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Evaluation of two novel decontamination methods for the recovery of Mycobacterium tuberculosis from clinically suspected pulmonary tuberculosis cases

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Background: Culture remains the most sensitive technique for the isolation of *Mycoabacterium tuberculosis* (MTB) from clinical specimens. Further, an effective decontamination method is required to accomplish an increased isolation rate of MTB (in culture) from clinical samples. Most of the mycobactaeriology laboratories use N-Acetyl L Cystiene (NALC) – sodium hydroxide (NaOH) decontamination method for the isolation of MTB from clinical specimens. However, the NaOH used in this method may be toxic to MTB. Further, the NALC solution is unstable (to be utilized within 24 hours after preparation) and also require additional training to perform, which limits its extensive use. Considering this, **t**he current study was designed to evaluate the performance of papain-cetylpyridinium chloride (papain-CPC), pepsin-cetylpyridinium chloride (pepsin-CPC) methods with NALC - NaOH decontamination method (the reference method) for the recovery of MTB from clinically suspected pulmonary tuberculosis cases using sputum specimens.

Material/methods: To evaluate the papain-CPC**,** pepsin-CPC and NALC-NaOH decontamination methods, sputum specimens (n = 864) were studied (after culturing on Löwenstein-Jensen medium) and the performances were compared.

Results: Of the 864 sputum specimens processed, a total of 94.44% (N=816) interpretable results were obtained in all the decontamination methods investigated. Out of the 816 interpretable results obtained in all the methods studied, 99.4% of the papain-CPC method (N=812) and 99.1 % of the pepsin-CPC method (N=810) were interpretable with NALC-NaOH decontamination method(N=816). The mean detection time of MTB after decontamination with papain-CPC**,** pepsin-CPC methods were 36.3 (SD 8.19) and 37.8 days (SD 6.9), respectively when compared to NALC-NaOH decontamination method (mean detection time 41.33 (SD 6.63) days) .Further, the papain-CPC decontamination method demonstrated a sensitivity, specificity, positive predictive value, and negative predictive value of 100%, 96.59%, 40%, and 100%, respectively, for the recovery of MTB when compared to NALC-NaOH method. Likewise, pepsin-CPC decontamination method

demonstrated the sensitivity, specificity, positive predictive value and negative predictive value of 100%, 97.72%, 50%, and 100%, respectively.

Conclusions: In summary, papain -CPC method effectively detected significantly higher number of MTB cases (N=45) than pepsin-CPC (N=36) and NALC-NaOH decontamination method (N= 18), indicating the potential of papain -CPC method to isolate MTB directly from sputum specimens than pepsin-CPC and NALC-NaOH decontamination methods.

Table1. Culture results obtained after decontamination with papain-CPC, pepsin-CPC and NALC-NaOH decontamination method

	Methods		
Results	Papain-CPC (N=864) %	Pepsin-CPC (N=864) %	NALC-NaOH (N=864) %
Interpretable results			
Growth of MTB	45 (5.21)	36 (4.17)	18(2.08)
No Growth	767(88.77)	774 (89.58)	798(92.36)
Subtotal	812(93.98)	810(93.75)	816(94.44)
Un- Interpretable results			
Contaminated Cultures	35(4)	35(4.05)	34(3.94)
Non Tuberculous Mycobacteria	17(1.97)	19(2.2)	14(1.62)
Subtotal	52(6.01)	54(6.25)	48(5.56)