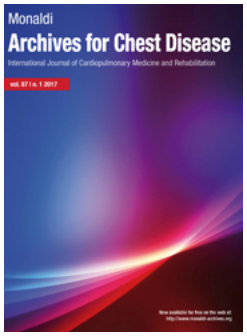

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Determinants of unsuccessful treatment outcome of pulmonary tuberculosis under the National Tuberculosis Elimination Program in Mohali district, India

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Abstract

Tuberculosis is a global healthcare concern, being the leading infectious cause of mortality by a single infectious agent. India bears the highest burden of tuberculosis. Disease outcome is an important indicator for the successful implementation of the National Program. Risk factors associated with unsuccessful outcomes must be identified, and differential care must be provided to those with risk factors. The study included all pulmonary tuberculosis patients registered from 1st October 2022 to 30th September 2023 at the Directly Observed Therapy Short Course Center, Dr. BR Ambedkar State Institute of Medical Sciences, Mohali, who received treatment. Data was collected from the Nikshay portal retrospectively. Out of 1103, 575 (52.13%) patients were declared cured, whereas 452 (40.97%) were declared treatment completed. A total of 19 (1.72%) pulmonary tuberculosis patients died during treatment, and 57 (5.16%) were declared failures. Advanced age [adjusted odds ratio (AOR) 4.028, 95% confidence interval (CI): 1.368-4.610, p=0.003], people living with HIV (AOR 0.185, 95% CI 0.031-1.082, p=0.05) and male gender (crude OR 1.611, 95% CI: 0.371-1.006, p=0.050) were associated with poor outcomes. Diabetes, retreatment, microbiological confirmation, and low body mass index were not statistically significant in the study. Age above 45 years, male sex, and HIV co-infection are determinants for unsuccessful treatment outcomes in patients with pulmonary tuberculosis.

Key words: tuberculosis, outcome, risk factors, successful, unsuccessful, determinants, pulmonary.

Introduction

Tuberculosis (TB) continues to be an overriding public health concern in low middle-income countries where India contributes to around 24% of the global incidence of TB surpassing Africa and China [1]. Despite stern efforts; we are still struggling to control this devastating disease. Early diagnosis and treatment are the key to stop the transmission. Apart from preventing the transmission, ensuring good cure rates with the available treatment is of paramount importance [2]. Efforts are being made across the globe to prevent transmission, detect early, confirm microbiologically and improve treatment compliance. Poor outcomes lead to more transmission and development of resistant strains by contributing to more morbidity and mortality [3]. The Objective of this study is to identify the determinants of poor outcome in Pulmonary Tuberculosis (PTB) patients which will further help in formulating patient centered approach, planning effective intervention and framing achievable goals for the future.

Global TB treatment success rate is around 86-90% [1], which is an important indicator of the successful implementation of the programme. Determinants of poor outcome must be identified and focused upon to improve the outcome and lead the way towards elimination. As per the available literature, most important factors associated with poor outcome include old age, HIV co-infection, male sex, retreatment, diabetes, smear negative PTB, and drug resistance [4-14]. However, old age, HIV, drug resistance and retreatment are associated with poor outcomes in unanimously most of the studies whereas gender and microbiological confirmation varies from place to place. Outcomes and risk factors are influenced by a variety of other determinants, including ethnicity, socioeconomic status, access to healthcare facilities, social disparities, education levels, poverty, population density, health education, and the effectiveness of program implementation — all of which can vary significantly by geographic region. Therefore, this study will identify risk factors for unsuccessful outcomes in patients of PTB in district Mohali, Punjab to further fill the evidence gaps for TB elimination.

Materials and Methods

Study design and setting

It was a single centre retrospective cohort study design. The study was conducted at Dr. BR Ambedkar state institute of medical sciences (AIMS), Mohali, Punjab, India. District Mohali is a

rapidly developing administrative and commercial hub situated near capital city, Chandigarh with an estimated population of 13.55 lacs by 2024 where prevalence of crude TB infection in Punjab is around 31.1% [15,16].Our centre serves as Treatment Unit for Mohali district under National Tuberculosis Elimination Program (NTEP). It covers 3 designated microscopic centres namely Kharar, Civil hospital Mohali and Employee's State Insurance, Mohali. It has Cartridge Based Nucleic Acid Amplification Test (CBNAAT) facility whereas Line Probe Assay (LPA), culture and drug sensitivity are being sent to Government Medical college, Patiala under NTEP. Free investigations and treatment are provided to all the patients diagnosed with TB. Standard guidelines by Ministry of health are followed for diagnosis and patient management [17]. Suspected PTB patients are tested for sputum CBNAAT or smear for microbiological confirmation. First line LPA is offered to all sputum positive patients whereas second line LPA is reserved for only resistant cases. Patients are categorized as either microbiologically confirmed PTB or clinico-radiological PTB. Adverse drug monitoring is done by active surveillance by Accredited Social Health Activist (ASHA). Drugs are provided to the patient at home by ASHA workers and follow up visits are planned at 2 and 6 months of the treatment. Outcome is defined by the treating clinician as per Ministry of health and family welfare guidelines. Cure and treatment completed outcomes are considered as successful outcomes whereas failure, lost to follow up and death are unsuccessful outcomes.

Study population

Registered data of all PTB patients at NTEP DOTS centre, Mohali during the period of one year from 1st October 2022 to 30th September 2023 was collected from Nikshay portal and data extraction sheet was prepared for the study population. Both microbiologically and clinico-radiological diagnosis were included. Patients with missing data on age, sex, site of TB, type of TB, bacteriological confirmation, diabetic status, HIV and outcome were excluded from the study.

Sample size and study period

The study included all PTB patients registered during 1st October 2022 to 30th September 2023 at Dots centre, AIMS, Mohali who received treatment (Figure 1).

Data collection, processing and analysis

Data was collected from Nikshay portal at DOTS Centre, Mohali. Nikshay portal serves as a surveillance tool for NTEP, functioning as a realtime case-based web-based patient management system operational since 2012. Data entries were manually reviewed for consistency and entries with missing data were excluded. The data was collected in two sections, with the first section containing information on socio-demographic characteristics of patients such as age, sex, residence and treatment sites and section two had information on clinical variables such as patient treatment category, site of TB, previous history of ATT, microbiological confirmation, human immune deficiency virus (HIV) test results, diabetic status and treatment outcome.

Frequencies, proportions and standard deviations were used to describe the data. Univariable and multivariable logistic regression analysis were performed to determine the risk factors for unsuccessful TB treatment outcomes. Crude(COR) and Adjusted(AOR) Odds ratio was calculated and p-value < 0.05 was considered statistically significant.

Operational definitions [17,18]

PTB -any microbiologically confirmed or clinically diagnosed case of TB involving lung parenchyma or trachea-bronchial tree.

Microbiologically confirmed TB case- a presumptive TB patient with biological specimen positive for AFB or MTB on culture, or through quality assured rapid diagnostic molecular test.

Clinically diagnosed TB case- a presumptive TB patient who is not microbiologically confirmed but has been diagnosed with active TB by a clinician on the basis of CXR, histopathology or clinical signs with a decision to treat the patient with full course of ATT.

New case- a TB patient who has never had treatment of TB or has taken ATT for less than 1 month.

Previously treated patient- who have received 1 month or more of anti TB drugs in the past.

Cure- a bacteriologically confirmed TB patient at the beginning of treatment who was smear or culture-negative at the end of the complete treatment.

Treatment complete-a TB patient who completed treatment without evidence of failure or clinical deterioration but with no record to show that sputum smear or culture results in the last month of treatment were negative, either because tests were not done or because results are unavailable.

Treatment Failure-a TB patient whose sputum smear or culture is positive at the end of the

treatment.

Lost to follow up- a TB patient whose treatment was interrupted for 1 consecutive month or more.

Not evaluated- a TB patient for whom no treatment outcome is assigned. This included former 'transfer out'.

Died-a TB patient who dies for any reason during the course of treatment.

Treatment success- TB patients either cured or treatment completed.

Ethical consideration

Ethical approval was taken from Institutional Ethics committee, AIMS, Mohali before starting the study (AIMS/IEC-HR/2024/63). The need for patients consent was waived off by the committee. All the data was kept confidential. All shared data was de-identified. Ethical considerations were followed in accordance to The Declaration of Helsinki.

Results

Socio-demographic factors

In a period of one year, total 1224 patients were registered at district, Mohali with the diagnosis of PTB whose outcome was available. Out of 1224, 62 were later confirmed as drug resistance cases, 23 were lost to follow up, 29 required treatment modification due to adverse drug reactions and in 7 treatment was initiated at some other centre. Total 1103 patients were enrolled for 1 year time period from fourth quarter of 2022 till third quarter of 2023. Males (637,57.7%) were more affected as compared to females(466,42.2%). Out of all, 604(54.7%) PTB patients were middle aged (18-44 years), 139(12.6%) below 18 years of age and 131(11.87%) were above 65 years of age (Table 1). Most of the patients were undernourished with a BMI of <18.5(512, 46.4%) and only 214(19.4%) had BMI above normal range. None of the patient was obese. Most of them were enrolled at public health facility (1014, 91.9%) as NTEP program is robust at public hospitals and needs strengthening in private set up.

Clinical characteristics

Majority of the patients were never exposed to anti TB treatment in the past (942, 85.4%) whereas 161(14.6%) had history of ATT in past for some form of TB. 1096(99.3%) patients were nonreactive

for HIV and only 7(0.6%) were reactive as the incidence of HIV is low in this area. Diabetes was diagnosed in 135(12.2%) and 952(86.3%) were non diabetic. Control of diabetes was not evaluated in this study. 891(80.77%) were microbiologically confirmed and 212(19.22%) were started ATT on clinic-radiological basis.

Treatment outcome

Out of 1103, 575(52.13%) patients were declared cured at the end of the treatment whereas 452(40.97%) were declared treatment completed. Later includes all clinic-radiological patients along with those who were not able to produce sputum at the end of the treatment. Both were considered successful treatment outcome. 19(1.72%) PTB patients died during the course of the treatment and 57(5.16%) were declared failure out of 1103 patients (Figure 1). Treatment success was 93% in this study. Since data was extracted from online portal, outcome was not updated for many patients and they were excluded from the study. Cure rate was 52.1% , Death rate was 1.72% and failure was seen in 5.2 %. Compliance was ensured in all the patients by family members and ASHA workers.

Determinants of outcome

Gender, age, BMI, HIV, diabetic status, retreatment and smear status were evaluated as determinants for treatment outcome. Advanced age was associated with poor outcomes (AOR 4.028, 95% CI: 1.368-4.610, p value 0.003). HIV reactive patients were associated with unsuccessful outcome as compared to HIV nonreactive (AOR 0.185, 95%CI 0.031-1.082, p value 0.05). Males had more unsuccessful outcomes as compared to females (AOR 1.251, 95% CI: 0.425-1.221). Pre-obese (AOR 0.569, CI 0.325-0.997, p value 0.0049) are at more risk as compared to normal or even underweight patients. However, Diabetes, retreatment and low BMI were not statistically significant in the study.

Discussion

Globally, an estimated 10.6 million people fell ill with TB in 2022 and there were 1.13 million deaths among HIV negative people attributable to TB. Eight countries contributed to two third of the TB incidence, India being at the top of the list followed by Indonesia, China, The Philippines,

Pakistan, Nigeria, Bangladesh and Congo. The global decline in TB incidence rate and death rate is 8.7% and 19% respectively between 2025 and 2022 which is far from End TB Strategy milestone of a 50% reduction in incidence rate and 75% in death by 2025. Five key risk factors attributable to TB in 2022 included undernourishment, HIV, alcohol use disorders, smoking and Diabetes in decreasing order.

Broad determinants associated with unsuccessful outcomes identified by WHO as per Global TB report 2023 included age>45 years, female sex, BMI >25 and HIV [1]. In our study, various covariates associated with treatment outcome included age, sex, HIV co-infection, Diabetes, retreatment for TB, sputum status and BMI.

Age is one of the most important determinants for successful treatment outcome. The evidence that elderly have poor outcome is supported by multiple studies [5,8-14]. It could be attributed to delayed diagnosis, varied presentation, decreased symptom perception, co morbidities and ADRs. In our study, age more than 45 years was associated with poor outcome as compared to younger patients (Table 2). Age group 45-64 years had 2.5 times more risk (95% CI: 2.140-7.581,p value <0.001) and above 65 years have even more 4 times more risk(95% CI:1.368-4.610, p value 0.003) of poor outcome (Table 3).

Males (AOR: 1.251, 95% CI: 0.425-1.221) had more chances of unsuccessful outcome in our study which is similar to various other studies [5,14,19].The probable reason for this finding could be due to the more exposure leading to more incidence. Recurrent TB is an important cause of morbidity and associated with poor outcome [11,14] whereas it was not statistically significant in this study likely due to lesser number of retreatment patients. Comparison of various recent studies is given in Table 4.

Malnutrition is a leading attributable risk factor for TB in India where government is providing free food baskets and financial incentives to ensure proper diet. 41 out of 471 (8 %) undernourished had unsuccessful outcome. (AOR 0.544, CI 0.236-1.250, p value 0.151) However, Pre obese have also been found as statistically significant risk factor for unsuccessful outcome (AOR 0.569, CI 0.325-0.997, p value 0.049).

HIV TB co-infection is an important cause of mortality in HIV patients (AOR 0.185, 95%CI 0.031-1.082, p value 0.05). One third of HIV AIDS related deaths are attributed to TB worldwide. The presentation of TB in PLHIV is varied depending upon the CD4 count. Incidence of

Extrapulmonary TB and multi drug resistant TB is high in PLHIV [20]. HIV is an independent risk factor for poor outcome in TB patients [5,12-15]. Default rates are higher due to drug interactions and high adverse drug reactions. Less than 200 CD4 count at diagnosis and retreatment are independent risk factors for poor outcome in HIV TB co-infection [21,22]. Early treatment initiation and screening for TB in all PLHIV are way forward for better prognosis.

Presence of Diabetes increases the risk of TB infection thrice as compared to normal individuals. It leads to delayed culture conversion, multi drug resistant TB and poor outcomes [10]. Diabetes impacts TB outcome by drug interactions, gastroparesis, presence of proinflammatory cytokines and metabolic syndrome. Control of diabetes is important for favourable outcome [23,24].

Diabetes as a risk for unsuccessful outcome is statistically not significant in our study. (AOR 0.799, CI 0.408-1.565, p value 0.51)

Strengths and limitations

Large sample size is a noteworthy strength of the study whereas retrospective nature of the study limits the information available for the analysis. The database did not contain information regarding few crucial factors like sputum grading, treatment delay, education, socioeconomic status, diet, number of times ATT taken, drug sensitivity, CXR severity and other co-morbidities which could influence the outcome. Data related to risk factors for unsuccessful outcome is very scarce in Punjab. This study is pertinent as outcome and risk factors differ geographically whereas national programme remains the same countrywide. It can help us improve national policies and provide differential care to patients with such risk factors. More frequent follow ups can be planned for them for strict monitoring and ensuring better compliance. In future, therapeutic drug monitoring can be done specifically in this set of population.

Conclusions

Age above 45 years, male sex and HIV co-infection are determinants for unsuccessful treatment outcome in patients with PTB. Active screening for associated risk factors must be done with priority concern. These patients should be followed up more frequently and differential care must be provided to them under NTEP. Therefore, to improve treatment outcome, risk factors focused intervention has to be implemented. Co morbidities associated with older age group and HIV must

be addressed.

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Abbreviations

NTEP- National Tuberculosis Elimination Program DOTS- Directly Observed Therapy Short course
PLHIV- People living with Human Immunodeficiency Virus ATT- Anti Tubercular Treatment
BMI- Body Mass Index CXR- Chest X Ray
PTB- Pulmonary Tuberculosis WHO- World Health Organization AFB- Acid Fast Bacilli
MTB- Mycobacterium Tuberculosis ASHA-Accredited Social Health Activist
CBNAAT- Cartridge Based Nucleic Acid Amplification Test LPA- Line Probe Assay
DOTS- Directly Observed Treatment Short Course AOR- Adjusted Odds Ratio
CI- Confidence Interval
CD4-Cluster of Differentiation 4

Table 1. Clinico-epidemiological profile of pulmonary TB patients in Mohali district and association between clinico-epidemiological factors and microbiological status (n-1103).

Variable	Clinico-radiological PTB (N-212) n(%)	Microbiologically confirmed PTB (N-891) n(%)	Total (N-1103) (n)	p
Gender				
Male	114 (17.9)	523 (82.1)	637	0.192
Female	98 (21.0)	368 (79.0)	466	
Age group				
<18 years	31 (22.3)	108 (77.7)	139	0.275
18-44 years	123 (20.4)	481 (79.6)	604	
45-64 years	35 (15.3)	194 (84.7)	229	
65 years	23 (17.6)	108 (82.4)	131	
BMI				
Undernourished(<18.5)	99 (19.3)	413 (80.7)	512	0.961
Normal (18.5-22.9)	70 (18.6)	306 (81.4)	376	
Overweight (23-24.9)	18 (19.1)	76 (80.9)	94	
Pre-obese (>25)	25 (20.8)	95 (79.2)	120	
HIV status				
Reactive	02 (28.6)	05 (71.4)	07	0.402
Nonreactive	210 (19.2)	886 (80.8)	1096	
Diabetes Status*(n-1087)				
Diabetic	22 (16.3)	113 (83.7)	135	0.220
Nondiabetic	186 (19.5)	766 (80.5)	952	
Category of patient				
New	190 (20.2)	752 (79.8)	942	0.031
Retreatment	22 (13.7)	139 (86.3)	161	

Table 2. Comparison among successful and unsuccessful TB treatment outcomes in pulmonary TB patients in Mohali district (n-1103).

Variable	Successful outcome (N-1027) n(%)	Unsuccessful outcome (N-76) n(%)	Total (N-1103) (n)	p
Gender				
Male	585 (91.8)	52 (8.2)	637	**0.05**
Female	442 (94.8)	24 (5.2)	466	
Age group				
<18 years	136 (97.8)	03 (2.2)	139	**<0.001**
18-44 years	576 (95.4)	28 (4.6)	604	
45-64 years	205 (89.5)	24 (10.5)	229	
65 years	110 (84.0)	21 (16.0)	131	
BMI				
Undernourished(<18.5)	471 (92.0)	41 (8.0)	512	0.568
Normal (18.5-22.9)	355 (94.2)	22 (5.8)	377	
Overweight (23-24.9)	89 (94.7)	05 (5.3)	94	
Pre-obese (>25)	112 (93.3)	08 (6.7)	120	
HIV status*				
Reactive	05 (71.4)	02 (28.6)	07	**0.023**
Nonreactive	1022 (93.2)	74 (6.8)	1022	
Diabetes Status(n-1087)**				
Diabetic	121 (89.6)	14 (10.4)	135	0.100
Nondiabetic	890 (93.5)	62 (6.5)	952	
Category of patient				
New	881 (93.5)	61 (6.5)	942	0.188
Retreatment	146 (90.7)	15 (9.3)	161	
Smear Status				
Smear Negative	201 (94.8)	11 (5.2)	212	0.276
Smear Positive	826 (92.7)	65 (7.3)	891	

*Fisher's exact test **a few values were missing.

Table 3. Association between socio-demographic predictors and clinical parameters with unsuccessful treatment outcome among drug sensitive Pulmonary tuberculosis patients in Mohali district.

Variable	Successful outcome n (%)	Unsuccessful outcome n (%)	COR, 95% CI	p	AOR, 95% CI	p
Gender						
Female	442 (94.8)	24 (5.2)	1	**0.050**	Reference	0.520
Male	585 (91.8)	52 (8.2)	1.611 (0.371-1.006)		1.251 (0.425-1.221)	
Age group*						
18-44 years	576 (95.4)	28 (4.6)	1		Reference	
45-64 years	205 (89.5)	24 (10.5)	2.408 (1.365-4.250)	**0.002**	2.512 (2.140-7.581)	**<0.001**
65 years	110 (84.0)	21 (16.0)	3.927 (2.152-7.166)	**<0.001**	4.028 (1.368-4.610)	**0.003**
<18 year	136 (97.8)	03 (2.2)	0.454 (0.136-1.515)	0.199	1.976 (0.134-1.533)	0.754
BMI**						
Normal (18.5-22.9)	355 (94.2)	22 (5.8)	1			
Undernourished (<18.5)	471(92.0)	41(8.0)	0.821 (0.374-1.799)	0.621	0.544 (0.236-1.250)	0.151
Overweight (23-24.9)	89 (94.7)	05 (5.3)	0.645 (0.248-1.678)	0.369	0.433 (0.161-1.160)	0.096
Pre-obese (>25)	112 (93.3)	08 (6.7)	0.712 (0.417-1.217)	0.214	0.569 (0.325-0.997)	**0.049**
HIV status						
Reactive	05 (71.4)	02 (28.6)	1	**0.043**	1	**0.05**
Nonreactive	1022 (93.2)	74 (6.8)	0.181 (0.035-0.949)		0.185 (0.031-1.082)	
Diabetes Status(n-1087)						
Diabetic	121 (89.6)	14 (10.4)	1	0.103	1	0.513
Nondiabetic	890 (93.5)	62 (6.5)	0.602 (0.327-1.108)		0.799 (0.408-1.565)	
Category of patient						
New	881 (93.5)	61 (6.5)	1		1	1.239
Retreatment	146 (90.7)	15 (9.3)	1.484 (0.821-2.681)	0.191	1.451 (0.781-2.693)	
Health Facility						
Private	84 (94.4)	05 (5.6)	1		1	0.459
Public	943 (93.0)	71 (7.0)	0.791 (0.311-2.012)	0.622	0.689 (0.257-1.847)	
Smear Status						
Smear Negative	201 (94.8)	11 (5.2)	1		1	0.520
Smear Positive	826 (92.7)	65 (7.3)	1.438 (0.745-2.775)	0.279	1.251 (0.632-2.478)	

*p value for age group is <0.001; **p value for BMI group is 0.678. Values in bold represents statistically significant value

Table 4. Comparison of few recent studies about the determinants of unsuccessful outcome in tuberculosis.

Study area (year of patient data)	N patients enrolled	Success rate (%)	Death rate (%)	Determinants of unsuccessful outcome
Ethopia, Africa [4] (2017-21)	362, all TB patients	88.4	2.5	Female, DRTB, HIV, poor nutrition
Karnatka, India [5] (2019)	4842, allTB patients	83.8	1	Male, old, co morbidity, new, smear positive
Ethopia, Africa [8] (2022)	400, all TB patients	89	5.7	HIV, sputum negative
Eriteria, Africa [9] (2014-2019)	1227, DSTB	90.4	6.2	Older, HIV, health facility
Brazil, South America [10] (2015-19)	915, DS PTB	79	3	HIV, Diabetes
Uzbekistan [11] (2005-20)	35122, TB patients on first line ATT	79	4	Older, HIV, PTB, disability, category 2
Zambia, Africa [12] (2020)	404, >15 year old TB patients	83.4	8.7	Older
China [13] (2005-13)	22998, New PTB	95	0.68	Older, CXR related
China [14] (2013-18)	306860, DSTB	98.6	0.5	Older, retreatment, male, severely ill
Current study, India (2023)	1103, DS PTB	93	1.72	Female, older, HIV

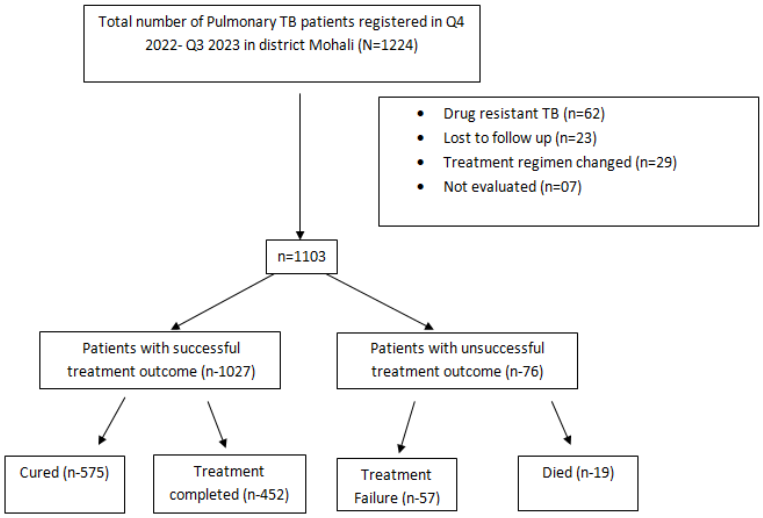

Figure 1. Flow diagram of case selection for analysis and their TB treatment outcomes in district Mohali, Q4 2022-Q3 2023 (n=1224).