Clinical Validation of a Low-cost Telemedicine Equipment Remote Medical Diagnostics Kit at a Tertiary Care Hospital

RS Math*, S Mishra*, KS Kumar*, VK Bahl*

Abstract

Background: The Remote Medical Diagnostics kit is an indigenous and low-cost technology that can measure and transmit via the internet 6 clinical parameters viz. Blood pressure (BP), pulse, temperature, oxygen saturation, 12-lead Electrocardiogram (ECG) and heart/breath sounds. Prior to commercial use, it needs clinical validation.

Methods: Fifty three patients (including 1 acute myocardial infarction) were evaluated for the above parameters using accepted standard methods and the Remote Medical Diagnostics kit.

Results: The intraclass correlation coefficient (ICC) for systolic BP (SBP), diastolic BP (DBP), saturation pulse, manual pulse and temperature was 0.927, 0.904, 0.989, 0.99 and 0.912 indicating a high degree of agreement between the two methods. For oxygen saturation, the ICC was 0.763 indicating a moderately high agreement. For heart sounds, the kappa coefficient (κ) for inter-rater reliability was 0.48 (observed agreement of 96.1%). For breath sounds, the ‘κ’ value was 0.48 indicating moderate agreement. For the breath sounds, the ‘κ’ value was 0.38 indicating fair agreement (the observed agreement of 94.2%). For the ECG, the observed agreement was 94.4% by visual assessment.

Conclusion: At the bedside, the Remote Medical Diagnostics kit was clinically validated for the above 6 parameters.

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INTRODUCTION

India has 80% of its main healthcare centres’ located in cities that are home to a mere 30% of its population. This leaves the vast rural majority with a paucity of qualified doctors, little or no specialist care, delayed diagnosis and treatment of ailments and in many cases treatment by unqualified practitioners. This also means long and repeated travel to metropolitan cities for treatment. Not only is the travel expensive, but it also leads to absentism from work for the accompanying family members.

Telemedicine offers one solution to this vexing problem. Telemedicine is the use of information and communications technology to provide health care services to individuals who are at some distance from the health care provider. This coupled with the expanding telecom and internet services in India can bridge the rural-urban divide and bring the specialist closer to the rural patient in a virtual sense.

A step in this direction has been the development of the ReMeDi™ (Remote Medical Diagnostics) kit (Figs. 1,2,3). This kit has been developed by Neurosynaptics Pvt. Ltd., Bengaluru in collaboration with Indian Institute of Technology, Chennai. It is a completely indigenous technology which is affordable and low-cost. This kit can measure and transmit 6 clinical parameters via the internet. These are the non-invasive Blood Pressure (BP), pulse, temperature, 12-lead Electrocardiogram (ECG), Oxygen saturation and heart and breath sounds. This kit can be installed at any remote location with internet connectivity. The kit is provided with a software that enables data compression and transmission as well as audio and video conferencing at extremely low bandwidths.

- 8 Kbps – For medical Data Transfer (i.e above 6 parameters) with online chat
- 32 Kbps – For online Chat/Audio Conferencing(AC) and Data Transfer (small image Video Conferencing (VC) can be done)
- 64Kbps – For good quality VC/AC and Data Transfer

Thus, even a dial-up connection (which provides speeds of upto 56 kbps) is sufficient for data transfer and small image VC. Both, real time and store-and-forward modes are supported. All this can be accomplished with a normal configuration personal computer (to which the Remote
Medical Diagnostics kit is connected) without any special accessories. The software is available for Windows 98/ME/XP. In addition, there is a central database that electronically stores all patients’ records and history. Other added features include multi-party conferencing, quality checks, treatment protocols etc.

Before the kit can be applied for commercial use, it needs to be validated for clinical accuracy of the various parameters that are to be tested.

METHODS

The kit was evaluated at the All India Institute of Medical Sciences (AIIMS), New Delhi in a two-phase study. The first phase involved bedside validation of the kit. The second phase involves remote transmission of the above parameters to a specialist via the internet. This second phase is ongoing.

The first phase involved 53 patients. The inclusion criterion was any patient above the age of 18 years. The exclusion criteria were (1) persons below 18 years 2) immobile or terminally ill patients and 3) those patients who did not give consent. An informed consent in the regional vernacular was taken from each patient. Approval from the AIIMS ethics committee was taken prior to the conduction of the study. The authors of this study had no role in the development of the kit and are not shareholders of the kit. There is no conflict of interest.

PROCEDURE

Patients visiting the out-patient department as well as in-hospital patients of the cardiology department of AIIMS were included in the study.

- BP was recorded from the forearm in accordance with the guidelines of the American heart association.
- Three sets of BP recordings were taken at intervals of at least one minute. The BP was recorded simultaneously by the standard mercury sphygmomanometer and the Remote Medical Diagnostics kit. A ‘Y’ connection was attached to the tubing arising from the BP cuff, one arm of which was connected to the mercury sphygmomanometer and the other arm to the Remote Medical Diagnostics Kit.
- The body temperature was recorded from the axilla using a standard mercury thermometer (kept for at least 5 minutes) and the Remote Medical Diagnostics thermistor. The readings were taken from the same axilla simultaneously.
- Oxygen saturation was measured with a standard pulse oximeter placed on the fingernail after the waveform had remained stable for at least 30 seconds. Immediately thereafter, the saturation was again recorded from the same finger using the Remote Medical Diagnostics saturation probe. The interval between the two readings was less than a minute in all cases.
- Pulse rate was recorded by two methods. In the first method, the pulse rate was counted manually for at least 30 seconds and this was then correlated with the reading obtained by the Remote Medical Diagnostics kit. In the second method, the pulse rates measured by the saturation probes were compared.
- The heart sounds were heard using a standard stethoscope and then again by the Remote Medical Diagnostics kit (head phones) by a trained cardiologist. The heart sounds (S1,S2,S3), murmurs, breath sounds were each graded (good, fair, poor) depending on the clarity with which they were heard by each method. In case of poor gradation, the auscultation was repeated again by another trained cardiologist and if the two cardiologists concurred, it was classified as a poor grade. Excessive background noise that interfered with proper auscultation or that was thought to contribute to a wrong diagnosis was also taken as a poor grade.
- A 12 lead ECG was obtained using an electronic ECG
machine and the Remote Medical Diagnostics kit. The 2 ECGs were either done immediately one after another or in stable cases an ECG done by the electronic ECG machine on the same day was used for comparison. The two ECG’s were compared visually.

**RESULTS**

The statistical analysis was done using the SPSS software (version 11.5) for windows. To determine the degree of agreement, the intraclass correlation coefficient (ICC) and the Bland-Altman plots were used. The strength of relation between two variables was measured by the Pearson’s Correlation coefficient (r). Of the 53 patients, one patient was evaluated only for the ECG. This patient had an acute myocardial infarction. So for the remaining 5 parameters, the analysis is restricted to 52 patients.

**Frequencies**

A wide range of patients were studied as noted in Table 1.

Table 2 shows the mean, standard deviation and the range of the systolic and diastolic BPs, pulse, oxygen saturation and temperature.

**Blood Pressure**

The Remote Medical Diagnostics kit has been calibrated for measurement of BP in the range of 50-200 mm Hg. Four patients had a diastolic BP (DBP) lower than 50 and in these patients the Remote Medical Diagnostics kit overestimated the BP.

The average of the 3 sets of readings was used for statistical purpose.

For the systolic BP (SBP), the ICC was 0.927, indicating a high degree of agreement (Table 3). The Bland-Altman plot (Fig. 4) shows the differences between SBP measured by the 2 methods data plotted against their mean. Most values fell between mean ± 2SD. The mean difference in the BP between the standard sphygmomanometer and the Remote Medical Diagnostics kit was 2.34 mm Hg (confidence interval CI 1.43, 3.24) (Table 3). This value although statistically significant is not clinically significant. There was a strong correlation between the SBP measured by the standard sphygmomanometer and that measured by the Remote Medical Diagnostics Kit (Pearson correlation coefficient (r) =0.878, p<0.001) (Table 3).

For the DBP, the ICC (including the 4 patients with low BP) was 0.904, indicating a high degree agreement (Table 3). The Bland-Altman plot also shows good agreement (Fig 5). The mean difference in the DBP between the standard sphygmomanometer and the remedy kit was -0.03 mm Hg (CI -0.8, 0.7) (Table 3) which is both statistically and clinically insignificant. There was a strong correlation between the DBP measured by the standard sphygmomanometer and that measured by the Remote Medical Diagnostics Kit (r=0.826, p<0.001) (Table 3). When the 4 patients with very low DBPs were excluded from analysis the correlation improved further (r=0.969, p<0.001).

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number</th>
<th>Diagnosis</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Stable Angina</td>
<td>10</td>
<td>Dilated Cardiomyopathy</td>
<td>4</td>
</tr>
<tr>
<td>Acute Coronary Syndrome</td>
<td>11</td>
<td>Pacemaker</td>
<td>3</td>
</tr>
<tr>
<td>Acute Myocardial Infarction</td>
<td>2</td>
<td>Infective Endocarditis</td>
<td>1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2</td>
<td>Hypertrophic Cardiomyopathy</td>
<td>1</td>
</tr>
<tr>
<td>Rheumatic Heart Disease</td>
<td>16</td>
<td>Constrictive Pericarditis</td>
<td>1</td>
</tr>
<tr>
<td>Normal</td>
<td>1</td>
<td>Atrial Septal Defect</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>53</td>
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**Table 2 : Frequencies**

<table>
<thead>
<tr>
<th></th>
<th>Systolic BP Std.</th>
<th>Diastolic BP Std.</th>
<th>Systolic BP Remote Medical Diagnostics kit</th>
<th>Diastolic BP Remote Medical Diagnostics kit</th>
<th>Systolic Pulse Std.</th>
<th>Diastolic Pulse Std.</th>
<th>Systolic BP Remote Medical Diagnostics kit</th>
<th>Diastolic BP Remote Medical Diagnostics kit</th>
<th>Systolic Pulse Std.</th>
<th>Diastolic Pulse Std.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>118.167</td>
<td>71.62</td>
<td>115.824</td>
<td>71.65</td>
<td>83.588</td>
<td>82.216</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td>88.0</td>
<td>47</td>
<td>83.7</td>
<td>49</td>
<td>50.0</td>
<td>50.0</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Maximum</td>
<td>170.7</td>
<td>102</td>
<td>170.3</td>
<td>100</td>
<td>120.0</td>
<td>112.0</td>
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<td></td>
</tr>
</tbody>
</table>

**Table 2 : (contd.)**

<table>
<thead>
<tr>
<th></th>
<th>Pulse Manual</th>
<th>Pulse By Remote Medical Diagnostics kit</th>
<th>O2 Saturation Std</th>
<th>O2 Saturation Remote Medical Diagnostics kit</th>
<th>Temp. Std</th>
<th>Temp. Remote Medical Diagnostics kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>81.08</td>
<td>97.686</td>
<td>97.218</td>
<td>96.983</td>
<td>97.069</td>
<td></td>
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<tr>
<td>Std. Deviation</td>
<td>17.090</td>
<td>1.9025</td>
<td>1.6649</td>
<td>1.3032</td>
<td>1.2983</td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td>50</td>
<td>91.0</td>
<td>89.0</td>
<td>94.2</td>
<td>94.5</td>
<td></td>
</tr>
<tr>
<td>Maximum</td>
<td>120</td>
<td>100.0</td>
<td>99.0</td>
<td>102.0</td>
<td>101.8</td>
<td></td>
</tr>
</tbody>
</table>
As per the AHA guidelines, new devices for BP measurement are recommended for approval if both systolic and diastolic readings taken are at least within 5 mm Hg of each other for at least 50% of readings.3 43/52 (82.7%) readings of the SBP obtained by the Remote Medical Diagnostics Kit were within 5 mm Hg of that measured by the mercury manometer. The value for DBP was even higher (47/52 (90.4%)). This figure includes the 4 patients with low DBP.

Pulse

One patient was excluded from analysis as he had atrial fibrillation and a markedly varying pulse rate. The pulse was measured by two methods (manually and with the saturation probe). The ICC for the two methods was 0.989 and 0.99 respectively indicating a high degree of agreement (Table 3). The Bland-Altman Plots also show good agreement (Figs. 6,7). The mean difference in the pulse measured was 1.5 (CI 0.5, 2.5) and -0.12 (CI -0.8, 0.66) respectively which is clinically insignificant (Table 3). Here again, we noted a strong correlation among the two methods in both cases (r=0.983 by manual method and r=0.987 by saturation method; p<0.001) (Table 3).

Oxygen Saturation

The pulse oximeter of the Remote Medical Diagnostics kit was noted to fit the finger well in adult patients of average built, but in those with a large and small built, the probe did not ensure a proper fit. One patient had to be excluded from analysis for this reason as the probe was not fitting well and the remedy kit gave a totally inappropriate reading (SaO2= 87% by Remote Medical Diagnostics Kit, SaO2=97% by standard method, the patient was acyanotic). Excluding this patient, the ICC was 0.763 indicating a moderately high

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Systolic BP</th>
<th>Diastolic BP</th>
<th>Pulse by SpO2</th>
<th>Manual Pulse</th>
<th>Oxygen Saturation</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlation Coefficient (r)</td>
<td>0.878*</td>
<td>0.826*</td>
<td>0.983*</td>
<td>0.987*</td>
<td>0.780*</td>
<td>0.839*</td>
</tr>
<tr>
<td>Regression Coefficient (β)</td>
<td>0.996</td>
<td>0.995</td>
<td>0.999</td>
<td>0.999</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Intraclass Correlation (ICC)</td>
<td>.9275</td>
<td>.9046</td>
<td>.9899</td>
<td>.9931</td>
<td>.7636</td>
<td>.9126</td>
</tr>
<tr>
<td>Mean Difference (CI)</td>
<td>2.34</td>
<td>-0.03</td>
<td>1.5</td>
<td>-0.12</td>
<td>0.65</td>
<td>-0.08</td>
</tr>
</tbody>
</table>

* p value<0.001, *p value<0.001, p value=0.003, **p value=not significant, *** p value=0.01, CI=Confidence Interval

![Fig. 4: Bland-Altman Plot of difference versus mean of SBP by the 2 methods](image)

![Fig. 5: Bland-Altman Plot of difference versus mean of DBP by the 2 methods](image)

![Fig. 6: Bland-Altman Plot of difference versus mean of saturation probes pulse by the 2 methods](image)

![Fig. 7: Bland-Altman Plot of difference versus mean of pulse by the 2 methods](image)
agreement (Table 3). The Bland-Altman plot also shows good agreement (Fig. 8). We again noted a good correlation between the two methods \((r=0.78, p<0.001)\) (Table 3). The mean difference in the oxygen saturation was 0.65 (CI 0.15, 1.14) which is not clinically significant (Table 3).

**Temperature**

The ICC was 0.912, indicating a high degree of agreement between the two readings (Table 3). The Bland-Altman plot also shows a high degree of agreement (Fig. 9). The mean difference between the two readings was -0.08 (CI -0.29, 0.12) (Table 3). Once again, a strong correlation was noted between the readings of the standard thermometer and the Remote Medical Diagnostics Kit \((r=0.839, p<0.001)\) (Table 3).

**Auscultation**

With the Remote Medical Diagnostics Kit, some background noise was heard in most patients and it did not interfere with proper diagnostic evaluation. In the presence of multiple electronic devices (e.g. cardiac monitors, ventilators, infusion pumps), the background noise increased and at times interfered with proper auscultation. This happened in 3 patients.

The Cohen’s kappa coefficient \((\kappa)\) for inter-rater reliability was used to compare the sounds heard with the two instruments. For the first and second heart sounds, the observed agreement was 96.1% (Table 4). The ‘\(\kappa\)’ value was 0.48 indicating moderate agreement. For the breath sounds, the observed agreement was 94.2% and the ‘\(\kappa\)’ value was 0.38, indicating fair agreement (Table 4).

For the added heart sounds and heart murmurs, a statistical analysis was not done as the numbers were small. Systolic murmurs and S3 gallops were well appreciated using the Remote Medical Diagnostics Kit. Low frequency sounds such as diastolic murmurs were not well appreciated. In 3 patients with diastolic murmurs, the murmur was not heard at all with the Remote Medical Diagnostics Kit.

**ECG**

Since the ECG involves a large number of parameters that needs to be compared and as we did not have automated software to do the same, the analysis was restricted to visual comparison. A visual comparison of the ‘P’ wave amplitude, width and polarity; PR segment; QRS complex width, polarity, and amplitude; ST segment and T wave width, amplitude and polarity of all the ECG leads were made. This was done by a trained cardiologist and in cases of a major discrepancy; the opinion of another senior cardiologist was taken.

Among the first 17 patients, a good comparison was noted between the two ECGs in most patients (Fig. 10 a,b). However in 3 patients who either had a Left Bundle Branch Block (LBBB) or Left ventricular hypertrophy (LVH), a marked ST elevation was noted in the Remote Medical Diagnostics ECG as compared to the Standard ECG (more than 5 mm ST elevation compared to the standard ECG). This could have lead to false diagnosis of myocardial infarction in these patients. In view of this major flaw, the manufacturers of the Remote Medical Diagnostics kit (viz. Neurosynaptic Communications Pvt. Ltd., Bangalore) decided to reexamine their software for the ECG recording. A new software was made available to us after making the necessary corrections. Patients with LBBB, RBBB and LVH as well as those without conduction or voltage abnormalities were again tested. This time, a very good correlation was noted for all ECG parameters including the ST segment for all patients (including those with and without conduction or voltage abnormalities). One patient with acute MI was also studied. An excellent correlation was noted for the degree of ST segment elevation, loss of R wave amplitude and development of Q waves (Figs. 11a,b).

In one patient, who had inverted P waves in the inferior leads on the standard ECG, the Remote Medical Diagnostics ECG recorded the P waves as upright. In another patient, a discrepancy was noted in the chest lead QRS amplitudes. With the exception of these 2 patients, overall there was

<table>
<thead>
<tr>
<th>Table 4: Kappa values for auscultation</th>
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<tbody>
<tr>
<td>Kappa coefficient</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>S1</td>
</tr>
<tr>
<td>S2</td>
</tr>
<tr>
<td>Breath Sounds</td>
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an excellent correlation between the standard and Remote Medical Diagnostics ECG. Thus 94.4% ECG’s had an excellent correlation with the improved version of the Remote Medical Diagnostics ECG software (Figs. 10, 11).

**DISCUSSION**

Since the first documented use of telemedicine at the University Of Nebraska, College Of Medicine in 1959, telemedicine has been growing progressively. Telemedicine in India began in December, 1999 with the Rural Telemedicine Centre in Aragonda, a remote village in the Chittoor district of Andhra Pradesh. The field of telemedicine has since expanded, with about 500 telemedicine centres linked with about 50 specialist hospitals across the country. An estimated 0.15 million tele-consultations have been provided. Some of the leading specialist hospitals include AIIMS, New Delhi; SGPGIMS, Lucknow; Apollo group of hospitals; Tata Memorial Hospital, Mumbai; Escorts Heart Institute, New Delhi etc. C-DAC, Pune; CEDTI, Mohali, and the various IITs have been actively involved in the development of indigenous software for telemedicine. The government’s 11th Five-Year-Plan (2007–2012) has allocated 200 crore rupees to telemedicine.

The field of cardiology has widely embraced telemedicine. Echocardiograms, electrocardiograms, heart sounds and other images can be readily transmitted electronically and evaluated accurately. However, application of these services in the developing countries has been limited by 2 factors, namely cost and limited bandwidth. In addition none of the existing telemedicine programs have the ability to evaluate multiple human parameters. The Remote Medical Diagnostics kit is a significant advance in that it needs a very low bandwidth. It is an indigenously developed technology and hence the cost is low and affordable. In addition, it can transmit 6 basic clinical parameters which can easily determine a patient’s clinical status.

The applications of this kit are numerous. Among the many fields, its application in critical care and cardiology are worth mentioning. BP and oxygen saturation enable us to determine whether a patient is in shock and whether he is in need of ventilator support. The presence of these features would indicate the need to immediately shift the patient to a more equipped hospital.

The ECG capability of the Remote Medical Diagnostics kit enables a diagnosis of acute MI to be made. This is especially useful in the setting of prehospital thrombolysis. Also, in case of doubt, the primary care physician can transmit the ECG to a cardiologist for a second opinion before administering thrombolytic therapy.

The electronic stethoscope enables a preliminary diagnosis of a valvular or congenital heart disease to be made. A final diagnosis would be made after transfer to a hospital with echocardiographic facilities.

As important as it is to diagnose a heart ailment, it is equally important to rule out a heart ailment. The relief
Medical Diagnostics kit was clinically validated as far as the agreement of 94.4%. In short, at the bedside, the Remote and Remote Medical Diagnostics kit ECG with an observed excellent correlation was seen between the standard methods and the Remote Medical Diagnostics kit for the measurement of systolic and diastolic BP, pulse and temperature. Two patients were on inotropic support with a narrow pulse pressure (SBP>90 mmHg). The Remote Medical Diagnostics kit accurately measured the BP in these patients although as mentioned earlier it overestimated the BP in patients with DBP < 50 mmHg. Further, the examining physicians were cardiologists. The results, as far as interpretation of heart sounds and murmurs are concerned, may not be replicated if the study is carried out in a different study environment by investigators with varying levels of expertise in auscultation.

**CONCLUSION**

There was a high degree of agreement between the standard methods and the Remote Medical Diagnostics kit for the measurement of systolic and diastolic BP, pulse and temperature. There was a moderately high agreement for the measurement of oxygen saturation. For the first and second heart sounds, there was moderate degree of agreement and for breath sounds, the agreement was fair. There were difficulties in appreciation of diastolic murmurs. An excellent correlation was seen between the standard and Remote Medical Diagnostics kit ECG with an observed agreement of 94.4%. In short, at the bedside, the Remote Medical Diagnostics kit was clinically validated as far as the parameters of BP, pulse, temperature, oxygen saturation, heart and breath sounds, and ECG are concerned.

**REFERENCES**

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Patrick W Tank, PhD and Thomas R Gest, PhD

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For further details contact : Dr. P Chandrasekhara, Programme Director and Dr. M Narayanaswamy / Dr. Prasanth, Convenors, Medical Education and Research Trust, API Bhavan, No. 16/F, Millers Tank Bed Area, Vasanthnagar, Bangalore - 560052.
Ph. No. 080-22353525; Email : poocha_sekhara@yahoo.co.in

Announcement

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