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Acoustic Epidemiology of Pulmonary Tuberculosis (TB) & Covid19 Leveraging explainable AI/ML

Rahul Pathri[1*], Shekhar Jha[1], Samarth Tandon[1] and Suryakanth Gangi Shetty[1]

[1]Docturnal Private Limited, India

Abstract

Involuntary cough is a prominent symptom for many a Lung Ailments ranging from Infectious to non-Infectious diseases. Early research around human cough established that the spectral signatures do not vary between Involuntary and Voluntary coughs. The study aimed at evaluating voluntary human cough sounds recorded under a stringent clinical protocol. India's ambitious goal to eliminate and eradicate TB by 2025 shall be facilitated by Machine Learning tools that address subjectivity in that the healthcare worker can now take the solution as a screening modality to the last mile as a part of outreach programs without having to rely on infrastructure & connectivity. In this paper we present the findings of Clinical Trials for Pulmonary TB registered at CTRI/2019/02/017672 conducted independently and included Covid19 during the pandemic as a part of Bi-Directional screening modality. The reference standards used were CBNAAT (Cartridge based nucleic acid amplification test) & CXR (Chest X-Ray) for TB while for Covid19; RT-PCR was used as the reference standard. As a non-invasive and contactless screening modality, a sophisticated third-party Microphone Array was used to record the cough under a stringent infection control protocol. Sensitivity achieved across the sites for TB ranged between 80% - 83% and Specificity was to the tune of 92% while using CBNAAT as a reference standard. CXR when used as a reference standard for TB achieved a sensitivity and specificity of 59% and 60% respectively. Covid19 achieved a sensitivity & specificity of 92% and 96% while using RT-PCR as the reference standard. The study was primarily focused on the Frequency domain that paved way for feature extraction and explainable Machine Learning Models operating upon lossless WAV files hypothesizing acoustic theory and demographic inputs. The solution titled "TimBre" can now be added to the healthcare workers arsenal in situations where a RT-PCR or CXR is not available and seamlessly conduct bidirectional screening with a single recording of cough and also offer insights into Non-Communicable diseases as a part of differential diagnosis.

***Corresponding author**

Rahul Pathri, Docturnal Private Limited, India. Email: rahul@docturnal.com

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Introduction

One of the famous quotes by Albert Einstein around music was – "It occurred to me by intuition, and music was the driving force behind that intuition. My discovery was the result of that musical perception" – [1]. Human Lungs infected with TB or Covid19/ Pneumonia introduces a certain Lung parenchymal changes that occasionally overlaps or mimics other Lung conditions. In case of TB, these are Cavities at different stages & in case of Pneumonia, alveoli getting filled with puss and other liquids forming liquefaction followed by air/fluid filled cavities [2]. These changes may be hypothesized with an Acoustic Guitar and other accessories that are discussed in this paper. Pulmonary Tuberculosis share of the global TB burden is to the tune of 70% with remaining cases being extra pulmonary & the numbers are increasing due to the obscuring of TB care as a result of the Pandemic caused by Covid19. In this paper we present findings of a non-invasive, point of care & real time results driven solution that addresses screening of both TB and Covid19 affecting the Lungs as a potential to be a bidirectional screening modality.

Materials and Methods

Informed consent was obtained via a traditional method to obtain signatures on paper available in English, Kannada and Bengali languages for Site2 that was conducted at NH, Bangalore while subsequent sites leveraged the digital screen on the TimBre app that is available as a private APK as of today. The app is not available on Google Play store given the fact that without a Microphone Array, the results could get compromised and cause unnecessary anxiety among users. Across the sites a very stringent hygiene protocol was mandated wherein the healthcare worker was equipped with n-95 masks, gloves while the subject coughing had to wear a surgical mask provided by the PI. The 3rd party microphone array filters were replaced after each cough and incinerated. The Microphone Array used was zoom H1 and H1n models and a representative image with the filter and is depicted in the following image:

With a replaceable filter to control infection spread & a tripod for community screening

The array was connected to the Mobile phone USB port via an OTG cable & subjects were advised to take a deep breath before coughing onto the array with a filter for approximately

10 seconds while the distance between the mouth and the device was approximately at an arm's length divided by 2. The deep breath ensured no superficial coughs were recorded. The TimBre app would also obtain demographic information pertaining to height and weight that would get recorded by a status meter and a digital weighing scale respectively for subsequent arrival of the BMI given the fact that known TB cases in the Machine Learning Model had a BMI lower that 18 for most part unless they were recovering. To maintain consistency with the Machine Learning Model data, clinical trial sites recorded cough sounds at 44.1 kHz for both TB and Covid19. The feature extraction resulted in data for both Left and Right channels facilitated by the XY design of the microphone array. While the array had built in ability to eliminate undesirable noise via a low cut filter & other settings, we also applied background noise reduction techniques that would eliminate any conversations between the healthcare worker and the subject. The TimBre app would facilitate data transfer of the WAV file and demographics to the cloud (Azure, IBM, GCP, and AWS) for further processing that included the following order:

1. Feature Extraction: Extracting features from both the channels for various frequency bands ranging from 0-200 Hz till 5000 Hz with an interval of 500 Hz for each band starting from 500 Hz. The features extracted for both the XY channels were – Sum, Standard Deviation, Variance, Coefficient of Variance, Top10 Amplitude, Spectral Centroid, Spectral Flatness, Spectral Skewness, Kurtosis, MFCC and Energy.
2. Compute the BMI and append height, weight & BMI to the feature extracted spectral record
3. Score against a RUS (random under sampling) Boosted Model given imbalanced class sets for TB and Covid19. Most importantly the advantages of Ensemble Models as seen from the higher AUC (Area under curve) & Sensitivity/ Specificity depicted by the by the ROC curve (receiver operating characteristic)
4. Shared the results with an SLA of 48 hours on a secured portal that would also generate a unique patient id
5. Results were classified as 0-Negative, 1-Positive and 2-Rejected due to lack of fidelity in the sound file

Spectrograms were not considered due to the fact that the MFCC (mel frequency cepestral coefficients) components were already included as a part of feature extraction & the sheer volume of data required for Deep Learning models was not available with an added risk of misrepresentation of data when augmented using tools & techniques such as VTLP – vocal tract length perturbation or MATLAB augmentation techniques. Most importantly, lack of explainability & interpretability with deep learning models

Starting from 2018 several pilot studies were conducted at schools, PLHIV, colleges, factories, courts, home for the aged and these were primarily for data harvesting for AI/ML models. The below table depicts the actual pre-clinical & clinical trial related studies:

Table 1: Clinical Trials and Pre-Clinical Validation

Sl.no	Site	Year	Ailment	Type	Reference	Count	Device	Ethics Approval
1	Chest Hospital, Erragadda, TS	2018	Pulmonary TB	Pre-Clinical	RNTCP protocol	30	Mobile	Waiver from Osmania Hospital 30/03/20190
2	NH/MSMF, Bangalore, KA	2019	Pulmonary TB	Clinical Trial	CXR, GeneXpert, Smear	474	Array (zoom H1)	IRB, NH hospital Bangalore - TimBre-01/Version 1.0 dated Nov 29, 2018
3	Gadwal district, TS	2020	Pulmonary TB	Clinical Trial	CXR	127	Array (zoom H1)	Waiver from Osmania Hospital – 30/03/2019
4	Warangal district, TS	2020	Pulmonary TB	Clinical Trial	CBNAAT	39	Array (zoom H1)	Waiver from Osmania Hospital- 30/03/2019
5	SR district, TS	2021	Pulmonary TB	Clinical Trial	CXR & TruNat	545	Array (zoom H1n)	Waiver from Osmania Hospital – 30/03/2019
6	Neelima Renovo, Hyderabad, TS	2021	Covid19	Pre-Clinical	RT-PCR	250	Array (zoom H1n)	IEC Neelima Renovo Hospital - IECNH/EC Approval_03/21/002/C0Vawe01

Zoom H1n has certain built-in features to source power from the Mobile phone, auto level, limiter that were leveraged. The streaming feature introduced in the latest model however gave inferior results & hence we continued to use WAV files recorded and stored on the SDCard as opposed to direct streaming of WAV files onto the cloud. Since the existing Machine Learning models harvested WAV files at a 44.1kHz / 16 bit, we continued with the SDCard approach which is considered as a gold standard.

Clinical Trial Results & Statistics

Sl.no 1 Table1

Preclinical validation was conducted on known data sets & golden truth was obtained from the case sheets of the Government Chest Hospital. At the time of running the Algorithms for prediction, the results were blinded. Study was broken into 5 cohorts & the results of SCORED data are below wherein the numerator represents the results of the Algorithm and the denominator represents the cohort count.

1. Healthy Patients (10/10)
2. MDR-TB (4/5)
3. Old PTB (3/5)
4. EPTB (Pleural Effusion) (2/3)
5. PTB (5/5)

As seen from the below screenshot-1 below, one MDR was misdiagnosed and one Pleural Effusion was diagnosed as false positive (needs clinical evaluation) since the patient may still be sputum positive. All healthy cases are diagnosed as negative & all known PTB are diagnosed as positive. The old TB patient's diagnosis was unavailable and hence we labelled positive for anyone with a BMI lower than 17.5.

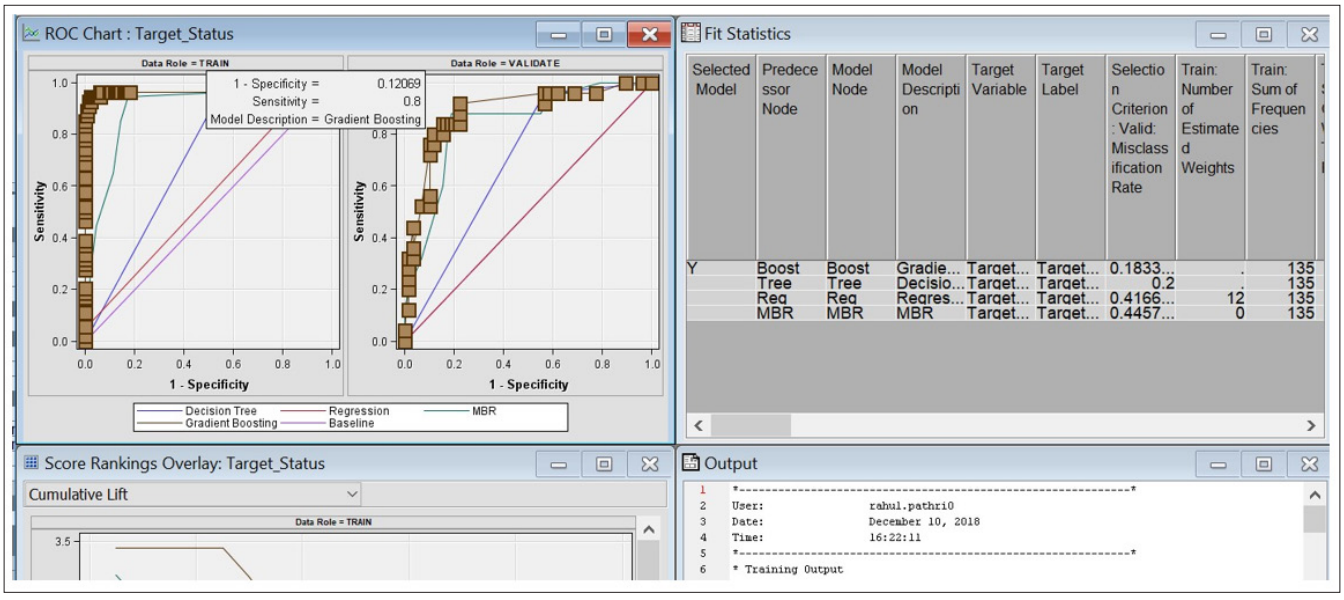
ScreenShot-1

EMWS1.Score_SCORE

	Target_Status	Prediction for Target_Status	Probability of Classification	Name	Gender	Age	Height	Weight	Occupation	BMI	Smoking	Alcohol	Patient_ID	_Marital_Status	VAR12	Current_Medications___existing_E
1	0.0	0	0.9599623230370606	Ren	Female	21.0	5.1	50.0	Others	21.35930625	No	No	2659.0	Married		Healdhi
2	0.0	0	0.9181968397578564		Female	18.0	4.3	35.0	Others	21.03238988	No	No	2660.0	Single		Healdhi
3	0.0	0	0.9179881607040028		Male	29.0	5.8	75.0	Others	24.77209671	No	No	2661.0	Married		Healdhi
4	0.0	0	0.9411534766880889		Female	24.0	5.1	52.0	Others	22.2136785	No	No	2662.0	Married		Healdhi
5	0.0	0	0.9397430855941196		Female	39.0	5.5	55.0	Others	20.2020202	No	No	2663.0	Married		Healdhi
6	0.0	0	0.9581194813721715		Female	35.0	5.5	52.0	Others	19.10009183	No	No	2669.0	Married		Healdhi
7	0.0	0	0.9188788429991087		Female	14.0	4.1	25.0	Others	16.52455549	No	No	2670.0	Single		Healdhi
8	0.0	0	0.9203773218242146		Female	35.0	5.6	70.0	Others	24.8015873	No	No	2672.0	Married		Healdhi
9	0.0	0	0.9184515130096335		Female	28.0	5.3	56.0	Others	22.15102251	No	No	2673.0	Married		Healdhi
10	0.0	0	0.8709198728772323		Male	19.0	5.5	40.0	Others	14.69237833	No	No	2674.0	Single		Healdhi
11	1.0	0	0.7092997533835905		Female	23.0	5.3	45.0	Others	17.7999288	No	No	2457.0	Married		MDR TB
12	1.0	1	0.6341993536867991		Female	52.0	5.2	45.0	Others	18.49112426	No	No	2458.0	Married		MDR TB
13	1.0	1	0.5272702077492546		Male	44.0	4.9	40.0	Others	18.51080568	Yes	Yes	2526.0	Married		MDR TB
14	1.0	1	0.5933616848628155		Male	30.0	4.9	40.0	Others	18.51080568	No	Yes	2527.0	Married		MDR TB
15	1.0	1	0.6649767306988277		Male	60.0	5.9	55.0	Others	17.55561939	No	Yes	2529.0	Married		MDR TB
16	1.0	1	0.5959321529140014		Male	63.0	6.1	58.0	Others	17.31911971	Yes	Yes	2392.0	Married		Old PTB
17	0.0	0	0.5961719253907194		Female	58.0	4.7	40.0	Others	20.11971229	No	Yes	2401.0	Married	Asthma	Old PTB
18	1.0	1	0.8314436806366275		Male	54.0	5.3	30.0	Others	11.8666192	Yes	Yes	2402.0	Married		Old pTB
19	0.0	1	0.7533938043996554		Female	21.0	4.3	35.0	Others	21.03238988	No	No	2406.0	Single	Asthma	Old PTB
20	1.0	0	0.508858702290856		Male	47.0	5.3	40.0	Others	15.82215893	Yes	Yes	2422.0	Married		Old PTB
21	0.0	1	0.5233204812957208		Female	15.0	4.5	30.0	Others	16.46090535	No	No	2412.0	Single		Pleural Effusion
22	0.0	0	0.9243405424518734		Female	18.0	5.2	58.0	Others	23.8330046	No	No	2602.0	Single		Pleural Effusion
23	0.0	0	0.932038215002863		Female	60.0	4.9	41.0	Others	18.97357582	No	No	2618.0	Married		Pleural effusion
24	1.0	1	0.8434205978083726		Male	60.0	5.2	35.0	Others	14.38198554	Yes	Yes	2393.0	Married		PTB
25	1.0	1	0.5051113005925147		Male	70.0	5.5	50.0	Others	18.36547291	Yes	Yes	2397.0	Married		PTB
26	1.0	1	0.8892530363664709		Male	44.0	5.5	40.0	Others	14.69237833	Yes	Yes	2405.0	Married		PTB
27	1.0	1	0.6347573196625972		Male	47.0	5.5	40.0	Others	14.69237833	Yes	Yes	2413.0	Married		PTB
28	1.0	1	0.7988762135245389		Male	40.0	5.5	48.0	Others	17.63085399	Yes	Yes	2424.0	Married		PTB

Data Collection & Machine Learning

Screenshot -2



- Data was collected using a Xaomi Redmi 6a smart phone for all the patients across three different devices by our field staff after obtaining patient consent
- Instrument was cleaned after each cough and made the patient wear a surgical mask while coughing into the phone
- The device was equipped with a single channel built-in microphone
- Data was partitioned into 70% Training and 30% Validation for a record set of 250 Patient
- Sensitivity was reported as 80% and specificity as 88% as seen from the ROC curve – screenshot-2
- Gradient Boosting was the Algorithm chosen with the lowest misclassification rate – Screenshot-2

Sl.no 2 Table1

The study was conducted at NH/MSMF hospital, Bangalore and the cohort included nonsuspicious cases that were asymptomatic. Data was collected by the hospital staff and all of the activity was double blinded. Results were shared with the PI within 48 hours

Clinical Trial Statistics

Results

Group 2 Table-1 Baseline characteristics

Variables	Descriptive statistics (N= 430)
Gender Male	255 (59.3%)
Age	36.0 [50.2, 28.0]
Height (feet)	5.5 [5.7, 5.3]
Weight (kg)	64.92 ± 12.8
BMI	24.0 [27.0, 21.0]
Marital Status Married Null Single	 304 (70.7%) 13 (3.0%) 113 (26.3%)
Smoker	37 (8.6%)
Consumes Alcohol	47 (10.9%)
Appetite Pattern Low Medium High	 165 (38.4%) 255 (59.3%) 10 (2.3%)

A total of 474 patients were recruited as of Feb 8, 2020. Among them 39 patients were diagnosed as positive by TimBre software. The details of their follow up are mentioned as follows:

Table 2: Timbre results for 474 patients

	Number (Percentage)
Number of cases detected positive by TimBre	39
Number of cases confirmed positive	4 (2 on treatment, one old case and one diagnosed subsequently)
Number of cases confirmed negative	10
Number of cases lost to follow up	13
Number of participants who were symptom free on telephonic follow up	12

Number of cases missed diagnosis of TB by TimBre 1

For a total of 474 participants screened 39 were detected as positive by TimBre software.

Among the 39 participants 4 were positive. Two were on ATT at the time of testing for TimBre software. One was an old case with no active bacilli in sputum. One patient was later found to be positive on further evaluation.

Ten participants had clinical evaluation and were confirmed as negative for TB by either clinical examination or sputum testing. Thirteen patients could not be reached further for telephonic follow up or hospital visit. Remaining 12 patients were followed telephonically for symptoms suggestive of TB like chronic cough, fever and weight loss. None of these 12 patients were symptomatically positive for tuberculosis.

One patient who was positive by GenXpert was missed by the software.

Table 3: Sensitivity, specificity of TimBre

	Clinical diagnosis positive	Clinical diagnosis negative	Total
TimBre diagnosis positive	4	35	39
TimBre diagnosis negative	1	434	435

Statistic	Value	95% CI
Sensitivity	80.00%	28.36% to 99.49%
Specificity	92.54%	89.77% to 94.75%
Positive Likelihood Ratio	10.72	6.24 to 18.43
Negative Likelihood Ratio	0.22	0.04 to 1.25
Disease prevalence (*)	1.05%	0.34% to 2.44%
Positive Predictive Value (*)	10.26%	6.23% to 16.42%
Negative Predictive Value (*)	99.77%	98.69% to 99.96%

Sl.no 3 & 4 Table1:
Clinical Trial Statistics:
Site-1 Warangal district
Table-1 Baseline demographic characteristics

Variable name	Value (N= 25)
Age	51.12 ± 15.38
Male	17 (65.4%)
Height	5.54 ± 0.39
Weight	47.06 ± 11.22
BMI	16.83 ± 4.21

Table 2: Comparison of Timbre results with CBNAAT

	Disease	No disease
Timbre positive	5	10
Timbre negative	1	10

Table 3: Diagnostic accuracy of TimBre

Total number	26
Sensitivity	0.83 (0.43 to 0.97)
Specificity	0.50 (0.29 to 0.70)
PPV	0.33 (0.15 to 0.58)
NPV	0.90 (0.62 to 0.98)
Prevalence	0.23

Note: This site was disrupted by Covid19 during the month of Jan/2020 & hence the specificity is low due to a lower denominator. Sensitivity was however at 83%.

Site-2 Gadwal district

Table 4: Baseline demographic characteristics

Variable name	Value (N= 125)
Age	51.41 ± 15.64
Male	83 (66.93%)
Height	5.20 ± 0.34
Weight	45.78 ± 10.81
BMI	18.70 ± 4.15
Smoking	21 (16.93%)
Appetite Low Medium	 89 (71.77%) 35 (28.22%)
Alcohol	23 (18.54%)

Table 5: Comparison of TimBre results with chest X-ray

	Disease	No disease	
Timbre positive	43	21	64
Timbre negative	30	31	61
	73	52	

Table 6: Diagnostic accuracy of TimBre

Total number	125	
Sensitivity	58.90%	(46.77% to 70.29%)
Specificity	59.62%	(45.10% to 72.99%)
PPV	67.19%	(58.29% to 75.00%)
NPV	50.82%	(42.03% to 59.56%)
Prevalence	58.40%	(49.25% to 67.15%)

Sl.no 5 Table1

This site was the first site to adopt bidirectional screening & used the reference standard CXR and TruNat. Only 77 out of 545 results were available and remaining were lost to follow up. The concordance with CXR was found to be 100% and 25% with TruNat. A glitch found on the field during the trial was related to streaming of the WAV files and also using C-Type USB convertor connecting the array to latest Oppo phone models cascaded the glitch & delayed reporting. A total of 57 presumptive positive Covid19 were reported that were not subjected to the reference standard RTPCR confirmatory test due to constraints caused by the Pandemic and also focus being on the Active Case Finding (ACF) for TB cases. The Machine Learning models AUC was at 92% with a sensitivity and specificity of 81% and 92% respectively for the RUS Boosted Models built separately for both TB and Covid19. We leveraged existing Pneumonia data for Covid19 models. Across the sites (Sl.No- 2,3,4,5 & 6 of Table-1), a 10-Fold cross validation was used to avoid over-fitting that implied the number of partitions facilitating each record to have an equal chance of being both in the Training and Validation sets as a part of the Ensemble Model

Date	District	Total Screened	Results Available	Reference Standard	Concordance	Sensitivity	Specificity	Type
Sept-Oct/2021	SangaReddy (ACF)	545	20	CXR	100%	Not Applicable	Not Applicable	Bi-Directional
Sept-Oct/2021	SangaReddy (ACF)	545	57	TruNat	25%	Not Applicable	Not Applicable	Bi-Directional

Sl.no 6 Table1

The Covid19 preclinical validation used RT-PCR as a reference standard and the golden truth was known during data harvesting and the results were blinded to the Algorithm during prediction and achieved at sensitivity & specificity of 92% and 96% respectively for a total screened patient count of 250 that included both Mobile Screening using Nokia 2.4 and the Microphone Array. The PPV and NPV were at 97% and 88% respectively

Discussion & Conclusion

Screenshot-3

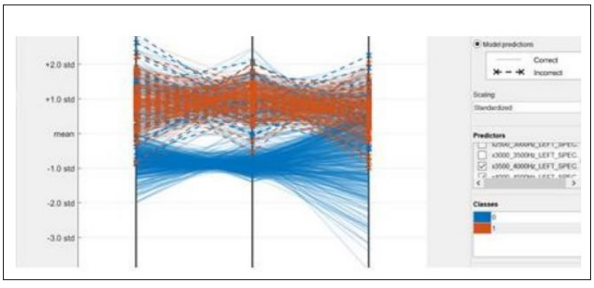


Table 3

Date	District	Total Screened	Results Available	Reference Standard	Concordance	Sensitivity	Specificity	Type
April/2019	NH/MSMF	474	474	Smear,Xpert, CXR	NA	80%	92%	Pulmonary TB
Jan/2020	Gadwal	200	126	CXR	56%	59%	60%	Pulmonary TB
Jan/2020	Warangal	51	39	CBNAAT	68%	83%	55%(disrupted)	Pulmonary TB
Sept-Oct/2021	SangaReddy (ACF)	545	20	CXR	100%	Not Applicable	Not Applicable	Bi-Directional
Sept-Oct/2021	SangaReddy (ACF)	545	57	TruNat	25%	Not Applicable	Not Applicable	Bi-Directional
May/2021	Neelima Renovo	250	250	RT-PCR	90%	92%	96%	Covid19

As seen from table-3, most sites reported at sensitivity between 80% - 92% when validated with CBNAAT or RT-PCR while specificity reported between 92% - 96%. While CXR is not a gold standard, the fact that there was a concordance of 56% at one site and 100% at another site makes TimBre a candidate for a screening tool at the last mile as a part of outreach programs with minimal training required by the healthcare worker.

A parallel coordinate graph plotted by Matlab Classification Learner – R2018b at screenshot-3 above depicts the solution has the ability to clearly differentiate healthy and pathological subjects while providing explainability around the Machine Learning Models for Pulmonary TB in that the pathological cases have a higher value for Spectral Centroid at frequency bands of 4000-5000 Hz. There are other variables that depict a clear demarcation such as Variance and Energy that are not depicted here. This is analogous with the Acoustic music theory of a stringed instruments under standard tuning with a low E string, when plucked at an open position that rings at a frequency of 82.3 Hz which when plucked while placing index finger on 1st fret (F note) rings at 87.3 Hz at an Octave-2 for both these notes. This is analogous to accenting higher frequencies for cavitated lungs as seen from screenshot-3 above when comparing the spectral centroid for healthy (blue) and pathological (red). Another acoustic scenario mimicking the cavities would be of placing the Capodastro (Capo) at first fret and second fret respectively that now results in all strings to sound one half step and two half steps higher respectively accenting higher frequencies and different keys/scales wherein the latter case of a capo on second fret converts an Em chord into a F#m chord/key. The reason these chords are hypothesized is that a TB cough is dark & sad sounding similar to the Minor chords or vice versa. Another scenario analogous to Lung changes at high altitudes or seasonal changes could be hypothesized to a different type of tuning such as Drop-D that tunes the low E at one whole step down to D ringing at 73 Hz & the next note ringing at 78 Hz. The relative increase in frequency is identical across both the type of tunings which is validated by the standard tuning. Connecting the acoustic theory we summarize that the latent and active infection has accented higher frequencies or variance is introduced when compared to a healthy lung. Viral Pneumonia rarely causes cavities and hence the acoustic theory discussed here is focusing on TB and Lung Cancers and other conditions causing cavities.

TB infection happens in 4 stages: the initial macrophage response, the growth stage, the immune control stage, and the lung cavitation stage. These four stages happen over roughly one month [3]. The first two stages can be classified as latently infected and starting third stage, Asymptomatic and Active TB can be concluded and can be mapped to the Acoustic theory described with various hypotheses. Lung cancer mimics cavity formation which however forms a single cavity that grows over a period of time & TimBre can also be used for such differential diagnosis. The formant frequencies F0, F1 & F2 for TB has no overlapping of frequencies post background noise reduction for Pulmonary TB cough sounds that is somewhat depicted by ResApp in their patent at page 12 & 88, Figure 7 pertaining to overlapping frequencies but different mean, kurtosis and skewness that fits the Acoustic Guitar analogy under different conditions and the frequencies they ring under the said conditions. The overlap however is seen in healthy cough sounds that becomes a key differentiator [4].

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3. Telangana State TB Office for providing us with access to active TB patients and also the clinical trials at 3 districts as a part of Site-1
4. NH/MSMF, Bangalore for the double blinded clinical trials as a part of Site-2

Limitations

- Subjects with age <18 age are not covered and is planned as a separate trial for pediatric group. We however did not deny screening and results thereon
- Omicron related cough sounds that are predominantly URTI (upper respiratory tract infection) were not covered
- The study focused on 3rd party Microphone Array - Zoom H1 & H1n models, Nokia 2.3 & Xiomi Redmi Mobile Phone Models & needs to evaluate other low cost microphones such as Bietrun

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