a multiarm, multi-stage, open-label, randomised controlled trial

	Standard 24-week treatment regimen (n=181)	Rifampicin-linezolid 8-week regimen (n=184)	Rifampicin-clofazimine 8-week regimen (n=78)	Rifapentine-linezolid 8-week regimen (n=42)	Bedaquiline-linezolid 8-week regimen (n=189)
Primary outcome					
Unfavourable outcome	7 (4%)	46 (25%)	10 (13%)	7 (17%)	26 (14%)
Estimated absolute risk (%, 95% BCI)	3·5% (1·5-6·6)	24·5% (18·4-31·0)	11·2% (5·4-18·9)	14·9% (6·2-26·8)	12·9% (8·6-18·0)
Probability that absolute risk ≤20%	1·000	0·076	0·984	0·831	0·996
Risk difference (%, 95% BCI)*	..	21·0% (14·3-28·1)	8·9% (2·0-17·2)	10·8% (0·1-23·7)	9·3% (4·3-14·9)
Probability that risk difference ≤12%	..	0·004	0·800	0·606	0·837
Outcome classification					
Unfavourable outcome (total)	7 (4%)	46 (25%)	10 (13%)	7 (17%)	26 (14%)
Switched treatment with positive culture	0	0	0	0	1
Failure at end of treatment	0	1	0	0	0
Relapse confirmed†	4	40	10	6	21
Relapse unconfirmed‡	0	0	0	0	3
Death, except unrelated§	2	3	0	1	0
Not seen at week 96, unfavourable¶	1	2	0	0	1
Unassessable outcome (total)	6 (3%)	29 (16%)	12 (15%)	13 (31%)	16 (8%)
Incomplete initial treatment‖	1	9	4	10	6
Missed >7 days' treatment in first 56 days	3	14	4	1	6
Switched treatment without positive culture	0	3	1	0	2
Restarted treatment without failure or relapse	1	3	3	2	0
Death, unrelated**	1	0	0	0	0
Not seen at week 96, unassessable††	0	0	0	0	2
Favourable outcome (total)	168 (93%)	109 (59%)	56 (72%)	22 (52%)	147 (78%)

***8-week regimens alone had lower efficacy than standard treatment.**

***They should only be used within the TRUNCATE management strategy.**

8주 치료

relapse monitoring

relapse 시 재치료 (표준치료)

96주 outcome 평가

Xpert MTB/RIF semi-quantitative결과

Very low + Low : probability ≈ 0.97

Lancet Infect Dis 2025; 25: 1084–96

Trial of High-Dose Oral Rifampin in Adults with Tuberculous Meningitis

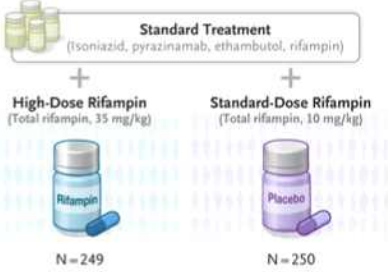
*Rifampin CSF penetration이 낮음
*CSF 농도 = plasma의 약 5%
→ standard dose (10 mg/kg)로는 **CSF에서 detectable level이 없는 경우 많음**
***N Engl J Med 2016;374:124-34**
→ rifampin 15 mg/kg → 효과 없음

Standard therapy Vs High dose group (Rifampin 35mg/kg/day for 8 weeks)

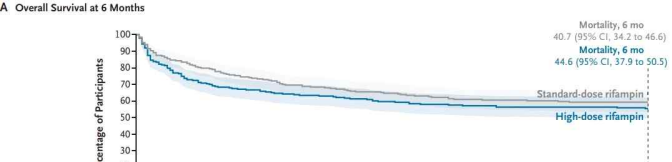
Treatment duration : 9-12 months
adjunctive glucocorticoids 사용

Primary outcome : 6-month mortality

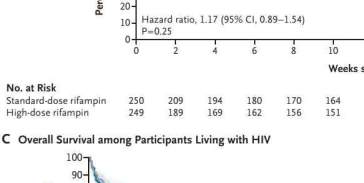
Secondary outcome:
12-month mortality
24주 시점의 modified Rankin scale
Safety outcomes

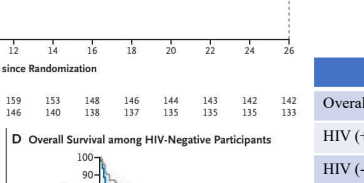


N Engl J Med 2025;393:2434-2446



	Standard	High-dose	Hazard Ratio
Overall	59.3%	55.4%	1.17 (0.89-1.54)
HIV (+)	51.6%	48.7%	1.13 (0.73-1.75)
HIV (-)	71.9%	65.9%	1.05 (0.80-1.37)





P-value (Interaction by HIV status): 0.78

N Engl J Med 2025;393:2434-2446

Trial of High-Dose Oral Rifampin in Adults with Tuberculous Meningitis

Table 2. Clinical Adverse Events and Laboratory Abnormalities.*

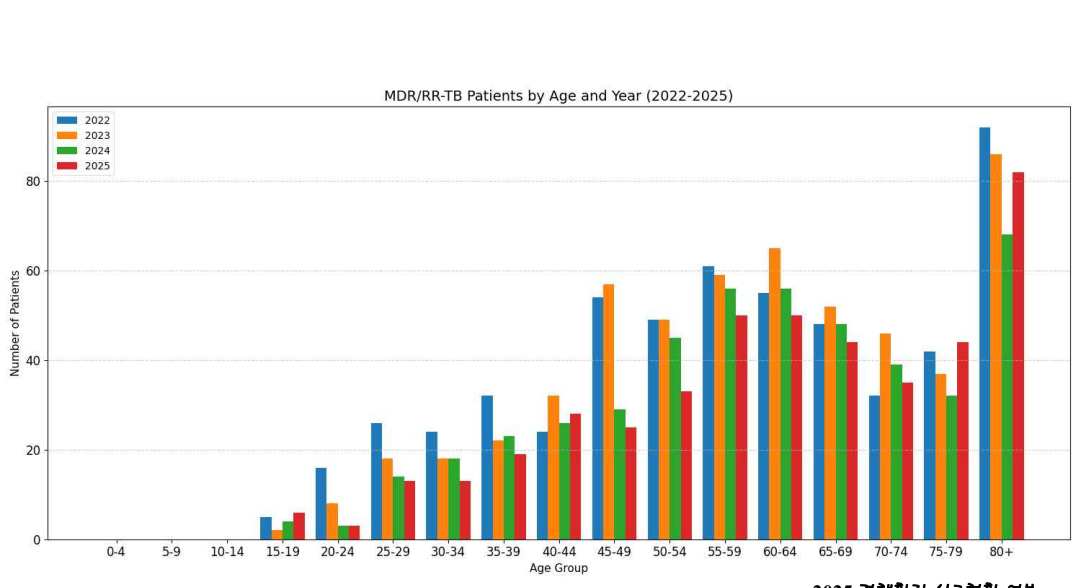
Adverse Event	High-Dose Rifampin (N=249)	Standard-Dose Rifampin (N=250)	P Value
Serious adverse events			
Participants with any serious adverse event — no. (%)	84 (33.7)	101 (40.4)	0.12
No. of serious adverse events	102	115	
Serious adverse events probably or definitely related to treatment — no./total no. (%)	7/102 (6.9)	5/115 (4.3)	
Most frequently reported grade 3–5 adverse events			
No. of grade 3–5 adverse events	192	194	
Participants with ≥1 adverse event — no. (%)	123 (49.4)	129 (51.6)	
Neurologic events — no. (%)			
Cerebrovascular accident	9 (3.6)	10 (4.0)	0.82
General seizures	5 (2.0)	6 (2.4)	0.77
Partial seizures	3 (1.2)	2 (0.8)	0.65
Space-occupying lesion	3 (1.2)	2 (0.8)	0.65
Immune reconstitution inflammatory syndrome	5 (2.0)	4 (1.6)	0.73
Aspiration pneumonia — no. (%)	16 (6.4)	4 (1.6)	0.006
Sepsis — no. (%)			
Systemic inflammatory response syndrome without identified bacteremia	6 (2.4)	7 (2.8)	0.78
Sepsis with bacteremia	4 (1.6)	10 (4.0)	0.11
Shock with multiorgan failure	14 (5.6)	13 (5.2)	0.83
Hepatic events of grade 3 or 4 — no. (%)			
Alanine aminotransferase ≥5×ULN	13 (5.2)	15 (6.0)	0.71
Alkaline phosphatase ≥5×ULN	0	0	—
Total bilirubin ≥2.6×ULN	24 (9.6)	9 (3.6)	0.007
Drug-induced liver injury †	20 (8.0)	11 (4.4)	0.09
Deaths related to drug-induced liver injury	0	0	—
Trial regimen discontinuation for >5 days	6 (2.4)	4 (1.6)	0.52

TB meningitis에서 rifampin dose escalation 전략은 임상적 benefit을 보여주지 못했다.
→ survival benefit 없음
→ neurologic recovery도 없음

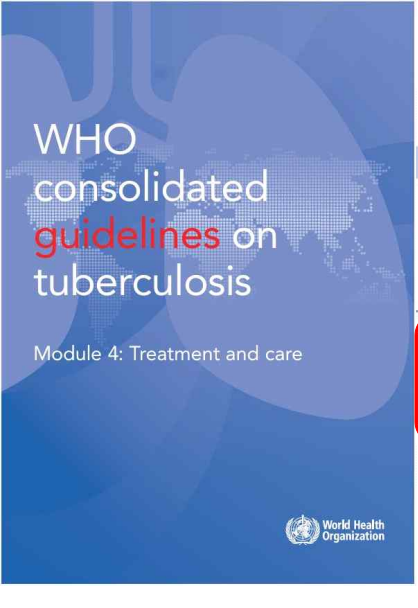
N Engl J Med 2025;393:2434-2446

MDR/RR TB

2025 결핵환자 신고현황 연보



2025 결핵환자 신고현황 연보



1. Treatment of drug-resistant TB using 6-month regimens

1.1 The 6-month bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) regimen for MDR/RR-TB and pre-XDR-TB (b)

WHO suggests the use of the 6-month treatment regimen composed of bedaquiline, pretomanid, linezolid (600 mg) and moxifloxacin (BPaLM) rather than 9-month or longer (18-month) regimens in MDR/RR-TB patients.

(Conditional recommendation, very low certainty of evidence)

1.2 The 6-month bedaquiline, delamanid, linezolid, levofloxacin and clofazimine (BDLLfxC) regimen (a)

WHO suggests the use of a 6-month treatment regimen composed of bedaquiline, delamanid, linezolid (600 mg), levofloxacin, and clofazimine (BDLLfxC) in MDR/RR-TB patients with or without fluoroquinolone resistance.

(Conditional recommendation, very low certainty of evidence)

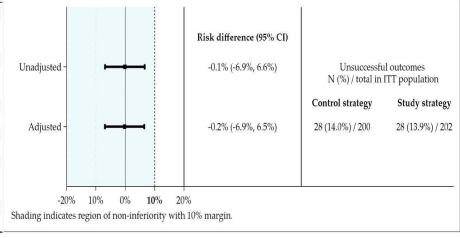
BEAT Tuberculosis

Population	Intervention	Comparator
Patients with microbiologically confirmed pulmonary MDR/RR-TB and with or without FQ resistance	6 Bdq-Dlm-Lzd-Lfx/Cfz (and/or)	•9 Bdq(6)-Lzd(2)-Lfx-Cfz-Hh-Z-E (for Fq-susceptible) •WHO currently recommended longer regimens (18-20 months) (for Fq-resistant)

Aged 6 years or older (Intervention 13 Pt.: Comparator 17 Pt.)
Including breast feeding and/or pregnant women (9 Pt.)

Table 2: Primary Efficacy Analysis, 76 week outcome, in the intention-to-treat anlaysis population.

Primary Outcome	Control Strategy	Study Strategy	Total
Total randomized (ITT population)	**200**	**202**	**402**
Successful outcome at end of treatment and follow-up			
Total	**172 (86.0%)**	**174 (86.1%)**	**346 (86.1%)**
Cured at end of treatment, and end of follow-up	162 (81.0%)	160 (79.2%)	322 (80.1%)
Cured at end of treatment, culture negative when last seen	10 (5.0%)	14 (6.9%)	24 (6.0%)
Unsuccessful end of treatment outcome			
Total	**22 (11.0%)**	**14 (6.9%)**	**36 (9.0%)**
Treatment failed	10 (5.0%)	7 (3.5%)	17 (4.2%)
Lost to follow-up on treatment	4 (2.0%)	2 (1.0%)	6 (1.5%)
Died while on treatment	7 (3.5%)	4 (2.0%)	11 (2.7%)
Not Evaluated (Participant withdrew consent)	1 (0.5%)	1 (<0.5%)	2 (<0.5%)
Unsuccessful end of follow-up			
Total	**6 (3.0%)**	**14 (6.9%)**	**20 (5.0%)**
Recurrence after cure at end of treatment	4 (2.0%)	10 (5.0%)	14 (3.5%)
Died after cure at end of treatment	2 (1.0%)	4 (2.0%)	6 (1.5%)



2. Treatment of drug-resistant TB using 9-month regimens

2.2	**The modified 9-month all-oral regimens for MDR/RR-TB (a)** WHO suggests using the 9-month all-oral regimens (**BLMZ, BLLfxCZ and BDLLfxZ**) over currently recommended longer (>18 months) regimens in patients with MDR/RR-TB and in whom resistance to fluoroquinolones has been excluded. Amongst these regimens, using BLMZ is suggested over using BLLfxCZ, and BLLfxCZ is suggested over BDLLfxZ. *(Conditional recommendation, very low certainty of evidence)*
2.3	WHO suggests against using 9-month DCLLfxZ or DCMZ regimens compared with currently recommended longer (>18 months) regimens in patients with fluoroquinolone-susceptible MDR/RR-TB. *(Conditional recommendation, very low certainty of evidence)*

- BLMZ
- BLLCfxZ
- BDLLfxZ

- DCLLfxZ
- DCMZ

Oral Regimens for Rifampin-Resistant, Fluoroquinolone-Susceptible Tuberculosis endTB Trial

Table 1 Description of endTB treatment arms {11a}

Trial regimens	Bedaquiline	Delamanid	Clofazimine	Linezolid	Fluoroquinolone	Pyrazinamide
endTB 1	Bdq			Lzd	Mfx	Z
endTB 2	Bdq		Cfz	Lzd	Lfx	Z
endTB 3	Bdq	Dlm		Lzd	Lfx	Z
endTB 4		Dlm	Cfz	Lzd	Lxf	Z
endTB 5		Dlm	Cfz		Mfx	Z
endTB 6 (Control)	Standard of care control, composed according to latest WHO Guidelines, including the possible use of Dlm or Bdq.					

Abbreviations: Bdq, bedaquiline; *Dlm,* delamanid; *Cfz,* clofazimine; *Lzd,* linezolid; *Mfx,* moxifloxacin; *Lfx,* levofloxacin; *Z,* pyrazinamide

Bactericidal activity - Bedaquiline, Delamanid, Linezolid, Fluoroquinolones

Sterilizing activity - Bedaquiline, Clofazimine, Delamanid, Linezolid, Pyrazinamide

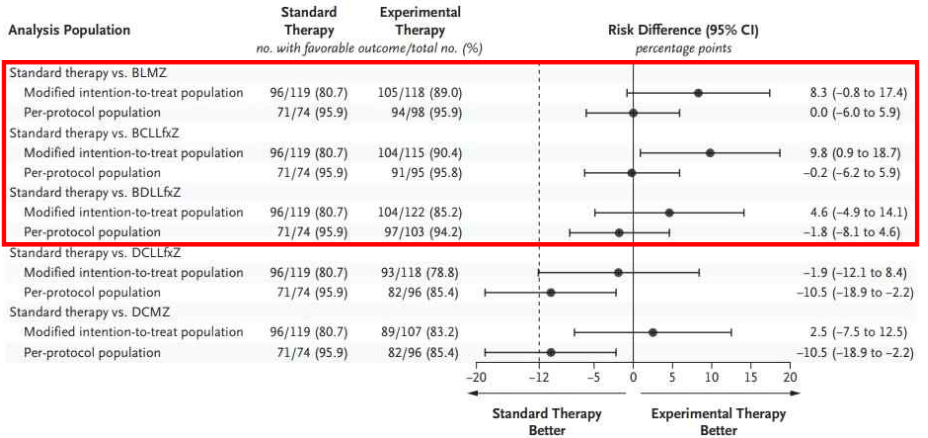
QT interval prolongation - Bedaquiline, Clofazimine, Moxifloxacin

Oral Regimens for Rifampin-Resistant, Fluoroquinolone-Susceptible Tuberculosis endTB Trial

Table 2. Primary Efficacy End Points at Week 73 (Modified Intention-to-Treat Population).*

Outcome	BLMZ (N = 118)	BCLLfxZ (N = 115)	BDLLfxZ (N = 122)	DCLLfxZ (N = 118)	DCMZ (N = 107)	Standard Therapy (N = 119)	Total (N = 699)
Favorable†							
Participants with favorable outcome — no. (%)	105 (89.0)	104 (90.4)	104 (85.2)	93 (78.8)	89 (83.2)	96 (80.7)	591 (84.5)
Difference from standard therapy (95% CI) — percentage points	8.3 (−0.8 to 17.4)	9.8 (0.9 to 18.7)	4.6 (−4.9 to 14.1)	−1.9 (−12.1 to 8.4)	2.5 (−7.5 to 12.5)	—	—
Negative culture results, wk 65 and wk 73 — no. (%)	102 (86.4)	100 (87.0)	102 (83.6)	90 (76.3)	87 (81.3)	91 (76.5)	572 (81.8)
Favorable bacteriologic, clinical, and radiologic evolution — no. (%)‡	3 (2.5)	4 (3.5)	2 (1.6)	3 (2.5)	2 (1.9)	5 (4.2)	19 (2.7)
Unfavorable†							
Participants with unfavorable outcome — no. (%)	13 (11.0)	11 (9.6)	18 (14.8)	25 (21.2)	18 (16.8)	23 (19.3)	108 (15.5)
Death from any cause — no. (%)§	2 (1.7)	1 (0.9)	3 (2.5)	3 (2.5)	2 (1.9)	2 (1.7)	13 (1.9)
Positive culture results — no. (%)¶	1 (0.8)	3 (2.6)	4 (3.3)	12 (10.2)	8 (7.5)	1 (0.8)	29 (4.1)
Recurrence — no. (%)‖	0	0	0	1 (0.8)	2 (1.9)	0	3 (0.4)
Permanent treatment discontinuation due to adverse event — no. (%)	3 (2.5)	3 (2.6)	1 (0.8)	1 (0.8)	1 (0.9)	2 (1.7)	11 (1.6)
Poor treatment adherence or loss to follow-up — no. (%)	3 (2.5)	2 (1.7)	3 (2.5)	3 (2.5)	4 (3.7)	8 (6.7)	23 (3.3)
Withdrawal of consent — no. (%)	1 (0.8)	1 (0.9)	4 (3.3)	3 (2.5)	0	7 (5.9)	16 (2.3)
Other unfavorable outcome — no. (%)**	3 (2.5)	1 (0.9)	3 (2.5)	2 (1.7)	1 (0.9)	3 (2.5)	13 (1.9)

Oral Regimens for Rifampin-Resistant, Fluoroquinolone-Susceptible Tuberculosis endTB Trial



N Engl J Med 2025;392:468-482

Bedaquiline, delamanid, linezolid, and clofazimine for rifampicin-resistant and fluoroquinolone-resistant tuberculosis (endTB-Q): an open-label, multicentre, stratified, non-inferiority, randomised, controlled, phase 3 trial

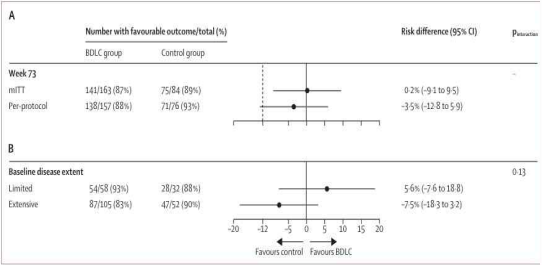
- Extensive disease
-39 weeks (9-month regimen)

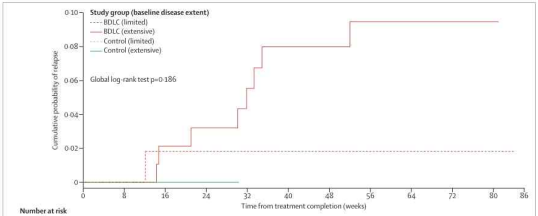
- Limited disease
-24 weeks (6-month regimen)
-a positive culture at 8 weeks or later : extend to 9 months

- Linezolid 600mg 16wks
→ 300 mg once per day or 600 mg three times per week

- 15세 이상, 산모는 제외

- Extensive disease
 - smear 2+ or 3+ irrespective of cavitation
 - smear 1+ in the presence of cavitation





Lancet Respir Med . 2025 Sep;13(9):809-820

Prevention

* BCG revaccination

* MDR/RR TB

BCG Revaccination for the Prevention of *Mycobacterium tuberculosis* Infection

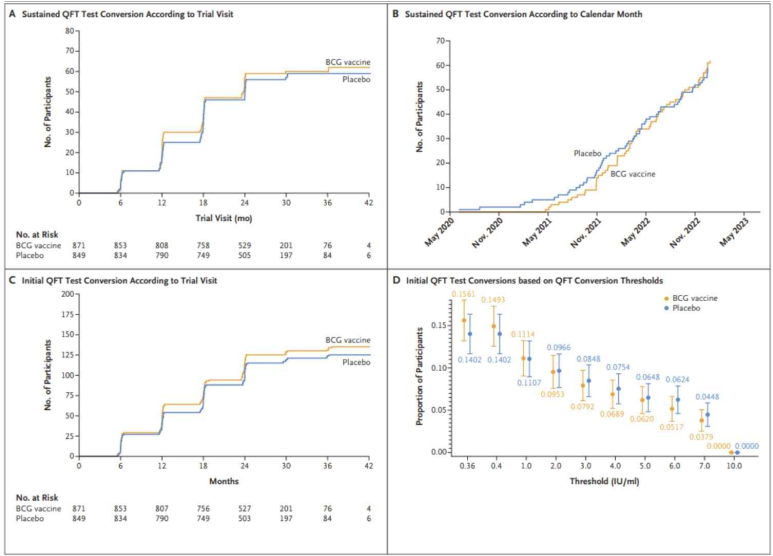
Double-blind, phase 2b, randomized, placebo-controlled trial
five sites in South Africa

Primary objective : the efficacy of BCG revaccination

The assessment of M. tuberculosis infection : QFT Gold-Plus test

Participants: 10 to 18 years of age and HIV-negative and QFT test–negative

BCG Revaccination for the Prevention of *Mycobacterium tuberculosis* Infection

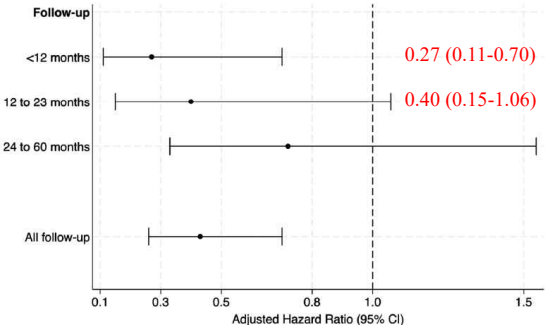


N Engl J Med . 2025 May 8;392(18):1789-1800

The effectiveness of isoniazid preventive treatment among contacts of multidrug-resistant tuberculosis: a systematic review and individual-participant meta-analysis

Table 2 Effectiveness of isoniazid on risk of incident tuberculosis in household contacts of multidrug-resistant tuberculosis cases.

Group	Treatment	Person-years of follow-up	Contacts, *n*	Progressing to disease, *n*	Age-adjusted HR (95% CI)	Fully adjusted HR (95% CI)
All participants (*N*=6668)	Not given TPT	12471	5648	167	1 (Referent)	1 (Referent)
	Given INH	1998	1020	20	0.43 (0.26-0.70)	0.41 (0.25-0.68)
Children <20 y (*n*=2749)	Not given TPT	3526	1847	50	1 (Referent)	1 (Referent)
	Given INH	1596	902	17	0.54 (0.30-0.97)	0.51 (0.28-0.92)



17개국에서 다제내성 결핵 환자와 접촉한 **6,668명**
6개월간 이소니아지드를 복용한 그룹과 예방 치료를 받지 않은 그룹

* 결핵 발생률이 인구 10만 명당 **100명 이상인 지역**
- aHR 0.40 (95% CI 0.24-067)

- **숙주의 면역 시스템(Host immune system)과 상호작용**하여 결핵균의 사멸
- **이종 감염 (Exogenous Infection)**
- 낮은 수준의 내성

AJRCCM, 2026, 212, 129–137

Drugs

*Linezolid **:** Dose, 대체제 (Sutezolid, Delpazolid)
- Peripheral & Optic neuropathy
- Bone marrow suppression

*Levofloxacin 용량

Linezolid

- **50S ribosomal subunit의 23S rRNA** 결합 부위에 작용
- 특히 Gram (+) 균의 ribosome을 표적

Mitochondria ribosome:

- 55S (28S + 39S)
- 구조적으로 **세균 70S(rRNA 구성 포함)**와 유사
- **Mitochondria 단백질 합성까지 억제**
- Autophagy inhibition

→ **Peripheral neuropathy, Optic neuropathy, Myelosuppression**

Optimal dosing and duration of linezolid for the treatment of multidrug-resistant and rifampicin-resistant tuberculosis: an individual patient data meta-analysis

Linezolid	600mg 8주	600mg 16 주 이후 300mg 8 주	600mg 39주	1200mg 25주

Treatment outcomes	Total	Group 1	Group 2	Group 3	Group 4	p-value[#]
Subjects (n)	945	215	447	183	100	
Cured or treatment completed (n)	794	127	404	167	96	<0.001
% (95% CI)	84.0 (81.7–86.4)	59.1 (52.5–65.6)	90.4 (87.6–93.1)	91.3 (87.2–95.3)	96.0 (92.2–99.8)	
Treatment failed (n)	47	34	5	6	2	
% (95% CI)	5.0 (3.6–6.4)	15.8 (10.9–20.7)	1.1 (0.1–2.1)	3.3 (0.7–5.9)	2.0 (0–4.7)	
Died (n)	21	17	1	3	0	
% (95% CI)	2.2 (1.3–3.2)	7.9 (4.3–11.5)	0.2 (0–0.7)	1.6 (0–3.5)		
Lost to follow-up (n)	26	15	6	5	0	
% (95% CI)	2.8 (1.7–3.8)	7.0 (3.6–10.4)	1.3 (0.3–2.4)	2.7 (0.4–5.1)		
Unevaluated or unassigned outcome (n)	57	22	31	2	2	
% (95% CI)	6.0 (4.5–7.5)	10.2 (6.2–14.3)	7.0 (4.6–9.3)	1.1 (0–2.6)	2.0 (0–4.7)	

CI: confidence interval. [#]: indicates the overall difference among the four groups.

Eur Respir J . 2025 Aug 22;66(2):2500315.

Optimal dosing and duration of linezolid for the treatment of multidrug-resistant and rifampicin-resistant tuberculosis: an individual patient data meta-analysis

SHRs for treatment success	Crude SHR (95% CI)	Adjusted SHR (95% CI)
Age (years)	0.99 (0.98–0.10)	0.98 (0.97–0.99)
Male sex	0.86 (0.82–0.90)	0.89 (0.79–1.01)
BMI ($kg \cdot m^{-2}$)	1.03 (1.00–1.06)	1.03 (1.01–1.06)
Cavity	1.03 (0.86–1.24)	1.08 (0.98–1.19)
Acid-fast bacilli smear positivity	1.06 (0.90–1.25)	1.14 (0.92–1.42)
Linezolid use pattern		
Group 1	0.28 (0.08–0.96)	0.24 (0.08–0.71)
Group 2	Reference	Reference
Group 3	0.36 (0.13–0.96)	0.36 (0.16–0.81)
Group 4	0.70 (0.22–2.20)	0.57 (0.23–1.43)

BMI: body mass index; CI: confidence interval; SHR: sub-distribution hazard ratio.

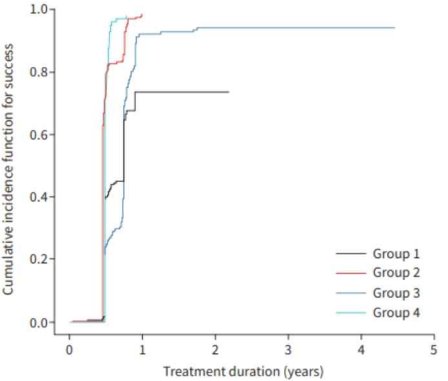


FIGURE 2 Cumulative incidence function plot for treatment success.

Adverse events of grade 3 or higher by group

	Total	Group 1	Group 2	Group 3	Group 4	p-value[#]
Subjects (n)	945	215	447	183	100	
Total (n)	235	66	101	25	43	<0.001
% (95% CI)	24.9 (22.1–27.6)	30.7 (24.5–36.9)	22.6 (18.7–26.5)	13.7 (8.7–18.6)	43.0 (33.3–52.7)	
Peripheral neuropathy (n)	33	4	8	6	15	<0.001
% (95% CI)	3.5 (2.3–4.7)	1.9 (0.1–3.7)	1.8 (0.5–3.0)	3.3 (0.7–5.9)	15.0 (8.0–22.0)	
Myelosuppression (n)	47	21	21	2	3	<0.001
% (95% CI)	5.0 (3.6–6.4)	9.8 (5.8–13.7)	4.7 (2.7–6.7)	1.1 (0–2.6)	3.0 (0–6.3)	
Optic neuropathy (n)	2	0	0	0	2	0.011
% (95% CI)	2.1 (0–0.5)				2.0 (0–4.7)	

CI: confidence interval. [#]: indicates the overall difference among the four groups.

SHRs for adverse events	Crude SHR (95% CI)	Adjusted SHR (95% CI)
Age (years)	1.01 (0.99–1.03)	1.02 (1.00–1.04)
Male sex	0.87 (0.73–1.04)	0.84 (0.73–0.97)
BMI (kg·m^{-2})	1.00 (0.97–1.03)	0.96 (0.94–0.99)
Cavity	0.91 (0.51–1.63)	0.69 (0.49–0.98)
Acid-fast bacilli smear positivity	0.82 (0.53–1.28)	0.91 (0.57–1.45)
Linezolid use pattern		
Group 1	1.60 (0.61–4.21)	1.84 (0.75–4.50)
Group 2	Reference	Reference
Group 3	0.51 (0.16–1.65)	0.55 (0.18–1.67)
Group 4	2.48 (1.28–4.82)	2.29 (1.37–3.83)

BMI: body mass index; CI: confidence interval; SHR: sub-distribution hazard ratio.

Sutezolid in combination with bedaquiline, delamanid, and moxifloxacin for pulmonary tuberculosis (PanACEA-SUDOCU-01): a prospective, open-label, randomised, phase 2b dose-finding trial

Sutezolid :

a linezolid analogue with a 2–4-fold lower minimum inhibitory concentration (MIC)

mitochondrial toxicity 감소 가능

탄자니아와 남아프리카의 4개 연구센터에서 DS-TB 환자들을 상대로 연구를 진행

12주 동안 bedaquiline + delamanid + moxifloxacin ± sutezolid

이후 standard therapy 진행 (HR)

The primary efficacy endpoint : sputum bacterial load 감소 (MGIT time-to-positivity)

	U0 (n=16)	U600 (n=15)	U1200 (n=14)	U600BD (n=15)	U800BD (n=15)	Total (n=75)
Sex						
Female	3 (19%)	4 (27%)	3 (21%)	5 (33%)	4 (27%)	19 (25%)
Male	13 (81%)	11 (73%)	11 (79%)	10 (67%)	11 (73%)	56 (75%)
Age, years	30·0 (25·5–36·2)	33·0 (26·0–37·0)	35·0 (28·8–41·5)	36·0 (25·5–46·0)	34·0 (28·5–38·5)	33·0 (27·0–39·5)
Black race	16 (100%)	15 (100%)	14 (100%)	15 (100%)	15 (100%)	75 (100%)
Weight, kg	54·9 (49·4–61·0)	50·0 (45·4–57·2)	55·2 (50·8–56·2)	54·8 (49·4–57·5)	49·1 (47·8–52·8)	53·0 (48·5–57·2)
Person living with HIV	1 (6%)	0	0	1 (7%)	0	2 (3%)
Time to positivity, days	4·9 (4·0–6·0)	4·4 (3·7–6·6)	4·9 (4·5–6·7)	5·0 (4·3–6·4)	4·6 (3·9–5·6)	4·8 (4·0–6·3)
Ralph score*	62 (42–70)	62 (59–71)	70 (38–90)	52 (34–71)	70 (60–83)	62 (52–80)

Data are n (%) or median (IQR). U0=no sutezolid. U600=sutezolid 600 mg once daily. U1200=sutezolid 1200 mg once daily. U600BD=sutezolid 600 mg twice daily. U800BD=sutezolid 800 mg twice daily. *Ralph score is a published scoring system to rate the severity of chest x-ray abnormalities in individuals with tuberculosis.

Table 1: **Baseline characteristics**

Lancet Infect Dis . 2025 Nov;25(11):1208-1218

Sutezolid in combination with bedaquiline, delamanid, and moxifloxacin for pulmonary tuberculosis (PanACEA-SUDOCU-01): a prospective, open-label, randomised, phase 2b dose-finding trial

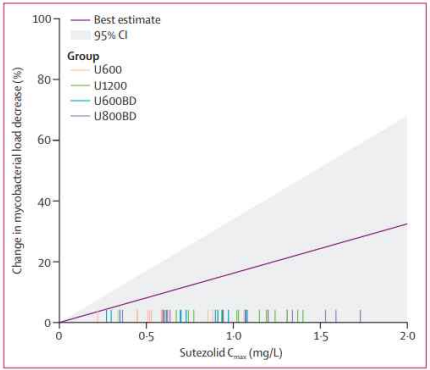


Figure 2: **Model-predicted sutezolid exposure–response effect**

	U0 (n=15)	U600 (n=15)	U1200 (n=13)	U600BD (n=15)	U800BD (n=15)	Overall (n=73)
Summary						
Any adverse event	6 (40%)	5 (33%)	7 (54%)	7 (47%)	4 (27%)	29 (40%)
Serious adverse event	0	1 (7%)	1 (8%)	4 (27%)	1 (7%)	7 (10%)
Severity grade						
Grade 1, mild	3 (20%)	2 (13%)	2 (15%)	4 (27%)	1 (7%)	12 (16%)
Grade 2, moderate	3 (20%)	4 (27%)	4 (31%)	4 (27%)	1 (7%)	16 (22%)
Grade 3, severe	1 (7%)	2 (13%)	3 (23%)	5 (33%)	2 (13%)	13 (18%)
Grade 4, life threatening	1 (7%)	1 (7%)	0	3 (20%)	0	5 (7%)
Grade 5, death	0	0	0	1 (7%)	0	1 (1%)
Relatedness to sutezolid						
Unrelated	4 (27%)	4 (27%)	6 (46%)	7 (47%)	3 (20%)	24 (33%)
Unlikely related	1 (7%)	1 (7%)	1 (8%)	4 (27%)	2 (13%)	9 (12%)
Possibly related	0	0	1 (8%)	4 (27%)	0	5 (7%)
Probably related	1 (7%)	1 (7%)	1 (8%)	1 (7%)	0	4 (5%)
Definitely related	0	0	0	0	0	0
Relatedness to other drugs of the regimen						
Unrelated	3 (20%)	4 (27%)	6 (46%)	7 (47%)	3 (20%)	23 (32%)
Unlikely related	2 (13%)	0	1 (8%)	1 (7%)	2 (13%)	6 (8%)
Possibly related	1 (7%)	0	1 (8%)	4 (27%)	1 (7%)	7 (10%)
Probably related	1 (7%)	1 (7%)	1 (8%)	1 (7%)	0	4 (5%)
Definitely related	0	0	0	1 (7%)	0	1 (1%)

dose-response는 있지만 plateau가 없어 optimal dose 결정 불가

Lancet Infect Dis . 2025 Nov;25(11):1208-1218

Delpazolid in combination with bedaquiline, delamanid, and moxifloxacin for pulmonary tuberculosis (PanACEA-DECODE-01): a prospective, randomised, open-label, phase 2b, dose-finding trial

Delpazolid :
a novel oxazolidinone
체내에서 빠르게 배설되어 mitochondria 단백질 합성 기능을 회복할 충분한 시간을 제공 → Toxicity가 감소

탄자니아와 남아프리카의 5개 연구센터에서 DS-TB 환자들을 상대로 연구를 진행
12주 동안 bedaquiline + delamanid + moxifloxacin ± Delpazolid
이후 standard therapy 진행 (HR)

The primary efficacy endpoint : sputum bacterial load 감소 (MGIT time-to-positivity)
The primary safety outcome : occurrence of oxazolidinone class toxicities, adverse events related to delpazolid

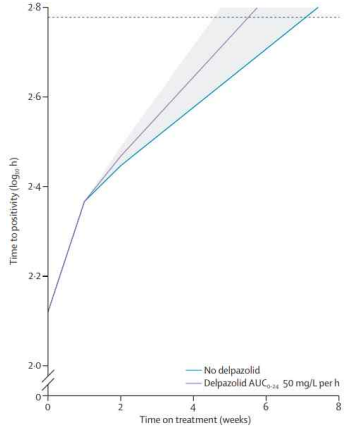
	U0 (n=16)	U600 (n=15)	U1200 (n=14)	U600BD (n=15)	U800BD (n=15)	Total (n=75)
Sex						
Female	3 (19%)	4 (27%)	3 (21%)	5 (33%)	4 (27%)	19 (25%)
Male	13 (81%)	11 (73%)	11 (79%)	10 (67%)	11 (73%)	56 (75%)
Age, years	30·0 (25·5-36·2)	33·0 (26·0-37·0)	35·0 (28·8-41·5)	36·0 (25·5-46·0)	34·0 (28·5-38·5)	33·0 (27·0-39·5)
Black race	16 (100%)	15 (100%)	14 (100%)	15 (100%)	15 (100%)	75 (100%)
Weight, kg	54·9 (49·4-61·0)	50·0 (45·4-57·2)	55·2 (50·8-56·2)	54·8 (49·4-57·5)	49·1 (47·8-52·8)	53·0 (48·5-57·2)
Person living with HIV	1 (6%)	0	0	1 (7%)	0	2 (3%)
Time to positivity, days	4·9 (4·0-6·0)	4·4 (3·7-6·6)	4·9 (4·5-6·7)	5·0 (4·3-6·4)	4·6 (3·9-5·6)	4·8 (4·0-6·3)
Ralph score*	62 (42-70)	62 (59-71)	70 (38-90)	52 (34-71)	70 (60-83)	62 (52-80)

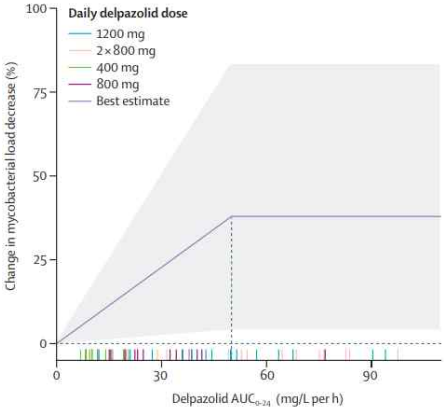
Data are n (%) or median (IQR). U0=no sutezolid. U600=sutezolid 600 mg once daily. U1200=sutezolid 1200 mg once daily. U600BD=sutezolid 600 mg twice daily. U800BD=sutezolid 800 mg twice daily. *Ralph score is a published scoring system to rate the severity of chest x-ray abnormalities in individuals with tuberculosis.

Table 1: Baseline characteristics

Lancet Infect Dis . 2025 Nov;25(11):1219-1229.

Delpazolid in combination with bedaquiline, delamanid, and moxifloxacin for pulmonary tuberculosis (PanACEA-DECODE-01): a prospective, randomised, open-label, phase 2b, dose-finding trial





Lancet Infect Dis . 2025 Nov;25(11):1219-1229.

Delpazolid in combination with bedaquiline, delamanid, and moxifloxacin for pulmonary tuberculosis (PanACEA-DECODE-01): a prospective, randomised, open-label, phase 2b, dose-finding trial

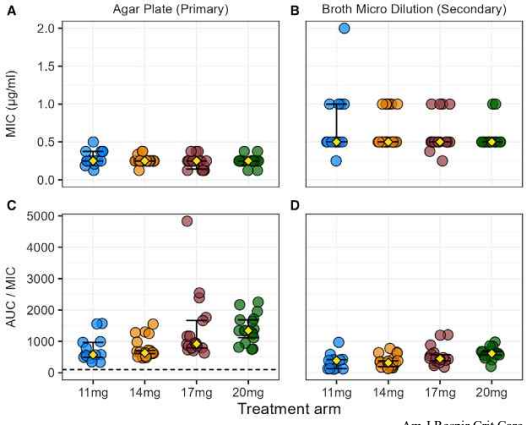
	D0 (n=15)	D400 (n=15)	D800 (n=15)	D1200 (n=16)	D800BD (n=15)	Total (n=76)
Treatment-emergent adverse events	8 (53%)	7 (47%)	8 (53%)	6 (38%)	10 (67%)	39 (51%)
Grade 1 (mild)	4 (27%)	3 (20%)	0	0	1 (7%)	8 (11%)
Grade 2 (moderate)	4 (27%)	4 (27%)	5 (33%)	5 (31%)	6 (40%)	24 (32%)
Grade 3 (severe)	0	0	1 (7%)	1 (6%)	3 (20%)	5 (7%)
Grade 4 (life-threatening)	0	0	2 (13%)	0	0	2 (3%)
Delpazolid-related treatment-emergent adverse events						
Unrelated	5 (33%)	3 (20%)	5 (33%)	3 (19%)	3 (20%)	19 (25%)
Unlikely related	0	1 (7%)	1 (7%)	1 (6%)	2 (13%)	5 (7%)
Possibly related	2 (13%)	1 (7%)	1 (7%)	1 (6%)	5 (33%)	10 (13%)
Probably related	0	1 (7%)	1 (7%)	1 (6%)	0	3 (4%)
Definitely related	1 (7%)	1 (7%)	0	0	0	2 (3%)
Serious adverse events	0	0	1 (7%)	0	2 (13%)	3 (4%)
Grade 3 (severe)	0	0	0	0	2 (13%)	2 (3%)
Grade 4 (life-threatening)	0	0	1 (7%)	0	0	1 (1%)
Delpazolid-related serious adverse events						
Unrelated	0	0	1 (7%)	0	0	1 (1%)
Possibly related	0	0	0	0	2 (13%)	2 (3%)

Efficacy and Safety of Higher Doses of Levofloxacin for Multidrug-resistant Tuberculosis
A Randomized, Placebo-controlled Phase II Clinical Trial

최대 efficacy + acceptable safety를 보이는 levofloxacin dose 찾기 : Target AUC/MIC = 100

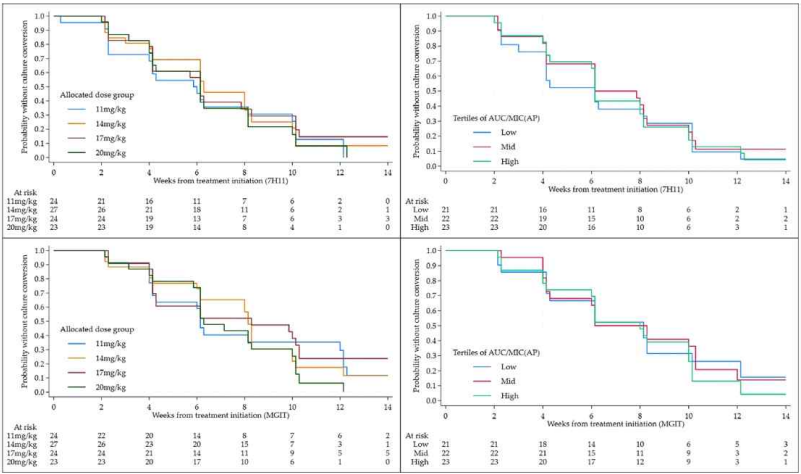
Efficacy
Time to sputum culture conversion

Safety
Grade ≥3 adverse events



Am J Respir Crit Care Med . 2025 Jul;211(7):1277-1287.

Efficacy and Safety of Higher Doses of Levofloxacin for Multidrug-resistant Tuberculosis
A Randomized, Placebo-controlled Phase II Clinical Trial



Am J Respir Crit Care Med . 2025 Jul;211(7):1277-1287.

Efficacy and Safety of Higher Doses of Levofloxacin for Multidrug-resistant Tuberculosis
A Randomized, Placebo-controlled Phase II Clinical Trial

Summary of Safety Outcomes by Allocated Treatment Arm

	Daily Levofloxacin Dose					
	11 mg/kg	14 mg/kg	17 mg/kg	20 mg/kg	Total	*P* Value
Total pts. in safety analysis	25	28	28	27	108	—
Any grade 3–5 AE	4 (16.0%)	4 (14.3%)	7 (25.0%)	10 (37.0%)	25 (23.1%)	0.042
Any SAE	2 (8.0%)	1 (3.6%)	4 (14.3%)	3 (11.1%)	10 (9.3%)	0.412
Death	0	0	1 (3.6%)	0	1 (0.9%)	0.667
QTcF >450 ms	0	6 (21.4%)	1 (3.6%)	3 (11.1%)	10 (9.3%)	0.604*
QTcF >500 ms	0	0	0	1 (3.7%)	1 (0.9%)	0.179*
Grade 3–5 AE†						
Blood uric acid increased	1 (4.0%)	2 (7.1%)	1 (3.6%)	3 (11.1%)	7 (6.5%)	—
Bronchospasm	1 (4.0%)	1 (3.6%)	0	0	2 (1.9%)	—
Deafness	0	0	0	2 (7.4%)	2 (1.9%)	—
Eosinophilia	1 (4.0%)	0	1 (3.6%)	0	2 (1.9%)	—
Hepatic function abnormal	1 (4.0%)	0	1 (3.6%)	0	2 (1.9%)	—
Total pts. in tolerability analysis	23	27	27	25	102	—
Completed treatment (168 doses within 200 d)	14 (61%)	21 (78%)	18 (67%)	18 (72%)	71 (70%)	0.442

Levofloxacin은 1000 mg/day 이상 증량해도 efficacy는 증가하지 않고 toxicity만 증가하므로 MDR-TB 치료에서 1000 mg/day가 optimal dose이다.

Am J Respir Crit Care Med . 2025 Jul;211(7):1277-1287.

목차 – 이제야 NTM으로….

Clinical Outcomes and Prognosis

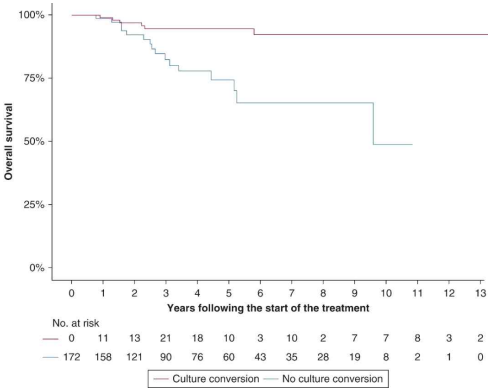
Refractory NTM-PD: Clinical Challenges and Therapeutic Strategies

New Therapeutic Options

Impact of Treatment Outcome on Mortality in Mycobacterium abscessus Complex Pulmonary Disease

- 6개월 이상 macrolide 기반 치료를 완료한 MABC-PD 환자 172명 (2012-2023, MAB 100명)
- 배양 음전을 시간 의존적 변수로 설정하여 사망률과의 연관성을 분석 (확장 콕스 모델)

  Age, BMI, Subspecies, No culture conversion at treatment completion으로 보정



	Culture conversion	
	(+)	(-)
5 yr-mortality	5.5%	25.7%
10 yr-mortality	7.7%	51%

→ 사망 위험 65% 감소 (adjusted HR 0.35)

Chest . 2026 Feb;169(2):349-359

Can the BACES score predict clinical outcomes in a Dutch cohort with nontuberculous mycobacterial pulmonary disease?

TABLE 1 A comparison of baseline characteristics and clinical outcomes across BACES risk groups

Characteristic	Low-risk (N=53)	Intermediate-risk (N=113)	High-risk (N=29)	p-value
BACES components				
BMI <18.5 kg·m^{-2}	4 (7.7)	31 (27.9)	17 (60.7)	NA
Age ⩾65 years	15 (28.3)	65 (57.5)	24 (82.8)	NA
Cavitary disease	5 (9.4)	62 (54.9)	28 (96.6)	NA
ESR ⩾15 in males or ⩾20 in females	7 (14)	67 (70.5)	28 (100)	NA
Sex, male	6 (11.3)	45 (39.8)	23 (79.3)	NA
Smoking history				
Current	7 (14)	33 (30.6)	15 (51.7)	0.01
Former	30 (60)	50 (46.3)	12 (41.4)	
Never	13 (26)	25 (22.9)	2 (6.9)	
Comorbidity				
COPD	26 (49.1)	56 (50.5)	14 (48.3)	0.97
Bronchiectasis	17 (32.1)	34 (30.1)	3 (10.3)	0.08
Asthma	15 (28.3)	23 (20.4)	4 (13.8)	0.28
Cardiovascular disease	14 (31.8)	37 (35.9)	16 (59.3)	0.05
History of malignant disease	10 (22.7)	18 (17.5)	5 (18.5)	0.76
Current or former alcohol abuse	2 (3.8)	19 (17)	12 (41.4)	<0.001
Diabetes mellitus	4 (9.1)	18 (17.5)	9 (33.3)	0.03
Immunocompromised status	4 (9.1)	13 (12.6)	0	0.14
Current or former pulmonary aspergillosis	6 (11.3)	13 (11.5)	2 (6.9)	0.77
History of tuberculosis infection	2 (3.8)	6 (5.3)	1 (3.4)	0.86
Interstitial lung disease	2 (3.8)	3 (2.7)	2 (6.9)	0.55
Active malignancy	0	4 (4)	1 (3.8)	0.39
Microbiology				
Myocardium avium complex	46 (86.8)	101 (89.4)	26 (89.7)	0.87
Myocardium abscessus	7 (13.2)	13 (11.5)	3 (10.3)	0.92
AFB smear positive	18 (37.5)	51 (48.6)	19 (67.9)	0.04
Clinical outcomes				
Treatment initiation	32 (61.5)	91 (80.5)	25 (86.2)	0.01
Time to treatment initiation, months	7.8 (1.8–13)	3.5 (1.9–9)	2.3 (1–6.7)	0.03
Culture conversion	24 (92.3)	62 (82.7)	12 (57.1)	0.01
Clinical improvement	19 (67.9)	56 (67.5)	11 (45.8)	0.13

ERJ Open Res . 2025 Dec 1;11(6):00550-2025

BACES score: a predictor of health-related quality of life and associated factors in patients with nontuberculous mycobacterial pulmonary disease

- 국내 다기관 NTM-KOREA 전향적 코호트에 등록된 NTM-PD 환자들을 대상으로
- BACES와 환자 설문(QOL-B)을 통해 수집된 삶의 질 데이터와의 상관관계를 다변량 회귀 분석으로 평가

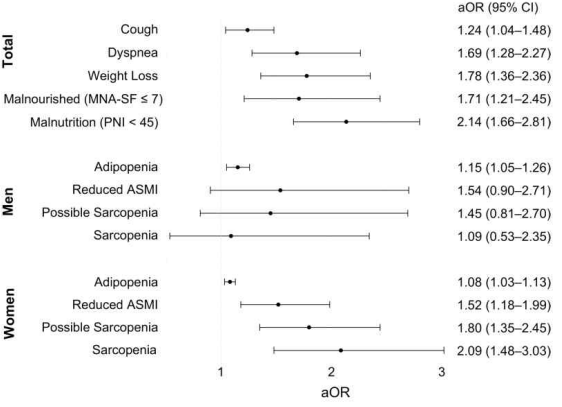


Fig. 1. Forest plot of adjusted odds ratios for the BACES score associated with HRQOL-related factors. The BACES score was treated as a continuous variable, ranging from 0 to 5.

- BACES 점수가 1점 증가할 때마다 낮은 삶의 질을 가질 위험(Odds Ratio)이 유의미하게 증가함.
- 특히 **호흡기 증상**, **신체 기능**, **활력** 도메인에서 강한 연관성을 보였으며, 영양 상태(MNA-SF, PNI) 및 신체 활동량 역시 삶의 질의 주요 결정 요인임을 확인함.

Multicentre retrospective observational study for development and validation of MAC prognostic score model

- 기존 BACES는 NTM-PD 전체를 대상으로 해서 M. abscessus 균도 섞여 있을수 있음

→ MAC-PD만 따로 본 연구

- BACES score는 all cause mortality 예측하는 점수

→ respiratory infection-related mortality를 예측하고자 함

- MAC-PD에서 respiratory infection-related mortality 예측 score 개발

2010–2017년에 새로 진단된 MAC-PD 1,165명

규슈(Kyushu) 18개 병원 다기관 후향적 코호트

derivation 932명, validation 233명으로 4:1 무작위 분할

Factor	aHR	Score
Age ≥65	3.32	1
Male	2.61	1
ILD	2.42	1
Albumin <3.5	**5.89**	2
Cavity ≥2 cm	2.18	1

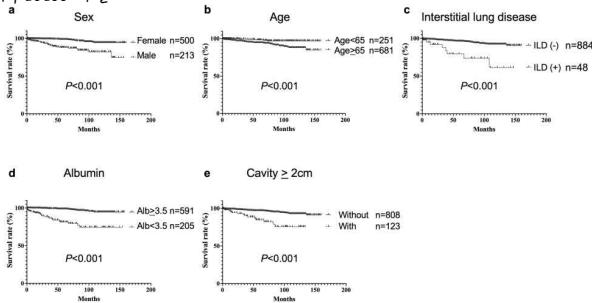


Fig. 2. Kaplan–Meier analyses of patients in the derivation group. Male sex (**a**), age over 65 years (**b**), IP (**c**), hypoalbuminemia (**d**), and cavity formation (**e**) were associated with a significantly poorer prognosis. Without cavity ≥ 2 cm includes patients with no cavity or cavities < 2 cm. Cases with missing data were excluded from the analysis. IP, interstitial pneumonia.

Multicentre retrospective observational study for development and validation of MAC prognostic score model

The AUCs of the MAC score 0.82
The AUCs of the BACES scores 0.88

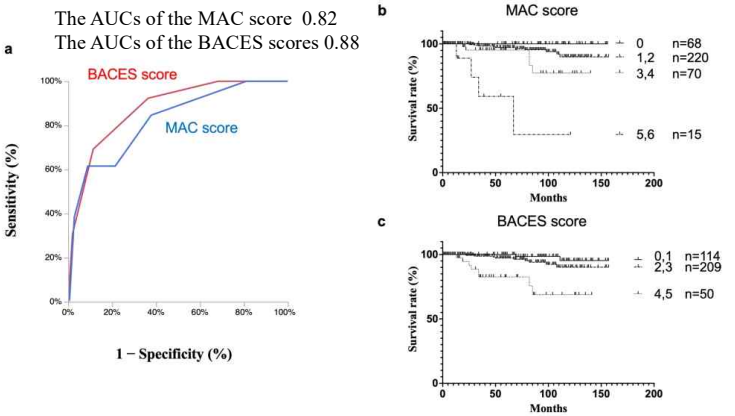


Fig. 5. Comparison of MAC and BACES scores. (**a**) ROC curves of MAC and BACES scores in the population without data loss ($n = 373$). The AUCs of the MAC and BACES scores were 0.82 and 0.88, respectively, with no significant differences. Kaplan–Meier curves for (**b**) the MAC score and (**c**) the BACES score showed comparable prognostic discrimination. AUC, area under the curve; ROC, receiver operating characteristic.

- **Refractory NTM-PD:**

Clinical Burden and Evolving Therapeutic Strategies

Natural history and burden of refractory Mycobacterium avium complex pulmonary disease: Insights from the US Bronchiectasis and Nontuberculous Mycobacterial Research Registry

- Diagnosis of refractory MACPD

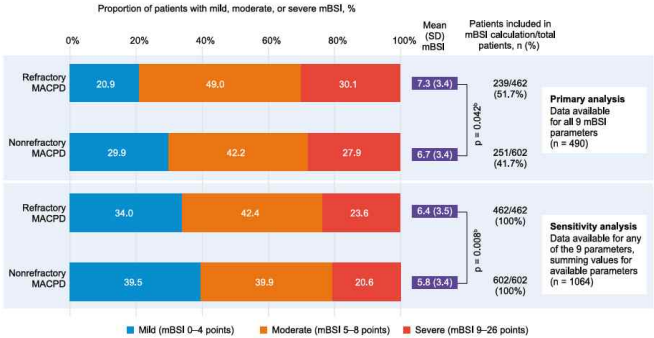
- regimen included oral clofazimine, or bedaquiline, or inhaled amikacin, or amikacin liposome inhalation suspension (ALIS)

- remained sputum culture positive for at least 6 months during treatment

Patient demographics, clinical characteristics, and healthcare resource utilization at MACPD treatment visit window and stratified by refractory status (n = 1064).

	Patients with available data	Overall treated MACPD[a] (n = 1064)	Refractory MACPD[b] (n = 462)	Non-refractory MACPD (n = 602)	P value[c] (non-refractory vs refractory)
BMI, mean (SD), kg/m^2	830	21.7 (4.0)	21.3 (3.9)	22.2 (4.1)	**<0.001**
Pre-bronchodilator spirometry					
FEV_1, mean (SD), L	787	1.9 (0.7)	1.8 (0.7)	1.9 (0.7)	**0.002**
FEV_1 % predicted, mean (SD)	785	73.6 (21.9)	70.1 (21.0)	76.5 (22.2)	**<0.001**
FVC, mean (SD), L	784	2.7 (0.9)	2.6 (0.9)	2.8 (0.9)	**0.011**
FVC % predicted, mean (SD)	780	82.0 (20.3)	78.4 (20.0)	84.8 (20.1)	**<0.001**
Bronchiectasis, n (%)	962	890 (92.5)	405 (96.2)	485 (89.7)	**<0.001**
GERD, n (%)	883	394 (44.6)	198 (50.5)	196 (39.9)	**0.002**
Hemoptysis, n (%)	944	195 (20.7)	107 (26.6)	88 (16.3)	**<0.001**
Predominant CT abnormality, n (%)	337	–	–	–	–
Bronchiectasis/nodular bronchiectasis	–	285 (84.6)	134 (80.2)	151 (88.8)	**<0.001**
Fibrocavitary	–	44 (13.1)	32 (19.2)	12 (7.1)	–
Other	–	8 (2.4)	1 (0.6)	7 (4.1)	–
Fibrocavitary abnormalities on CT scan or cavities on chest X-ray, n (%)	388	95 (24.5)	62 (33.5)	33 (16.3)	**<0.001**

Natural history and burden of refractory Mycobacterium avium complex pulmonary disease: Insights from the US Bronchiectasis and Nontuberculous Mycobacterial Research Registry



Effects of Amikacin Liposome Inhalation Suspension and Amikacin Resistance Development in Patients With Refractory *Mycobacterium avium* Complex Pulmonary Disease

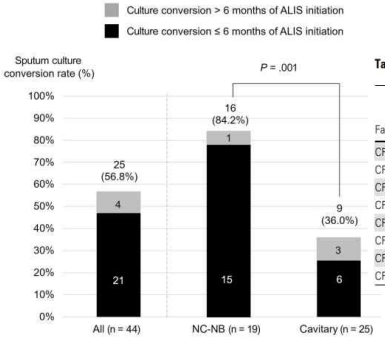


Table 3. Risk Ratios[a] for Persistently Positive Cultures by CRP Level, Radiographic Subtype, and CLM Susceptibility

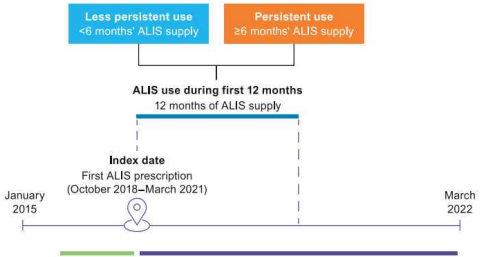
			Culture Conversion		Nonadjusted Model		Adjusted Model[b]	
Factors			Yes, No. (%)	No, No. (%)	RR (95% CI)	*P* Value	RR (95% CI)	*P* Value
CRP (–)	NC-NB	CLM S	12 (92.3)	1 (7.7)	1.00 (reference)	-	1.00 (reference)	-
CRP (–)	NC-NB	CLM R	3 (75.0)	1 (25.0)	3.25 (0.25–42.21)	0.368	3.24 (0.24–44.16)	.377
CRP (–)	Cavitary	CLM S	5 (71.4)	2 (28.6)	3.71 (0.39–34.98)	0.252	3.86 (0.39–37.65)	.246
CRP (–)	Cavitary	CLM R	1 (100)	0 (0)	NA	-	NA	-
CRP (+)	NC-NB	CLM S	1 (100)	0 (0)	NA	-	NA	-
CRP (+)	NC-NB	CLM R	0 (0)	1 (100)	NA	-	NA	-
CRP (+)	Cavitary	CLM S	2 (28.6)	5 (71.4)	9.28 (1.30–66.07)	0.026	8.47 (1.22–58.87)	.031
CRP (+)	Cavitary	CLM R	1 (10.0)	9 (90.0)	11.70 (1.72–79.45)	0.012	10.81 (1.66–70.40)	.013

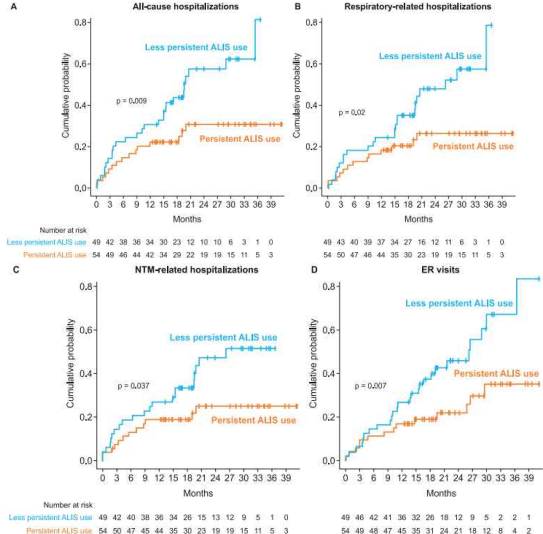
AMK Susceptibility of MAC-PD Patients With Persistent Positive Cultures After ALIS Treatment (n = 19)

Factors	AMK Susceptible (n = 12)	AMK Resistant (n = 7)	*P* Value
Rrs mutations,[a] No. (%)	0 (0)	5 (71.4)	.0018
Position 1408	0 (0)	4 (80.0)	
Position 1482	0 (0)	1 (20.0)	

Open Forum Infect Dis. 2025 Mar 1;12(3):ofaf118.

Persistent use of amikacin liposome inhalation suspension associated with lower risk of hospitalizations and emergency room visits in refractory Mycobacterium avium complex lung disease





Respiratory Medicine 249 (2025) 108406

Recombinant interleukin-7 treatment of refractory *Mycobacterium avium* complex lung disease (IMPULSE-7): a pilot phase II, single-center, randomized, clinical trial

- Interleukin 7 (IL-7)

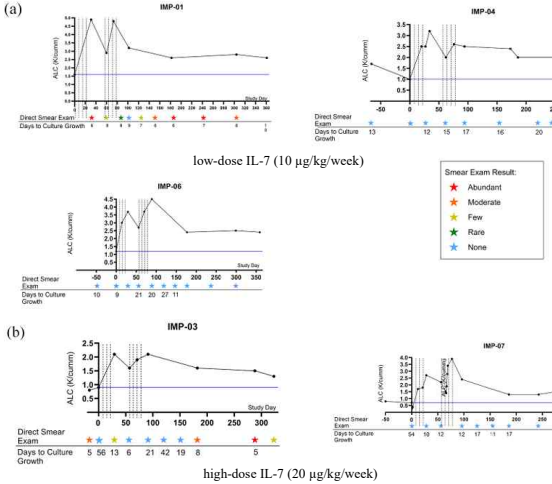
Increases $CD4^+$ and $CD8^+$ T-cell proliferation
Enhances macrophage function
Increases IFN-γ production
Improves survival in bacterial, fungal, and mycobacterial infections in animal models

- Methods

IL-7 was administered 10 or 20 μg/kg/week based on ideal body weight for two 4-week treatment cycles (totaling 8 injections).

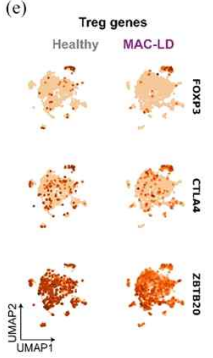
- Primary outcome:

Sputum culture conversion at 6 months



Treg (Regulatory T cells)

- $FOXP3^{+}$ $CD4^{+}$ T cells
- Suppress immune responses



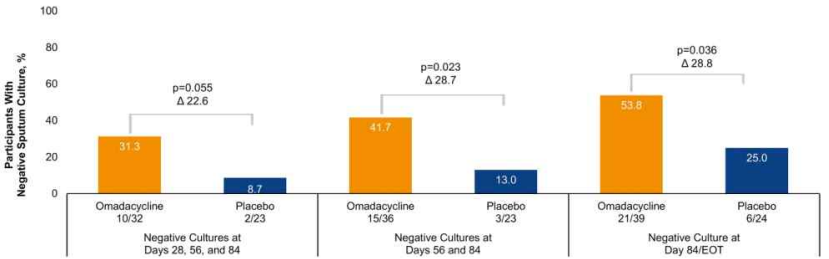
- **New Therapeutic Options**

Omadacycline Monotherapy in Nontuberculous Mycobacterial Pulmonary Disease Caused by *Mycobacterium abscessus*: Results From a Phase 2, Double-blind, Randomized, Placebo-controlled Study

Omadacycline: novel tetracycline derivative (aminomethylcycline)
: acute bacterial skin and skin structure infections
: community-acquired bacterial pneumonia

M. abscessus 폐질환 환자 66명

Omadacycline(300mg, 1일 1회 경구 투여)군 41명 vs 위약(Placebo)군 25명으로 나누어 84일(약 3개월)간 관찰



Clin Infect Dis . 2026 Mar 3:ciag062

Omadacycline Monotherapy in Nontuberculous Mycobacterial Pulmonary Disease Caused by *Mycobacterium abscessus*: Results From a Phase 2, Double-blind, Randomized, Placebo-controlled Study

Table 2. Clinical Response at Day 84, ITT Population

	Omadacycline (n = 41)		Placebo (n = 25)
Clinical Responder, Definition 1[b]; n (%) 증상 개선 중심	14 (34.1)		5 (20.0)
Treatment difference		14.2	
P-value[b]		0.218	
Odds ratio (95% CI)		2.07 (0.64, 6.71)	
Reasons for nonresponse[c]; n (%)			
Improvement in fewer than half of symptoms present at baseline	23 (85.2)		20 (100)
Received alternative antibiotic therapy for NTM (not including macrolide)	1 (3.7)		1 (5.0)
Withdrew from treatment before day 84	5 (18.5)		0
Died on or before day 28	0		0
Clinical Responder, Definition 2[b]; n (%) 개선 + 악화 방지 중심	14 (34.1)		3 (12.0)
Treatment difference		22.2	
P-value[b]		0.046	
Odds ratio (95% CI)		3.80 (0.97, 14.94)	
Reasons for nonresponse[c]; n (%)			
Improvement in fewer than half of symptoms present at baseline	23 (85.2)		20 (90.9)
Received alternative antibiotic therapy for NTM (not including macrolide)	1 (3.7)		1 (4.5)
Withdrew from treatment before day 84	5 (18.5)		0
Died on or before day 28	0		0
Worsening in severity of ≥1 symptom present at baseline	9 (33.3)		12 (54.5)

Table 3. Summary of Treatment-Emergent Adverse Events, Safety Population

Patients With; N (%)	Omadacycline (n = 41)	Placebo (n = 25)
Any TEAE	35 (85.4)	21 (84.0)
Nausea	22 (53.7)	2 (8.0)
Headache	7 (17.1)	4 (16.0)
Fatigue	7 (17.1)	1 (4.0)
Abdominal pain	6 (14.6)	1 (4.0)
Vomiting	6 (14.6)	0
Diarrhea	5 (12.2)	1 (4.0)
Alanine aminotransferase increase	4 (9.8)	0
Night sweats	4 (9.8)	0
Aspartate aminotransferase increased	3 (7.3)	0
Hemoptysis	3 (7.3)	3 (12.0)
TEAE of maximum severity:		
Mild	11 (26.8)	9 (36.0)
Moderate	20 (48.8)	11 (44.0)
Severe[a]	4 (9.8)	1 (4.0)
Serious TEAE[b]	0	2 (8.0)
TEAE leading to death	0	0
Early treatment discontinuation for AE[c]	4 (9.8)	0

Clin Infect Dis . 2026 Mar 3:ciag062

감사합니다.