

SOA07-1073-25



# Time to Sputum Culture Conversion, identifying independent modifiable risk factors

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# Background and Rationale

- Time to sputum culture conversion is widely used surrogate marker in early phase clinical trials
- Delayed sputum culture conversion may be associated with poor TB treatment outcome
- Time to sputum culture conversion, associated risk factors among drug sensitive pulmonary tuberculosis (PTB) have not been adequately documented
- Clinical, socio-demographic and phyco-social characteristics that may influence time to sputum culture conversion may be helpful
- Characterizing factors associated with delayed time to sputum culture may help targeting risk groups to optimize favourable TB treatment outcome.

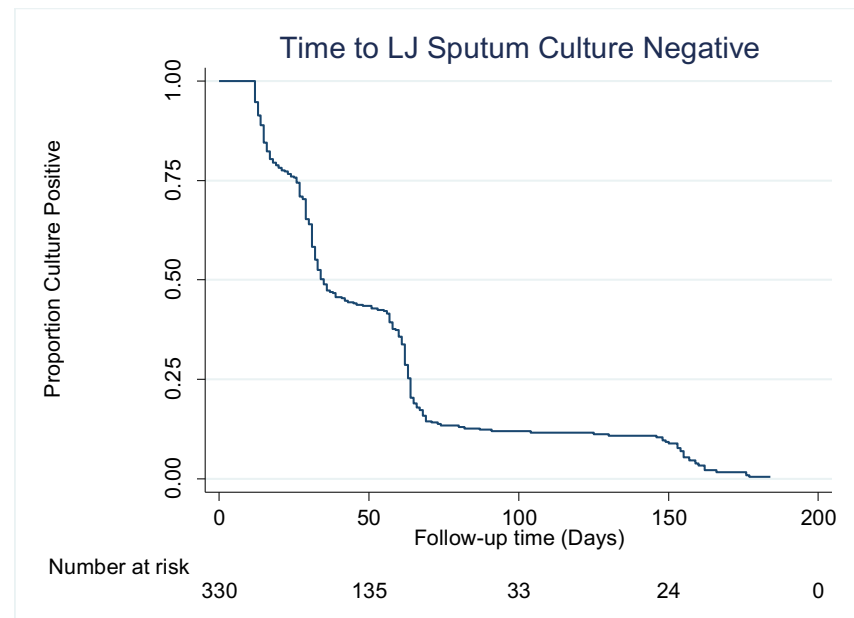
# Methods

- 330 Adults ( $\geq 18$  years), drug sensitive PTB patients from Pune and Chennai – CTRIUMPh Study sites
- Sputum culture on Lowenstein-Jensen medium was done at entry, and weeks: 2, 4, 8, 16, 24 and 72.
- Socio-demographic, behavioural and clinical data was collected at baseline and follow-up visits using structured case report forms
- Time (in days) to first negative sputum culture, from AKT start date, was calculated
- Kaplan-Meier product limit estimator was used to estimate the time to sputum culture conversion
- Cox Proportional hazards models were used to identify independent and overlapping risk factors

# Selected baseline characteristics & K-M Curve

Baseline Characteristics	N n = 330
<b>Age Group</b>	
< 25	71 (22%)
25 – 40	109 (33%)
40 – 50	80 (24%)
> 50	70 (21%)
<b>Gender</b>	
Male	222 (67%)
Female	108 (33%)
<b>BMI</b>	
Normal	109 (34%)
Underweight	198 (61%)
Overweight	18 (6%)
<b>Residence</b>	
Rural	176 (53%)
Urban	154 (47%)
<b>Smoking</b>	
Never	189 (62%)
Current	47 (15%)
Former	71 (23%)
<b>Smokeless tobacco</b>	
No	85 (26%)
Yes	238 (74%)

Baseline Characteristics	N n = 330
<b>AUDIT</b>	
< 8	209 (63%)
> 8	121 (37%)
<b>DM</b>	
No DM	108 (37%)
Pre DM	73 (25%)
DM	110 (38%)
<b>Smear Baseline</b>	
Negative	87 (27%)
Positive	240 (73%)
<b>Cavitation</b>	
No	144 (52%)
Yes	133 (48%)
<b>HIV</b>	
Uninfected	319 (97%)
Infected	11 (3%)
<b>TB Treatment</b>	
Daily	1 (0.3)
Thrice Weekly	328 (99.7%)



Time to culture conversion  
 Median (IQR): 35 (32 – 43)

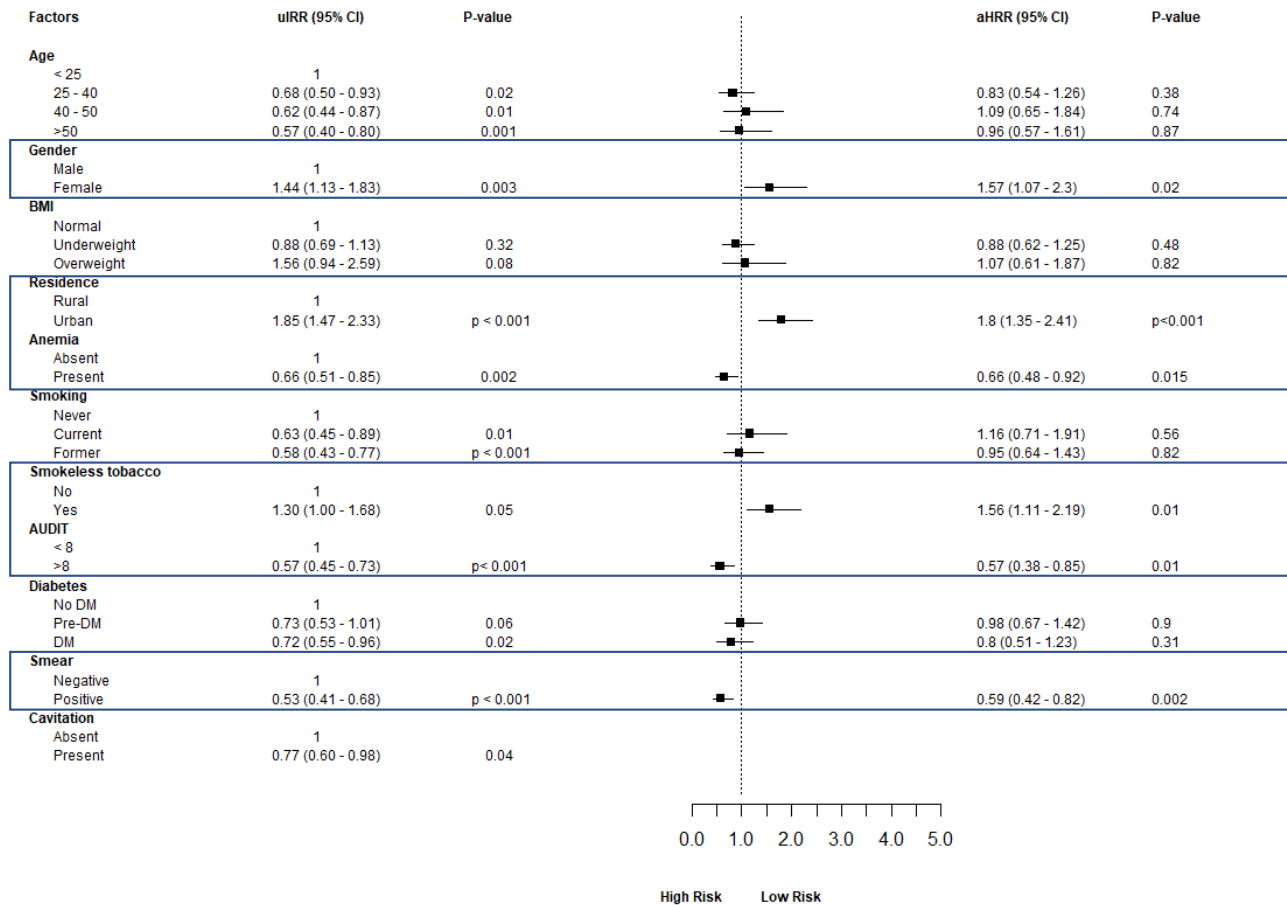
# Exploratory & Univariable Analysis

Baseline Characteristics	Median <sup>†</sup> (IQR)	log-rank p-value	uHR (95% CI)	p-value
<b>Age Group</b>				
< 25	29 (16 – 57)	0.004	Ref	
25 – 40	33 (24 – 63)		0.68 (0.50 – 0.93)	0.02
40 – 50	36 (29 – 65)		0.62 (0.44 – 0.87)	0.01
> 50	<b>58 (30 – 64)</b>		0.57 (0.40 – 0.80)	0.001
<b>Gender</b>				
Male	39 (29 – 64)	0.002	Ref	-
Female	31 (16 – 62)		1.44 (1.13 – 1.83)	0.003
<b>BMI</b>				
Normal	34 (21 – 64)	0.05	Ref	-
Underweight	37 (27 – 64)		0.88 (0.69 – 1.13)	0.32
Overweight	31 (17 – 60)		1.56 (0.94 – 2.59)	0.08
<b>Residence</b>				
Rural	<b>61 (32 – 65)</b>	< 0.001	Ref	-
Urban	27 (15 – 51)		1.85 (1.47 – 2.33)	< 0.001
<b>Anaemia</b>				
No	32 (21 – 60)	0.001	Ref	-
Yes	42 (27 – 64)		0.66 (0.51 – 0.85)	0.002

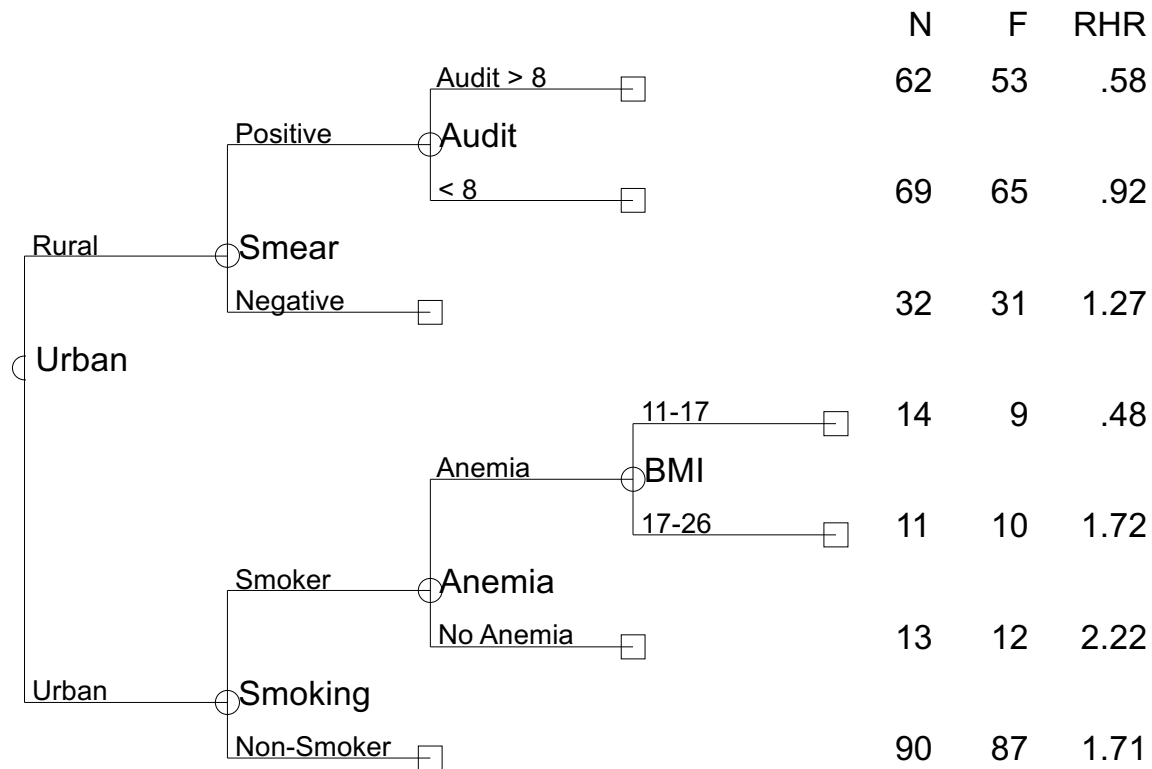
Baseline Characteristics	Median <sup>†</sup> (IQR)	log-rank p-value	uHR (95% CI)	p-value
<b>Smoking</b>				
Never	32 (16 – 62)	< 0.001	Ref	Ref
Current	<b>55 (31 – 64)</b>		0.63 (0.45 – 0.89)	0.01
Former	<b>62 (68 – 31)</b>		0.58 (0.43 – 0.77)	< 0.001
<b>Smokeless tobacco</b>				
No	31 (16 – 59)	0.04	Ref	-
Yes	46 (29 – 64)		1.30 (1.00 – 1.68)	0.05
<b>AUDIT</b>				
< 8	21 (17 – 62)	< 0.001	Ref	-
> 8	<b>58 (31 – 71)</b>		0.57 (0.45 – 0.73)	< 0.001
<b>DM</b>				
No DM	31 (17 – 58)	0.04	Ref	-
Pre DM	35 (16 – 64)		0.73 (0.53 – 1.01)	0.06
DM	39 (29 – 64)		0.72 (0.55 – 0.96)	0.02
<b>Smear Baseline</b>				
Negative	29 (16 – 39)	< 0.001	Ref	-
Positive	<b>55 (29 – 64)</b>		0.53 (0.41 – 0.68)	< 0.001
<b>Cavitation</b>				
No	32 (21 – 62)	0.03	Ref	-
Yes	51 (30 – 64)		0.77 (0.60 – 0.98)	0.04

**Findings: Older age, Males, Rural residence, Anaemia, Smoker, Alcohol dependence, Diabetes, AFB Positive & Cavitation were at an increased risk of delayed sputum culture conversion**

# Alcohol use disorder, anaemia & smear positivity are independently associated with high risk of delayed culture conversion



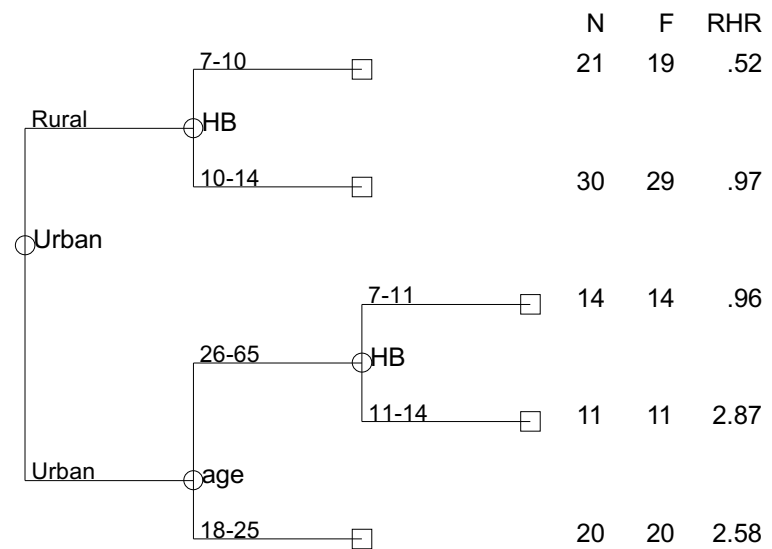
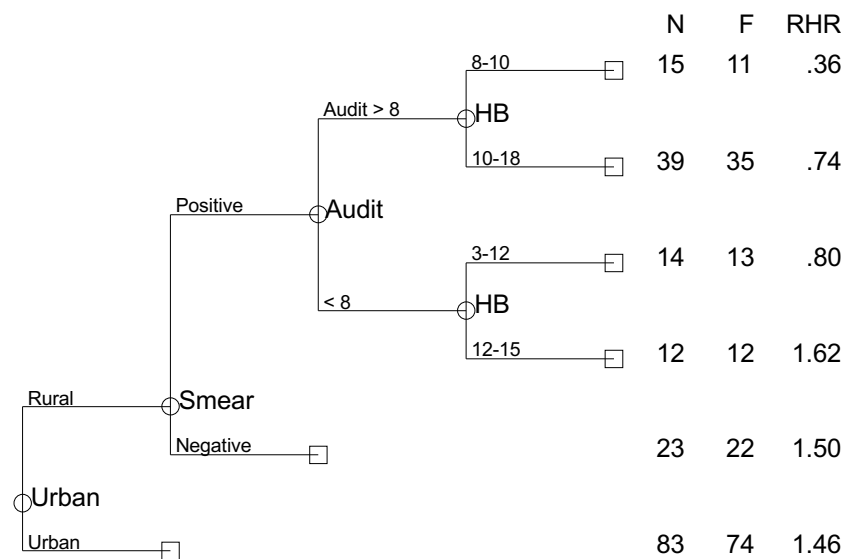
# Rural residence, smear positive and high AUDIT score are affected most!



# Differences in overlapping factors by gender

**Rural, alcoholic males at increased risk**

**Anaemia in rural females increases risk**

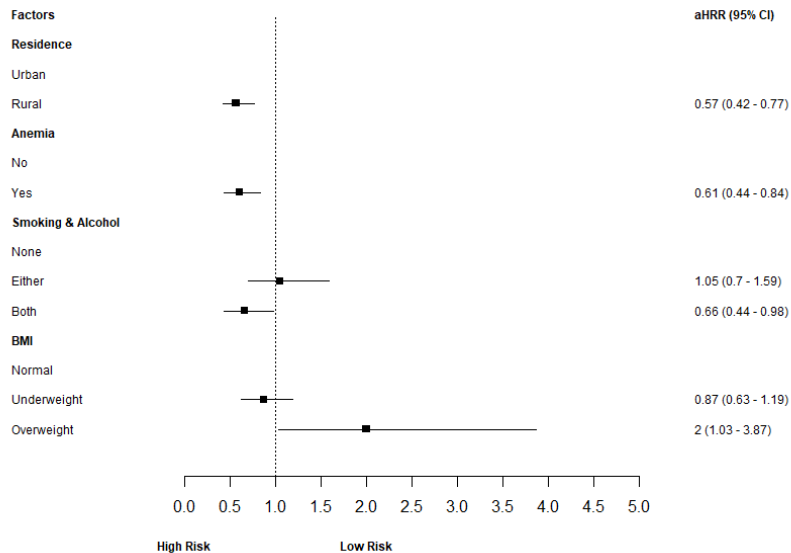




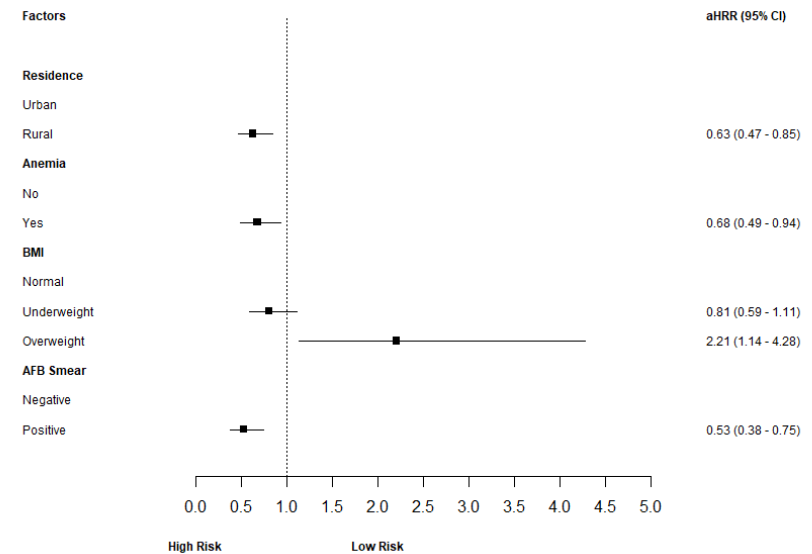
# Smoking & Alcohol dependence among males is independently associated with time to sputum culture conversion



## Males



## Females



# Conclusions

- Smoking and alcohol consumption increased the risk of longer time to sputum culture conversion by approximately 40%
- Male gender, alcohol and smoking, young age and rural residence were associated with longer time to culture conversion, thus are transmitting longer, more likely to have unfavourable outcomes
- Anaemia among AFB smear positive women in rural areas may be associated with longer time to culture conversion

# Thank You

- **CTRIUMPh**  
**Study teams**
- **Study**  
**participant &**  
**their families**

