Respiratory Review of 2023
: Tuberculosis/NTM

충북의대 호흡기내과
양범희

Global Tuberculosis Report 2022

Fig. 1.1 Global trend in case notifications of people newly diagnosed with TB, 2015–2021

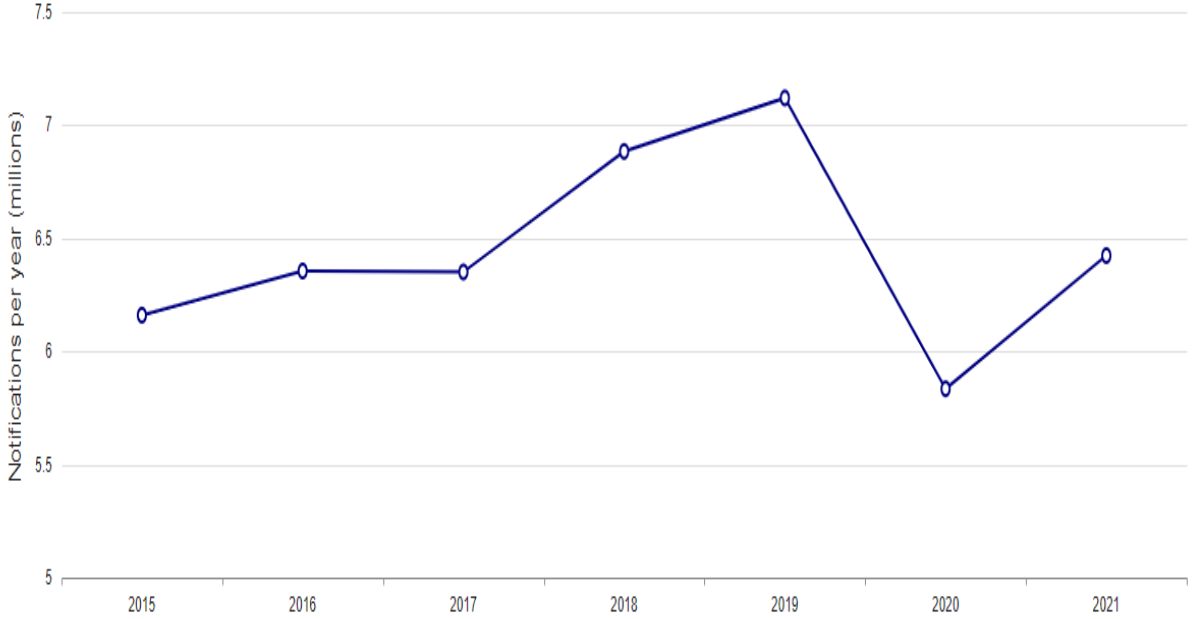
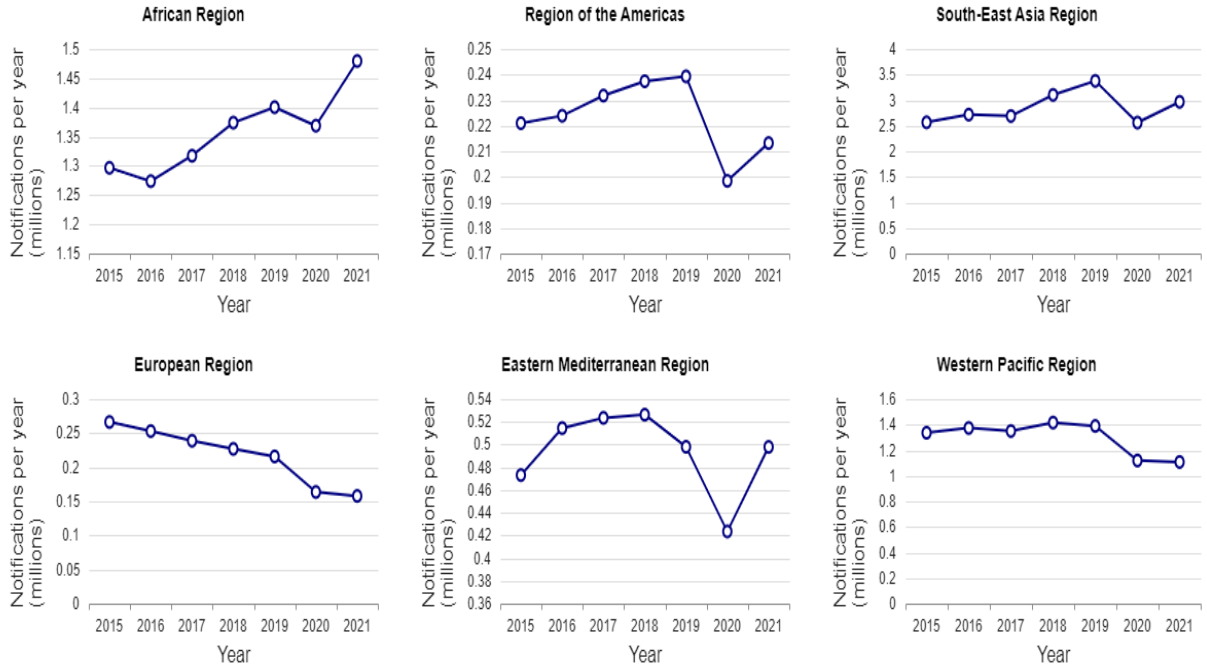
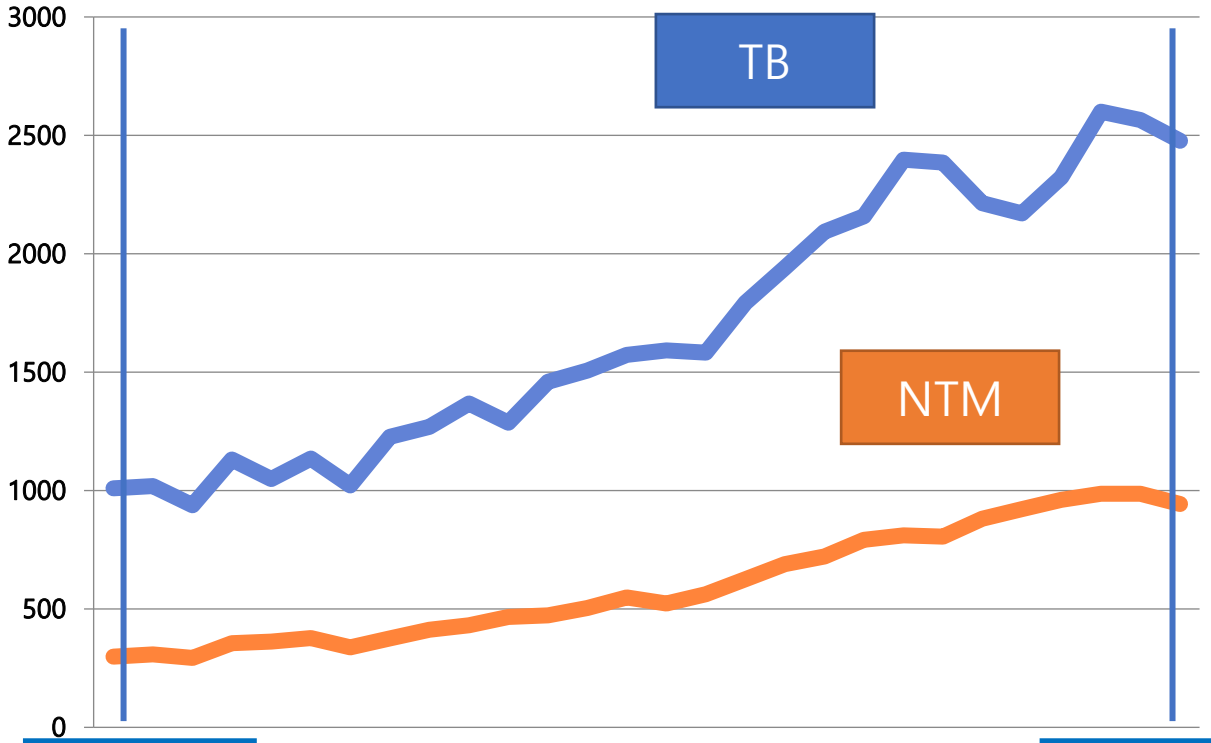


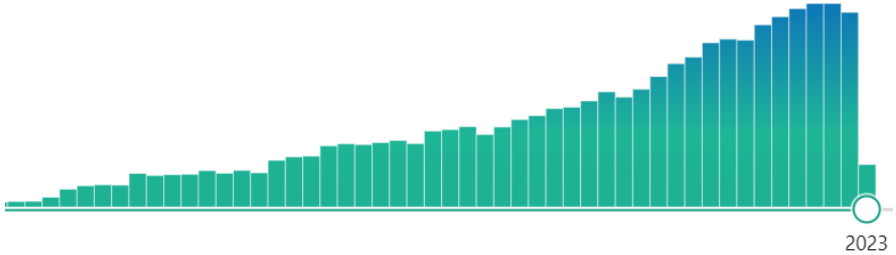
Fig. 1.2 Trends in case notifications of people newly diagnosed with TB by WHO region, 2015–2021



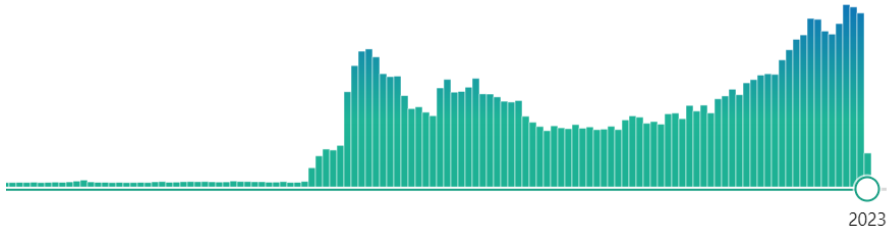
Story begins



NTM: 943



Pulmonary tuberculosis: 2477



Agenda

- **Tuberculosis**
  - ✓ **Diagnosis [1]**
  - ✓ Treatment [1]
  - ✓ multidrug-resistant tuberculosis, MDR-TB [3]

- **Nontuberculous mycobacteria, NTM [2]**

Clinical Infectious Diseases

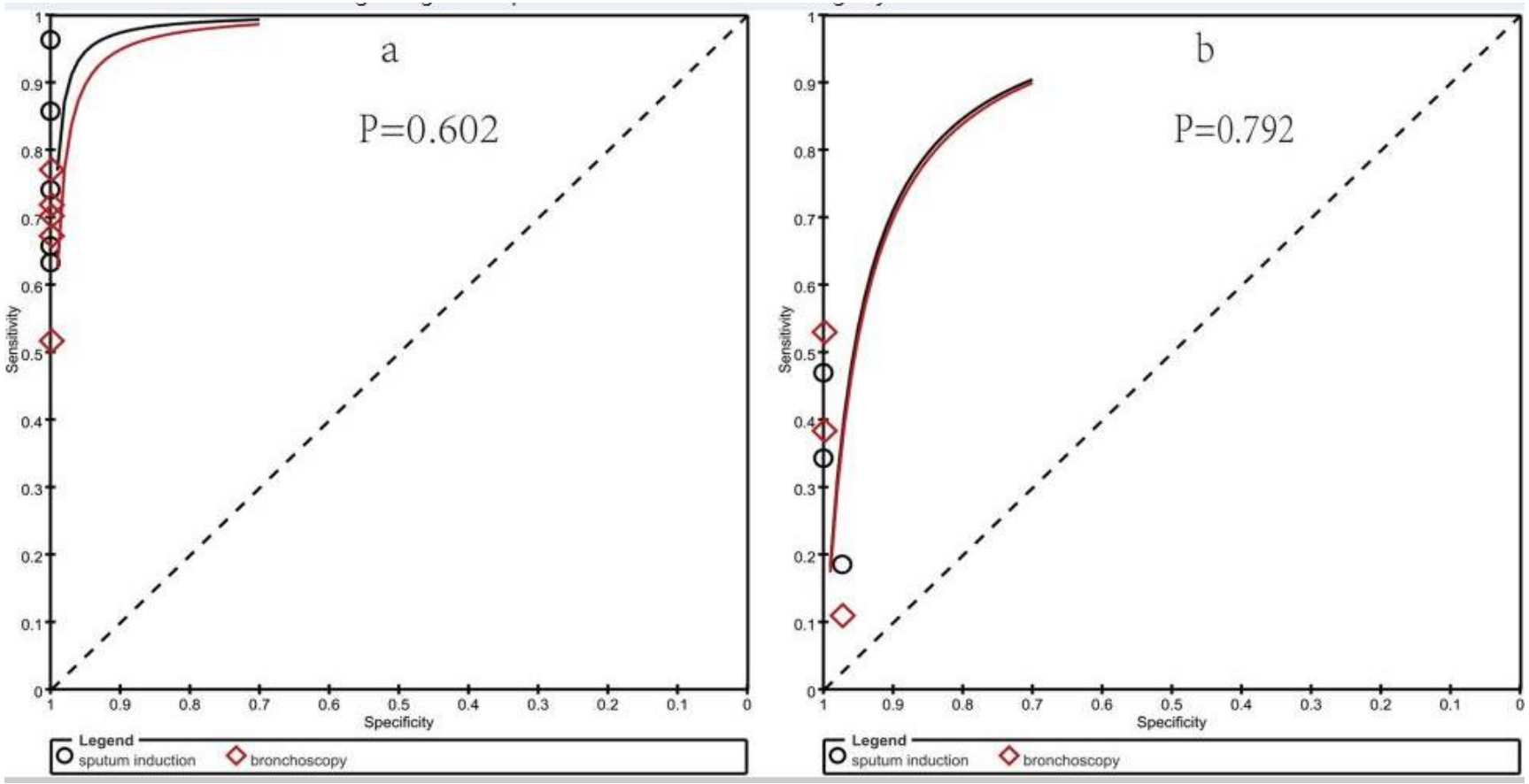
MAJOR ARTICLE

Bronchial Washing Using a Thin Versus a Thick Bronchoscope to Diagnose Pulmonary Tuberculosis: A Randomized Trial

Jung Seop Eom,[1,2,3,a] Seyeon Park,[4,a] Hyojin Jang,[1] Saerom Kim,[1] Wan Ho Yoo,[1] Soo Han Kim,[1] and Jeongha Mok[1,2,3]

[1]Department of Internal Medicine, Pusan National University Hospital, Busan, Republic of Korea; [2]Department of Internal Medicine, Pusan National University School of Medicine, Busan, Republic of Korea; [3]Biomedical Research Institute, Pusan National University Hospital, Busan, Republic of Korea; and [4]Department of Internal Medicine, Daerim St Mary's Hospital, Seoul, Republic of Korea

Diagnostic yield of bronchoscopy in TB



Sputum induction VS. Bronchoscopy

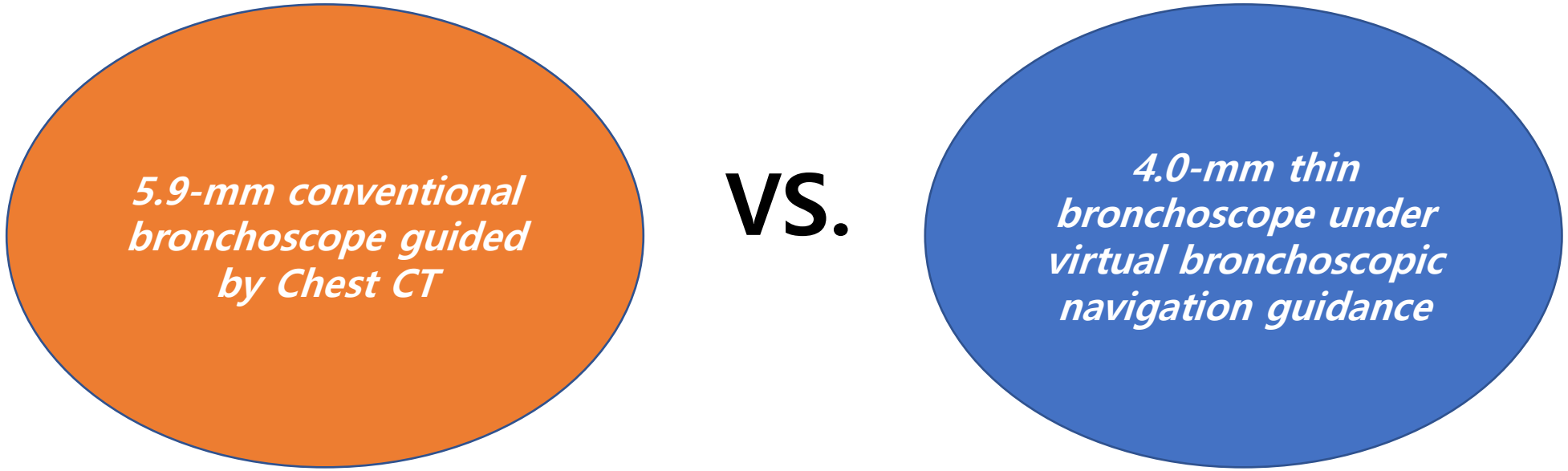
배양

도말

BMC Pulm Med. 2020 May 25;20(1):146.

Navigational bronchoscopy

- **Bronchial washing from as close to the TB lesion** as possible increases the diagnostic accuracy



Objectives

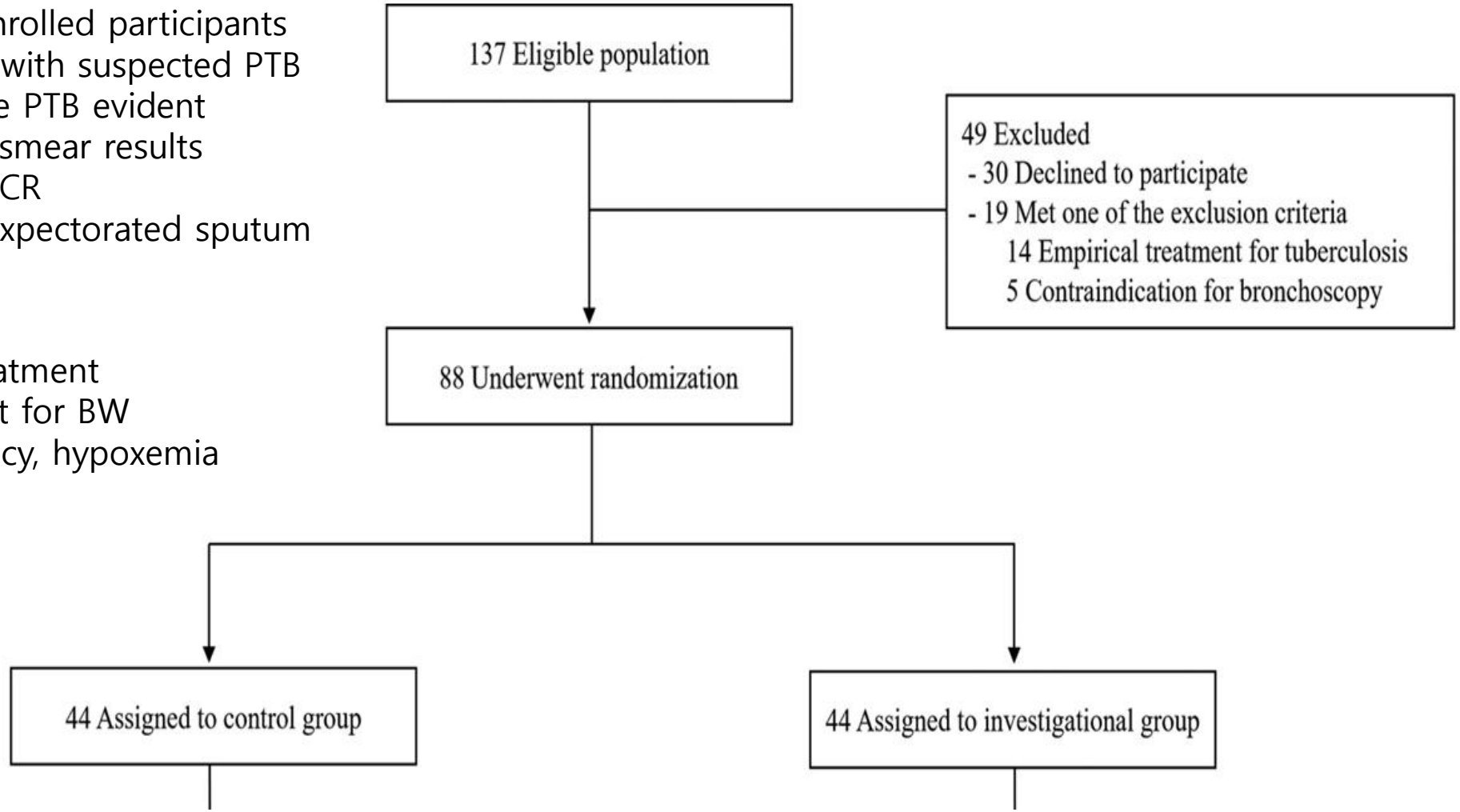
1. **Detection of TB** in BW fluid, defined as a positive result in the Xpert MTB/RIF assay

2. AFB smear and Mycobacterium tuberculosis culture positivity, time to treatment initiation

Study population

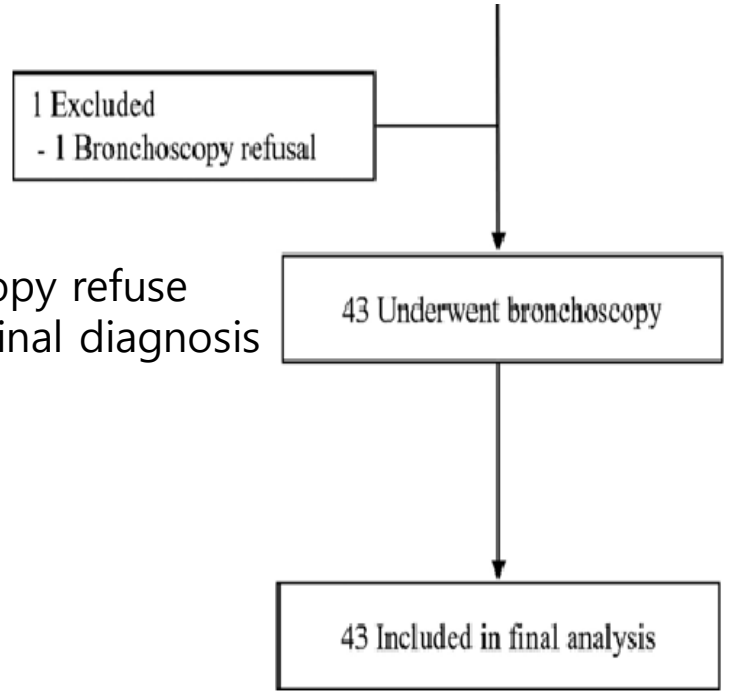
1) prospectively enrolled participants aged ≥18 years with suspected PTB
   - possible active PTB evident
   - negative AFB smear results
   - negative TB-PCR
   - inability self-expectorated sputum

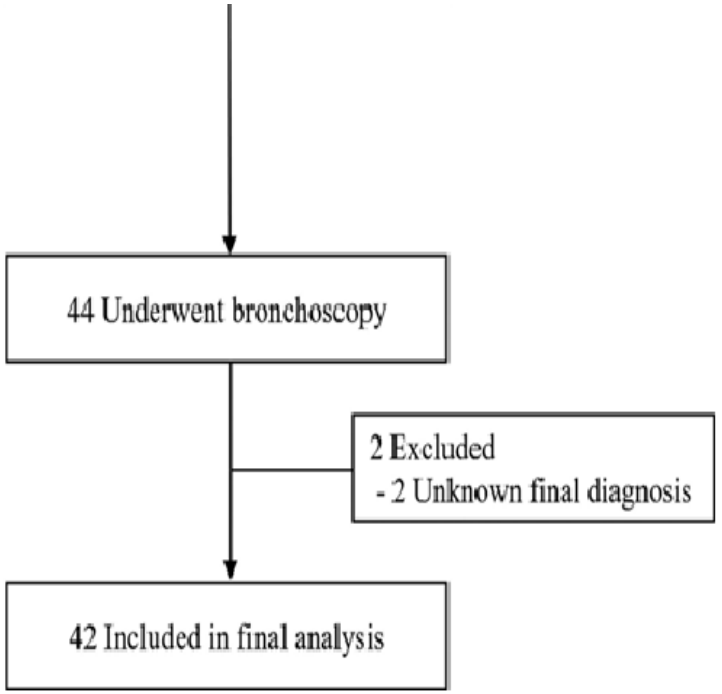
2) Exclusion
   - empirical TB treatment
   - difficult to target for BW
   - bleeding tendency, hypoxemia



CID 2023 Jan 13;76(2):238-244.

3) Exclusion
- bronchoscopy refuse
- Unknown final diagnosis





4) Final group

Control group (n=43)
: 5.9-mm conventional bronchoscope guided by Chest CT

Investigational group (n=42)
: 4.0-mm thin bronchoscope under virtual bronchoscopic navigation guidance

CID 2023 Jan 13;76(2):238-244.

Baseline characteristics

Table 1. Baseline Characteristics of the Study Participants

Characteristic	Control Group (n = 43)	Investigational Group (n = 42)	Total (N = 85)	*P* Value[a]
Age, y, median (IQR)	62.0 (50.0–69.0)	58.0 (42.8–67.0)	61.0 (48.0–68.0)	.592
Male sex	19 (44.2)	24 (57.1)	43 (50.6)	.232
BMI, kg/m^2, median (IQR)	21.9 (19.8–23.9)	22.2 (20.5–24.6)	21.9 (20.5–24.1)	.572
Ever-smoker	18 (41.9)	19 (45.2)	37 (43.5)	.754
Comorbidities				
Hypertension	8 (18.6)	9 (21.4)	17 (20.0)	.745
Diabetes mellitus	8 (18.6)	8 (19.0)	16 (18.8)	.958
Malignancy	11 (25.6)	7 (16.7)	18 (21.2)	.315
Chronic lung disease[b]	4 (9.3)	2 (4.8)	6 (7.1)	.676
Chronic liver disease[c]	3 (7.0)	1 (2.4)	4 (4.7)	.616
Chronic kidney disease[d]	3 (7.0)	1 (2.4)	4 (4.7)	.616
HIV infection	0 (0.0)	0 (0.0)	0 (0.0)	NA
History of previous TB treatment	10 (23.3)	8 (19.0)	18 (21.2)	.635
Respiratory symptoms present at the first visit[e]	10 (23.3)	13 (31.0)	23 (27.1)	.425
Reasons for bronchoscopy				
Negative results on the AFB smear and TB-PCR tests[f]	35 (81.4)	37 (88.1)	72 (84.7)	.391
Unable to expectorate sputum	8 (18.6)	5 (11.9)	13 (15.3)	.391
Final diagnosis				
Pulmonary TB	23 (53.5)	29 (69.0)	52 (61.2)	.141
NTM lung disease	8 (18.6)	8 (19.0)	16 (18.8)	.958
Malignancy	6 (14.0)	2 (4.8)	8 (9.4)	.265
Pneumonia/bronchiolitis	5 (11.6)	2 (4.8)	7 (8.2)	.433
Aspergilloma	1 (2.3)	1 (2.4)	2 (2.4)	>.999

CID 2023 Jan 13;76(2):238-244.

1st objective-Xpert MTB/RIF Assay

23 case

29 case

Value	Control Group (n = 43)	Investigational Group (n = 42)	*P* Value[a]
Sensitivity	43.5 (23.9–65.1) (10/23)	72.4 (52.5–86.6) (21/29)	.035
Specificity	100.0 (80.0–100.0) (20/20)	100.0 (71.7–100.0) (13/13)	NA
Positive predictive value	100.0 (65.5–100.0) (10/10)	100.0 (80.8–100.0) (21/21)	NA
Negative predictive value	60.6 (42.2–76.6) (20/33)	61.9 (38.7–81.0) (13/21)	.924

CID 2023 Jan 13;76(2):238-244.

2nd objective-Microbiological Outcomes

Outcome	Control Group (n = 23)	Investigational Group (n = 29)	Total (N = 52)	*P* Value[a]
AFB smear positive	3 (13.0)	7 (24.1)	10 (19.2)	.482
Mycobacterium tuberculosis culture positive	12 (52.2)	23 (79.3)	35 (67.3)	.038
Xpert MTB/RIF assay positive	10 (43.5)	21 (72.4)	31 (59.6)	.035
RIF resistance on Xpert MTB/RIF assay	2 (8.7)	2 (6.9)	4 (7.7)	.577
Time to treatment initiation, d[b], median (IQR)	4.0 (3.0–7.0)	2.0 (1.0–2.0)	2.0 (1.0–6.0)	.001

Time to treatment was the date of initiation of anti-TB medication minus the date of bronchoscopy

CID 2023 Jan 13;76(2):238-244.

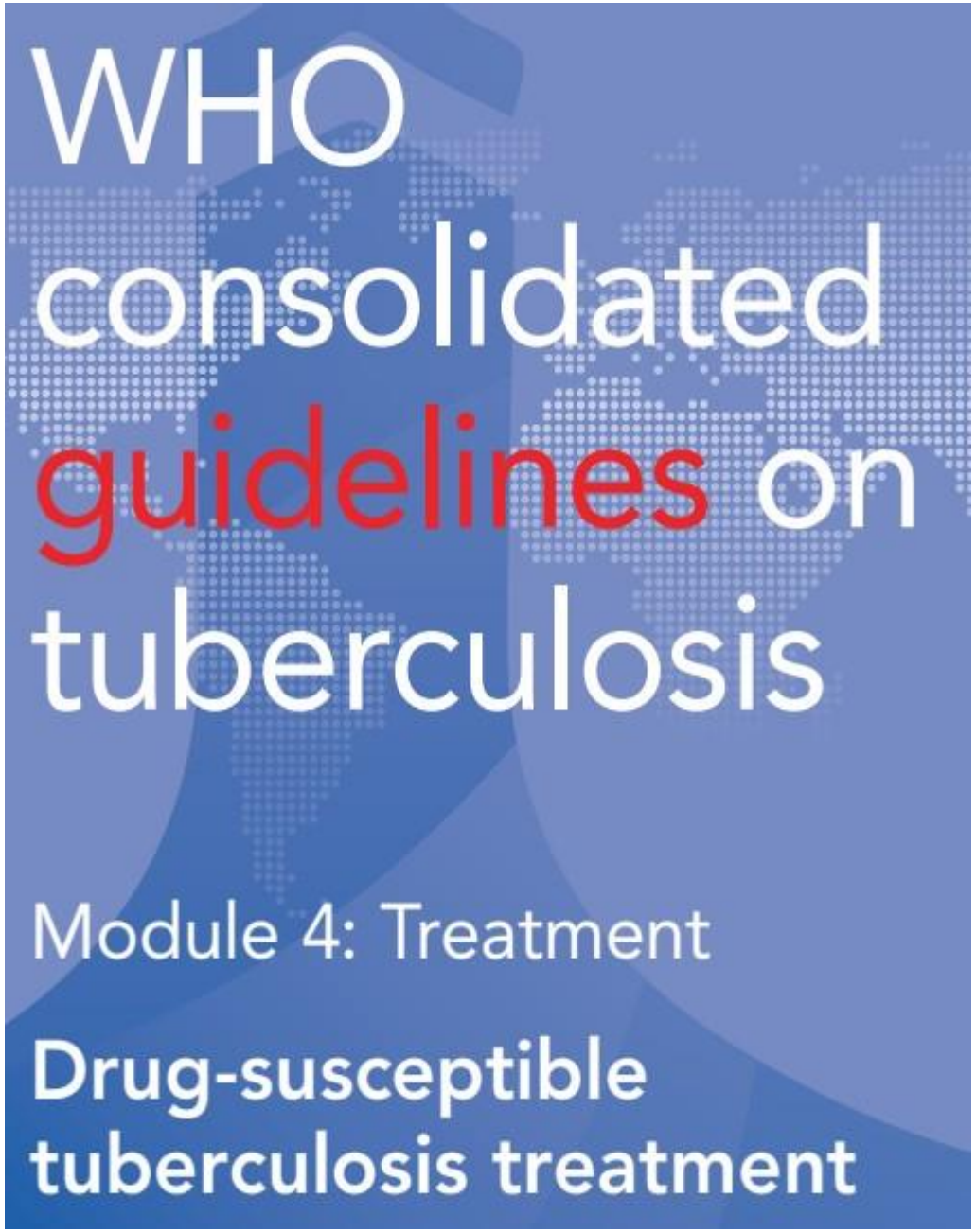
Summary

1. BW using a **thin bronchoscope (4.0-mm thin bronchoscope under virtual bronchoscopic navigation guidance)** increases the TB detection rate in patients with PTB compared to conventional bronchoscopy **(5.9-mm conventional bronchoscope).**

Agenda

- **Tuberculosis**
  - ✓ Diagnosis [1]
  - ✓ **Treatment [1]**
  - ✓ multidrug-resistant tuberculosis, MDR-TB [3]

- **Nontuberculous mycobacteria, NTM [2]**



Summary of WHO recommendations on drug-susceptible TB treatment

Treatment of drug-susceptible TB using 6-month regimen

1. *New patients with pulmonary TB should receive a regimen containing 6 months of rifampicin: 2HRZE/4HR (strong recommendation, high certainty of evidence).*
2. *Wherever feasible, the optimal dosing frequency for new patients with pulmonary TB is daily throughout the course of therapy (strong recommendation, high certainty of evidence).*
3. *In all patients with drug-susceptible pulmonary TB, the use of thrice-weekly dosing is not recommended in both the intensive and continuation phases of therapy, and daily dosing remains the recommended dosing frequency (conditional recommendation, very low certainty of evidence).*
4. *The use of fixed-dose combination (FDC) tablets is recommended over separate drug formulations in treatment of patients with drug-susceptible TB (conditional recommendation, low certainty of evidence).*
5. *In new pulmonary TB patients treated with the regimen containing rifampicin throughout treatment, if a positive sputum smear is found at completion of the intensive phase, the extension of the intensive phase is not recommended (strong recommendation, high certainty of evidence).*

Treatment of drug-susceptible TB using 4-month regimens

6. *People aged 12 years or older with drug-susceptible pulmonary TB may receive a 4-month regimen of isoniazid, rifapentine, moxifloxacin and pyrazinamide (2HPMZ/2HPM) (conditional recommendation, moderate certainty of evidence) – new recommendation.*
7. *In children and adolescents between 3 months and 16 years of age with non-severe TB (without suspicion or evidence of MDR/RR-TB), a 4-month treatment regimen (2HRZ(E)/2HR) should be used (strong recommendation, moderate certainty of evidence) – new recommendation.*

ORIGINAL ARTICLE

Four-Month Rifapentine Regimens with or without Moxifloxacin for Tuberculosis

S.E. Dorman, P. Nahid, E.V. Kurbatova, P.P.J. Phillips, K. Bryant, K.E. Dooley, M. Engle, S.V. Goldberg, H.T.T. Phan, J. Hakim, J.L. Johnson, M. Lourens, N.A. Martinson, G. Muzanyi, K. Narunsky, S. Nerette, N.V. Nguyen, T.H. Pham, S. Pierre, A.E. Purfield, W. Samaneka, R.M. Savic, I. Sanne, N.A. Scott, J. Shenje, E. Sizemore, A. Vernon, Z. Waja, M. Weiner, S. Swindells, and R.E. Chaisson, for the AIDS Clinical Trials Group and the Tuberculosis Trials Consortium

N Engl J Med 2021 May 6;384(18):1705-1718.

Short treatment in patients with TB

- **Improved adherence and potentially reducing adverse drug effects and costs**
- **Rifapentine : Cyclopentyl derivative of rifampin**, 식사 1시간 후에 복용
- Rifapentine 1200 mg qd with or without moxifloxacin 400 mg – 4 months regimen

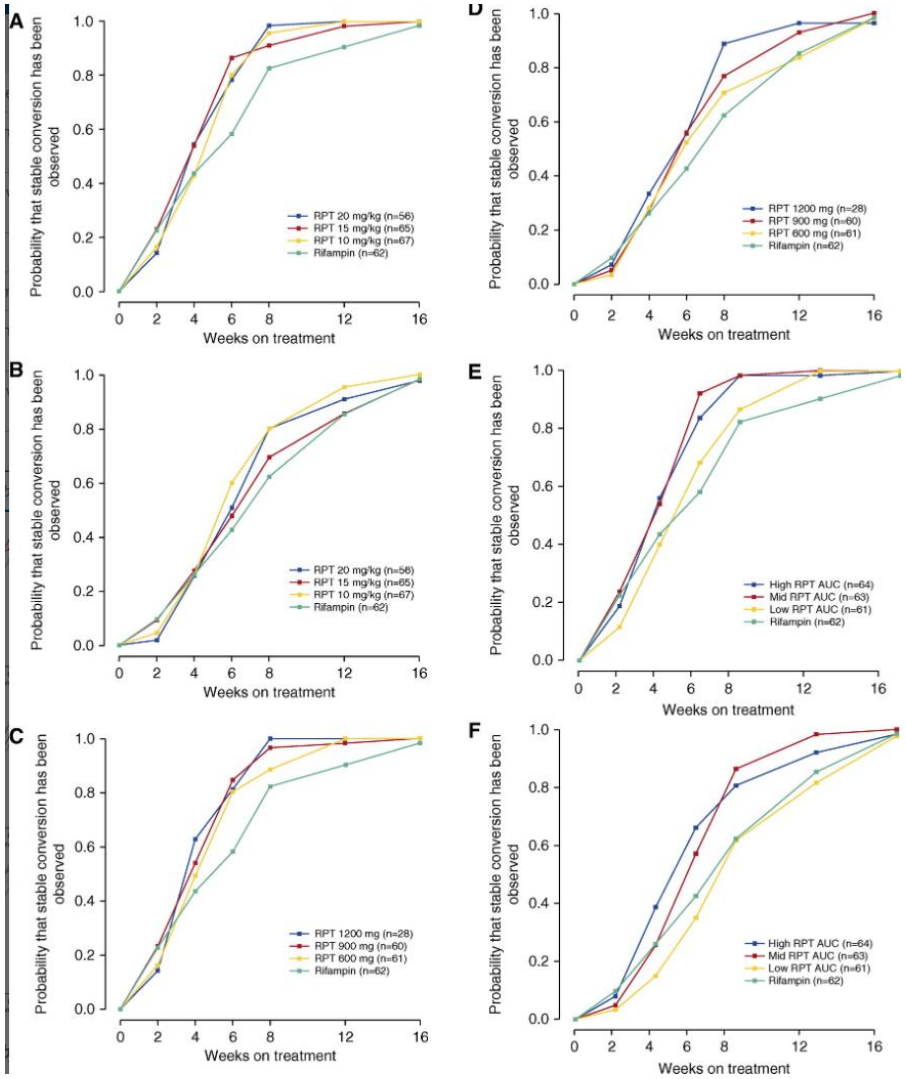
Rifapentine : Cyclopentyl derivative of rifampin

Rifapentine 1200 mg qd

Table 3. Percentages of Participants with Negative Cultures at Completion of Intensive Phase Treatment, by Treatment Assignment, for the Modified Intention-to-Treat Analysis Group

	Rifampin	Rifapentine 10 mg/kg	Rifapentine 15 mg/kg	Rifapentine 20 mg/kg
Solid culture medium				
% (n/n) with negative cultures	81.3 (52/64)	92.5 (62/67)	89.4 (59/66)	94.7 (54/57)
% difference vs. rifampin (95% CI)		11.3 (−1.7 to 24.3)	8.1 (−5.5 to 21.8)	13.5 (0.6 to 26.3)
P value		0.097	0.29	0.049
Liquid culture medium				
% (n/n) with negative cultures	56.3 (36/64)	74.6 (50/67)	69.7 (46/66)	82.5 (47/57)
% difference vs. rifampin (95% CI)		18.4 (0.8 to 35.9)	13.4 (−4.5 to 31.4)	26.2 (8.9 to 43.5)
P value		0.042	0.16	0.004

Definition of abbreviation: CI = confidence interval.



Dorman SE, et al. Am J Respir Crit Care Med. 2015.

Objectives

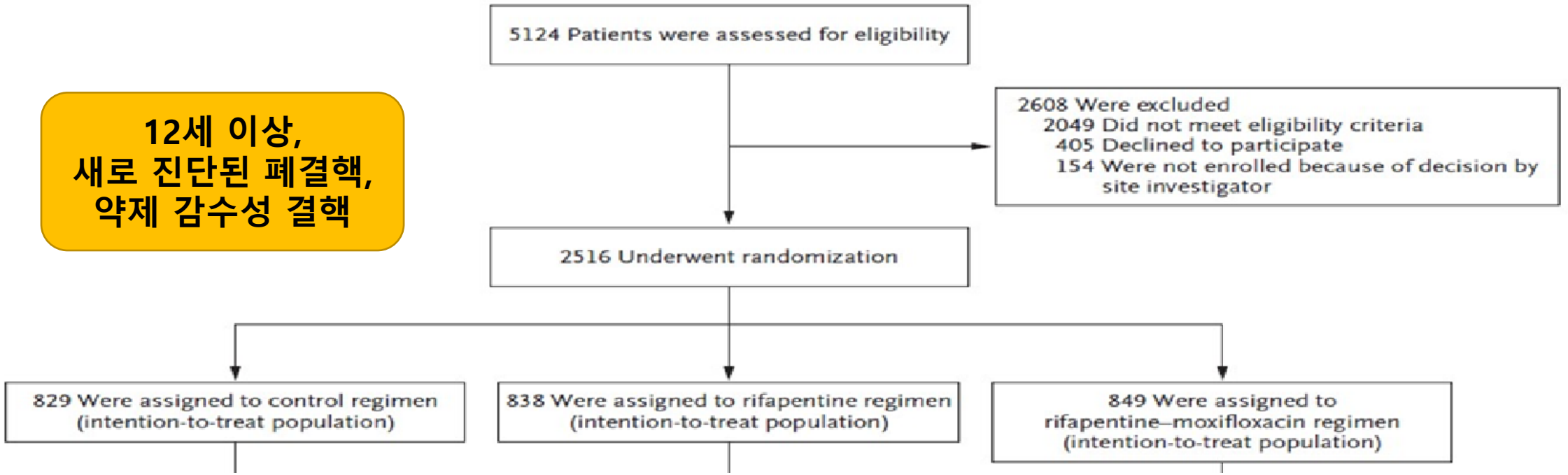
1. The primary efficacy outcome was survival free of tuberculosis at 12 months

N Engl J Med 2021 May 6;384(18):1705-1718.

Study population

An open-label, phase 3, randomized, controlled trial, Noninferiority, 13 countries

**12세 이상,
새로 진단된 폐결핵,
약제 감수성 결핵**



***Standard regimen**
HREZ 8weeks + HR(e) 16weeks

***Rifapentine regimen**
Rifapentine + HEZ 8weeks
Rifapentine + INH 9weeks

***Rifapentine + Moxi regimen**
Rifapentine+Moxi+HZ 8weeks
Rifapentine+Moxi+H 9weeks

N Engl J Med 2021 May 6;384(18):1705-1718.

Study population

***Standard regimen**
HREZ 8weeks + HR(e) 16weeks

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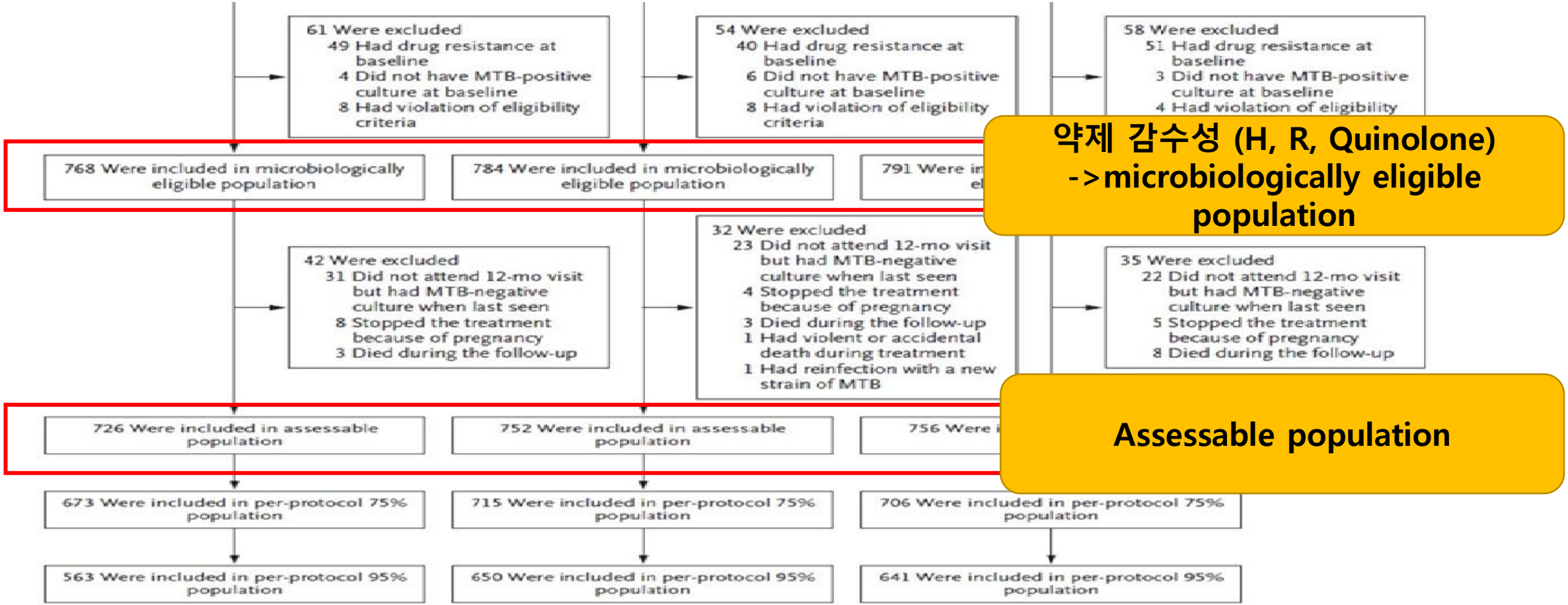


N Engl J Med 2021 May 6;384(18):1705-1718.

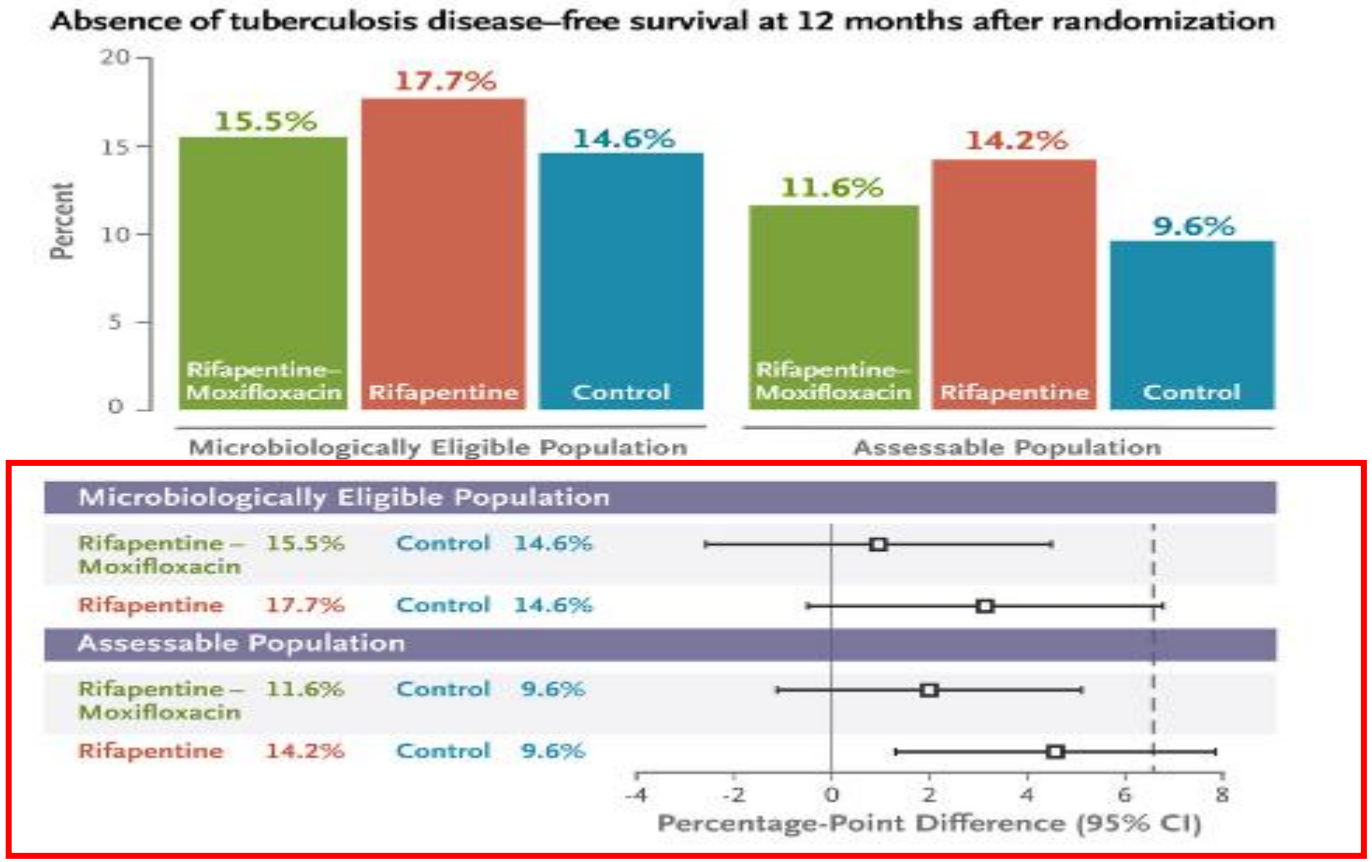
Baseline characteristics

Table 1. Characteristics of the Participants at Baseline in the Microbiologically Eligible Population.*

Characteristic	Control (N=768)	Rifapentine–Moxifloxacin (N=791)	Rifapentine (N=784)	Total (N=2343)
Male sex — no./total no. (%)	544/768 (71)	563/791 (71)	563/784 (72)	1670/2343 (71)
Median age (range) — yr	30.9 (13.7–77.5)	31.0 (14.6–72.5)	31.0 (14.1–81.4)	31.0 (13.7–81.4)
Age group — no./total no. (%)				
12–17 yr	19/768 (2)	25/791 (3)	19/784 (2)	63/2343 (3)
18–35 yr	479/768 (62)	486/791 (61)	485/784 (62)	1450/2343 (62)
>35 yr	270/768 (35)	280/791 (35)	280/784 (36)	830/2343 (35)
Race — no./total no. (%)†				
Asian	86/765 (11)	89/790 (11)	93/783 (12)	268/2338 (11)
Black	553/765 (72)	552/790 (70)	571/783 (73)	1676/2338 (72)
White	15/765 (2)	13/790 (2)	8/783 (1)	36/2338 (2)
Multiracial	111/765 (15)	136/790 (17)	111/783 (14)	358/2338 (15)
HIV positivity — no./total no. (%)	64/768 (8)	62/791 (8)	68/784 (9)	194/2343 (8)
Median CD4 count among those with HIV positivity (IQR)	334 (249–485)	346 (253–458)	351 (221–437)	344 (223–455)
Cavitation on chest radiography — no./total no. (%)‡				
Absent	206/768 (27)	213/791 (27)	206/784 (26)	625/2343 (27)
<4 cm	251/768 (33)	277/791 (35)	246/784 (31)	774/2343 (33)
≥4 cm	307/768 (40)	295/791 (37)	327/784 (42)	929/2343 (40)
Median body weight — kg	52.0	53.0	53.3	53.1
WHO smear grade — no./total no. (%)§¶				
Negative	21/766 (2.7)	31/789 (3.9)	36/782 (4.6)	88/2337 (3.8)
Scanty or 1–9 acid-fast bacilli	121/766 (15.8)	147/789 (18.6)	124/782 (15.9)	392/2337 (16.8)
1+	187/766 (24.4)	168/789 (21.3)	172/782 (22.0)	527/2337 (22.6)
2+	229/766 (29.9)	228/789 (28.9)	227/782 (29.0)	684/2337 (29.3)
3+	198/766 (25.8)	209/789 (26.5)	214/782 (27.4)	621/2337 (26.6)
Positive smear, WHO scale not used§	10/766 (1.3)	6/789 (0.8)	9/782 (1.2)	25/2337 (1.1)
Median body-mass index (range)‖	18.9 (12.8–45.2)	19.0 (14.1–39.1)	18.9 (13.4–35.4)	18.9 (12.8–45.2)
Current smoker — no./total no. (%)	196/768 (26)	175/791 (22)	200/784 (26)	571/2343 (24)
Prior course of tuberculosis treatment — no./total no. (%)	83/768 (11)	97/791 (12)	85/784 (11)	265/2343 (11)

N Engl J Med 2021 May 6;384(18):1705-1718.

1st objective - Absence of tuberculosis disease-free survival



N Engl J Med 2021 May 6;384(18):1705-1718.

Summary

1. The efficacy of a **4-month rifapentine-based regimen containing moxifloxacin** was noninferior to the standard 6-month regimen in the treatment of tuberculosis.

Agenda

- **Tuberculosis**
  - ✓ Diagnosis [1]
  - ✓ Treatment [1]
  - ✓ **multidrug-resistant tuberculosis, MDR-TB [3]**

- **Nontuberculous mycobacteria, NTM [2]**

WHO consolidated guidelines on tuberculosis

Module 4: Treatment

Drug-resistant tuberculosis treatment

2022 update

World Health Organization

Section 1. The 6-month bedaquiline, pretomanid, linezolid and moxifloxacin (BPaLM) regimen for MDR/RR-TB (NEW)

1.1 Recommendation

NEW RECOMMENDATION

No.	Recommendation
1.1	WHO suggests the use of a 6-month treatment regimen composed of bedaquiline, pretomanid, linezolid (600 mg) and moxifloxacin (BPaLM) rather than the 9-month or longer (18-month) regimens in MDR/RR-TB patients. *(Conditional recommendation, very low certainty of evidence)*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Bedaquiline–Pretomanid–Linezolid Regimens for Drug-Resistant Tuberculosis

F. Conradie, T.R. Bagdasaryan, S. Borisov, P. Howell, L. Mikiashvili, N. Ngubane, A. Samoilova, S. Skornykova, E. Tudor, E. Variava, P. Yablonskiy, D. Everitt, G.H. Wills, E. Sun, M. Olugbosi, E. Egizi, M. Li, A. Holsta, J. Timm, A. Bateson, A.M. Crook, S.M. Fabiane, R. Hunt, T.D. McHugh, C.D. Tweed, S. Foraida, C.M. Mendel, and M. Spigelman, for the ZeNix Trial Team*

1. XDR- TB
2. pre-XDR tuberculosis
3. rifampin-resistant TB (not responsive a second-line regimen had been discontinued because of side effects)

Nix-TB trial

Linezolid 1200mg 26wks

1. bedaquiline
2. Pretomanid
3. Linezolid 1200mg 26wk

Table 2. Primary Efficacy Analysis.*

Outcome	XDR	MDR	Overall
Intention-to-treat population†			
No. of patients	71	38	109
Favorable outcome			
No. of patients	63	35	98
Percent of patients (95% CI)	89 (79–95)	92 (79–98)	90 (83–95)
Unfavorable outcome — no. (%)	8 (11)	3 (8)	11 (10)
Deaths — no.	6	1	7
Withdrawal during treatment — no.	1	0	1
Lost to follow-up after end of treatment — no.	0	1	1
Relapse — no.	1	1	2‡

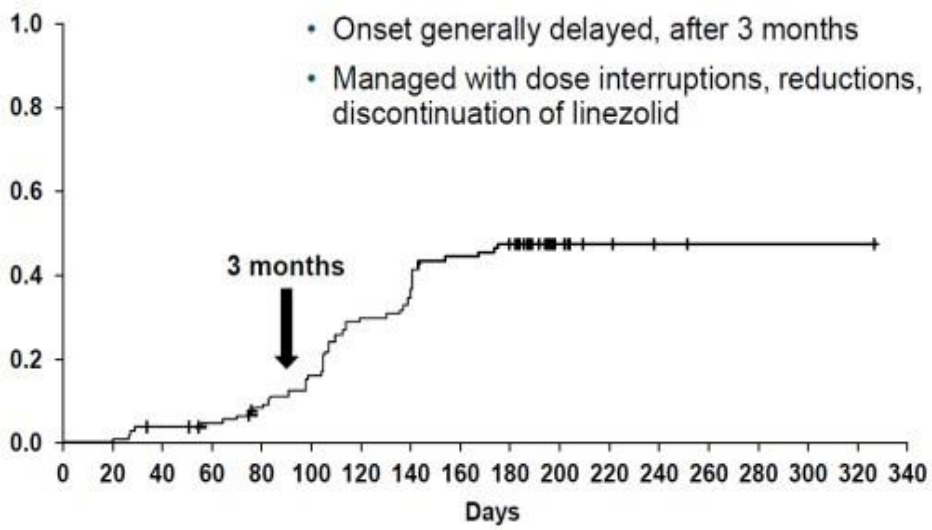
NEJM 2020;382:893-902

Linezolid toxicity at Nix-TB trial

Linezolid 1200mg 26wks

Myelosuppression (48%)

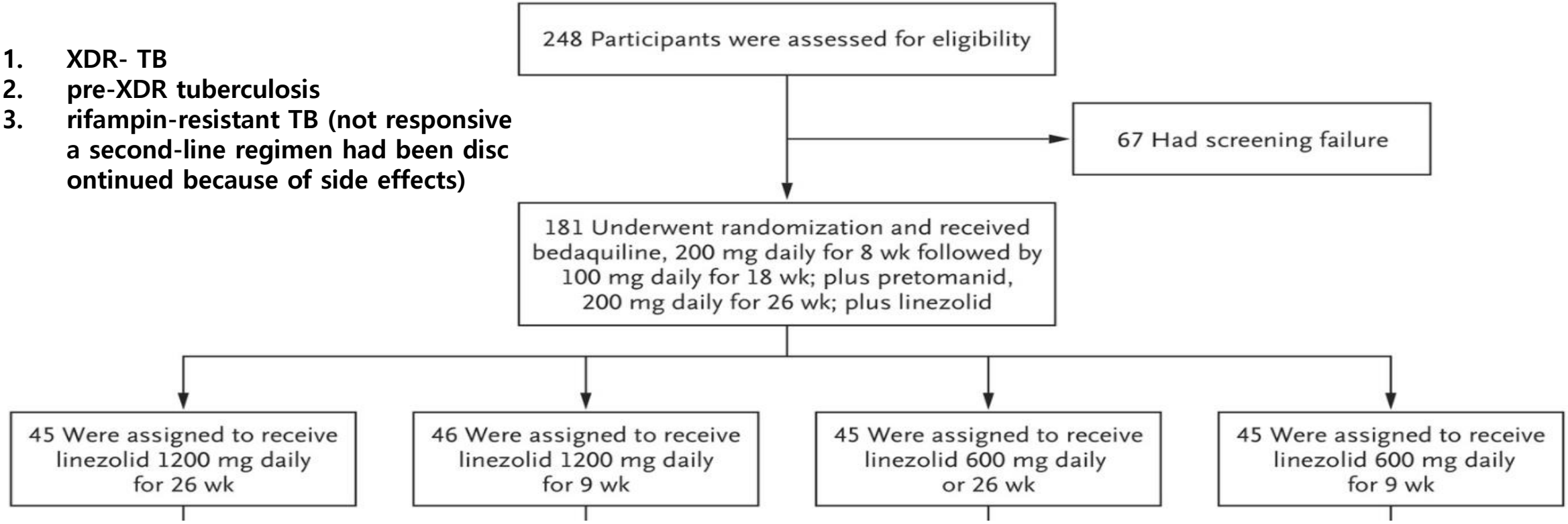
Peripheral neuropathy (81%)



NEJM 2020;382:893-902

Study population

1. XDR- TB
2. pre-XDR tuberculosis
3. rifampin-resistant TB (not responsive a second-line regimen had been discontinued because of side effects)



1. bedaquiline
2. Pretomanid
3. Linezolid 1200mg 26wk

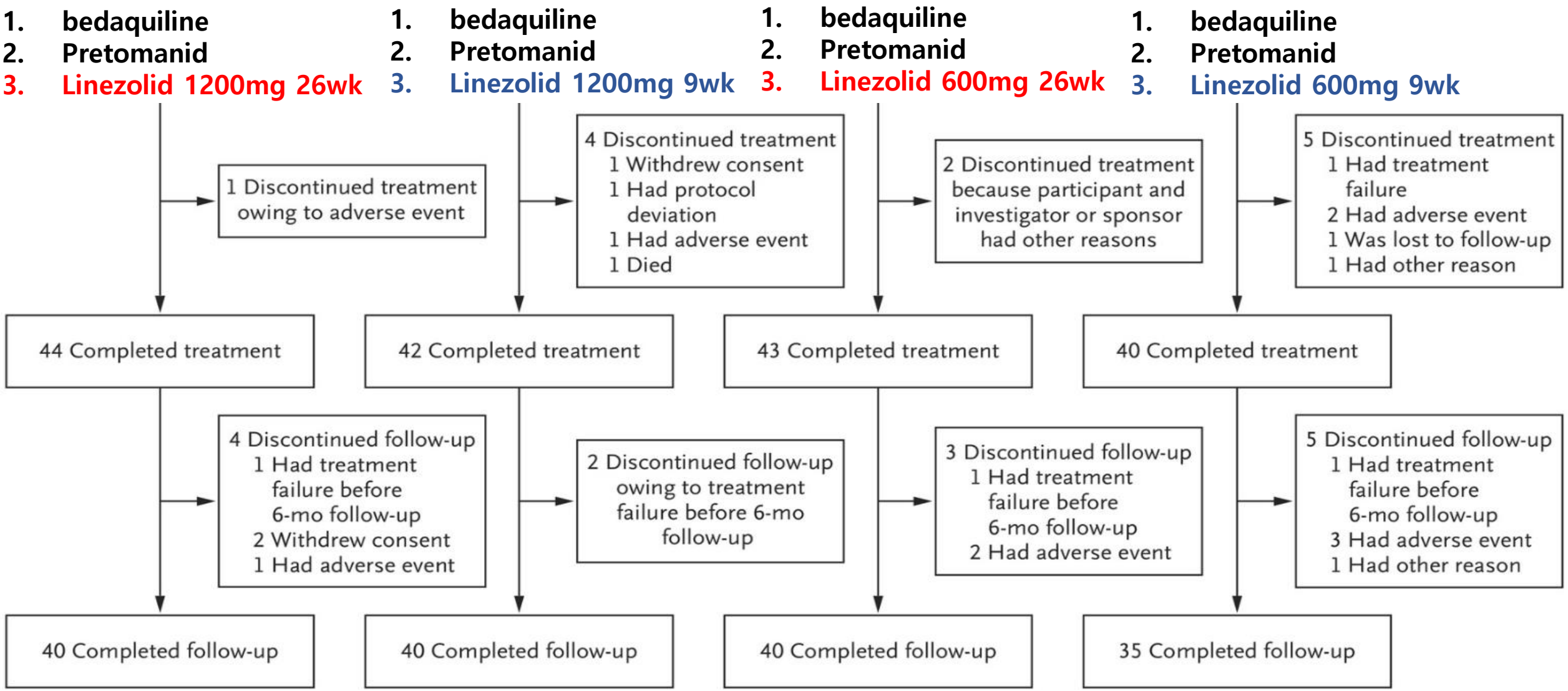
1. bedaquiline
2. Pretomanid
3. Linezolid 1200mg 9wk

1. bedaquiline
2. Pretomanid
3. Linezolid 600mg 26wk

1. bedaquiline
2. Pretomanid
3. Linezolid 600mg 9wk

N Engl J Med. 2022 Sep 1;387(9):810-823.

Study population



N Engl J Med. 2022 Sep 1;387(9):810-823.

Objectives

1. The incidence of an **unfavorable outcome**, defined as treatment failure or disease relapse (clinical or bacteriologic) at 26 weeks after completion of treatment.

2. Safety

1st objective-Unfavorable outcome

Primary Efficacy Analysis (MITT)

IAS 2021 18–21 July ZeNix

	Linezolid 1200mg 26 weeks (N=45) n (%)	Linezolid 1200mg 9 weeks (N=46) n (%)	Linezolid 600mg 26 weeks (N=45) n (%)	Linezolid 600mg 9 weeks (N=45) n (%)	Total (N=181) n (%)
Unassessable	1	1	1	1	4
Total assessable	44	45	44	44	177
Favourable	41 (93.2%)	40 (88.9%)	40 (90.9%)	37 (84.1%)	158 (89.3%)
Unfavourable	3 (6.8%)	5 (11.1%)	4 (9.1%)	7 (15.9%)	19 (10.7%)
95% CI for Favourable	81.3% to 98.6%	75.9% to 96.3%	78.3% to 97.5%	69.9% to 93.4%	83.7% to 93.4%

TB Alliance

N Engl J Med. 2022 Sep 1;387(9):810-823.

2nd objective-Safety

Table S22. Overview of Treatment Emergent Adverse Events (Safety population)

	Linezolid 1200mg 26 weeks (N=45) n (%)	Linezolid 1200mg 9 weeks (N=46) n (%)	Linezolid 600mg 26 weeks (N=45) n (%)	Linezolid 600mg 9 weeks (N=45) n (%)	Total (N=181) n (%)
Any TEAE	40 (88.9%)	41 (89.1%)	39 (86.7%)	36 (80.0%)	156 (86.2%)
Any grade ≥ 3 TEAE	14 (31.1%)	11 (23.9%)	9 (20.0%)	11 (24.4%)	45 (24.9%)
Any study drug-related TEAE	34 (75.6%)	29 (63.0%)	27 (60.0%)	26 (57.8%)	116 (64.1%)
Any TEAE related to Linezolid	29 (64.4%)	27 (58.7%)	24 (53.3%)	22 (48.9%)	102 (56.4%)
Any TEAE related to Bedaquiline	26 (57.8%)	25 (54.4%)	22 (48.9%)	24 (53.3%)	97 (53.6%)
Any TEAE related to Pretomanid	21 (46.7%)	24 (52.2%)	22 (48.9%)	21 (46.7%)	88 (48.6%)
Any serious TEAE	3 (6.7%)	4 (8.7%)	1 (2.2%)	3 (6.7%)	11 (6.1%)
Any TEAE leading to discontinuation of Linezolid	4 (8.9%)	2 (4.4%)	2 (4.4%)	3 (6.7%)	11 (6.1%)
Any TEAE leading to reduction of Linezolid	9 (20.0%)	6 (13.0%)	3 (6.7%)	4 (8.9%)	22 (12.2%)
Any TEAE leading to interruption of Linezolid	4 (8.9%)	4 (8.7%)	0	0	8 (4.4%)
Any TEAE leading to interruption of full regimen*	5 (11.1%)	5 (10.9%)	3 (6.7%)	6 (13.3%)	19 (10.5%)
Any TEAE leading to bedaquiline/pretomanid discontinuation	1 (2.2%)	2 (4.4%)	1 (2.2%)	3 (6.7%)	7 (3.9%)
Any TEAE leading to study discontinuation	1 (2.2%)	2 (4.4%)	1 (2.2%)	3 (6.7%)	7 (3.9%)
Any TEAE leading to death	0	1 (2.2%)	0	0	1 (0.6%)
Any liver-related TEAE	12 (26.7%)	12 (26.1%)	11 (24.4%)	12 (26.7%)	47 (26.0%)
Any drug related and liver-related TEAE	11 (24.4%)	10 (21.7%)	9 (20.0%)	9 (20.0%)	39 (21.6%)
Any serious liver-related TEAE	0	1 (2.2%)	1 (2.2%)	1 (2.2%)	3 (1.7%)

TEAE: Treatment-emergent adverse event.

N Engl J Med. 2022 Sep 1;387(9):810-823.

Summary

1. **A total of 84 to 93%** of the participants across all four bedaquiline–pretomanid–linezolid treatment groups had a favorable outcome.

2. The overall risk–benefit ratio favored the group that received the thr ee-drug regimen with linezolid at **a dose of 600 mg for 26 weeks**, with **a lower incidence of adverse events** reported and fewer linezolid dose modifications.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A 24-Week, All-Oral Regimen for Rifampin-Resistant Tuberculosis

Bern-Thomas Nyang'wa, M.B., B.S., Catherine Berry, B.Med., Emil Kazounis, M.Med.Sci., Ilaria Motta, Ph.D., Nargiza Parpieva, Sc.D., Zinaida Tigay, M.D., Varvara Solodovnikova, M.D., Irina Liverko, Sc.D., Ronelle Moodliar, M.B., B.S., Matthew Dodd, M.Sc., Nosipho Ngubane, M.B., B.Ch., Mohammed Rassool, M.B., B.Ch., Timothy D. McHugh, Ph.D., Melvin Spigelman, M.D., David A.J. Moore, M.D., Koert Ritmeijer, Ph.D., Philipp du Cros, M.B., B.S., and Katherine Fielding, Ph.D., for the TB-PRACTECAL Study Collaborators*

TB-Practecal Clinical Trial

- Aims to find **shorter**, **safer** more **effective** treatment for people living with drug-resistant tuberculosis (DR-TB).
- Evaluates the safety and efficacy of three **new drug regimens** compared to the World Health Organization (WHO) standard of care.

START

TRIAL LAUNCHED | JAN 2017 – DEC 2020 | NOV 2020 – MAR 2021 | MAR 2021

Stage 1

TB-Practecal — **6 month** treatment regimens

All oral medication

1. Bedaquiline, Pretomanid and Linezolid + Moxifloxacin (BPaLM)
2. Bedaquiline, Pretomanid and Linezolid + Clofazimine (BPaLC)
3. Bedaquiline, Pretomanid and Linezolid (BPaL)

WHO recommended standard of care — **9-24 months** treatment regimens +/- injections

Stage 2

BPaLM proved most effective & safe, thereby progressing to Stage 2.

Patient enrolment ends

552 patients

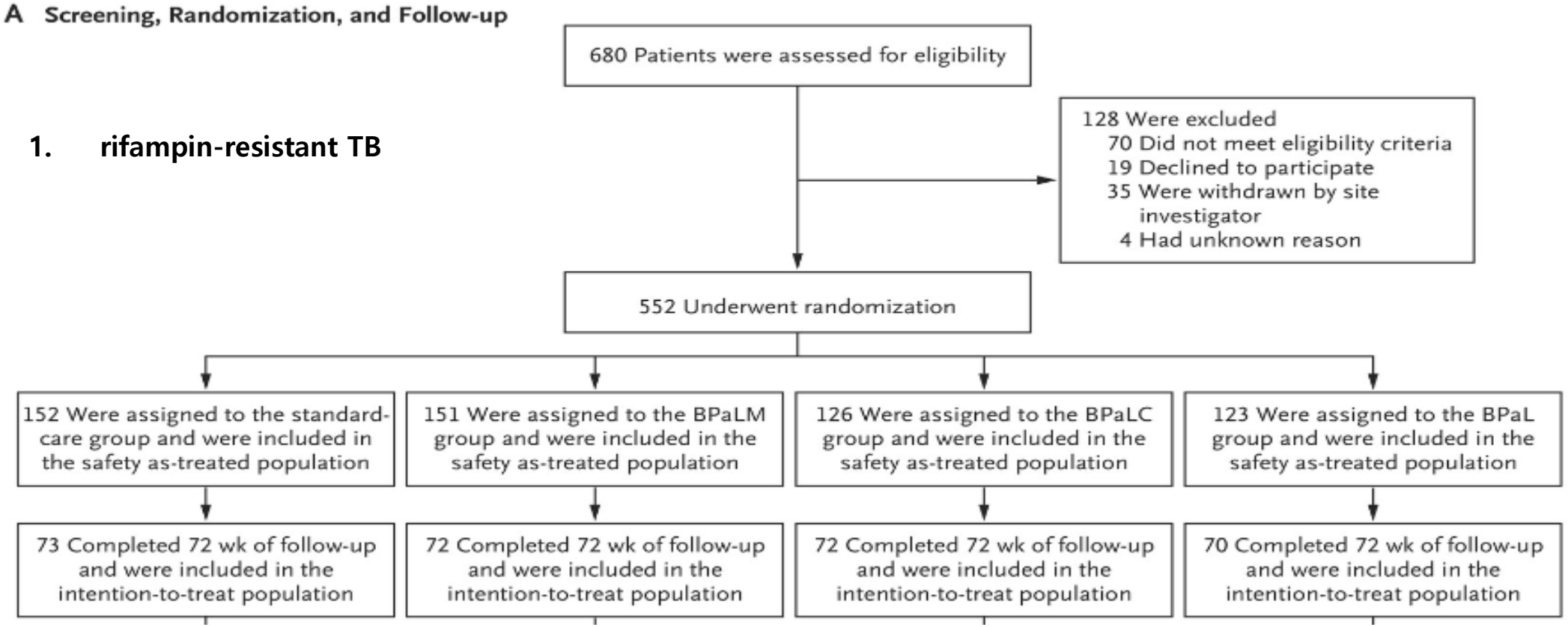
Data analysis

Stage I
- Identify regimens on safety and efficacy outcomes after 8 weeks of treatment.

Stage II
- The primary outcome
was an unfavorable status at 72 weeks
- The secondary
efficacy outcomes were culture conversion

Study population

1. rifampin-resistant TB



*** Standard treatment**

*** BPaLM**
1. **bedaquiline**
2. **Pretomanid**
3. **Linezolid**
4. **Moxifloxacin**

*** BPaLC**
1. **bedaquiline**
2. **Pretomanid**
3. **Linezolid**
4. **Clofazimine**

*** BPaL**
1. **bedaquiline**
2. **Pretomanid**
3. **Linezolid**

N Engl J Med. 2022 Dec 22;387(25):2331-2343

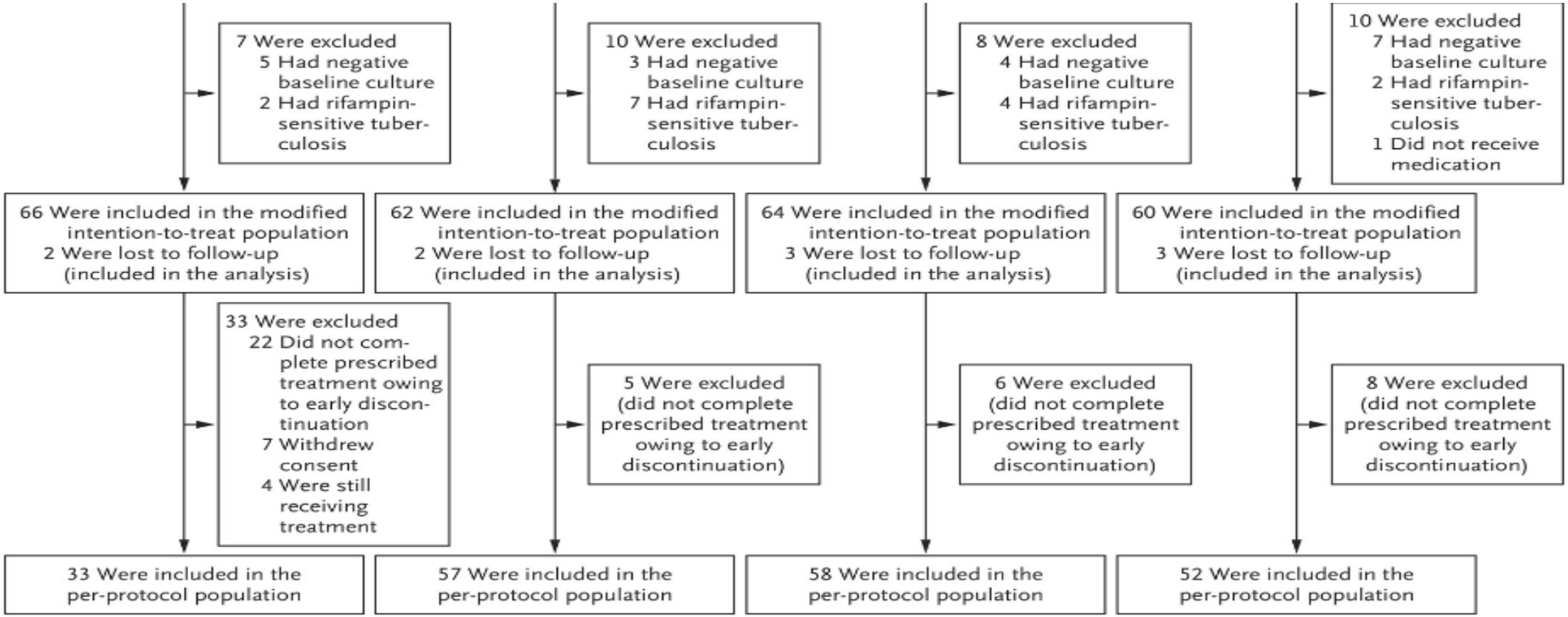
Study population

* Standard treatment

* BPaLM
1. bedaquiline
2. Pretomanid
3. Linezolid
4. Moxifloxacin

* BPaLC
1. bedaquiline
2. Pretomanid
3. Linezolid
4. Clofazimine

* BPaL
1. bedaquiline
2. Pretomanid
3. Linezolid



N Engl J Med. 2022 Dec 22;387(25):2331-2343

Objectives-Primary efficacy and safety

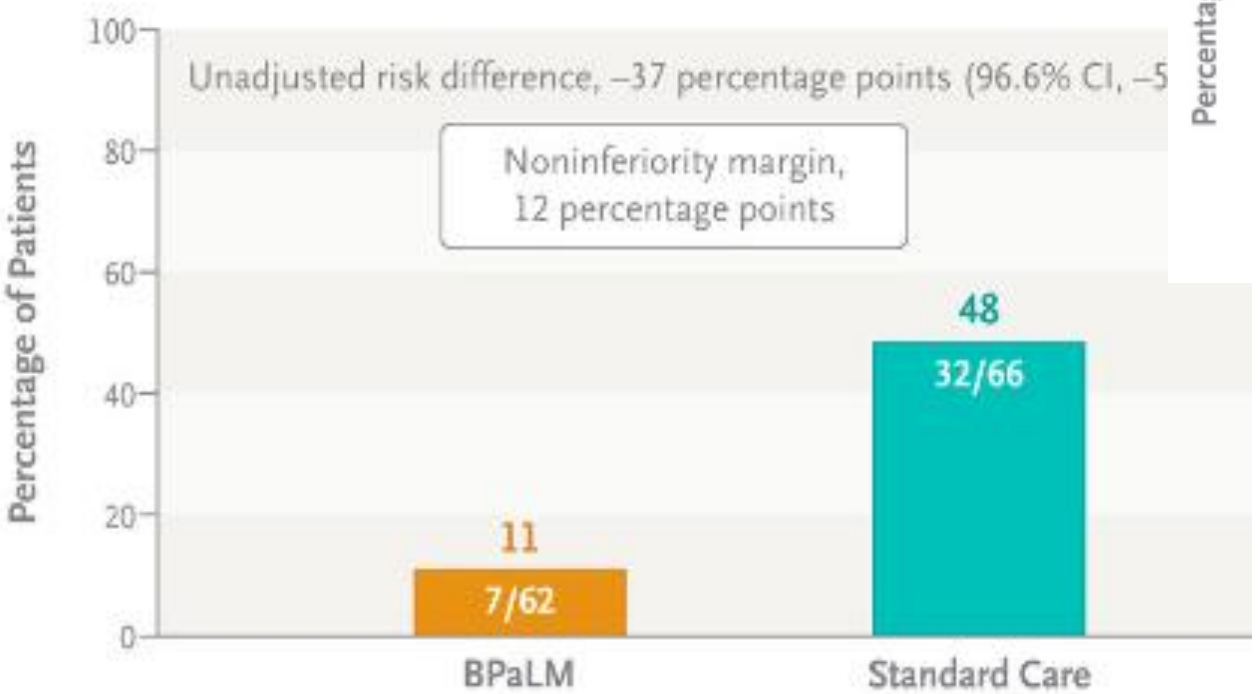
Table S8. Stage 1 primary efficacy and safety outcomes at week 8 (modified-intention-to-treat population, stage 1 analysis)

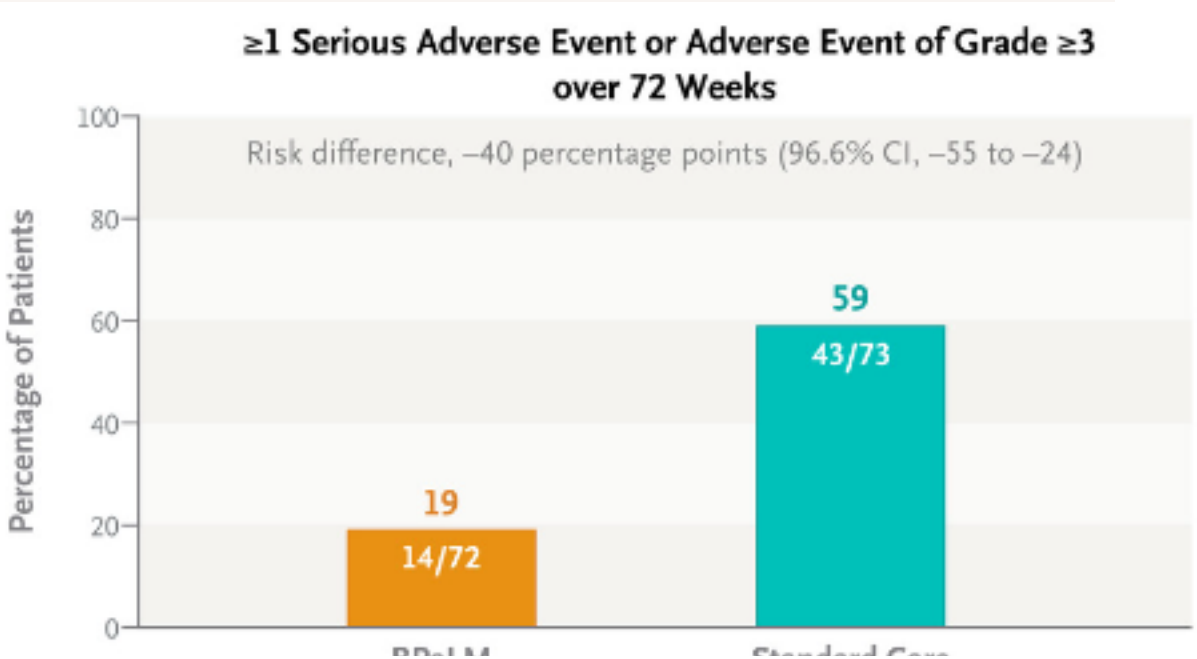
	Standard of care	BPaLM	BPaLC	BPaL
Number with culture conversion in liquid media at 8 weeks post randomization, n/N (%)	N/A	37/48 (77.1%)	33/49 (67.3%)	21/46 (45.7%)
[85 % CI]		[66.4, 85.6]	[56.2, 77.2]	[34.4, 57.3]
Patients with treatment discontinuation for any reason and death at 8 weeks post randomization, n/N (%)	N/A	4/52 (7.7 %)	3/52 (5.8 %)	5/51 (9.8%)
[90% CI]		[2.7, 16.7]	[1.6, 14.2]	[3.9, 19.5]

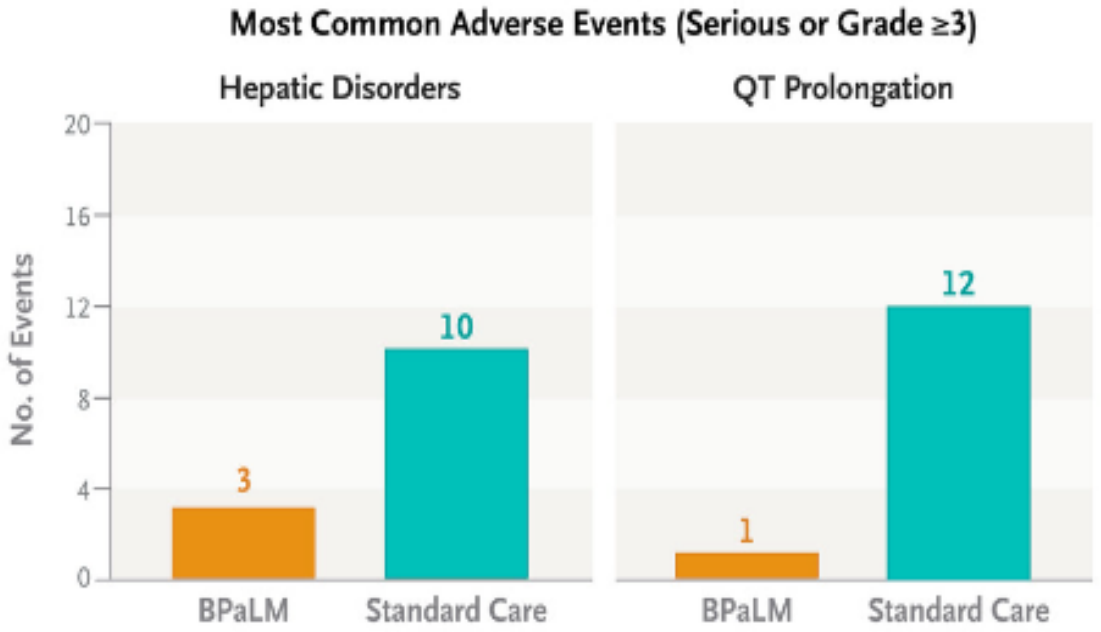
N Engl J Med. 2022 Dec 22;387(25):2331-2343

Table 2. Primary Efficacy Analysis at 72 Weeks.

Variable	Intention-to-Treat Population	
	Standard-Care Group (N=73)	BPaLM Group (N=72)
Unfavorable Outcome in Modified Intention-to-Treat Ar		
points (96.6% CI)‡		(−46 to −14)







* The per-protocol population included all patients in the modified intention-to-treat populatio course of treatment (>80% of doses within 120% of the prescribed duration), other than beca because they did not meet the inclusion or exclusion criteria.

† The "other outcome" category included one patient who could not be cared for at a trial site b patient who could not be cared for because the patient had acute behavioral challenges.

Summary

1. All-oral regimens containing bedaquiline, pretomanid, and linezolid for the treatment of rifampin-resistant tuberculosis showed that treatment with **BPaLM was more effective and had a better safety profile than standard care**. BPaLC and BPaL were also highly efficacious.

WHO consolidated guidelines on tuberculosis

Module 4: Treatment

Drug-resistant tuberculosis treatment

2022 update

World Health Organization

Section 2. The 9-month all-oral regimen for MDR/RR-TB (NEW)

2.1 Recommendation

NEW RECOMMENDATION

No.	Recommendation
2.1	WHO suggests the use of the 9-month all-oral regimen rather than longer (18-month) regimens in patients with MDR/RR-TB and in whom resistance to fluoroquinolones has been excluded. *(Conditional recommendation, very low certainty of evidence)*

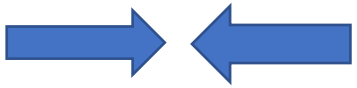
Articles

9 months of delamanid, linezolid, levofloxacin, and pyrazinamide versus conventional therapy for treatment of fluoroquinolone-sensitive multidrug-resistant tuberculosis (MDR-END): a multicentre, randomised, open-label phase 2/3 non-inferiority trial in South Korea

Jeongha Mok, Myungsun Lee*, Deog Kyeom Kim, Ju Sang Kim, Byung Woo Jhun, Kyung-Wook Jo, Doosoo Jeon, Taehoon Lee, Ji Yeon Lee, Jae Seuk Park, Seung Heon Lee, Young Ae Kang, Jung-Kyu Lee, Nakwon Kwak, Joong Hyun Ahn, Tae Sun Shim, Song Yee Kim, Seungmo Kim, Kyungjong Kim, Kwang-Hyuk Seok, Soyeong Yoon, Young Ran Kim, Jisu Kim, Dahae Yim, Seokyung Hahn, Sang Nae Cho, Jae-Joon Yim, on behalf of the MDR-END investigators*

Objectives

Investigational group (9-month)
1. **Delamanid**
2. **linezolid,**
3. **Levofloxacin**
4. **pyrazinamide)**



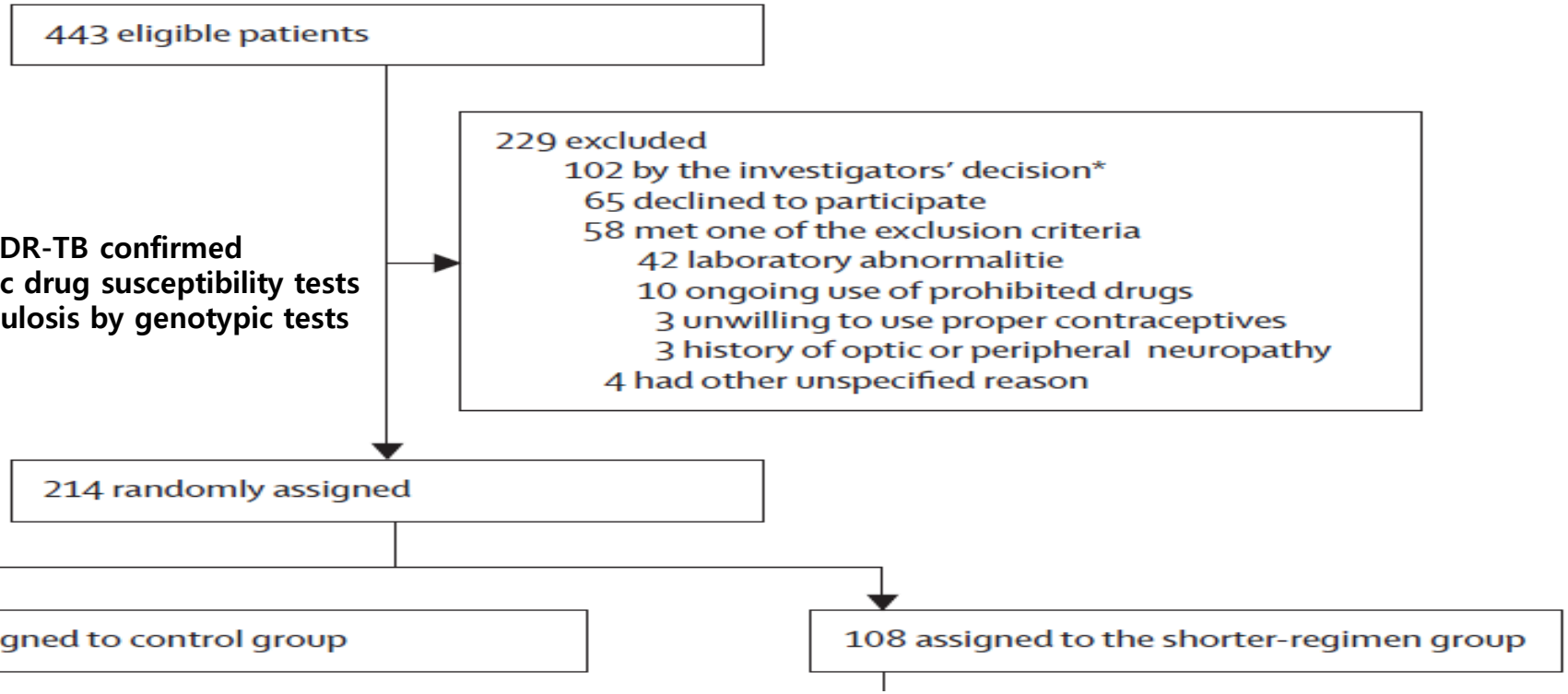
Control group (20-24 month)
: conventional treatment

1. **The primary outcome was the treatment success rate**

2. **Safety**

Study population

1. Aged 19–85 years with MDR-TB confirmed by phenotypic or genotypic drug susceptibility tests
2. rifampicin-resistant tuberculosis by genotypic tests



Control group (20-24 month)
: conventional treatment

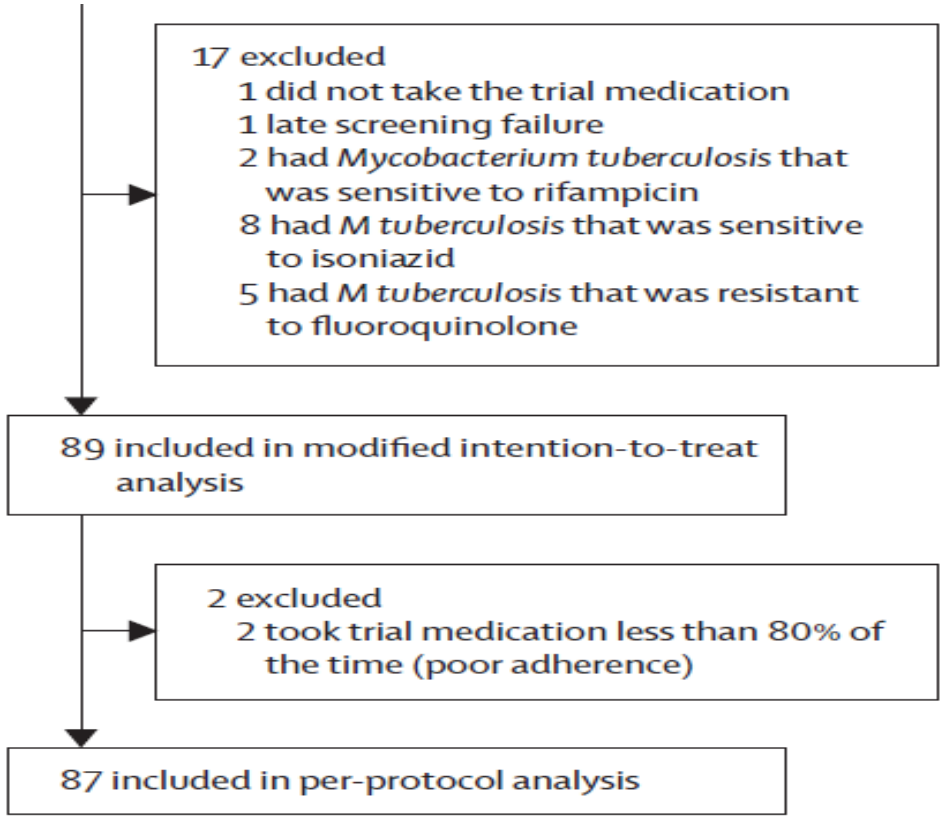
Investigational group (9-month)
1. **Delamanid**
2. **linezolid,**
3. **Levofloxacin**
4. **pyrazinamide)**

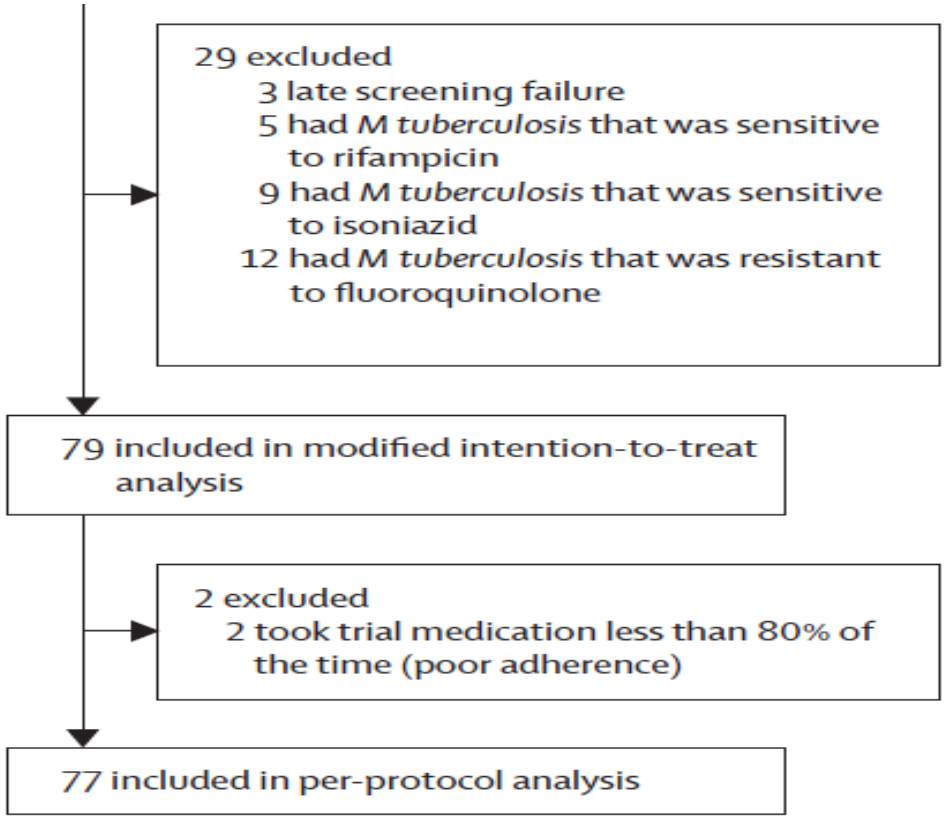
Lancet 2022 Oct 29;400(10362):1522-1530.

Study population

Control group (20-24 month)
: conventional treatment

Investigational group (9-month)
1. **Delamanid**
2. **linezolid,**
3. **Levofloxacin**
4. **pyrazinamide)**





Lancet 2022 Oct 29;400(10362):1522-1530.

Baseline characteristics

	Control group (n=89)	Shorter-regimen group (n=79)
Sex		
Male	63 (70·8%)	53 (67·1%)
Female	26 (29·2%)	26 (32·9%)
Age (years)	46 (34–60)	49 (39–57)
BMI (kg/m²)	21·1 (19·2–23·1)	20·7 (18·9–22·7)
Comorbidities		
History of previous tuberculosis	39 (43·8%)	36 (45·6%)
Diabetes	17 (19·1%)	16 (20·3%)
Positive HIV antibody	0*	0
Bacteriological examinations		
Acid-fast staining of sputum		
Negative	65 (73·0%)	55 (69·6%)
Trace	2 (2·2%)	2 (2·5%)
1+	8 (9·0%)	9 (11·4%)
2+	5 (5·6%)	4 (5·1%)
3+	4 (4·5%)	4 (5·1%)
4+	5 (5·6%)	5 (6·3%)
Positive *M tuberculosis* culture on liquid medium	52 (58·4%)	49 (62·0%)
Positive *M tuberculosis* culture on solid medium	39 (43·8%)	37 (46·8%)
Phenotypic drug susceptibility test†		
Performed	77 (86·5%)	74 (93·7%)
Resistance to pyrazinamide	22 (24·7%)	26 (32·9%)
Resistance to second-line injectable drugs	7 (7·9%)	4 (5·1%)
Radiographic examinations		
Bilateral involvement	38 (42·7%)	48 (60·8%)
Presence of cavity	46 (51·7%)	38 (48·1%)
QTcF (ms)‡	406 (398–417)	409 (394–423)

Lancet 2022 Oct 29;400(10362):1522-1530.

1st objective - Treatment success rate

	Modified intention-to-treat population		Per-protocol population	
	Control group	Shorter-regimen group	Control group	Shorter-regimen group
Disposition of the participants				
Underwent randomisation	106	108	106	108
Included in the population	89 (84%)	79 (73%)	87 (82%)	77 (71%)
Not assessable	4 (4%)	7 (9%)	4 (5%)	7 (9%)
Became pregnant during treatment	0	1 (1%)	0	1 (1%)
Achieved negative culture conversion but were lost to follow-up after trea	4 (4%)	3 (4%)	4 (5%)	3 (4%)
Achieved n treatm	0	3 (4%)		
Inclu	0%)	72 (67%)		
O				
		54 (75%		
		4·4%		
		18 (2		
		1† (1		
		0		
	)	4 (6%)		
Relap		1‡ (1%)		
Died durin	2 (2%)	2 (3%)		
Lost to follow-u	4 (5%)	1 (1%)		
Withdrew consent during tre	5 (6%)	6 (8%)	5 (6%)	6 (9%)
Other investigators' decision	3 (4%)	3 (4%)	3 (4%)	2 (3%)

*97·5% one-sided CI for non-inferiority test. †The minimum inhibitory concentrations (MICs) of delamanid in the *Mycobacterium tuberculosis* strain isolated after 8 months of treatment was 0·00625 µg/mL and for linezolid, it was 0·5 µg/mL. ‡Confirmed to be the same strain as the original *M tuberculosis* based on an analysis of Mycobacterial Interspersed Repetitive Units-Variable Tandem Repeats. The MIC of delamanid in the relapsed strain was 0·00625 µg/mL and for linezolid, it was 0·125 µg/mL.

Table 2: **Primary outcome (treatment success rate at 24 months after the initiation of treatment) by treatment group in the modified intention-to-treat and per-protocol analyses**

Control group (20-24 month)
: conventional treatment
70.6%

Investigational group
(9-month)
75%

Lancet 2022 Oct 29;400(10362):1522-1530.

2nd objective - Safety

	Control group (n=89)	Shorter-regimen group (n=79)
Participants with at least one adverse event	87 (97·8%)	78 (98·7%)
Participants with at least one adverse event considered possibly, probably, or definitely related to the study drugs	56 (62·9%)	59 (74·7%)
Participants with at least one grade 3 or greater adverse event	26 (29·2%)	29 (36·7%)
Participants with serious adverse events	19 (21·3%)	20 (25·3%)
Death		
Any	2 (2·2%)	5 (6·3%)
Tuberculosis-related	0	0

All adverse events and serious adverse events were collected during the 24 months of the study period.

Table 3: **Safety analysis**

Lancet 2022 Oct 29;400(10362):1522-1530.

Summary

1. **60 (70·6%) of 85 participants in the control group** had treatment s uccess, as did **54 (75·0%) of 72 participants in the shorter-regimen group,** satisfying the predefined non-inferiority margin.

2. **No difference in safety outcomes** was identified between the control group and the shorter-regimen group.

Agenda

- **Tuberculosis**
  - ✓ Diagnosis [1]
  - ✓ Treatment [1]
  - ✓ multidrug-resistant tuberculosis, MDR-TB [3]

- **Nontuberculous mycobacteria, NTM [2]**

frontiers | Frontiers in Medicine

BRIEF RESEARCH REPORT
published: 18 April 2022
doi: 10.3389/fmed.2022.793453

Healthcare Utilization and Medical Cost of Gastrointestinal Reflux Disease in Non-tuberculous Mycobacterial Pulmonary Disease: A Population-Based Study, South Korea, 2009–2017

Taehee Kim[1†], Jai Hoon Yoon[2†], Bumhee Yang[3†], Jiin Ryu[4], Chang Ki Yoon[5], Youlim Kim[6], Jang Won Sohn[7], Hyun Lee[7] and Hayoung Choi[1*]*

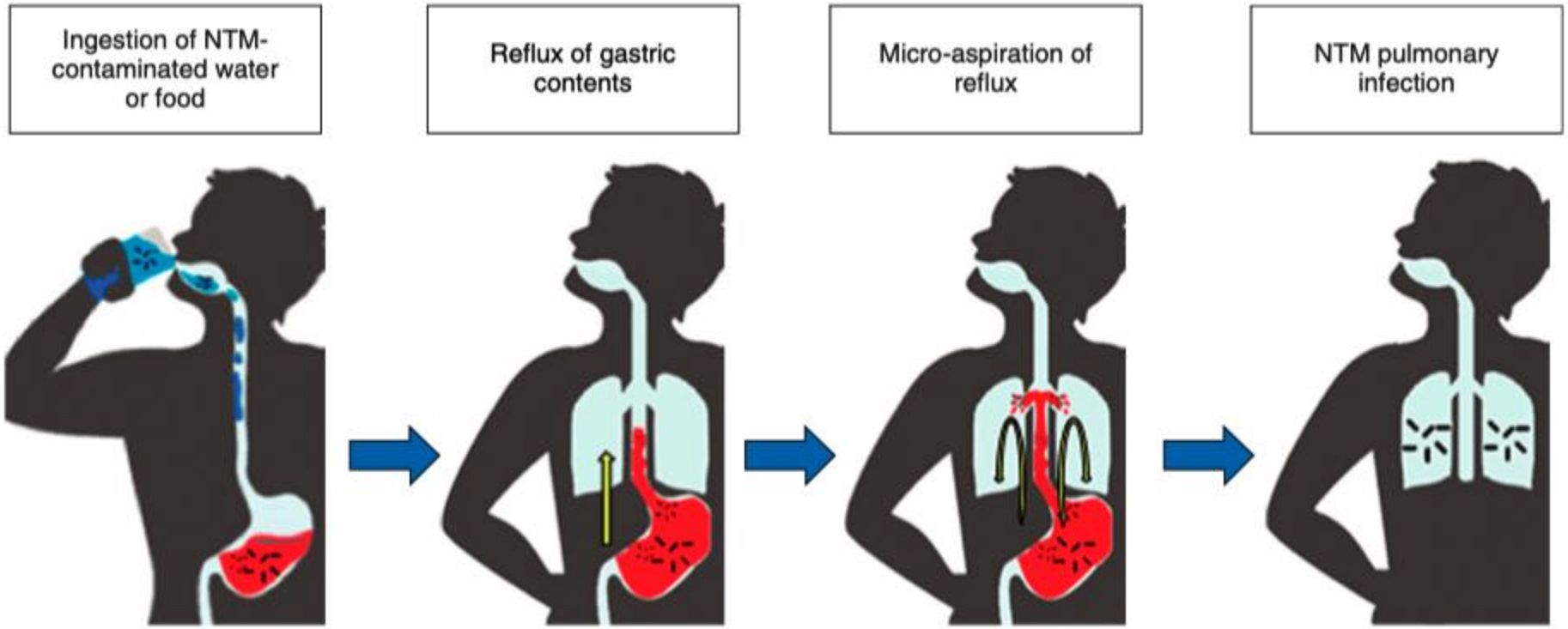
[Chest Infections Original Research]

CHEST

Gastroesophageal Reflux Disease Increases Susceptibility to Nontuberculous Mycobacterial Pulmonary Disease

Youlim Kim, MD, PhD; Jai Hoon Yoon, MD, PhD; Jiin Ryu, MS; Bumhee Yang, MD; Sung Jun Chung, MD; Hyung Koo Kang, MD; Dong Won Park, MD, PhD; Tai Sun Park, MD, PhD; Ji-Yong Moon, MD, PhD; Tae-Hyung Kim, MD, PhD; Sang-Heon Kim, MD, PhD; Jang Won Sohn, MD, PhD; Ho Joo Yoon, MD, PhD; Hyun Lee, MD, PhD; and Hayoung Choi, MD, PhD

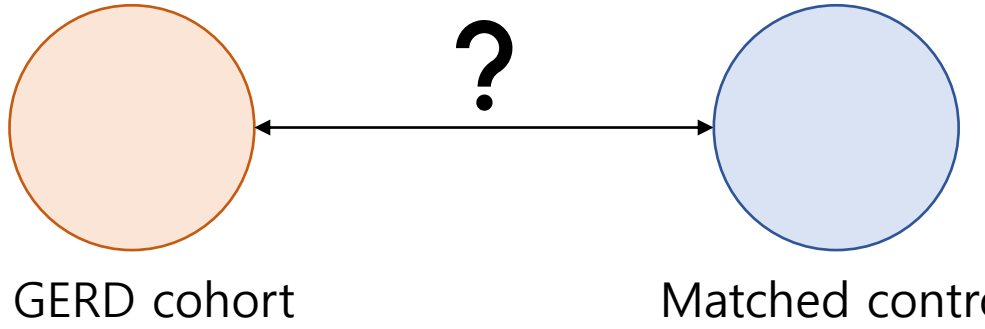
Gastroesophageal reflux and NTM



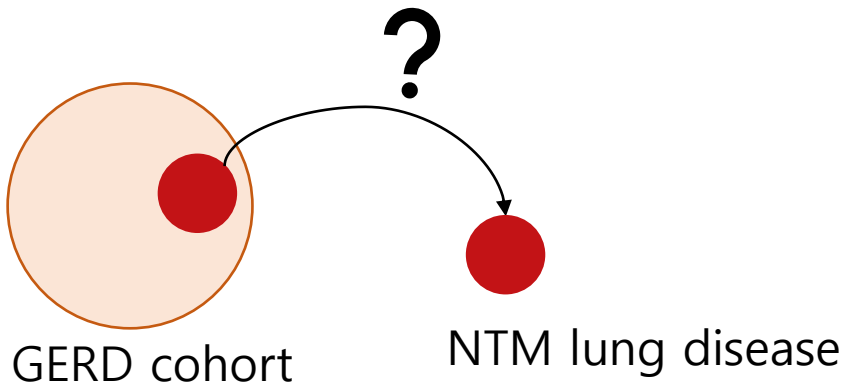
Am J Respir Crit Care Med 2020;202:466

Objectives

1. To evaluate the effects of GERD on NTM lung disease development



2. To assess risk factors for incident NTM lung disease among patients with GERD

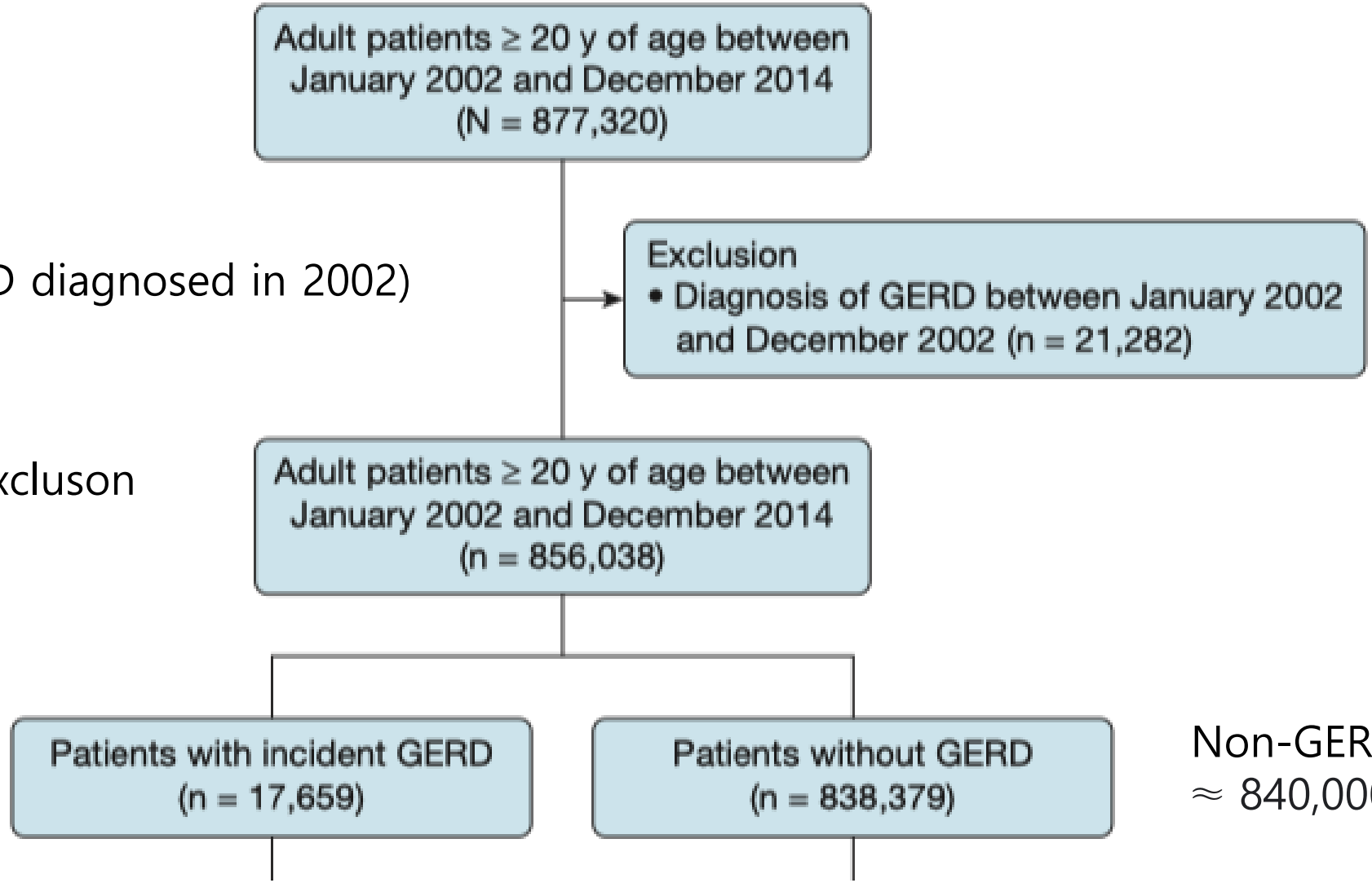


Study population

1) Initial dataset
≈ 880,000

2) Exclusion (GERD diagnosed in 2002)
≈ 20,000

3) Dataset after excluson
≈ 860,000

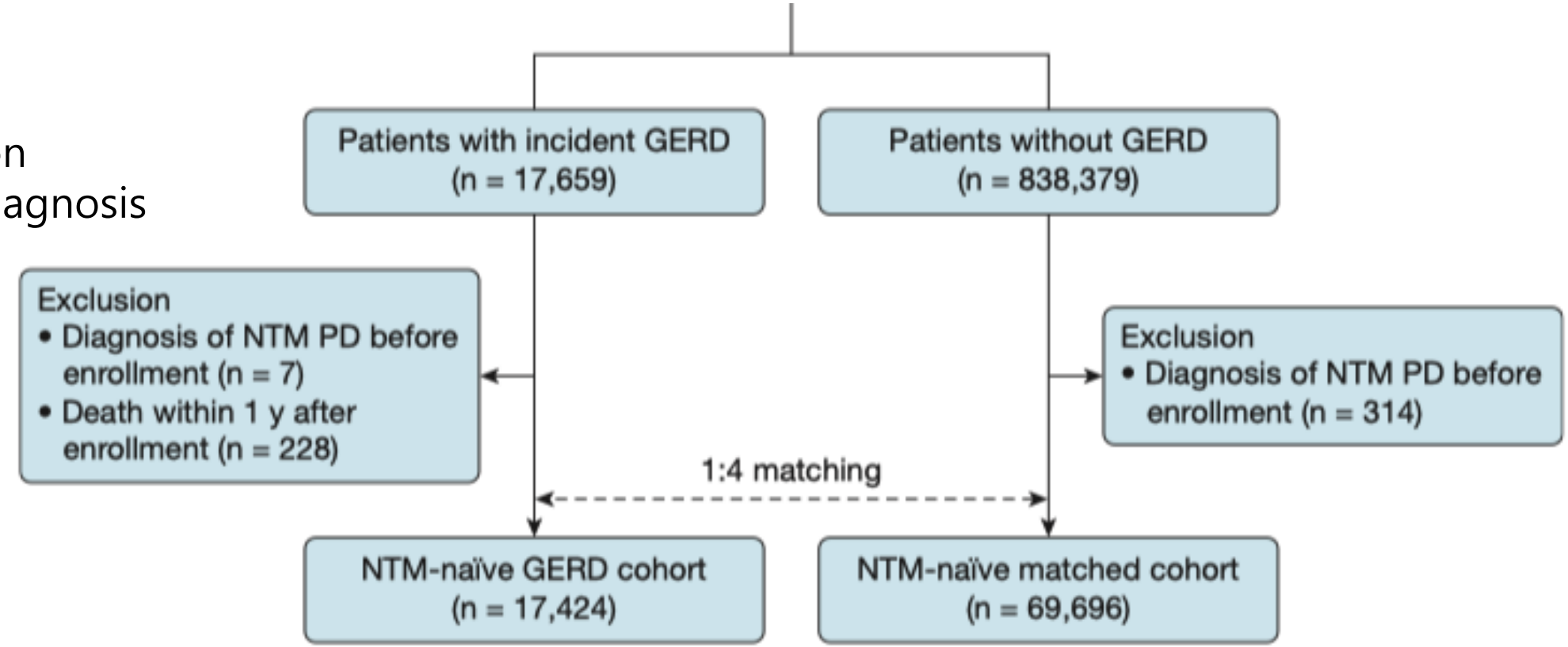


GERD cohort
≈ 18,000

Non-GERD cohort
≈ 840,000

Chest 2022;163:270

4) Exclusion
- NTM diagnosis



5) Matching

GERD cohort (n≈17,000)

Matched cohort (n≈69,000)
- *age*
- *sex*
- *type of insurance (income)*
- *comorbidities*

Chest 2022;163:270

Baseline characteristics

TABLE 1] Baseline Characteristics of the Study Population

Variable	Total (N = 87,120)	GERD Cohort (n = 17,424)	Matched Cohort (n = 69,696)	Standardized Difference
Age group, y				
20-29	3,195 (3.7)	639 (3.7)	2,556 (3.7)	0.00
30-39	6,730 (7.7)	1,346 (7.7)	5,384 (7.7)	0.00
40-49	14,735 (16.9)	2,947 (16.9)	11,788 (16.9)	0.00
50-59	22,895 (26.3)	4,579 (26.3)	18,316 (26.3)	0.00
60-69	20,580 (23.6)	4,116 (23.6)	16,464 (23.6)	0.00
≥ 70	18,985 (21.8)	3,797 (21.8)	15,188 (21.8)	0.00
Sex				
Male	43,630 (50.1)	8,726 (50.1)	34,904 (50.1)	0.00
Female	43,490 (49.9)	8,698 (49.9)	34,792 (49.9)	0.00
Type of insurance				
Self-employed health insurance	29,425 (33.8)	5,885 (33.8)	23,540 (33.8)	0.00
Employee health insurance	50,280 (57.7)	10,056 (57.7)	40,224 (57.7)	0.00
Medical aid	7,415 (8.5)	1,483 (8.5)	5,932 (8.5)	0.00

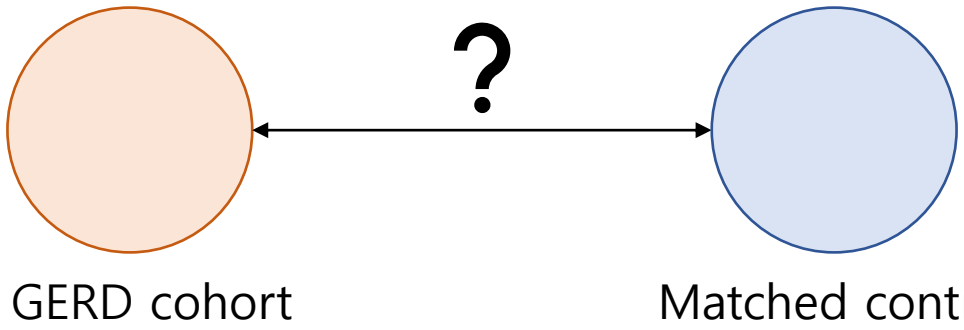
Chest 2022;163:270

Pulmonary comorbidities				
COPD	7,108 (8.2)	1,432 (8.2)	5,676 (8.1)	0.00
Asthma	12,762 (14.7)	2,405 (13.8)	10,357 (14.9)	−0.03
Bronchiectasis	912 (1.1)	186 (1.1)	726 (1.0)	0.00
Extrapulmonary comorbidities				
Cerebrovascular disease	10,541 (12.1)	2,008 (11.5)	8,533 (12.2)	−0.02
Angina or MI	8,196 (9.4)	2,135 (12.3)	6,061 (8.7)	0.12
Diabetes mellitus	24,609 (28.3)	4,446 (25.5)	20,163 (28.9)	−0.08
Chronic kidney disease	1,326 (1.5)	223 (1.3)	1,103 (1.6)	−0.03
Connective tissue disease	4,995 (5.7)	1,268 (7.3)	3,687 (5.3)	0.08
Charlson Comorbidity Index				
0	12,600 (14.5)	2,520 (14.5)	10,080 (14.5)	0.00
1	23,435 (26.9)	4,687 (26.9)	18,748 (26.9)	0.00
2	19,060 (21.9)	3,812 (21.9)	15,248 (21.9)	0.00
3	11,945 (13.7)	2,389 (13.7)	9,556 (13.7)	0.00
4	7,790 (8.9)	1,558 (8.9)	6,232 (8.9)	0.00
≥ 5	12,290 (14.1)	2,458 (14.1)	9,832 (14.1)	0.00

Chest 2022;163:270

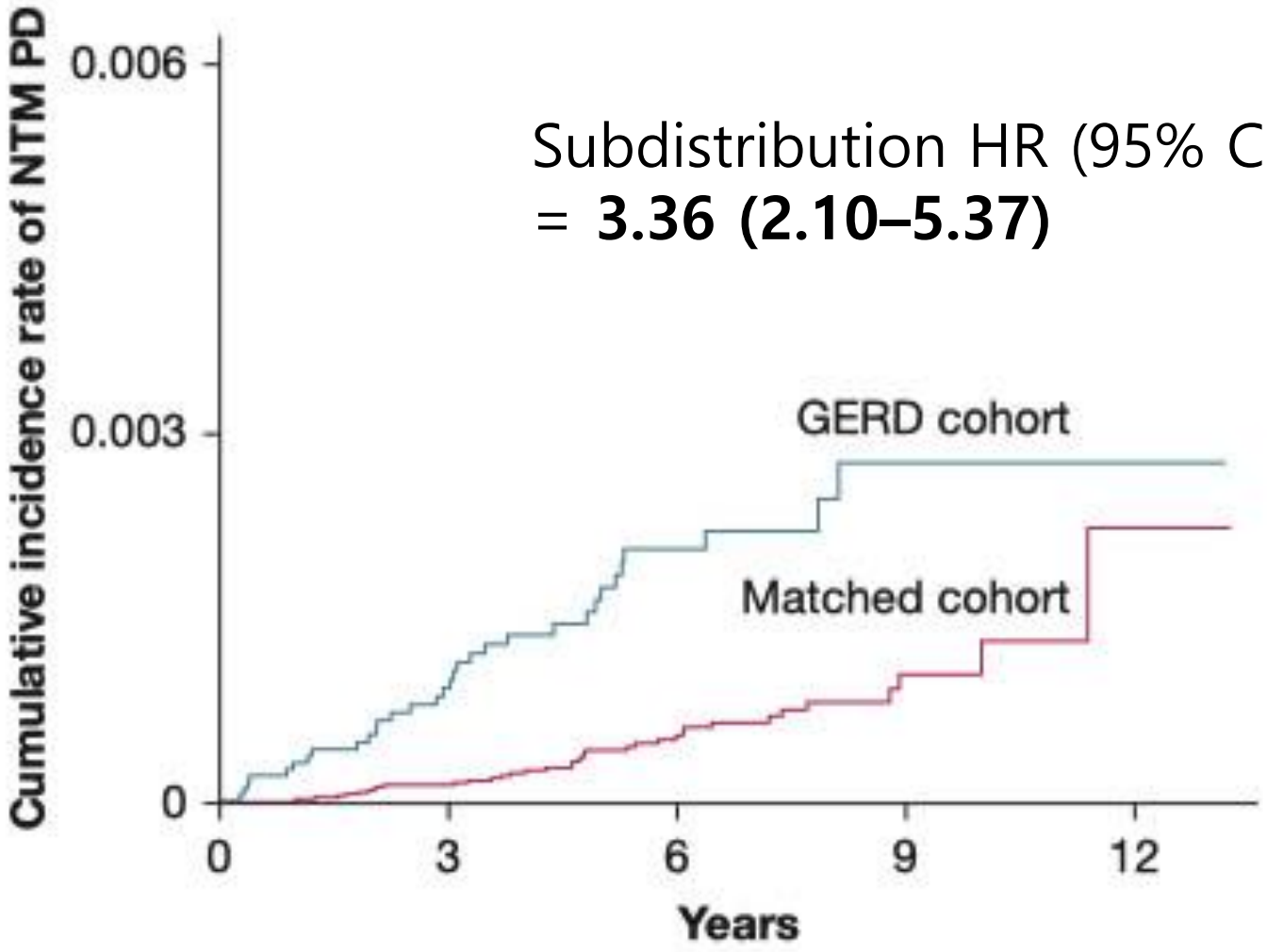
1st objective

- Effects of GERD on NTM LD development



Incident NTM LD – GERD vs. Matched

Median follow-up duration: 5.1 years

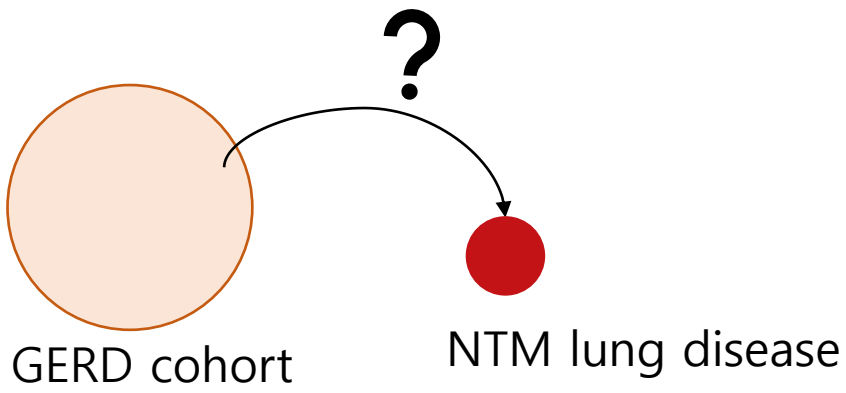


Subdistribution HR (95% CI)
= **3.36 (2.10–5.37)**

Chest 2022;163:270

2nd objective

- Risk factors for NTM LD among GERD cohort



Risk factors for **NTM LD** in **GERD cohort**

- Multivariate Cox regression analysis

	Adjusted HR (95% CI)
Age group	
<60 years	Reference
≥60 years	**3.37 (1.58–8.07)**
Sex	
Male	Reference
Female	0.93 (0.45–1.88)
Pulmonary comorbidities	
COPD	1.01 (0.33–3.11)
Asthma	0.90 (0.33–2.45)
Bronchiectasis	**18.69 (6.68–52.28)**

Adjusted for age, sex, type of insurance, pulmonary and extrapulmonary comorbidities and Charlson comorbidity index

Chest 2022;163:270

Summary

1. **GERD** – important predisposing factor for the deve lopment of **NTM lung disease**

2. Risk factors for incident NTM lung disease in patients with GERD
   - **Older age**
   - **Bronchiectasis**

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RESEARCH ARTICLE

Antibiotic Maintenance and Redevelopment of Nontuberculous Mycobacteria Pulmonary Disease after Treatment of *Mycobacterium avium* Complex Pulmonary Disease

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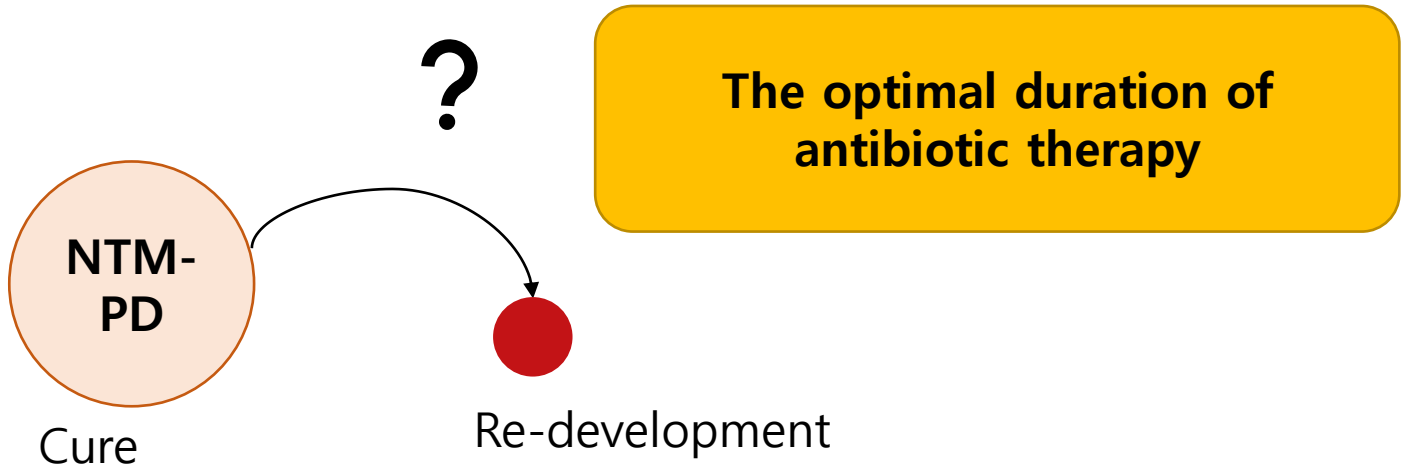
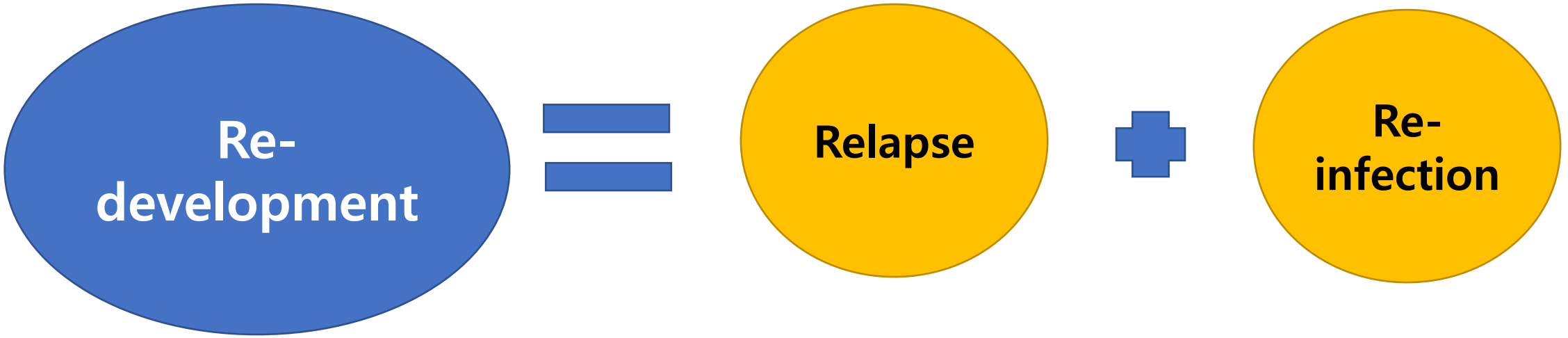
Optimal antibiotic maintenance period in MAC-PD

- To improve treatment outcomes and reduce the recurrence rate, current guidelines recommend maintenance of antibiotics for a minimum of 12 months after achievement of negative culture conversion

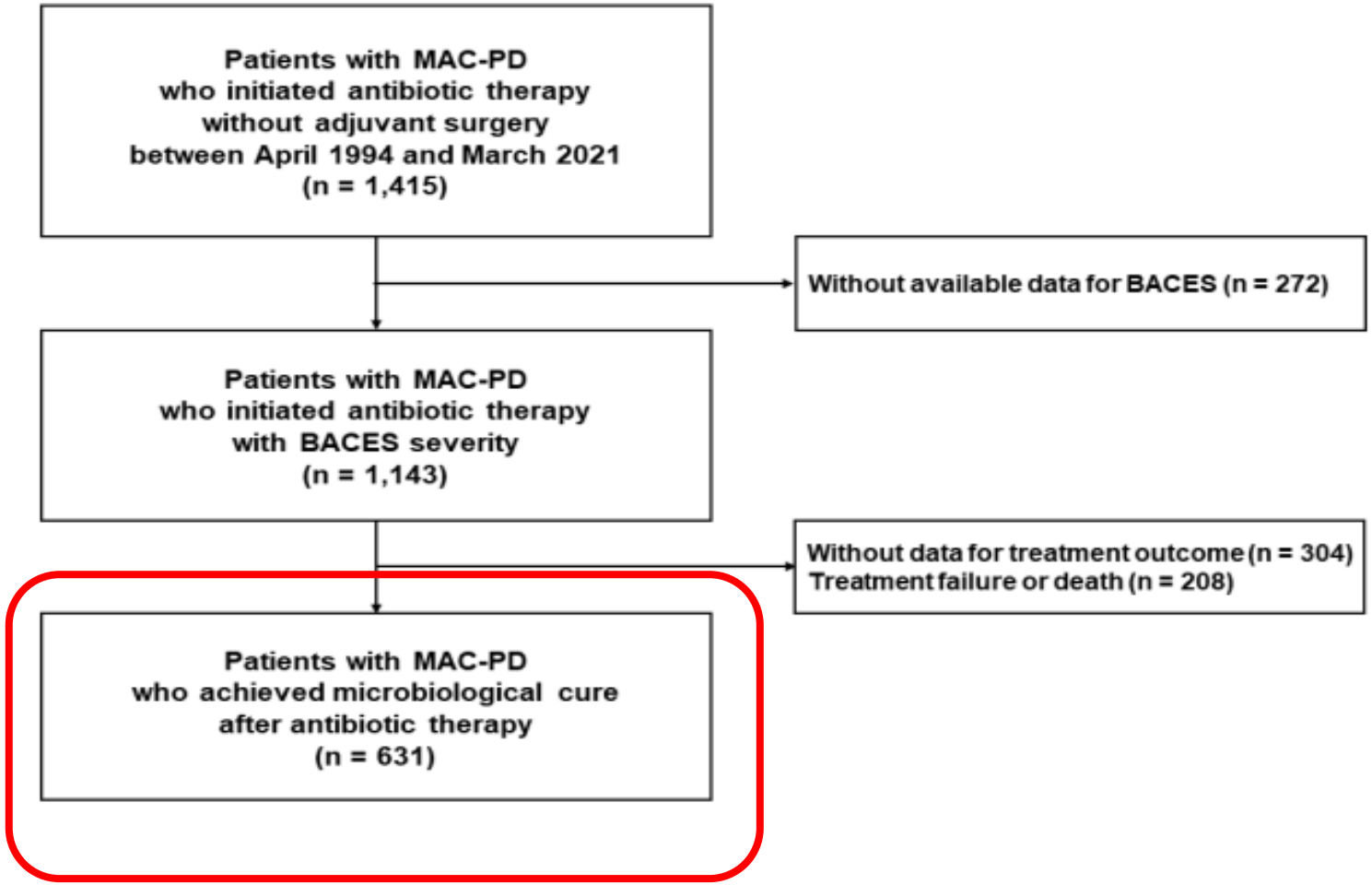


Objectives

1. To evaluate whether **the maintenance period affects disease redevelopment in patients** with MAC-PD who achieved microbiological cure, after adjustment for disease severity



Study population



Baseline characteristics

TABLE 1 Characteristics of study patients at the time of diagnosis with MAC-PD[a]

Characteristics	Total ($n = 631$)	Without redevelopment ($n = 426$)	With redevelopment ($n = 205$)	*P* value
Body mass index, <18.5 kg/m²	151 (24)	98 (23)	53 (26)	0.493
Age ≥65 yrs	123 (20)	91 (21)	32 (16)	0.109
Cavity	220 (35)	161 (38)	59 (29)	0.033
Elevated erythrocyte sedimentation rate	453 (72)	311 (73)	142 (69)	0.378
Sex, male	207 (33)	141 (33)	66 (32)	0.892
BACES severity				0.079
Mild	262 (41)	168 (39)	94 (46)	
Moderate	315 (50)	215 (51)	100 (49)	
Severe	54 (9)	43 (10)	11 (5)	
Comorbidity				
Previous pulmonary tuberculosis	225 (36)	144 (34)	81 (40)	0.189
Chronic obstructive pulmonary disease	73 (12)	49 (12)	24 (12)	>0.999
Chronic pulmonary aspergillosis	12 (2)	9 (2)	3 (2)	0.804
Lung cancer	13 (2)	9 (2)	4 (2)	>0.999
Ever-smoker[b]	152 (24)	103 (24)	49 (24)	>0.999
Acid-fast bacillus smear positivity	255 (40)	162 (38)	93 (45)	0.094
Etiology				0.639
M. avium	324 (51)	222 (52)	102 (50)	
M. intracellulare	307 (49)	204 (48)	103 (50)	
Radiological form				0.033
Nodular bronchiectatic form	520 (82)	341 (80)	179 (87)	
Fibrocavitary form	111 (18)	85 (20)	26 (13)	

1st objective

TABLE 2 Comparisons of treatment period according to redevelopment of MAC-PD[a]

Characteristics	Total (n = 631)	Without redevelopment (n = 426)	With redevelopment (n = 205)	P value
Time between initiation of antibiotics and culture conversion, mo	1.0 (1.0–3.0)	2.0 (1.0–4.0)	1.0 (1.0–3.0)	0.078
Maintenance period, mo[b]	14.0 (12.0–19.0)	14.0 (12.0–17.0)	15.0 (13.0–22.0)	<0.001
Maintenance period				
≤12 mo	87 (14)	67 (16)	20 (10)	0.056
Maintenance period of ≤12 mo group, mo	10.0 (8.5–12.0)	10.0 (8.0–11.0)	11.0 (9.0–12.0)	0.168
>12 mo	544 (86)	359 (84)	185 (90)	0.056
Maintenance period of >12 mo group, mo	15.0 (13.0–21.0)	15.0 (13.0–18.0)	15.0 (14.0–22.0)	0.003
Overall treatment duration, mo	18.0 (15.0–24.0)	17.0 (15.0–23.0)	18.0 (15.0–24.0)	0.001
Time from treatment completion to redevelopment, mo	NA	NA	18.0 (7.0–34.0)	
Total follow-up duration, mo	36.0 (24.0–53.0)	35.0 (23.0–52.0)	38.0 (29.0–53.0)	0.008

[a]Data are presented as number (percentage) or median (interquartile range). NA, not applicable.

[b]Time from culture conversion to treatment completion.

TABLE 4 Effects of maintenance period on redevelopment of MAC-PD[a]

HR of Maintenance period >12 mo[b]	HR (95% CI, P value)
Crude HR	0.99 (0.63–1.58, 0.976)
Model 1[c]	0.99 (0.61–1.59, 0.961)
Model 2[d]	1.05 (0.65–1.71, 0.838)
Model 3[e]	1.05 (0.65–1.71, 0.839)

[a]HR, hazard ratio; CI, confidence interval. Detailed variables in each model are described in Table S3

1st objective

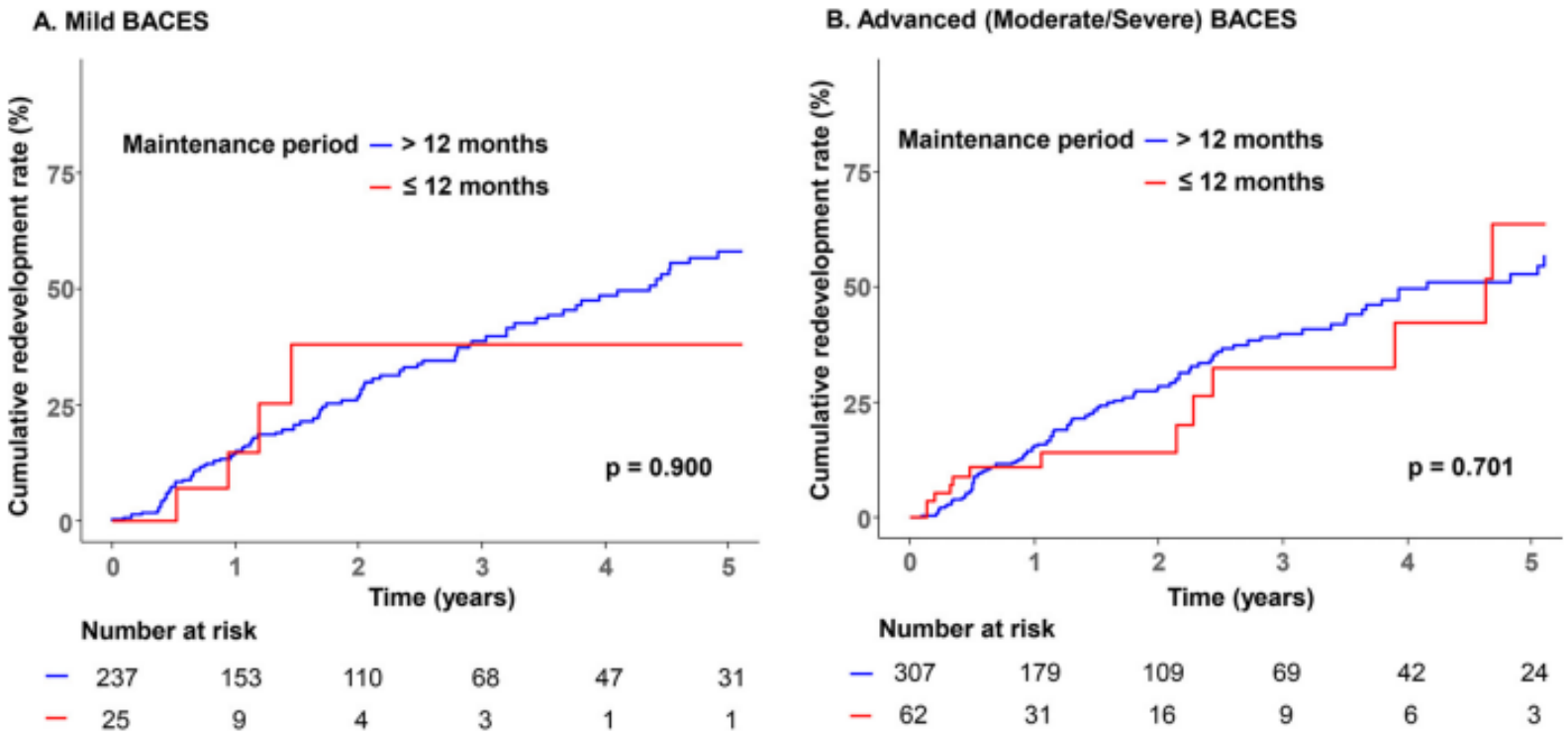


FIG 2 Cumulative rate of redevelopment of each BACES group, according to the maintenance period. (A) Mild BACES; (B) advanced (moderate/severe) BACES. BACES, body mass index, age, cavity, erythrocyte sedimentation rate, and sex.

Summary

1. Extending the antibiotic maintenance period more than 12 months was not associated with the reducing redevelopment rate despite adjustment for disease severity, suggesting the need to further optimize the duration of the antibiotic maintenance period.

[결핵 연구회] [저널] 2022년결핵 신고 연보, PRO in MAC-PD, Post-TB bronchiectasis

결핵연구회 회원 여러분들께,

안녕하세요? 3월 24일은 13회 결핵 예방의 날 이었습니다.

질병관리청에서 발표한 2022년 결핵환자 신고현황연보에 따르면 2022년 결핵 신고환자는 전체 환자 20383명 (39.8/100,000), 신환자 16264명 (31.7/100,000), 다제 내성/리팜핀내성 결핵 환자560명 (다제 내성 314, 리팜핀내성 177, 광범위 약제 내성전단계 66, 광범위약제내성 3) 이었습니다. 첨부한 2022년 결핵 신고 환자 연보를 참고하시기 바랍니다.
https://tbzero.kdca.go.kr/tbzero/board/boardList.do

Patient-Reported Symptom and Health-Related Quality-of-Life Validation and Responsiveness During the First 6 Months of Treatment for Mycobacterium avium Complex Pulmonary Disease , Chest 2023 Feb 17;S0012-3692(23)00260-X.
https://pubmed.ncbi.nlm.nih.gov/36803647
NTM 폐질환 치료에서, 증상호전이나 건강관련삶의 질(health related quality of life ,HRQoL) 과 같은 환자 중심치료 결과를 측정하는 것의 중요성이 대두되고 있으나, 아직까지 NTM 폐질환에서 validation 된 측정도구가 없습니다. 미국에서 진행되는 MAC2v3 RCT 에서는 MAC - PD 환자의 치료를 azithromycin-based regimen에서 two drug vs three drug 을 비교하고 있는데, 참여자들의 patient-reported outcome (PRO)를 QOL-B로 측정하여 이지표의 적절성을 validation 하였습니다. 치료전과 치료 6개월 후 비교 하였을 때, QOL-B의 호흡기 증상 점수와 physical functioning scale은 치료에 따른 호전을 잘 반영하고 good psychometric properties를 보여주었습니다.

Post-TB bronchiectasis: from pathogenesis to rehabilitation, Int J Tuberc Lung Dis .2023 Mar 1;27(3):175-181. https://pubmed.ncbi.nlm.nih.gov/36855043
결핵 치료 후에도 post-TB lung disease 가 후유증으로 남을 수 있으며 폐기능 저하와 삶의 질 저하를 가져옵니다. 기관지확장증은 post-TB sequalae 로 생길 수 있는 대표적인 질환이며 진료실에서도 많이 보게됩니다. Post-TB bronchiectasis 의 발생과 치료에 대한 짧은 리뷰가 실렸습니다.

감사합니다