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Short Paper

A comparison of the quality of images of chest X-ray between handheld portable digital X-ray & routinely used digital X-ray machine

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***Background & objectives*: Chest X-ray (CXR) is an important screening tool for pulmonary tuberculosis (TB). Accessibility to CXR facilities in difficult-to-reach and underserved populations is a challenge. This can potentially be overcome by deploying digital X-ray machines that are portable. However, these portable X-ray machines need to be validated before their deployment in the field. Here, we compare the image quality of CXR taken by a newly developed handheld X-ray machine with routinely used reference digital X-ray machine through the conduct of a feasibility study.**

***Methods*: A total of 100 participants with suspected pulmonary TB were recruited from the outpatient departments of a medical college and a community health centre in Agra. Each participant underwent CXR twice, once with each machine. Both sets of de-identified images were independently read by two radiologists, who were blinded to the type of X-ray machine used. The primary outcome was agreement between image qualities produced by these two machines.**

***Results*: The intra-observer (radiologist) agreements regarding the status of the 15 CXR parameters ranged between 74 per cent and 100 per cent, with an unweighted mean of 87.2 per cent (95% confidence interval: 71.5-100). The median Cohen's kappa values for intra-observer agreement were 0.62 and 0.67 for radiologists 1 and 2, respectively. In addition, on comparison of the overall median score of quality of the image, the handheld machine images had a higher score for image quality.**

***Interpretation & conclusions*: The current study shows that a handheld X-ray machine, which is easy to use and can potentially be carried to any area, produces X-ray images with quality that is comparable to digital X-ray machines routinely used in health facilities.**

Key words Agreement - comparison - hard-to-reach - portable X-ray - quality

Chest X-ray (CXR) serves as a primary tool in the screening of pulmonary tuberculosis (TB) and also helps in establishing diagnosis, when TB cannot be confirmed bacteriologically[1]. In addition, it offers useful diagnostic aid in many other chest ailments. However, access to high-quality CXR is limited in many settings within India, especially hilly and hard-to-reach areas. In order to fulfil the national TB elimination goal in the country, it is crucial to reach out to underserved and hard-to-reach communities for timely diagnosis and effective management of TB cases[2]. CXR, in these areas, in combination with laboratory-based diagnostic tests and clinical symptom assessment, could help in early diagnosis of TB.

Digital X-ray machines have been in use for the past several years; however, their availability and portability remain a challenge. Against this background, newer technologies such as portable handheld digital X-ray machines could play an important role. Any such mobile X-ray machine, which provides high-quality images, minimum radiation exposure, is lightweight and battery operated aided with easy charging facility, can be a boon for screening TB among hard-to-reach population groups.. While handheld X-rays have been used for dental imaging, the diagnostic quality of handheld devices for chest imaging is unknown.

We conducted a study to compare the quality of CXR images taken by the handheld X-ray machine and health facility based digital X-ray service used in the National TB Elimination Programme (NTEP) for patients suspected of pulmonary TB. This being a new technology, we generated initial evidence regarding the quality of images produced through this new approach. The results from this study could help decide if larger multicentric diagnostic trials would be needed. The results of this investigation and further investigation can potentially provide solutions to overcome barriers in the implementation of TB diagnosis algorithm in hard-to-reach and underserved communities by providing quality CXR services.

Material & Methods

This study was conducted in the department of Clinical division, ICMR-National Jalma Institute for Leprosy and Other Mycobacterial Diseases, Agra, Uttar Pradesh, between November 2021 and December 2021. The study was approved by the Institute Human Ethics Committee. The study was conducted at two sites namely: (*a*) S.N. Medical College, Agra, and (*b*) Community Health Centre, Bah, Agra.

Study design: This was a cross-sectional comparative study wherein, the image quality of CXR in suspected pulmonary TB patients presenting at the outpatient departments of urban and rural settings captured by a newly developed handheld X-ray machine was compared with the image produced by the digital X-ray machine used routinely under NTEP. No comparison of characteristics or diagnosis of pathological findings was made in this study. This new device, Mine 2© (Lipomic India Pvt. Ltd.), a portable handheld X-ray machine, has three components, an X-ray generator, a digital detector and a laptop with inbuilt router for transfer of images from the detector to the laptop. Both X-ray generator and digital detector are battery operated and can be carried in a backpack together with a laptop and thus have the potential to be used in hard-to-reach areas. The Mine 2 X-ray unit requires an input power of 12 volts. The exposure time is from 0.1 sec to 1.3 sec, with a focal spot size of 0.4 mm. The machine weighs 1.8 kg and, with only a 60 kV and 2 mA X-ray generator, produces lesser radiation compared to a conventional machine. The digital X-ray machine used was ProRad Atlas Mobile X-ray unit, which had a kV range of 40 to 110 kVp, Ma range of 25 to 100 mA, focal spot of 0.5 mm and exposure time of 2 sec. Its detection type is amorphous silicon with CsI scintillator with a size of 14 by 17 inches, pixel pitch of 140 μm and resolution 2500 × 3052.

Sample size: Using Cohen's kappa for testing the agreement between two X-rays images from the same participant as the primary outcome, with a kappa value of 0.5 under alternate hypothesis *vs*. the null value of kappa, with 95 per cent confidence and 90 per cent power of the test, the calculated sample size was 38. The study was conducted at two centres thus, the total patients enrolled were 76. After allowing for a 15-20 per cent correction to account for the loss of reading/ data, we conducted this study on 100 participants who were suspected to have pulmonary TB[3].

Inclusion and exclusion criteria: The inclusion criteria comprised adult patients (age >18 yr) with suspected pulmonary TB as per the NTEP criteria presenting at the outpatient departments of the study sites. Pregnant women or women with missed menstrual period, severely ill individuals and individuals with any spinal deformity making them unable to stand erect were excluded from the study.

After obtaining written informed consent, eligible participants from the aforementioned outpatient departments were consequently enrolled. The study physician recorded the medical history and conducted a clinical examination following which the participants underwent CXR twice, with a posterior-anterior view

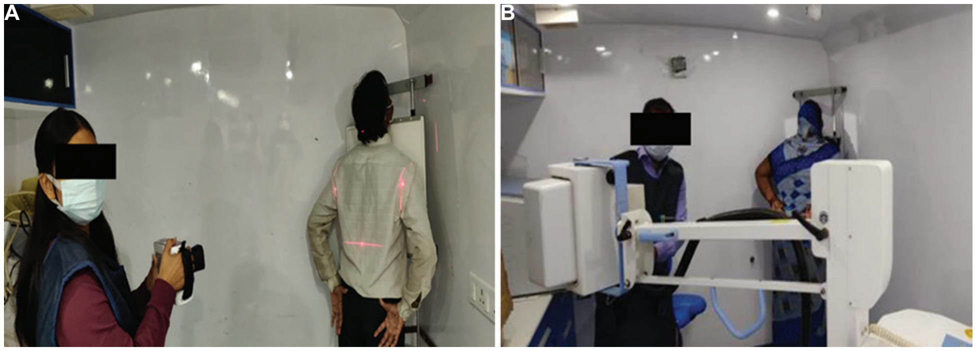

Fig. 1. Photos of both machines and patient positioning. (**A**) mine 2 X-ray machine and patient positioning, (**B**) digital X-ray machine

during inspiration; once with the digital X-ray machine used under NTEP and once with handheld X-ray machine in a mobile van (Fig. 1). Both machines used a chest stand which held the digital radiography (DR) panel. X-ray images of both the machines from DR flat panel were directly received, viewed and managed in the laptop with image pilot software. Respective serial numbers and predetermined random numbers, generated by a study statistician from the ICMR-National Institute of Medical Statistics, New Delhi, India, were placed on the X-ray images. The images did not have any personal identifier of a participant or of the machine used, and each random number had the machine code attached in a separate file maintained by the statistician.

Statistical analysis: Both sets of de-identified X-ray images (handheld and routinely used in under NTEP) were sent to two radiologists who read them independently. The images were analyzed based on a set of 15 parameters related to CXR image as well as an overall score for the quality of image. The variables compared were as follows: (*a*) state of respiration, *i.e.* inspiration/expiration; (*b*) rotation; (*c*) costophrenic angles; (*d*) airway including mediastinum size; (e) bones; (*f*) cardiac shadow; (*g*) diaphragm position and shape; (*h*) effusion; (*i*) lung fields (six subfields) and (*j*) hilum. These variables were binarily graded as per their characteristics, as mentioned in Tables I and II. In addition, the radiologists as signed an overall score to each X-ray image for its quality, which was graded on a scale of 1 to 10, with 10 denoting highest quality and 1 denoting lowest quality. The primary outcome evaluated was intra-rater agreement and Cohen's kappa value for each of the 15 parameters between the two machines, individually for each radiologist. Further, we calculated an unweighted mean and median percentage agreement and kappa value of the 15 parameters.

Results & Discussion

The results from 100 participants were analyzed. Figure 2 shows the CXR images of the same participant with no evidence of disease from both machines, whereas Figure 3 shows the CXR images of the same participant with evidence of disease from both machines.

On comparison of the overall median score of quality of image on a scale of 1 to 10, with 10 denoting highest quality and 1 denoting lowest quality, it was found that overall, handheld X-ray machine images had a score of 9 and digital CXR images had a score of 8. One of the radiologists had given equal median scores of 8 to both machines while the other had scored a median of 10 for the handheld machine and 8 for the digital machine under NTEP.

Table I shows that intra-rater agreement for radiologist 1 ranged between 74 per cent and 100 per cent while the median value of kappa was 0.62. For radiologist 2, the intra-rater agreement had a narrower range, with an unweighted mean of 89 per cent [95% confidence interval (CI): 79.7 to 98.2], while the median value of kappa was 0.67 (95% CI: 0.5 to 0.66). Except for the fields of the state of respiration, hilum and bones, the kappa statistics was >0.4.

A similar analysis was performed for inter-rater agreement between the two radiologists for images produced only by the handheld machine. As shown in Table II, the inter-rater agreement ranges from 74 per cent for the left lower zone field to 100 per cent agreement for the state of inspiration and bones. Cohen's kappa value for inter-radiologist agreement for handheld X-ray machine images is statistically significant ($P<0.05$) for all the indicators.

In both the analyses, Cohen's kappa statistics was more than 0.5, which was assumed for the sample

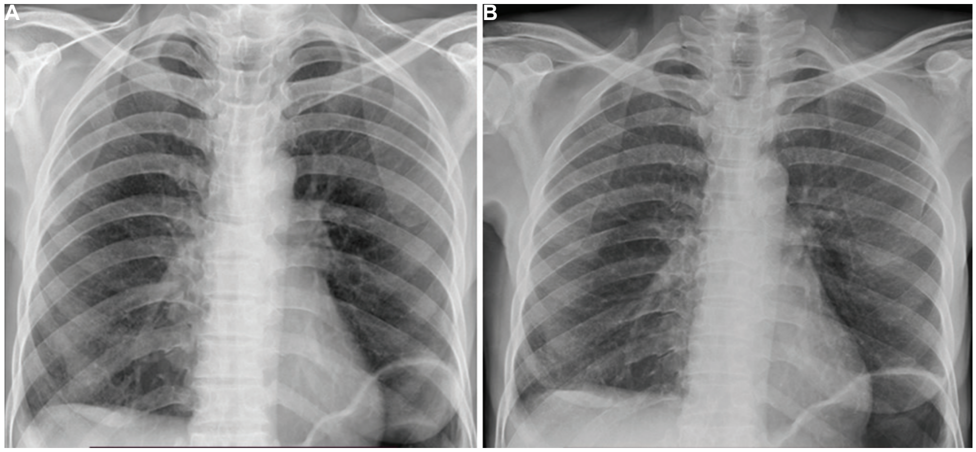

Fig. 2. Chest X-ray images for the same individual without evidence of disease using (**A**) mine 2 machine, and (**B**) digital X-ray machine.

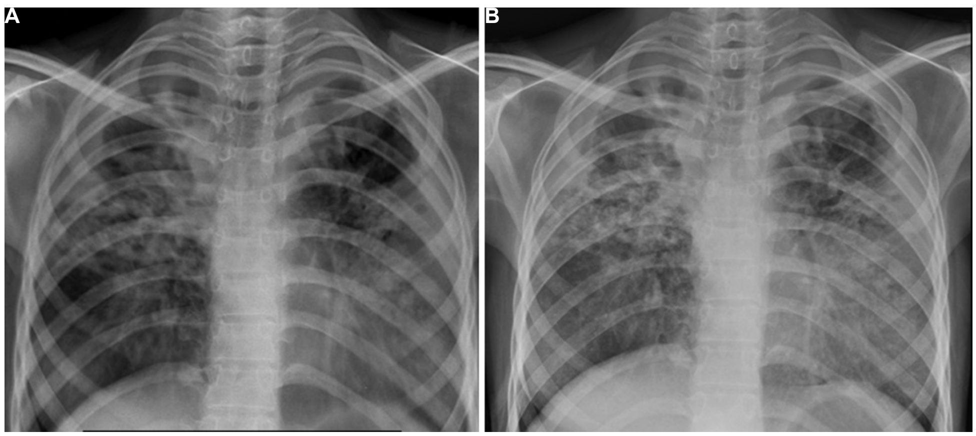

Fig. 3. Chest X-ray images for the same individual with evidence of disease using (**A**) mine 2 machine, and (**B**) digital X-ray machine.

size calculation. Thus, the study had more than 90 per cent power to have estimated the obtained kappa values.

The current study shows that a handheld X-ray machine, which is easy to use and can potentially be carried to any area, produces X-ray images with quality that is comparable to digital X-ray machines routinely used under NTEP.

The intra-observer (radiologist) agreements regarding the status of the 15 CXR parameters ranged between 74 per cent and 100 per cent, with an unweighted mean of 87.2 per cent (95% CI: 71.5 to 100). The median Cohen's kappa values for intra-observer agreement were 0.62 and 0.67 for radiologists 1 and 2, respectively, whereas the inter-rater Cohen's kappa values in our study were lower than intra-rater ones. These results compare well with other similar studies. A study conducted in Switzerland in 2006 on intra-observer as well as overall agreement in CXR interpretation reported overall kappa of 0.55 between all three readers for any abnormality[4]. A multi-country study in the U.K. and the Netherlands reported an overall kappa value of 0.61 for signs of active TB on CXR and 0.51 for normal CXR between different readers[5]. In a Canadian study in 2002, where 973 films were read twice by three independent observers, the intra-reader agreement using five diagnostic categories was moderate to good (0.59-0.72) for TB, but inter-reader agreement was only fair (0.44-0.56)[6]. It has previously been reported that the use of CXR for screening of TB is limited by modest specificity with high inter-observer variability in radiological reports[7].

Further, in our study, the overall median score given to the quality of CXR images was higher for the handheld machine, indicating that this machine had produced better quality image compared with that of digital X-ray machine available at health facilities. However, it may be helpful to note that the digital X-ray

Table I. Intra-rater agreement between hand-held and routine Digital CXR images

Parameter (Characteristics and Score)	Agreement (%)	Radiologist 1			Radiologist 2		95% CI	*P*
		Cohen`s Kappa	95% CI	*P*	Agreement (%)	Cohen`s Kappa (*P*)		
State of respiration: (Inspiration-1/Expiration-2)	89.5			N.A.	99	N.A.		
Rotation: aligned-1/rotated-2)	87.3	0.665	0.491, 0.839	<0.001	83.3	0.368	0.118, 0.616	<0.001
Costo-phrenic angles: clear-1/blunt-2)	91.5	0.747	0.580, 0.914	<0.001	90.6	0.635	0.417, 0.853	<0.001
Airway including mediastinum size: normal-1/not midline or wide-2)	95.8	0.822	0.653, 0.991	<0.001	92.7	0.767	0.604, 0.930	<0.001
Bones: normal-1/abnormal-2)	100			N.A.	93.8	N.A.		
Cardiac shadow: normal-1/wide or blunt-2)	96.8	0.65	0.282, 1.018	<0.001	94.8	0.259	-0.188, 0.706	0.01
Diaphragm position and shape: normal-1/not clear or higher-2)	94.8	0.753	0.545, 0.961	<0.001	89.6	0.388	0.084, 0.692	<0.001
Effusion: absent-1/present-2)	88.3	0.552	0.317, 0.787	<0.001	86.5	0.443	0.192, 0.694	<0.001
Hilum: normal-1/nodes seen-2)	90.6	0.142	-0.168, 0.452	<0.001	85.4	0.159	-0.100, 0.418	<0.001
Right Upper zone: clear-1/infiltrates-2)	82.5	0.639	0.488, 0.790	<0.001	89.6	0.772	0.639, 0.905	<0.001
Right Middle zone: clear-1/infiltrates-2)	80	0.594	0.435, 0.753	<0.001	87.5	0.710	0.559, 0.861	<0.001
Right Lower zone: clear-1/infiltrates-2)	75.8	0.504	343, 0.665	<0.001	93.8	0.666	0.417, 0.915	<0.001
Left Upper zone: clear-1/infiltrates-2)	81	0.621	0.464, 0.778	<0.001	94.8	0.888	0.793, 0.985	<0.001
Left Middle zone: clear-1/infiltrates-2)	80	0.595	0.432, 0.758	<0.001	88.5	0.720	0.565, 0.875	<0.001
Left Lower zone: clear-1/infiltrates-2)	73.7	0.46	0.286, 0.634	<0.001	91.6	0.619	0.378, 0.860	<0.001
Mean values (95% CI) (unweighted)	87.2 (71.5 to 100)	0.6 (0.3-0.9)			89 (79.7 to 98.2)	0.6 (0.1-0.9)		
Median values	88.3%	0.62			90.6%	0.67		

CXR: Chest X-ray; CI: confidence interval; NA: not applicable

Table II. Inter-rater agreement for X-ray images of Hand-held machine

Variable (Characteristics and Score)	Agreement (%)	Cohen`s Kappa (*P*)	95% CI	*P*
State of respiration: (Inspiration-1/Expiration-2)	94.3	N.A.		
Rotation: aligned-1/rotated-2)	80.8	0.397	0.179, 0.615	<0.001
Costo-phrenic angles: clear-1/blunt-2)	89.2	0.574	0.360, 0.788	<0.001
Airway including mediastinum size: normal-1/not midline or wide-2)	88.6	0.625	0.413, 0.837	<0.001
Bones: normal-1/abnormal-2)	96.9	N.A.		
Cardiac shadow: normal-1/wide or blunt-2)	93.7			
Diaphragm position and shape: normal-1/not clear or higher-2)	89.1	0.556	0.284, 0.828	<0.001
Effusion: absent-1/present-2)	91.1	0.499	0.256, 0.742	<0.001
Hilum: normal-1/nodes seen-2)	87.0	0.260	-0.077, 0.597	0.009
Right Upper zone: clear-1/infiltrates-2)	86.0	0.706	0.559, 0.853	<0.001
Right Middle zone: clear-1/infiltrates-2)	80.8	0.48	0.296, 0.664	<0.001
Right Lower zone: clear-1/infiltrates-2)	68.4	0.34	0.144, 0.536	<0.001
Left Upper zone: clear-1/infiltrates-2)	82.4	0.705	0.566, 0.844	<0.001
Left Middle zone: clear-1/infiltrates-2)	80.3	0.64	0.483, 0.797	<0.001
Left Lower zone: clear-1/infiltrates-2)	69.4	0.32	0.138, 0.502	<0.001
Mean values (95% C.I.) (unweighted)	86.86 (71.7 to 100)	0.51 (0.21 to 0.8)		
Median values	87.3	0.53		

machines used in this study were only a comparator as reference machines and not a gold standard.

We did not assess the presence or absence of TB, but only agreement between the status of parameters of CXR which is in line with NTEP guidelines, wherein CXR is only used as a screening tool for suspecting pulmonary TB cases. Our study results showed that the handheld X-ray machine had comparable image quality with routinely used digital X-ray machine and could be used where digital X-ray machines cannot be made available in facilities or are not accessible. In addition, there seemed to be short learning curves with regard to image acquisition when using a handheld device. This is particularly useful in hard-to-reach areas, wherein X-ray technicians, who are usually posted at primary health centres, can be trained to use handheld machines and can travel to subcentres or villages. In the context of national target for TB elimination by 2025, handheld X-ray machine can potentially provide a rapid scale-up of diagnosis of pulmonary TB, especially in resource-constrained areas, as well as monitoring the prognosis of treatment.

Further research is needed to evaluate the efficacy and effectiveness of handheld CXR devices, as well as to examine implementation issues such as feasibility, adoption and cost-effectiveness[8]. Experience of using handheld X-rays for dental purposes has shown that certain issues arise in their use such as operator movements, protection of operator and other persons, operator fatigue and disinfection[9]. We believe that these issues can be overcome by adequate planning, training and monitoring. We also maintain that this study does not address issues around physical/radiation performance parameters applicable to diagnostic X-ray systems.

The present study had certain limitations. While it did provide evidence in favour of using handheld X-ray, we realized that, to provide strong clinical evidence regarding the diagnostic accuracy of handheld X-ray machine, a multi-centric, non-inferiority trial would be needed. We did not collect data on disagreement and discuss on potential causes for intra- or inter-observer disagreements. No objective methods such as spatial resolutions were used to assess X-ray images, which could be considered in a larger study. Finally, we did not measure radiation doses in this study; however, we ensured that the manufacturer complied with all requirements as per the Indian regulatory authorities.

Overall, the study showed that small handheld lightweight X-ray machines were able to provide reproducible quality CXR images, which were comparable to those produced by routinely used reference X-ray machines under NTEP. Acceptable levels of radiation from handheld CXR machine made it safer to use in field settings.

We expect that the handheld X-ray machine, can potentially become a valuable screening and diagnostic tool not only for pulmonary TB but also for other chest disease in vulnerable populations and communities living in hard-to-reach areas, The results from this study can inform the design and conduct of larger multicentre studies and investigation around feasibility issues to generate adequate evidence which can help in providing more reliable options for using newer technologies to overcome barriers in the implementation of TB diagnosis algorithms in hard-to-reach and underserved communities.

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Conflicts of Interest: None.

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