Evaluation of the electronic stethoscope (FONODOC) as a cardiac screening tool during the preoperative evaluation of children

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ABSTRACT

Background and Aims: An electronic stethoscope with an inbuilt phonocardiogram is a potentially useful tool for paediatric cardiac evaluation in a resource-limited setting. We aimed to compare the acoustic and electronic stethoscopes with respect to the detection of murmurs as compared to the transthoracic echocardiogram (TTE). Methods: This was an observational study. Fifty children aged 0–12 years with congenital heart diseases (CHDs) and 50 without CHD scheduled for echocardiography were examined using both stethoscopes. The findings were corroborated with clinical findings and compared with the echocardiography report. Results: Among the 50 cases without CHD, no murmur was detected using either of the stethoscopes. This was in agreement with TTE findings. The calculated specificity of both stethoscopes was 100%. Amongst the 50 cases with CHD, the electronic stethoscope picked up murmurs in 32 cases and missed 18 cases. The acoustic stethoscope picked up murmurs in 29 cases and missed 21 cases. Thus, the sensitivity of electronic and acoustic stethoscopes as compared to TTE was calculated to be 64% and 58%, respectively. The positive predictive value of the electronic stethoscope as compared to TTE was 100% while the negative predictive value was 73%. The kappa statistic was 0.93 suggesting agreement in 93%. McNemar’s test value was 0.24 suggesting that the electronic stethoscope did not offer any advantage over the acoustic stethoscope for the detection of CHD in children. Conclusion: A comparison of the electronic stethoscope with an acoustic stethoscope suggests that the rate of detection of CHD with both stethoscopes is similar and echocardiography remains the gold standard.

Key words: Congenital heart disease, electronic stethoscope, murmur

INTRODUCTION

As per the Centers for Disease Control (CDC), congenital heart diseases (CHDs) are the most common type of birth defect. The birth prevalence of CHD is between 8–12/1000 live births. Taking the birth prevalence as an average of 9 per 1000 live births, the number of babies born with CHD in India is more than 2,00,000 per year.[1,2]

Preoperative cardiac evaluation of children usually begins with history taking and physical examination followed by investigations as necessary. When there are a large number of patients waiting to be screened and there is a paucity of time and resources, or if the screening area is too noisy, it may be difficult to appreciate any murmur using the acoustic stethoscope, even for trained ears. The tachycardia that is natural in children, especially when they are agitated makes it even more difficult.

An accurate, quick, cost-effective and user-friendly screening tool may be very useful in this context. An electronic stethoscope is an audio-visual auscultation tool.
device, which combines a phonocardiogram with a conventional stethoscope. Phonocardiogram is the graphical recording of heart sounds. It helps appreciate the timing, quality, intensity and frequency of heart sounds.[3]

Thus, the purpose of this study was to study the usefulness of an electronic stethoscope as a bridge between screening and diagnosis of paediatric murmurs and CHDs, especially in low and middle-income countries. The primary objective was to observe for the detection of murmurs using an electronic stethoscope that were not detected by an acoustic stethoscope. The secondary objective included evaluation of the accuracy of the electronic stethoscope as compared with that of the acoustic stethoscope as well as transthoracic echocardiography (TTE) in the detection of congenital and valvular heart disease.

METHODS

This was an observational study conducted between the years 2020 and 2021 in the department of Anaesthesiology of a medical college hospital. The study was started after taking approval from the ethics committee and Clinical Trial Registry of India (CTRI) registration [IEC (798/2019), (CTRI/2020/11/029125)].

Children aged 0–12 years, of either gender, who were referred for transthoracic echocardiography to the paediatric cardiology department, were enrolled after taking parental consent. The enrolment continued until we had a total of 50 patients with and 50 without CHD as diagnosed by echocardiography. Since there were no similar studies reported in the literature, we chose a convenient sample of a total of 100 patients.

All patients enrolled in this study were examined using an acoustic stethoscope and electronic stethoscope and underwent TTE.

The electronic stethoscope used in the present study was HD Fono/HD FonoDoc manufactured by HD Medical Services (India) Pvt. Ltd, Chennai [Figure 1].

Every electronic stethoscope has a basic design consisting of three modules - the data acquisition module, the pre-processing module and the signal processing module.[3-7] The data acquisition module consists of the sensor, amplifier, filter and analogue to digital converter. The sensor is usually either a microphone or a piezoelectric crystal. It picks up the heart sounds and converts them into electrical signals. These signals are then amplified, filtered and converted to a digital signal. The pre-processing module filters the signals further by de-noising using a digital filter and removing artefacts. This helps in removing unwanted frequencies and enhancing the frequencies of interest. The signal then undergoes segmentation into cycles, which helps in better identification of the heart sound. The data obtained is fed into a software that helps in diagnostic classification and decision making.[8-13]

There are some manufacturer’s guidelines for using the electronic stethoscope: Before beginning auscultation, it is advised that all the mobile phones near the device be switched off. The patient must remain quiet during the examination with the device. The ambient noise has to be kept to the lowest level possible. The patient is instructed to assume the necessary posture for auscultating - sitting/supine/ side-supine. The appropriate audio mode is selected by pressing the toggle key (by default, the device is set to ‘Bell’ mode). The device is placed on the patient such that the chest piece is in contact with the patient’s chest at one of the four auscultation positions. During auscultation, one will observe two waveforms on the display: The top display shows the murmur-signal wave (labelled ‘MUR’) and the bottom display shows heart sound waveforms (labelled as ‘HS’). Heart sounds are also heard during auscultation. A minor trace of S1 and S2 appearing in ‘MUR’ (top visual) is normal. This is not a diagnostic display and the clinician must use his/her own clinical judgment to interpret. A phonocardiogram of a normal heart would show only the first (longer vertical lines) and second heart sounds (shorter vertical lines) and a flat horizontal baseline. When there are additional sounds
such as murmurs, they are displayed as vertical lines; the size, position and duration of which will depend on the flow as well as whether it is systolic, diastolic or both [Figure 2].

There were three observers in the study. Observer 1 was the principal investigator, a postgraduate student in anaesthesia. Observer 2 was the consultant anaesthesiologist/cardiologist/paediatrician who independently screened the patients using both acoustic as well as an electronic stethoscope. Observer 3 was the echo technician who performed the echocardiography.

Observer 1 contacted the parent/s, explained the study and took informed consent to examine their child using the acoustic (regular) and electronic stethoscope. A detailed history taking and physical examination of the child were done to look for signs of cardiac disease. The child was examined using both the stethoscopes and the findings were recorded. The cardiac examination included auscultation in each of the auscultatory areas of the heart – the mitral, aortic, pulmonary and tricuspid areas. Observer 2 independently examined the child using both stethoscopes. The main focus was on the detection of murmurs as heard by either or both stethoscopes. No formal grading of the murmur or attempt at differentiating it as physiological or pathological was done.

The following situations were possible:
1. No murmur was detected either with the acoustic or electronic stethoscope.
2. A murmur was not detected with the acoustic stethoscope but was detected using an electronic stethoscope.
3. A murmur was heard with both the acoustic stethoscope and the electronic stethoscope.

The clinical findings in each case (presence or absence of CHD) as observed by Observers 1 and 2 were recorded first to avoid bias and compared with the findings of TTE performed thereafter by Observer 3. The clinical implications of any murmur detected by the electronic stethoscope but not detected clinically were noted.

The sensitivity, specificity and positive and negative predictive values of the electronic stethoscope as compared to the acoustic stethoscope and TTE in detecting congenital or valvular heart disease were calculated.

RESULTS

A total number of 120 patients referred for TTE were enrolled and clinically examined. The enrolment continued until we had included 50 patients with CHD and 50 without CHD as diagnosed by TTE. Both groups of children were comparable in terms of age and gender distribution [Table 1].

The results as per Observer 1 were as follows: Among the 50 cases without CHD, no murmur was detected using either the electronic stethoscope or the acoustic stethoscope [Tables 2 and 3]. This was in agreement with TTE findings since no positive findings were obtained. Thus, the calculated specificity of both electronic and acoustic stethoscopes was 100%.

Figure 2: Examples of phonocardiogram (as seen in HD-FONODOC) in a normal patient and in some congenital heart diseases. Please note that the authors did not make any attempt to diagnose the clinical condition based on the phonocardiogram alone. The objective was to detect any murmur that would warrant further evaluation with echocardiography

| Parameter                  | With CHD          | Without CHD       | P    |
|----------------------------|-------------------|-------------------|------|
| Age in years (Mean±SD)     | 1.69±3.01         | 4.5±3.3          | 0.98*|
| Gender (M/F) (n)           | 24/26             | 31/19            | 0.15**|

SD: Standard deviation; CHD: Congenital heart disease; M/F: Male/female; n: number. *Mann–Whitney U-test. **Chi-square test
Amongst the 50 cases with CHD, murmurs of 32 cases were picked up by electronic stethoscope while 18 were missed. With the acoustic stethoscope, murmurs of 29 cases were picked up while 21 cases were missed.

Thus, the sensitivity of the electronic stethoscope as compared to TTE was calculated to be 64%, and the sensitivity of the acoustic stethoscope as compared to echocardiography was 58%. The positive predictive value of the electronic stethoscope as compared to TTE was 100% while the negative predictive value was 73%.

The findings of Observer 1 and 2 were similar. Using an electronic stethoscope, Observer 1 detected a murmur in 32 cases while Observer 2 detected a murmur in 31 cases. Using an acoustic stethoscope, Observer 1 detected a murmur in 29 cases whereas Observer 2 detected a murmur in 30 cases. CHDs that were missed included a small patent ductus arteriosus (in 8 patients), and a small atrial septal defect/patent foramen ovale (remaining patients). The flow across these connections was probably low explaining the absence or inaudibility of murmur in these patients. Thus, as per Observer 2, the sensitivity of detection of CHD by electronic stethoscope as compared to TTE was 62%. The positive predictive value of an electronic stethoscope was found to be 100% while the negative predictive value was 70%. Similarly, according to Observer 2, the sensitivity of acoustic stethoscope as compared to TTE was found to be 60% and the specificity was 100%. The positive and negative predictive values were 100% and 70%, respectively. We had Observer 2 to reassure us that the findings of Observer 1 were concurring with that of Observer 2. Since the results obtained by Observer 1 and Observer 2 were comparable, further results were calculated using the findings of only Observer 1.

Since echocardiography is considered to be the gold standard, acoustic and electronic stethoscopes were compared with each other using kappa statistics [Table 4]. The observed agreement was calculated using the formula \((a + d)/N\), the value being 0.97. The electronic stethoscope detected a murmur 32% of the times \((a + c)/N\). The acoustic stethoscope detected a murmur 29% of the times \((a + b)/N\). Thus, the probability that both the electronic and the acoustic stethoscopes detected a murmur was \(0.29 \times 0.32 = 0.093\).

Similarly, the electronic stethoscope did not detect a murmur 68% of the times \((b + d)/N\). The acoustic stethoscope did not pick up a murmur 71% of the times \((c + d)/N\). Thus, the probability that both the electronic and acoustic stethoscopes did not detect a murmur was \(0.68 \times 0.71 = 0.48\).

The overall probability of chance agreement between the electronic and the acoustic stethoscopes is \(0.093 + 0.48 = 0.573\).

Using the above calculated observed agreement and chance agreement, the kappa statistics can be calculated as follows:

Kappa statistic
\[
\text{Kappa statistic} = \frac{\text{Observed agreement} - \text{Chance agreement}}{1 - \text{Chance agreement}}
\]
\[
= \frac{(0.97-0.57)}{(1-0.57)} = 0.93
\]

This suggests that the probability of agreement between electronic and acoustic stethoscopes is 93%
implying that their findings are expected to agree 93 times out of 100. According to Table 4, a kappa value of > 0.75 is suggestive of excellent agreement between the two stethoscopes. A comparison using McNemar’s test showed a P value of 0.24, which was statistically insignificant, suggesting that the electronic stethoscope did not offer any advantage over the acoustic stethoscope for the detection of CHD in children.

**DISCUSSION**

Cardiac auscultation has long been the earliest means of detection of abnormalities in the cardiovascular system. The electronic stethoscope may serve as a valuable tool for screening of CHD, especially in remote places. It may also be used in the upcoming and booming field of tele-medicine. A low-cost digital stethoscope was created by Lakhe et al. in Mumbai using bluetooth technology to improve cardiac auscultation and for its application in tele-medicine. A microphone was fitted in the chest piece. The sound waves were amplified, de-noised and digitised. The digitised data was transferred to a software where it was stored and read as a text file. It was transferred to a personal computer (PC) using bluetooth and heard in the PC.

The data recorded via the electronic stethoscope can also be stored, visualised many times, shared for expert opinion and used at a later date for reference.

Degroff used an electronic stethoscope to screen heart murmurs in children. Sixty-nine children, aged 1 week to 15 years, with a mean age of 2 years, were enrolled in the study. Their heart murmurs were recorded and fed into an artificial neural network (ANN). The sensitivity and specificity obtained were 100% for the diagnosis of murmur as compared to a mean sensitivity of 63% and specificity of 100%.

Hedayioglu and co-researchers shared their experience of developing a tele-stethoscope and using the same for paediatric cardiology in 2006. Their project was a four-fold-development of an electronic stethoscope, the development of software to analyse the data collected from the electronic stethoscope, testing the developed proto-type and making a library of the collected data for future reference. Hundred heart sounds were collected from children and reviewed. The recorded sounds were found to be ‘satisfactory’ for coming to a diagnosis.

Dalh and co-authors conducted a study in Norway to prove the role of the electronic stethoscope in tele-medicine. Recorded heart sounds from 47 children with no murmur, innocent murmur or pathological murmur were e-mailed to a remote location. These were analysed by four paediatric cardiologists individually and classified. The mean sensitivity and specificity were observed to be 89.7% and 98.2%, respectively, and the inter- and intra-observer differences were noted to be insignificant. The average time taken was 2.1 min/patient.

Botha and co-researchers conducted a study in the rural areas of Africa where they used an electro-phonocardiogram for screening of cardiovascular diseases in people. Cardiac sounds from patients with cardiovascular disease and those without were recorded. These signals were de-noised, segmented and later analysed using an ANN. The electro-phonocardiogram combined with the ANN showed a sensitivity of 82% and specificity of 88%.

CHD with no murmurs or low-grade murmurs (but detected by TTE) may not be detected by either an electronic or acoustic stethoscope. Those that are undetected are usually tiny defects and may not be significant enough to cause cardiovascular changes in children.

In the current study, patients who were referred by paediatric surgeons or paediatricians for TTE were enrolled. The original plan was to compare the use of acoustic and electronic stethoscopes to screen paediatric patients posted for surgery in the pre-anaesthetic clinic and to see the utility of an electronic stethoscope in the detection of CHD in children attending a busy pre-anaesthetic clinic. It would have been fairly easy to enrol a large number of patients, but to verify the accuracy, getting TTE in each of them would have become necessary. This was difficult due to a lack of personnel and funds.

The preoperative detection of CHD has important clinical implications. The technology involved in the construction of an electronic stethoscope and its possible use in tele-medicine and other applications has received greater attention after the coronavirus disease (COVID)-19 pandemic. Many research papers have been published recently on newer technologies and applications of the electronic stethoscope. These include a real-time smart digital stethoscope system for heart diseases monitoring, phonocardiogram signal
processing for automated diagnosis of congenital heart disorders, a low-cost ear-contactless electronic stethoscope Auscul Pi powered by Raspberry Pi and Python (for auscultation in patients with COVID-19 and even a soft wearable electronic stethoscope.[22-25]

Clinical studies can be expected to follow in the coming years; nevertheless, technology and innovations have always been powerful tools in the improvement of the quality of perioperative care.[26,27]

CONCLUSION

A comparison of an electronic stethoscope (FONODOC) with an acoustic stethoscope as a cardiac screening tool during the preoperative evaluation of children shows that the rate of detection of CHD with both, the acoustic as well as the electronic stethoscope is similar. The sensitivity and specificity of the electronic stethoscope are 64% and 100%, respectively, and are comparable to that of an acoustic stethoscope (58% and 100%, respectively). Hence, echocardiography remains the gold standard for the diagnosis of CHD.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the parents have given their consent for their child's images and other clinical information to be reported in the journal. The parents understand that the patient's names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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