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Evaluating the efficacy of digital otoscopes in rural pediatric otitis media diagnosis: A comparative study of general practitioners and ENT specialists

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ABSTRACT

Background: Otitis media is a prevalent childhood illness, particularly among specific groups. However, its diagnosis has been of a serious issue, which is exacerbated in underprivileged regions with limited access to Ear, nose and throat specialists. This study aimed to evaluate the agreement between diagnoses of ear diseases made by general practitioners using digital otoscope and standard otoscope, and the diagnoses determined by an otolaryngologist, as the gold standard.
Methods: This study examined ear examinations in rural health centers, comparing digital otoscope and standard otoscope, screenings by general practitioners (GPs) with remote digital otoscope evaluations by an ENT specialist. The research involved grading tympanic membranes using the OM-grade scale across three diagnostic groups: GP otoscope, ENT video otoscope, and GP video otoscope. Diagnostic agreement was assessed using Cohen's kappa coefficient, and both parents/guardians and physicians provided feedback on the examination methods, exploring the potential of telemedicine in remote medical assessments.
Results: A total of 82 children, 45 boys and 37 girls, were included in the study from 4 rural health centers. There was a significant agreement (0.90%) between the diagnoses of the ENT specialist and the general practitioner with the video-otoscope examining the patients' ears. The results of the physician survey showed that the physicians were in complete agreement (100%). The system is easy to use and the video-otoscope can be useful for telemedicine and greater patient interaction. It is worth noting that the results of this study showed a high level of satisfaction (98%) among the parents of the children after exposure.
Conclusion: Our findings provide strong evidence that digital video otoscope can enhance the diagnostic accuracy of GPs in detecting ear diseases, especially in settings with limited access to ENT specialists. By facilitating improved visualization, remote consultation, and more efficient referrals, this technology holds promise for empowering primary care providers and expanding the reach of quality ear healthcare. Integration of video otoscope into telemedicine platforms could further support GPs in underserved areas, improving patient outcomes while optimizing healthcare resources.

1. Introduction

Otitis media is the most common disease [1] and the main cause of hearing loss in children [2]. However, diagnostic inaccuracies are prevalent [3]. Errors in diagnosis and treatment can increase the adverse effects on the quality of life and increase healthcare costs [4]. According to the American Academy of Clinical Practice (AAP) clinical guidelines, visualization of the tympanic membrane is necessary for the AOM diagnosis [4]. Otoscopic evaluation is commonly used to visualize the tympanic membrane not only for otolaryngologists but also for GPs [5]. In many developing countries, due to restricted access to otolaryngology specialists in poor areas marked by a higher burden of OM, GPs manage

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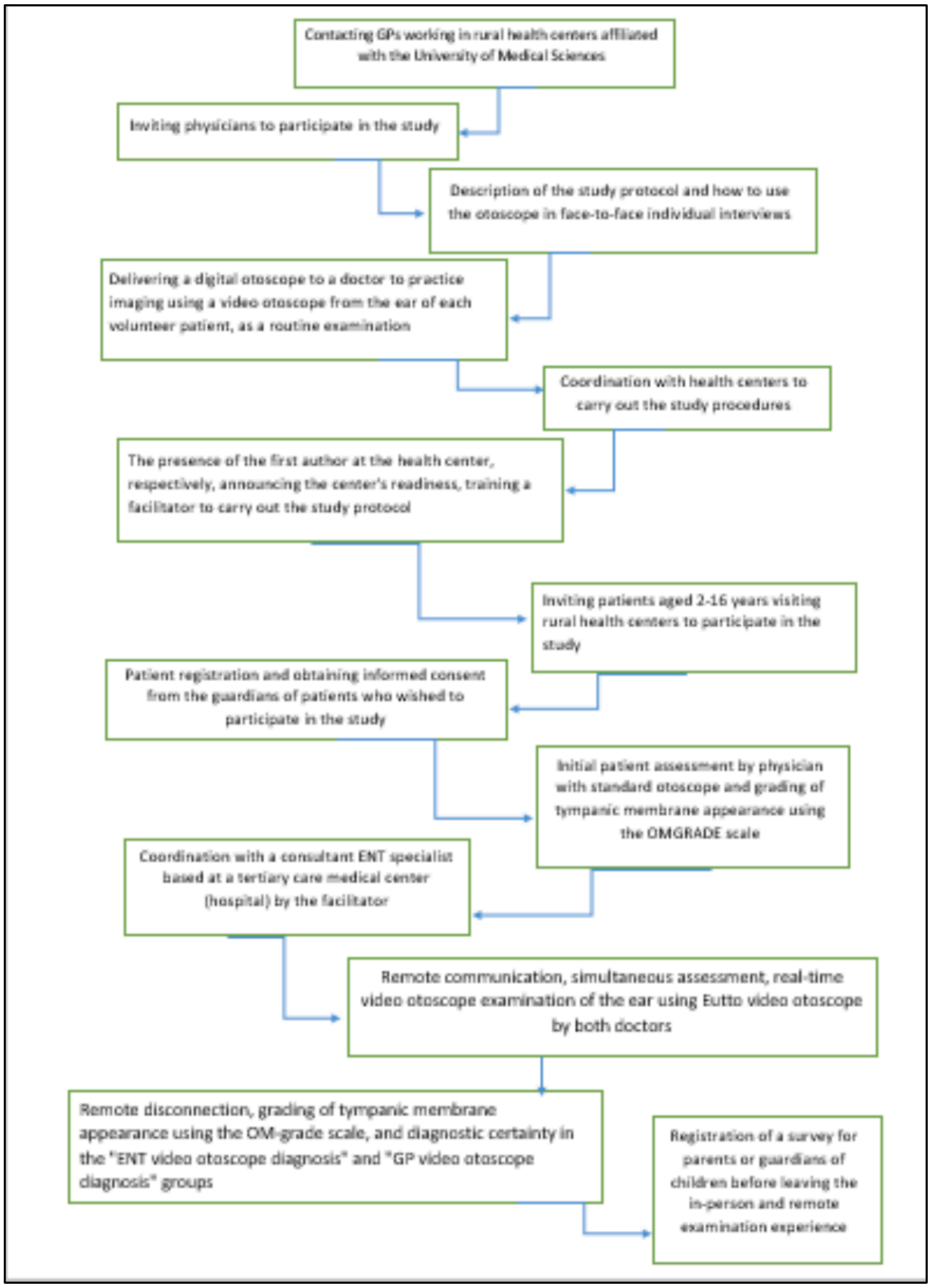


Fig. 1. Shows a schematic workflow/patient/data analysis.

most ear diseases using manual otoscopes.

Clinical evaluation using a manual otoscope is not easy due to problems such as the narrowness of children's external ear canal (OEC), orientation of the earlobe and child's restlessness [6] and in some cases can lead to the wrong diagnosis of otitis media [7]. Misdiagnosis can delay treatment and increase the risk of hearing loss and antibiotic resistance [8,9]. Therefore, it is necessary for GPs to acquire Otoscopic diagnostic skills for a correct diagnosis and treatment.

Teaching the otoscope evaluation of tympanic membrane during medical internship is based on a learning model of apprenticeship training in ambulatory care environments [4]. Medical students need hands-on experience with the otoscope and visualization and evaluation of the tympanic membrane to master otoscope diagnostic skills. Evidence shows that newly graduated physicians, while anxious about children's ear evaluation [10], complained about the lack of learning opportunities for otoscope practice and requested better training to improve otoscope skills [11–13].

The suggested ways to improve otoscope skills are the use of digital video otoscopes as an educational aid [14], which allows medical students and professors to record or document a patient's simultaneous evaluation [15].

Traditional video otoscopes pose challenges regarding portability, primarily due to their reliance on external attachments such as laptop computers and a stable wireless internet connection. Additionally, their relatively high cost limits accessibility, particularly for healthcare providers in rural areas, low-income countries, or economically disadvantaged communities [1]. Studies indicate that traditional otoscopes can hinder timely diagnoses in these settings due to limited availability and high costs [2]. In response to these barriers, video otoscopes priced under $50 have been developed to transform smartphones into digital otoscopes [3]. These affordable options are marketed directly to consumers and are readily available for purchase online, potentially increasing access to Otoscopic examination in underserved populations [4].

Studies have shown GPs' interest in using such video-otoscopes for ear evaluation [16]. It has also been reported that the video-otoscope evaluation has the same or better accuracy than the face-to-face otoscope performed by a GP [17–19]. With the emergence of epidemics such as COVID-19, the healthcare system is in dire need of cost reductive measures and mechanisms to provide tele-health care services through telemedicine. Therefore, it is necessary to evaluate the potential application of low-cost tools for remote visits. For this purpose, the present study examines the agreement between GPs' diagnoses based on ear evaluation using the digital otoscope with the gold standard.

2. Materials and methods

2.1. Design of study

This cross-sectional study aimed to evaluate the diagnostic accuracy of Otoscopic examinations in children visiting rural health centers between August 2019 and June 2020. The study involved three diagnostic assessments: [1] OTO-GP: general practitioners (GPs) using a standard otoscope, [2] VO-GP: GPs using a video otoscope, and [3] VO-ENT: remote diagnosis by an otolaryngologist using a video otoscope, which served as the reference standard.

2.2. Experimental environment

A quiet room with sufficient lighting and stable internet connectivity was prepared at each rural health center for Otoscopic evaluations. The video otoscope was conducted using a portable digital otoscope connected to a smartphone via Bluetooth. The device featured a high-definition (HD) camera with integrated LED illumination and a narrow probe suitable for visualizing the tympanic membrane. The device transmitted live images or video of the external auditory canal and tympanic membrane to the smartphone, enabling real-time remote consultation. Custom software was installed on the smartphone to support image capture and sharing. Remote communication with the ENT specialist was conducted via Google Meet.

At the hospital site, a laptop (Dell Inspiron N5110) was utilized by an ENT specialist in a quiet room to provide remote screening services. Otoscope video software and Google Meet were installed on this laptop for remote computer-based examinations.Internet connectivity at the hospital was primarily established using a wired LAN. Since the internet speed and stability varied during the testing days, various internet solutions, including dongle devices and mobile-based internet, were occasionally employed. In rural health centers, internet connectivity was maintained using mobile-based internet.

2.3. Participants

A total of 33 GPs from rural health centers affiliated with Jiroft University of Medical Sciences were contacted, and 26 agreed to participate. After receiving training on the use of the digital otoscope, participating GPs were asked to use the device for one week in routine examinations to become familiar with video otoscope in children. Technical support was available from the research team as needed.

2.4. Setting of study

Each child was initially examined at the clinic by a GP using a standard otoscope (Macroview Otoscope, Welch Allyn, and Skaneateles Falls, New York, USA), age-appropriate audiometry (Interacoustics AD226/AC30), and Earscan tympanometry, conducted by an audiology specialist or a trained remote medical facilitator. Diagnoses were recorded using the OM grading scale under the category "OTO-GP.".

Subsequently, the same child was evaluated in real-time remotely by an otolaryngologist located approximately 360 miles away, using a video otoscope. The diagnosis provided by the otolaryngologist was considered the gold standard, consistent with previous studies [20–23] and because otolaryngologists typically guide the management of pediatric patients.

Table 1
Diagnosis of otitis media.

Diagnosis	Description
Normal	A translucent TM in a fairly normal position without signs of middle ear fluid
OME	A translucent TM with visible middle ear fluid or an opaque TM in a fairly normal position and no clinical signs of acute infection
AOM	An opaque and bulging TM together with clinical signs of acute infection such as nostalgia and fever
CSOM	A TM with chronic perforation
NPD	Ear status not possible to determine

This evaluation was conducted simultaneously by both physicians to minimize redundancy in patient assessments. Physicians who evaluated patients' ears using a digital otoscope were not constrained by time. However, based on informal observation and pilot testing, most reviews appeared to take between 30 s to 2 min, depending on case complexity. This approach was chosen to simulate real-world diagnostic conditions, especially in telemedicine environments where such flexibility is common. After the evaluation and online communication were completed, both the ENT and the GP independently recorded their diagnoses based on the appearance of the tympanic membrane, utilizing the OM-grade scale in the "VO-ENT" and "VO-GP" groups. Before leaving the room, the children's parents or guardians completed a survey regarding their experiences with both face-to-face and tele-evaluation. Upon the study's conclusion, the physicians filled out a survey to assess the quality of the video otoscope evaluation (Fig. 1).

2.4.1. Tele-consultation

The Eutto wireless otoscope used in this study was selected based on affordability, accessibility, and technical compatibility with smartphones. The device offers 1920 x1080P (2.0MP) resolution imaging, 1.0x to 4.0x digital magnification of the tympanic membrane, and connects to a smartphone or tablet via Wi-Fi. It was easy to operate in low-income rural areas. Neither the research team nor the participating physicians had any financial affiliation with the manufacturer of the device.

2.5. Diagnosis

Face-to-face and remote examination diagnoses were made using the OM-grade scale [24]. Table 1 shows the types of diagnosis of otitis media including normal tympanic membrane (n-TM), otitis media with effusion (OME), acute otitis media (AOM) and chronic suppurative otitis media (CSOM). If the state of TMs was not determined in otoscope or in simultaneous video otoscope evaluation (due to non-cooperation, Cerumen obstruction, or low image quality), it was labeled as NPD.

2.6. Subjects, inclusion and exclusion criteria

2.6.1. Population of study

Children (aged 2–16) among the outpatient visitors to 4 rural health centers affiliated with Jiroft University of Medical Sciences (in the cities of Roodbar, Ghal'e-Ganj, Manujan, and Faryab), who had ear discomfort, were selected to participate in the study. The exclusion criterion for physicians was their unwillingness to participate in the study. The exclusion criteria for patients included external ear infections, the presence of tympanostomy tubes, or chronic perforation of the tympanic membrane, as well as conditions affecting the anatomy of the ear canal or middle ear (for example, Down syndrome). Each child was included in the study only once. All children and their caregivers were interviewed by the research team. A range of clinical measures, including ear assessment results, were recorded as part of the baseline evaluation.

2.6.2. Instrumentation and procedure

The Otoscopic ear evaluation questionnaire for patients consisted of two items. The first item enquired about the patients' demographic information, including age and sex. The second item enquired about the appearance of tympanic membrane rated on the OM-grade scale. Physicians evaluated the quality of video otoscope examination through a 5-item qualitative questionnaire on a 5-point Likert scale. Each of the five-choice items was rated on a range between "totally agree" (score 5) and "totally disagree" (score 1). The satisfaction of patients' guardians with the experience of face-to-face evaluation and simultaneous evaluation was rated using an 11-item questionnaire on a 5-point Likert scale. Each of the five-choice items was rated on a range between "totally agree" (score 5) and "totally disagree" (score 1). The validity and reliability of the questionnaires were substantiated using face validity and content validity tests and the opinions of three medical informatics professors and three otolaryngology specialists (faculty members). The reliability of questionnaire was confirmed using Cronbach's alpha test ($r = 0.95$).

The physicians' (GP and ENT) evaluations were recorded in an Excel spreadsheet and analyzed in SPSS24. The primary analysis involved the estimation of absolute difference between the clinicians' evaluation and the gold standard in the proportion of ears evaluated via the two methods. The diagnostic consistency of otoscope and video-otoscope was measured as the percentage of agreement, and Cohen's kappa was also calculated using video-otoscope as the gold standard. Landis and Koch's kappa values below 0 meant no agreement, 0–0.20 implied mild, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0. 80 substantial, and 0.81–1 almost complete agreement.

2.7. Ethical considerations

This study was approved by the ethics committee of Jiroft University of Medical Sciences (# IR.JMU.REC.1399.063). All patients or their parents gave an informed consent to participate, record videos or digital images, and publish anonymized photos for research purposes.

3. Results

Among the 26 physicians who initially agreed to participate in the study, only 8 successfully completed the Otoscopic and video-Otoscopic examinations. This reduction in participation can be attributed to several factors, including time constraints, logistical challenges, personal circumstances, and a lack of clarity regarding the study protocol, which may have led some physicians to withdraw from the study.

In this study, we analyzed a cohort of 110 patients (220 ears), with a mean age of 6 ± 2.7 years, who attended four rural health centers over four months. Notably, 66 ears were excluded from the calculations of diagnostic accuracy, specificity, and sensitivity due to the inability to establish a definitive diagnosis. This exclusion was necessitated by ambiguities arising from factors such as inadequate image quality, the presence of artifacts obstructing visualization, and incongruity between clinical symptoms and the diagnostic criteria utilized. Consequently, these cases were categorized as Non-Diagnostic Patients (NPD), ensuring that the resultant data reflects only those instances where a clear diagnosis was attainable.

A total of 154 Otoscopic and video-Otoscopic examinations conducted on 82 patients were included in the analysis. This sample size is considered sufficient for meaningful statistical evaluation, ensuring enough power to assess the differences in diagnostic accuracy and image quality between the two techniques.

Table 2
Research participants' demographic information.

	Site1 (Roodbar)	Site2 (Ghal'e_Ganj)	Site3 (Manujan)	Site4 (Faryab)	Total
n	20	33	17	12	82
Sex(n = male),%	65(13)	17(51.5)	8(47)	7(58.3)	45 (54.8)
Number of Video Otoscopic	39	63	30	22	154

Table 3
Distribution of diagnosis of included ears (n = 154).

	OTO-GP	VO-GP	VO-ENT
Normal	107(69.4 %)	125(81 %)	123(80 %)
OME	32(20.7 %)	17(11.1 %)	15(10 %)
AOM	6(3.89 %)	1(0.7 %)	2(1.3 %)
CSOM	9(5.8 %)	11(7.2 %)	14(9.1 %)

OTO-GP = otoscope −general practice; VO-GP = video-otoscope GP; VO-ENT = video-otoscope ENT; OME = otitis media with effusion; AOM = acute otitis media; CSOM = chronic suppurative otitis media.

3.1. Demographics and site distribution

Table 2 presents the demographic distribution of participants by site. Most patients were from Ghal'e-Ganj, and sex distribution was relatively balanced. A total of 154 Otoscopic and video-Otoscopic evaluations were included for analysis.

3.2. Diagnostic distribution

Table 3 shows diagnostic outcomes across three evaluation methods. Notably, the majority of ears (70–81 %) were classified as having normal tympanic membranes. In contrast, acute otitis media (AOM) accounted for a mere 0.9 % of the cases. Furthermore, chronic suppurative otitis media (CSOM) was identified in 10 % of the instances, while otitis media with effusion (OME) and non-specific pathological diagnoses (NPD) represented 8 % and 9.1 %, respectively. This distribution underscores the predominance of normal TM findings in the study cohort.

3.2.1. Agreement between GP diagnosis and gold standard

To estimate diagnostic agreement, the diagnoses made by general practitioners using both devices (otoscope-GP) and simultaneous assessment (video-otoscope-GP) were compared with the diagnosis of an ear, nose, and throat specialist as the "gold standard." A stronger agreement with the gold standard (90 %) was observed compared to the standard otoscope (66 %). Cohen's kappa coefficient also demonstrated higher reliability with the video-otoscope (0.75 versus 0.63) (Table 4).

3.2.2. Sensitivity and specificity

Sensitivity, specificity, and predictive values were calculated for both diagnostic approaches. For the video otoscope by GPs, sensitivity was 0.90, specificity 0.98, positive predictive value 0.86, and negative predictive value 0.98. For the standard otoscope by GPs, sensitivity was 0.86, specificity 0.94, positive predictive value 0.68, and negative predictive value 0.93. The confusion matrix for correct and incorrect classifications is presented in Table 5.

3.3. Physician and patient feedback

All participating physicians (100 %) reported that the video otoscope was easy to use and helpful for enhancing communication with patients. Nearly all (98 %) expressed interest in purchasing the device for future use. They believed that video otoscope could significantly enhance diagnostic accuracy, especially in rural settings.

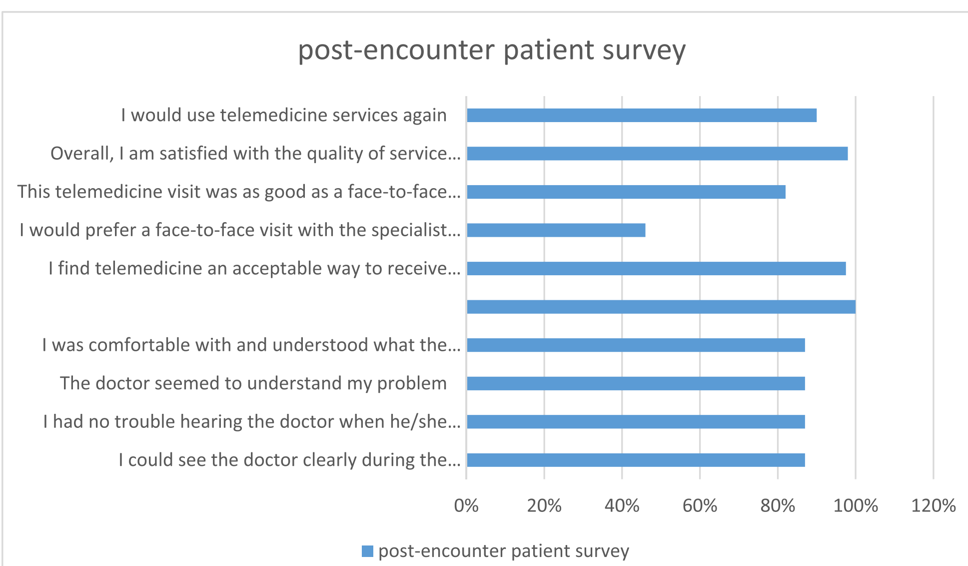
Table 4
Distribution of correct diagnoses and diagnostic agreement for otoscope and video-otoscope- GP compared to video-otoscope-ENT.

	Correct diagnosis	Overall agreement	Cohen's kappa coefficient	SE	*95 % CI*
Otoscope-GP	102/154	0.66	0.633	0.069	0.543–0.826
Video-Otoscope-GP	140/154	0.90	0.75	0.068	0.515–0.870

Table 5
Confusion matrix for Video otoscope-GP and standard otoscope-GP.

N = 154	Actual positive	Actual negative	
Video otoscope-GP			
Predicted positive	TP = 27	FP = 7	34
Predicted negative	FN = 4	TN = 116	120
standard otoscope–GP			
Predicted positive	TP = 28	FP = 2	30
Predicted negative	FN = 3	TN = 121	124
	31	123	

The analysis of patients' survey (TESQ) showed a high degree of parents' satisfaction with the tele-medical encounter (visit). In fact, 98 % expressed an overall satisfaction with tele-medicine. All patients' caregiver (100 %) agreed that care is more available via this technology. Most parents (72 of 82 overall, 87.8 %) stated they could see and hear the tele-consultant adequately and felt comfortable discussing their health-related complaints. The majority of patients (80 of 82, 97.5 %) felt that tele-medicine was an appropriate way of receiving healthcare, while only 20 of 82 patients (24.3 %) felt that the encounter was truly prolonged. Ninety percent of patients (74 of 82) reckoned they would use this technology again. Forty-six percent of parents said they preferred face-to-face consultation with a specialist to tele-consultation when an otolaryngology specialist was not available.



4. Discussion

This study evaluated the diagnostic concordance between general practitioners' diagnoses of ear diseases using a digital otoscope and a standard otoscope, and the diagnoses established by an otolaryngology specialist as the gold standard in rural primary care centers. The findings revealed a notably high level of agreement; specifically, out of 154 ears examined, diagnoses by general practitioners were consistent with the gold standard in 140 cases, representing an impressive concordance rate of 90 %. Furthermore, the evaluations conducted via GP video otoscope exhibited a superior agreement with the gold standard when compared to earlier research that assessed the agreement between primary healthcare physicians and audiologists, which reported kappa values ranging from 0.68 to 0.74. These results underscore the efficacy of the digital otoscope as a tool for general practitioners in accurately diagnosing ear conditions [26].

The comparable diagnostic performance between general practitioners and ENT specialists when using video otoscope is a promising finding that highlights the potential of this technology in rural and underserved areas. The ability to capture high-quality video, review it multiple times, and consult remotely provides general practitioners with enhanced diagnostic capabilities that go beyond the limitations of conventional otoscope [18,25,26]. These features can help reduce diagnostic uncertainty, improve early detection of otitis media subtypes, and support clinical decision-making. However, it is important to recognize that while video otoscope can augment GP performance, it is not intended to replace the comprehensive expertise of ENT specialists. Complex or ambiguous cases may still require specialist evaluation. Therefore, we view video otoscope as a valuable adjunct to support primary care providers, particularly in telemedicine frameworks, rather than a substitute for specialist care.

The present findings are consistent with similar studies of tele-Otoscopic diagnoses, including the body of research conducted in Australia, Nepal and South Africa. In Australia, screening was done by a well-trained facilitator using a digital otoscope to transmit images of patients' ears through a live Internet connection or through store and forward transmission [25]. In South Africa, the screening of children was done by a non-medical assessor with a hand-held video otoscope (Dino-Lite Pro Ear-scope) connected to a laptop computer, with data collection and subsequent review of images by an expert [26]. In Nepal, the Cupris device was used in a rural hospital to record history and examination of ears. This device included hardware to convert the smartphone camera into a platform for taking Otoscopic images of the ear canal and tympanic membrane, and customized software to process and analyze the captured images and save them as images or videos. The format of this device can also record the patient's history. The history and images stored in the UK were assessed by a consultant otolaryngologist, who compared the diagnosis to the gold standard, expert on-site assessment with a standard otoscope [18].

A trend analysis of diagnostic distribution among the three diagnostic methods—OTO-GP, VO-GP, and VO-ENT—revealed notable differences in accuracy and classification. The ENT specialist using video otoscope reported 80 % of ears as having a normal tympanic membrane (TM), compared to 81 % by GPs using video otoscope and only 69.4 % by GPs using standard otoscope. This suggests that video otoscope enhances diagnostic confidence and accuracy for GPs, aligning their assessments more closely with the ENT gold standard. This is due to the improved visualization of tympanic membrane using real-time video Otoscopic playback. However, the variable range of images classified as normal may overlap with the appearance of other pathologies, especially otitis media with effusion. In the present study, video records were used instead of snapshot images, because according to the existing literature, the former provides a better and deeper understanding of evaluation [25,26]. In fact, simultaneous evaluation with video otoscope improves the visualization of tympanic membrane. Due to the natural movement of evaluator's hand holding the otoscope, live images are displayed at different angles and the visualization of tympanic membrane improves.

Interestingly, GPs using standard otoscope diagnosed more cases of OME (20.7 %) and AOM (3.89 %) than with video otoscope (OME: 11.1 %, AOM: 0.7 %), and also compared to the ENT findings (OME: 10 %, AOM: 1.3 %). This pattern suggests a potential over diagnosis trend in the absence of enhanced visualization, possibly due to limitations in TM visibility. The trend of CSOM diagnosis remained relatively similar across all three diagnostic methods, indicating consistency in identifying chronic cases, though ENT specialists slightly outnumbered GPs in detection (9.1 % vs. 7.2 % VO-GP and 5.8 % OTO-GP).

As the analysis of physicians' survey showed, the physicians agreed that the system was easy to use and that video otoscope could be useful for telemedicine and better interaction with the patient (100 %). Most physicians (98 %) stated they were willing to buy the device. Overall, physicians felt that video otoscope could help improve their diagnostic performance. Biagio et al. (2014) stated that the use of video otoscope to diagnose ear problems through telemedicine can be very useful for low-income patients and those with limited facilities [26]. Similarly, Erkkola et al. (2019) showed that the use of video otoscope with a smartphone by parents was effective in diagnosing otitis media. They went on to claim that otoscope was beneficial, and overall, parents' experiences of using a smartphone otoscope at home were positive. Therefore, the result of the above-mentioned study is consistent with the present study [27].

5. Limitations

There are several limitations to the present study. Firstly, this study was conducted in an environment with a low prevalence of ear diseases, and most participants had normal ears. Second, the device was tested by GPs. Though we believe that well-trained non-medical staff can use the device with equal efficiency, it requires further evaluation. In this study, 66 ears were excluded from the data analysis due to the poor quality of videos recorded for the patients' non-cooperation, use of wax, and GPs' insufficient experience of using video otoscope at the beginning of study. Certainly, including what has been omitted can lower the agreement between the digital otoscope device and the standard assessment. It is, however, emphasized that the quality of videos in these cases depends on the operator rather than the device. It is likely that with more training and experience, the failure rate will be minimized. In this study, due to the unavailability of an otolaryngology specialist, it was not possible for the specialist to independently examine all children in person. If so, the number of ears not examined due to the low quality of images may have been reduced.

6. Conclusion

Our findings provide strong evidence that digital video otoscope can enhance the diagnostic accuracy of GPs in detecting ear diseases, especially in settings with limited access to ENT specialists. By facilitating improved visualization, remote consultation, and more efficient referrals, this technology holds promise for empowering primary care providers and expanding the reach of quality ear healthcare. Integration of video otoscope into telemedicine platforms could further support GPs in underserved areas, improving patient outcomes while optimizing healthcare resources.

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CRediT authorship contribution statement

Najmeh Pourshahrokhi: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Somaye Norouzi:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Conceptualization. **Aliasghar Arabi Mianroodi:** Writing – review & editing, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Leila Ahmadian:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Funding acquisition.

Declaration of competing interest

The authors had no competing financial interests or personal relationships that influenced this work.

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