

Research Article

Advances in Telemedicine: Remote Vs. Conventional Physical Examination

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Abstract

Importance: The accuracy of novel devices enabling remote physical examination (PE) of patients has not been clinically established.

Objective: In this study we sought to evaluate the performance of a remote-based diagnostic tool enabling PE as compared to the standard PE.

Design: A prospective study of a convenience sample.

Setting: The emergency department (ED) of a university affiliated, tertiary, pediatric facility between July 2016 and January 2017.

Participants: Children aged 2-18 years referred to the ED.

Intervention: Eligible patients underwent PE of the heart, lungs, ears and throat by a single physician using a remote device (RD), and data captured got stored on a cloud-based server and later interpreted by a single EDA physician. Upon completion of the RD examination, a standard PE was held by an ED attending (EDA) physician and results were documented in the hospital electronic medical records. All physicians were blinded to each other PEs. The quality of the data retrieved, user satisfaction and RD adverse events were also recorded.

Outcome measures: The agreement between the RD and standard PE results served as the main outcome measure. Secondary outcome measures were the quality of the data retrieved and user satisfaction of the RD.

Results: The cohort included 138 children (59% male) of mean age 8.1 ± 5 years. Analysis of the agreement between the remote device and conventional examinations yielded the following kappa values: heart, 0.674; right lung, 1.000; left lung 1.000; right ear, 0.467; left ear, 0.725; and throat 0.796. The average scores for quality of the data were as follows: heart, 4.94; right lung, 4.35; left lung, 4.31; right ear, 3.93; left ear, 4.00; and throat, 4.93. The corresponding average scores for user satisfaction with the remote device experience were 4.95, 3.92, 4.10, 4.64, 4.76 and 4.77. No adverse events were recorded.

Conclusions and Relevance: Remote device assisted PE of children presenting to the ED appears to be efficient and safe, with overall good agreement of the results with the standard PE. Further research is required to establish its role as part of a routine telehealth visit and its performance when used by non-professional persons.

Keywords: Pediatrics; Children; Emergency medicine; Medical service; Physical examination; Telemedicine; Telehealth; Remote device; Tele-examination; COVID-19

Abbreviations: ED: Emergency Department; EDA: Emergency Department Attending; PE: Physical Examination; RD: Remote Device

Introduction

Telemedicine is the use of electronic communication technologies to provide and support health care for individuals separated by distance, time, or mobility from the medical practitioner [1-6]. Importantly, it also enables communication between remote physicians in medical specialties with a manpower shortage, including internal, and emergency medicine [7-9]. Telemedicine is applicable to a broad array of medical fields and both the quality and quantity of transferable data are increasing with the ongoing development of novel technological solutions and services [10-12].

Telemedicine is currently available in three primary operating modes: online, for example, for electrocardiography readings on home cardiac monitors [13] and pediatric consultations [14,15]; offline, for interpretation of radiology, dermatology, and pathology findings; and interventional, for cardiac and other surgical procedures [16,17]. Its scope is expected to expand in the wake of increasing patient requirements for accessible quality medical care on the one hand, and the need to reduce skyrocketing healthcare costs on the other. Indeed, hospitals have begun to incorporate telemedicine into daily medical routines in a wide array of disciplines [18-25]. In a recent prospective study, McDaniel et al. compared the performance of a novel handheld telehealth device with stand-alone digital examination tools and showed that the telehealth device outperformed the stand-alone digital stethoscope and otoscope [26]. However, there are no studies comparing its performance with the conventional standard physical diagnosis.

Herein, we sought to investigate the use of a new telemedicine device in the setting of pediatric medical care and compared the virtual examination tool with the standard PE in 138 pediatric ED patients. Basic physical examination findings such as heart rate and breath sounds, as well as user and patient satisfaction, were assessed.

Device Description

The remote device used in the study (TytoCare) is comprised of a camera, microphone, screen and wireless communication

unit. It is equipped with an infrared basal thermometer, digital stethoscope, digital otolaryngoscope and tongue depressors. The device can operate in online and offline modes; while voice and on-screen instructions help navigate users toward the necessary anatomic structures. Physical examination (PE) outcomes are displayed locally and/or submitted via internet to the remote server where they are stored for documentation and interpretation by medical staff in real time and/or at a later date. The device adheres to the International Electrotechnical Commission standard for medical products and is Food and Drug Administration approved.

Research Hypothesis

We hypothesized that utilizing the remote device to conduct a medical examination in the pediatric emergency department and establish a diagnosis from a remote location achieves high performance scores in terms of patient and user satisfaction along with a good diagnostic accuracy.

Methods

Setting and Patients

The study was approved by the local Institutional Review Board and the Israel Ministry of Health and registered with the National Institutes of Health (no. NCT02723890). A preliminary 3-day trial was conducted to calibrate the device and assess a test sample.

A prospective comparative study of a convenience sample was carried out in a university-affiliated tertiary pediatric medical center. The cohort included children aged 2-18 years who were referred to the emergency department in a 3-month period and had a score of 3-5 on the Canadian Triage and Acuity Scale (CTAS) [27,28] at presentation. Patients with a lower CTAS score, pregnant teenagers, carriers of resistant bacteria, and patients with disabilities were excluded. The parents of all study participants signed an informed consent form before enrollment.

Study Procedure

Eligible patients were transferred to a room within the emergency department prepared in advance for the study. A standard medical history was obtained, and patients were examined (heart, lungs, ears, throat) by a single physician using the remote device (Physician A). The data captured (video and audio recordings) got stored on a cloud-based server.

The heart examination consisted of pulse measurement (20 seconds) and evaluation of the traditional 4 auscultation points (aortal, pulmonic, tricuspid, and mitral). The lungs were examined

at 8 auscultation points, 4 anterior and 4 posterior. At each auscultation point (heart and lungs), an 8-second segment was recorded. Disposable child-size-adapted speculums (tips) were used for the ear examination and disposable tongue depressors for the throat examination. Prior to and following each examination, the device and its modules were disinfected.

Upon completion, a standard PE was held by one of the ED attending (EDA) physicians (Physician B). The results were documented in the Electronic Medical Record (EMR) (Chameleon system, Elad Health, Tel Aviv, Israel).

The data collected using the remote device and saved in the cloud were reviewed and interpreted by another single EDA physician at a later date (Physician C).

All the results were documented in dedicated Excel sheets. During and after the study, complete compartmentalization of the examination results was maintained among the various physicians involved.

Safety evaluation

Potential adverse effects and complications were evaluated during the RD PE. These possible complications included lacerations, bleeding (auricular, oral) and rapture of the tympanic membrane, burns, allergic reactions and contamination similar to those found while conducting conventional PE.

Data Analysis

The results for each anatomic site examined for each patient were rated by Physician B (standard PE) and Physician C (reviewed data from remote device) on a scale of 0 (not assessable due to poor image/audio quality or physical factors), 1 (normal), and 2 (abnormal) documenting a tentative diagnosis.

Physician C rated the quality of the remote examination for each patient on a scale of 1 (poor) to 5 (excellent).

Physician A rated the experience of using the remote device on a scale of 1 (dissatisfied) to 5 (highly satisfied).

Statistical Methods

Statistical analyses were performed with BMPD software [29]. Categorical variants were tested using the kappa method and interpreted as follows: $\kappa > 0.75$, excellent agreement; $\kappa = 0.4-0.75$, moderate-good agreement; $\kappa < 0.4$, weak agreement, $\kappa = 0$, agreement based only on incidence; $\kappa < 0$, agreement worse than that based only on incidence.

Results

Of the 156 patients found eligible for the study, 138 agreed to participate. Two of them were disqualified because the parents withdrew consent. Two additional patients were referred for further medical investigation at the emergency department prior to an examination by Physician A. Thus, 134 patients were evaluated with the remote device. An additional 17 patients were later excluded from the analysis (due to technical difficulties or partial documentation on the EMR). The final cohort consisted of 117 patients (Figure 1), 48 females (41%) and 69 male patients (59%), with a mean age of 8.1 ± 5 years (median 7.9; range 2-17.6). The distribution of chief complaints in patients enrolled were as follows (Figure 2): Minor Trauma (34%), Ear-Nose-Throat (13%), Respiratory (7%), Allergy (6%), Abdominal Pain (5%), and Miscellaneous in 13% of patients. Conservative heart auscultation revealed murmurs in 13 of 114 patients. Seven of them were also documented by the remote physician (re-evaluation of recorded data revealed normal heart sounds in the 6 “missed” murmurs), 6 patients were clinically diagnosed with lung pathologies (pneumonia, asthma exacerbation), all confirmed by chest X-rays, of which 4 had bi-lateral involvement, 2 unilateral. All had abnormal auscultation using the remote auscultation. Eleven ear pathologies (including acute otitis media and externa, foreign body, and cholesteatoma) were identified, 9 of them were also diagnosed using the device. To note, an additional 7 abnormal ear findings were diagnosed by tele-examination only. Eleven oral cavity abnormalities (foreign bodies, tonsillitis, pharyngitis, peritonsillar abscess, aphthous stomatitis) were found, 9 of them were confirmed with the remote device.

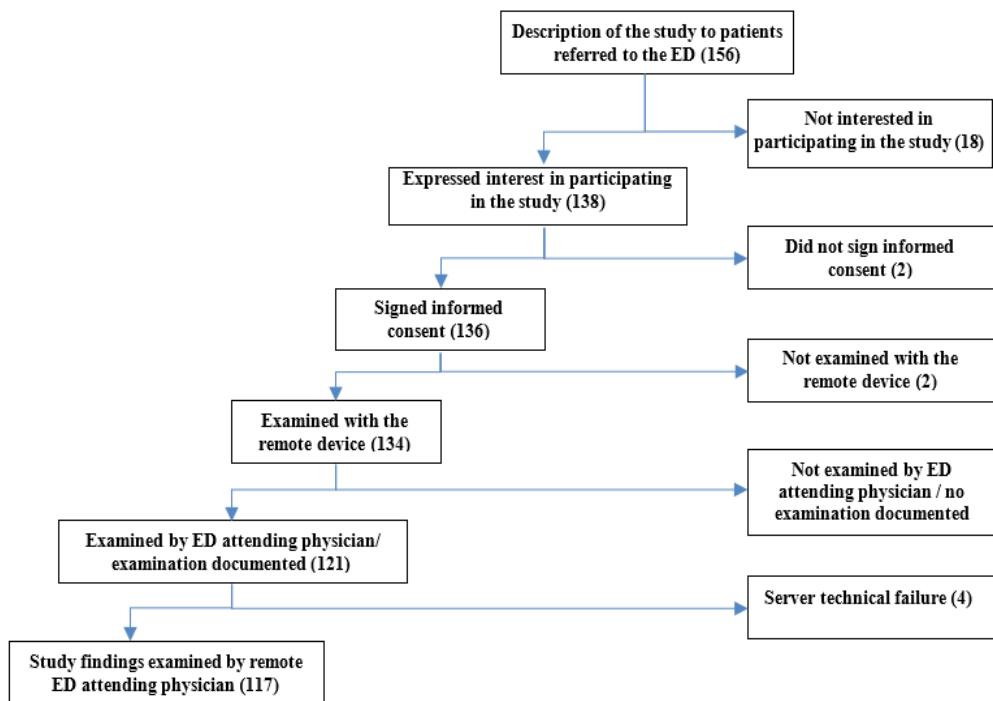


Figure 1: Flow chart of study enrollment process.

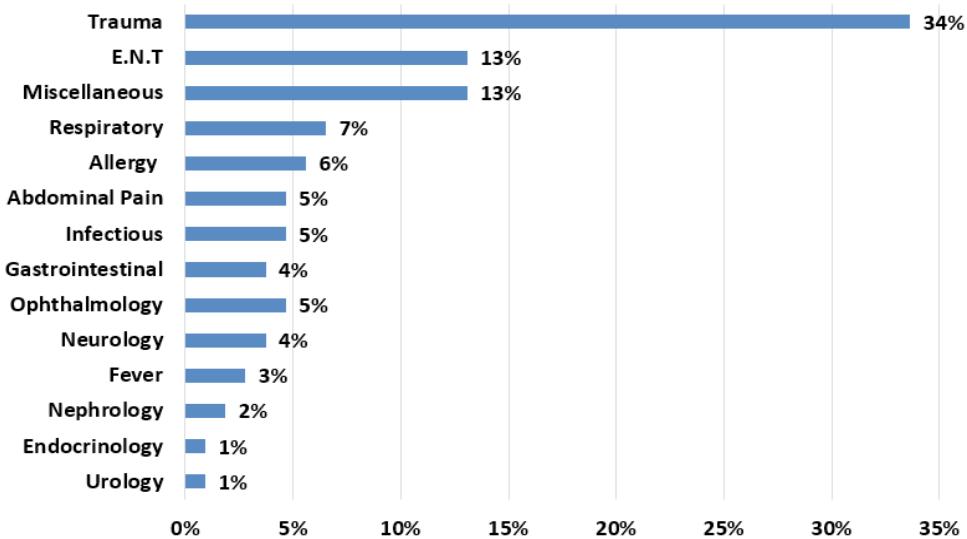


Figure 2: Final diagnoses according to the discharge sheets.

The agreement between the conventional and tele-examinations yielded the following kappa values: heart, 0.674; right lung, 1.000; left lung 1.000; right ear, 0.467; left ear, 0.781; and throat, 0.796. The overall average score for examination quality (as rated by analyzing Physician C) was 4.44 (range 1-5). User satisfaction (as rated by device users) was 4.52 (range 1-5) (Table 1). The specific findings for each site are described below and in Table 2.

Anatomic site	n	Calculated n	Kappa	Remote Device Examination Quality	User Experience (n=134)
Heart	115	114	0.674	4.94	4.96
Right lung	115	114	1	4.35	3.96
Left lung	115	114	1	4.31	4.12
Right ear	115	87	0.467	3.93	4.65
Left ear	114	89	0.781	4	4.76
Throat	109	102	0.796	4.93	4.78

Note: Quality of examination and user experience were rated on scales of 1 (low) to 5 (high).

*EDA, ED attending physician.

Table 1: Average scores for quality of remote examination, user experience, and kappa value of agreement between the remote and senior ED physician, by organs examined.

Anatomic site		Normal exam	Pathologic finding [^]	Total cases
Heart	EDA	101	13	114
	R	107	7	
Right lung	EDA	108	6	114
	R	108	6	
Left lung	EDA	110	4	114
	R	110	4	
Right ear	EDA	83	4	87
	R	79	8	
Left ear	EDA	82	7	89
	R	81	8	
Throat	EDA	91	91	102
	R	11	11	

R*, Remote Physician (physician C); EDA**, Attending Emergency Department physician (physician B).

Pathologic Finding ^ - heart murmurs; Lungs - pneumonia, asthma exacerbation; Ears - acute otitis media and externa, foreign body, and cholesteatoma; Throat - foreign body, tonsillitis, pharyngitis, peri-tonsillar abscess, aphthous stomatitis

Table 2: Distribution of Physical Examination Results between Remote* and EDA** physicians by normal versus pathologic findings.

Sensitivity and specificity of the exams (as compared with physical examination) ranged between 75-100% sensitivity, and 94-100% specificity (Table 3). No adverse events or side effects were reported.

Anatomic site	Sensitivity	Specificity	PPV	NPV	Efficiency
Heart	53%	100%	100%	100%	94.70%
Right lung	100%	100%	100%	100%	100%
Left lung	100%	100%	100%	100%	100%
Right ear	75%	93.98%	37.50%	98.73%	93.10%
Left ear	75%	97.53%	75%	97.53%	95.51%
Throat	81.82%	97.80%	81.82%	97.80%	96.08%

PPV: Positive Predictive Value; NPV: Negative Predictive Value

Table 3: Sensitivity, specificity, positive predictive value, negative predictive value, and efficiency of the remote examination as compared with the standard physical examination.

Discussion

This study shows that the remote device is efficient and safe for remote diagnosis of pathologies in 6 anatomic areas as compared to the standard PE in the emergency department. Although the medical literature contains a considerable number of studies describing telemedicine trials, only one was found comparing performance of this remote device with other stand-alone digital examination tools [30], and there are no studies comparing its performance with the conventional standard physical diagnosis, precluding comparisons with the present study.

In the heart examination, results were discrepant in 6 patients: rated normal by Physician C and abnormal by Physician B ($\kappa=0.674$). Four of those were examined by the same EDA physician and might be attributed to over-diagnoses. The average score for examination quality (4.94) was similar to the score for user experience (4.95). Both these indexes were slightly impacted by examination variants (e.g., adolescent age in girls, restlessness during examination).

The lungs were examined with the same device module used for the heart with the addition of a filtering mechanism to increase respiration sounds and distinguish them from background noises. The availability of the filters may account for the complete agreement between the RD and standard examinations ($\kappa=1.0$). However, the scores for examination quality (right lung 4.35, left lung 4.31) and user experience (3.92 and 4.1, respectively) were lower than for the other anatomic sites, reflecting the problems inherent in lung examinations: primarily, screening the heart sounds on the left side, in addition to patient cooperation, considerations of individual body build, age and gender, and the conic shape of the device itself, which makes the fix on the auscultation point less stable. Moreover, non-auscultation-dependent factors related to the individual respiratory process, for example, chest expansion during respiration and signs of respiratory distress, which are integral to the PE and essential for the accurate assessment of the respiratory system, are not available within the remote examination device. Nevertheless, it seems that despite these deficiencies, the overall performance was particularly good.

Agreement was moderately good for the right ear ($\kappa=0.467$) and excellent for the left ear ($\kappa=0.781$). We attributed the discrepant cases, in part, to differences in image quality. When image quality was high, the RD-assisted examination was superior: It identified 3/4 pathologies in the right ear and 6/8 in the left ear found on conventional examination, in addition to another 7 missed on conventional examination (5 right ear, 2 left ear). All were verified on repeated evaluation of the saved data. However, when the eardrums were not optimally demonstrated visually, whether because of the presence of cerumen, an anatomically narrow canal, poor inspection technique, or low patient cooperation, the remote-assisted diagnosis was unsatisfactory (quality scores: 4.0

right ear, 3.93 left ear). The high number of equivocal results occurred mainly because such decision-supporting data as topical sensitivity and pain, auricular bulge, and enlarged lymph nodes were unavailable to the interpreting physician. Nevertheless, we have no good explanation for the difference in performance between the left and right ears other than Physician's A otoscopic technique.

The high user experience ratings for the ears (left, 4.76; right, 4.64) and the high rate of patient cooperation (94.3%) perhaps reflect the simple and convenient operation of the device.

In the throat examination, physician agreement was found for 98 of the 102 examinations performed ($\kappa=0.796$). The throat examination was associated with the highest number of uncooperative patients. Among the 4 discrepant cases, the RD missed physician findings of redness in one and enlarged tonsils in another. In the other 2 cases, the EDA physician missed RD findings of postnasal drip in one and small exudates in the other.

Although direct comparison of our study with the literature was impractical, we compared our findings for overall image quality with previous studies that evaluated the extent of agreement between independent physicians for diagnoses in the heart, lungs, ears, and throat. The studies were identified by a PubMed search using the following keywords: interobserver variability, interobserver agreement, and reliability. We found that in the few studies that measured this factor, moderate-low and even lesser agreement was reported. Margolis et al. reported kappa values of 0.08 to 0.61 for final diagnoses in a study of 350 patients evaluated by two ear, nose, and throat specialists [31]. In studies of lung examinations, Gjlrup, et al. reported kappa values of 0.68 to 0.15 for the final diagnosis in 350 patients [32] and Wipf, et al. reported values of 0.43 to 0.18 [33]. Schwartz, et al. found moderate agreement for throat examinations [34] and Lok, et al. calculated kappa values of 0.05 to 0.18 for the diagnosis of Gallop sounds S4, S3 [35].

We believe that this experience emphasizes the unique and timely opportunity telemedicine services and technologies may play, as has been suggested, during pandemics [36-38], in addition to its role in the routine pediatric medical care.

Limitations

This study has a few inherent weaknesses. The small sample size precluded segmentation by age or other variables. The sample population was selected randomly from patients referred to the emergency department, such that a change in the relative percentage of participants with pathological findings could lead to different results. As the study was conducted in a single medical center, the findings are not generalizable. It was also conducted during the spring/summer months; in the winter/fall season, the relative percentages of patients might have been different and

the willingness of families to participate might have been lower. Finally, auscultation times and the length of the video segments could have impacted the ability of Physician C to interpret the findings.

Conclusion

Remote device assisted physical examination (heart, lungs, ears, throat) of children presenting to the emergency department appears to be efficient and safe, with overall good to cautiously excellent agreement of the results with the standard PE. Further research is required to establish its promise as a tool to assist in the accurate diagnosis of patients as part of a routine telehealth visit, and its potentially beneficial contribution in times of pandemics such as the current COVID-19, as well to investigate its performance when used by non-professional persons.

Clinical Trial Registration: The Efficacy and Safety of Using the novel Tyto Device, NCT02723890. Data Sharing Statement: Unidentified individual participant data will not be made available.

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Conflict of Interest: The authors declare that they have no conflict of interests whatsoever. The corresponding authors had sole access to all the data in the study and were solely responsible for the study design, collection, analysis, interpretation of the data, writing of the report and the decision to submit the paper for publication.

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