Remote Patient Monitoring System: Evaluation of Medical Devices from Patients’ Perspective

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Abstract
Currently, remote health monitoring is one of the emerging areas of healthcare directed towards a better healthcare delivery. Worldwide acceptance of such solutions is due to the use of internet and its related services; being ‘online’ at all times and ease of communication anywhere and everywhere. Remote patient monitoring systems can be considered as low cost, reliable and accurate way of advanced healthcare delivery. Our main focus is to evaluate a remote vital sign monitoring system consists of a computer based software application and wireless medical devices and compare with other existing systems in terms of users’ acceptability, comfort, mobility and usability. We have successfully tested and evaluated the adopted system with 30 individuals for mobility, usability, comfort, and overall acceptability of the latest wireless medical devices. It is found that not all medical devices are acceptable from the users’ perspective; either they lack user centeredness or clinical usefulness.

1. Introduction
Remote, mobile, wireless and wearable systems can be considered as a part of telehealthcare system, which is often considered as the extension of telemedicine and is defined as: the use of information, computing, electronics and telecommunications technologies to provide healthcare delivery when patient and clinician are separated by a distance [1]. Moreover, it employs advanced telecommunications technologies for the exchange of medical information via electronic medium for the delivery of healthcare [2]. Telehealth technologies ranges from simple text messaging and phone calls to advanced remote patient monitoring and to the innovative real-time monitoring of vital signs and video consulting with the combination of digital video cameras, simple online questionnaires, medical measurement devices and/or sensors [3]. The focus of current healthcare is changing from the traditional/original medical treatment to the prediction, prevention early detection and early warning [4, 5].

The use of internet-based services which are offered across desktop computer, laptop, tablet and/or smartphone, enable the telehealth applications to revolutionize current delivery of healthcare by healthcare professionals. Patient monitoring systems in particular are playing a critical role in decision support, early diagnosis and knowledge based support in assisting healthcare professionals. Today, such telehealth systems are being designed and developed for various healthcare areas i.e. emergency department, remote monitoring of indoor and outdoor locations [6]. Commonly monitored vital signs are: blood pressure (BP); heart rate (HR); respiratory rate, Pulse volume (PV); oxygen saturation (SpO2); and body temperature.

1.1. Current healthcare applications
Tele-healthcare solutions seem to be capable of enhancing the quality of patient care while reducing cost [6, 7]. Current telehealth services have demonstrated efficiency and cost-effectiveness and currently employed the following basic services:

Medical Imaging: The waiting time and hospital cost is significantly reduced by accessing high quality digital images by various specialists and/or departments such as radiology and cardiology.
Remote monitoring and video consultation: This technology allows clinicians and patients to interact virtually (using physiological data and audio/video conferencing) and efficiently.

Email: The increasing use of internet related services enables the integration of basic communications such as electronic mail in the healthcare settings which is proved as a low cost, fast and effective medium of communication [8, 9].

Call and Text Messaging: Using a basic cell phone calling or short message service (SMS), today healthcare providers can ease the appointments, bookings, reminders and alerts which saves time as well as cost. Currently there are number of mobile phone (SMS) based projects aimed to improve healthcare such as mobile phone based quit smoking project ‘Text2Quit’ and ‘txt2Stop’ [10-13].

Electronic Health Record (EHR): Access, storage or transfer of patient’s EHR, high resolution images, consultation notes, medical documents and patient’s background history are some of the telehealth care services currently in use [14].

Physiological Data: Currently a number of studies have been reported in literature which includes patient’s vital signs often described as: electrocardiography (ECG); blood pressure (BP); pulse volume (PV); weight and body temperature. These signs transmit remotely to the patient management system for centralized processing and/or consultation [15].

1.2. Systematic review of current monitoring systems

The majority of work in this area is divided into two approaches: body attached sensor-based monitoring and medical device based monitoring. Some systems possess potential of acceptance in clinical settings, such as ‘Electronic Doctor’s Bag’ [16] which uses the mobile communication platform tool for a home visit medical service. This system was tested in two clinics and one hospital with three medical doctors and two nurses. It measures physiological data, ECG, BP, blood sugar and ultrasonic diagnosis with compressed and coded video images of the patient to the doctor. A case study [17] has been extracted from a pilot trial of the system towards integrating tele-healthcare and decision support system (DSS) in the patient care management of chronic obstructive pulmonary disease and chronic heart failure. Identification of any risk in this system is achieved by identifying individual measurements that exceed predetermined or adaptive thresholds limits and using the core DSS knowledge base. Up to 24 hours of constant monitoring of older adults is proposed. This application is capable of meeting everyday needs as abnormal events and emergency alarms are reported to relatives by telephone, SMS and/or e-mail, and the system is sensitive to security and privacy issues [18]. A computer aided bedside vital signs monitoring system has been developed based on industrial standards [19], consisting of a bedside monitor and a central monitor. The central monitor allows the real-time access of bedside data via standard software interfaces, so the communication between the devices is made easy. The performance shows the system is capable of robust real-time handling of up to 16 bedsides at a time. The use of video communication in companies (teleconferencing), academic institutions (educational videos) and personal or social use (video chat) has enabled the technology to be integrated in the medical environment and provides innovative healthcare services. Telehealthcare systems gradually starting to use video consultation as it is emerging as cost-effective and efficient platform for the healthcare sector. The efficiency of this technology is constantly evaluated in the research studies and literature reviews. A comparison between face-to-face and closed circuit television (CCTV) interview with 85 psychiatric disordered people has found no significant differences on the end result while interviewing via CCTV or in-person [20]. A similar comparison in neuropsychological assessment of 98 patients by Schopp et al. showed no significant difference and reported the videoconferencing approach be cost-effective [21].

A research study on the use of equipment in telehealth care has reported that a cheap computer with basic components including audio/video capabilities is enough to carry out the video consultation for basic treatments but suggested more sophisticated equipment required for advanced treatment via video consultation [22]. Figure 1 shows the basic understanding of four-way (multiple) video conferencing managed by single server for online use of healthcare consultation in real-time. The four blocks with dotted lines are the external/internal data process performed on the same server simultaneously. The architecture model adopted from the literature uses similar concept. Such tele-communication systems are reported useful in the fields of heart disease [23], wound care [24], mental health [25], diabetes management [26] and dermatology [27].
1.3. Limitations and challenges

While a number of benefits are reported in the literature on the use of such monitoring applications, there are challenges which need to be addressed in order to increase the adoption and global acceptance of these systems. There are number of critical issues and challenges such as acceptability, users’ comfort, mobility, usability, user interface, medical data quality, energy usage, battery life (mobile systems), platform variability, cost effectiveness, reliability, efficiency and security & privacy [28, 29]. It is beyond the scope of this paper to address all the mentioned issues and challenges; our focus is on patient (end user) acceptability which includes comfort, usability, mobility and overall acceptability. This is one of the most important concerns which is often ignored or avoided when reporting the system’s performance results.

With the ever growing number of remote/wireless patient monitoring systems, end-user acceptability is becoming an important aspect in the design of such systems. There is still an open research question to be worked on. Do wireless/wearable monitoring systems make a difference to the patient’s (end-users) acceptability? To answer this important aspect of healthcare very few researchers have included the patients as well as medical professional’s consideration at every stage of design and development [30]. We believe the acceptance of any system in the healthcare industry depends on the user/clinician awareness and acceptability. Adaptation of any device within the clinical field is stuck when they are negatively perceived. User-centred design is essential in order to incorporate these perceptions into the product, especially at the earlier stages of the project development. When analysing user’s needs, contextual inquiry, user’s profiling the designer should consider a number of factors such as task analysis, surveys, interviews and focus groups to address the user acceptability issues [31]. We support the proposal of Steele et al. [32] that future studies should document any attitudes, perceptions and concerns of its users. It is known that highly sophisticated technology becomes immaterial if the user doesn’t have complete knowledge about the specific using conditions and also, data analysis technique becomes irrelevant for example if the user does not wear the ‘sensor/device’ for the allocated periods of time [33].
2. Remote patient monitoring systems and a working model

Vital signs based telehealth monitoring systems usually monitor one single vital sign and transmit the data to the clinician. Very few systems consider all vital signs as well as video data simultaneously, and often these systems send data with time-delay due to either real-time processing or wireless data transfer. Figure 2 shows the basic functionality and working structure of the proposed telehealth system defined from the patient as well as clinician’s points of view. The patients’ side consists of a wireless transmission unit, medical peripherals for data collection and video camera (not very common at the moment) for the transfer of vital signs and video data via the internet. Whereas the clinicians’ side consists of software application installed on a personal computer (PC) or laptop with audio/video capabilities.

2.1. Medical devices and their connectivity

Figure 3 shows the medical devices and set-top-box used in this research study. We use the market available clinically proven medical devices and incorporated them into one system in order to have a high data reliability and accuracy. The system has the capability of collecting multiple data simultaneously from multiple patients. A brief description of the devices numbered 1-8 in Figure 3 is given below:

1. **Set-top box**: This runs the software application which receives patients’ physiological data from different medical devices and transmit it in real-time over the secure internet connection to personal PC or laptop.

2. **Blood pressure monitor**: Boso-medicus prestige blood pressure monitor [34] is a wireless Bluetooth device. It measures blood pressure (systolic and diastolic) and pulse rate. It records at user defined time intervals and it’s easy to operate.

3. **Pulse Oximeter**: Nonin’s Onyx II finger clip oximeter [35] is a wireless Bluetooth device which records oxygen saturation and heart rate continuously.
4. Blood glucose meter: Accu-Chek Compact plus blood glucose meter [36] is wireless infrared connected device which records the blood glucose level.

5. Ear temperature: Omron’s instant ear thermometer [37] is an accurate and fast ear temperature measurement device.

6. Body temperature: G-plus wireless remote body temperature [38] is a wireless and continuous body temperature device.

7. Spirometer: nSpire’s Piko-6 meter [39] is a wireless infrared connected device which gives FEV6 and FEV1/FEV6 readings.

8. Accelerometer: Gulf Coasts Data Concept’s accelerometer/Magnetometer Data Logger X8M-3mini [40] is a compact, continuous data collection device used for fall detection.

2.2. Basic design functionalities of the monitoring system

It consists of an advanced set-top box, which runs the VitelMed software application providing connectivity with a wide variety of medical devices. A special feature of VitelMed is the one touch button, for easy and instant connectivity. Users press a button to automatically connect to a call centre or their medical professional. A TV or any other screen can be connected to enable two way video/audio tele-visiting (conferencing) using a high resolution camera. It collects vital signs via wired or wireless medical devices and sends that information to the medical professional in real-time without any delay. In parallel, a medical professional can have two way video conferencing, as a virtual face-to-face clinical consultation, using a tilt, pan, zoom high resolution camera for advanced care.

Figure 3 - Medical devices used for the proposed patient monitoring system
2.3. Connecting Patients and Clinicians

The simple and easy-to-use patients’ side enables the patients (users) to quickly become familiar with the solution. Using one-touch button, the patient can instantly connect to a call centre, nurse or doctor. In a home setting it is usually connected to a TV (with remote) to give the user the advantages of familiar technology, not the drawback of using a PC or advanced software which can be easily rejected by older adults due to the lack of technological interest or understanding. Fully customisable medical parameters collection/information, clear and large multi-media keys and on-screen navigation and control settings gives the patient a personalised and individual healthcare delivery. Figure 4 show the medical professional is provided with a software application, which can be installed on any PC and/or laptop with audio and video features, with access to the patient’s electronic health record and medical history. A clear, easy to understand and user friendly graphical display helps clinicians to provide medical care to the user. The clinician’s side application can have two way video conferencing with real-time physiological data from the patients’ side.

2.4. Interoperability in medical devices connectivity

VitelMed offers connectivity to a large number of medical devices for patients’ physiological data collection. It connects the latest medical devices from almost all medical device manufacturers, providers and/or vendors. The medical devices which are fully compatible with VitelMed and available in the market are: heart rate monitors; ECG monitors; blood glucose monitors; vital sign monitors; peak flow meters; blood pressure monitors; weight scales; pulse oximeters and foetal monitors. This provides for a wide scope of patient monitoring, especially for patients with Diabetes mellitus, congestive heart failure and chronic obstructive pulmonary disease.

2.5. Technical Capabilities

Some of the advanced technical capabilities which make the proposed solution a reliable, cutting edge and advanced telehealth care solution are:

- Communication protocols - audio/video with adaptive bandwidth of 16-2048KBps
- Network communications - LAN, WAN, IP addressing (static, DHCP or PPPoE), TCP/IP protocols
- Data ports - two RS-232, four USB, one SD card connector, IR remote control and Bluetooth class 2
- Communication Security-XML based messaging, first key exchange and streaming encryption
3. System evaluation and results

3.1. Technical verification of medical devices

Medical devices shown in Figure 3 were tested individually with the manual meters before the start of the experimental data collection. Automatic blood pressure meter is evaluated with the manual mercury column meter, wireless BP meter is more accurate on left hand and in relaxed (2 minutes) sitting position. Pulse Oximeter is verified using manual one minute test which shows the accurate result but in some cases wireless meter takes longer than 10 seconds to give stable measurements due to the finger position. Ear thermometer is verified with the mercury thermometer and found to be accurate with both ears. All devices are tested and verified with hospital devices in order to conduct the experimental data collection using 30 individual. Wireless data transmission test shows no errors in real-time patient physiological data transmission from patient set-top-box to PC based software. We used the mobile internet USB data stick which uses 3G networks and is found to be fast and efficient internet connection. Few connection losses occurred due to signal interference and/or bad location.

3.2. Device specifications

Table 1 shows the medical devices specification in terms of device model, connectivity, transmission, size and body position. These are considered as critical factors for remote/wireless system to be accepted by patient (user) and medical professional [41]. The medical devices (Table 1) selected for this project because they are low cost, accurate, medically approved, and most importantly they all have wireless data transfer feature.

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Model</th>
<th>Connectivity / Transmission</th>
<th>Size / Body position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure</td>
<td>Bosco-Medicus Prestige BT</td>
<td>Wireless / BT</td>
<td>Small / arm cuff</td>
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<tr>
<td>Pulse Oximeter</td>
<td>Onyx-II</td>
<td>Wireless / BT</td>
<td>Compact / finger tip</td>
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<tr>
<td>Blood Glucose</td>
<td>Compact Plus</td>
<td>Wireless / IR</td>
<td>Small / fingertip blood</td>
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<td>Ear Temp.</td>
<td>Instant ear thermometer</td>
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<tr>
<td>Body Temp.</td>
<td>Wireless body thermometer</td>
<td>Wireless / BT</td>
<td>Compact / armpit</td>
</tr>
<tr>
<td>Spirometer</td>
<td>Piko-6</td>
<td>Wireless / IR</td>
<td>Small / air blow</td>
</tr>
<tr>
<td>Accelerometer</td>
<td>8-XM3-mini</td>
<td>Wireless</td>
<td>Compact / chest</td>
</tr>
</tbody>
</table>

Where BT is class-2 Bluetooth and IR is infrared
3.3. System evaluation

It is important to make note that, here the authors are not trying to verify the clinical accuracy and product validation of these devices, because it is not the scope of this research and in fact all the devices made available in the market only after necessary safety certification, clinical validation and accuracy testing. Instead we are evaluating these devices in terms of user (patient) acceptability of the device, usability and comfort with their feedback on each device and its usage. 30 individuals (P1 – P30) were asked to participate in the proposed system’s evaluation. 30 individual (18 males and 12 females), average age 60 years were given 11 point scale (10 is completely satisfied, 5 is neutral and 0 is completely unsatisfied) to rate the medical devices for mobility (size and weight), usability (how easy the device can be operate), users’ comfort (how comfortable they feel when using the device) and overall acceptability. Table 2 shows the evaluation data in 11 point scale from the 30 participants. Each participant was given the basic instructions on how to operate the device, use the device to test, before device evaluation. The patients were given the opportunity to get familiar with the devices by performing some measurements on their own and then evaluation were performed by a registered nurse for all devices. During the evaluation, all devices were connected to the set top box so that accuracy of data transmission could be checked.

We believe the score above seven is acceptable; however there are several aspects where the outcome has been recorded as six or less. Comfort in using blood glucose monitor is recorded as an average score of six, due to the use of the needle onto the finger tip. Usability and comfort of Spirometer has been recorded as five, majority of participants find difficulty in using the device and blowing the air without any error, almost everyone took more than one attempt to get the accurate reading. Usability of accelerometer has rated six, because of the difficulty in operating the device, which requires a magnet to be held near the device for two seconds and when both the lights (blue and red) stops flashing, then magnet should be immediately removed, or else it will switch off the device again.

4. Discussion

Table 2 shows the medical device evaluation in terms of mobility, usability, comfort and overall acceptability. Most widely used vital sign monitoring devices (blood pressure and pulse oximeter) have been compared with other similar systems reported in literature for in-depth evaluation.

4.1. Blood Pressure Device

Boso-medicus prestige blood pressure monitor [34] has achieved the mobility of 70%, usability of 80%, and users’ comfort of 80% and acceptability of 70%. The mobility score is given as seven, because the participants felt constrained when carrying devices’ base unit and cuff attached to the participants arm. We selected this device for its clinical accuracy, easy availability and low cost. There are few arm wrist BP devices in market today, but they are not very accurate and/or lack in wireless data transmission. Table 3 compares similar blood pressure monitoring devices.

4.2. Pulse Oximeter

Nonin’s Onyx II finger clip pulse oximeter [35] has achieved the mobility of 90%, usability of 80%, and comfort of 90% and acceptability of 80%. Table 4 compares similar pulse oximeter devices.

4.3. Blood Glucose Meter, Ear Thermometer and Spirometer

Accu-Chek Compact plus blood glucose meter [36] has achieved the mobility of 80%, usability of 70%, and comfort of 60% and acceptability of 80%. Participants felt difficult not only to take the measurement but also to transfer the readings remotely, comfort rate is low because of the use of needle. Omron’s instant ear thermometer [37] has achieved the 70% score for mobility, usability, users’ comfort and acceptability. It is reported that initially it was difficult to understand how to use the device, especially on which beep the device should be removed from the ear while pressing the top button.

nSpire’s Piko-6 meter [39] has achieved the mobility of 70%, usability of 50%, and comfort of 50% and acceptability of 60%. In order to achieve high measurement accuracy user have to be in standing position, have to take deep breath in and then have to blow out fast in the mouth piece of the device, which participants experienced to be difficult to achieve correct results initially. Gulf Coasts Data Concept’s accelerometer/Magnetometer Data Logger X8M-3mini [40] has achieved the mobility of 80%, usability of 60%, and comfort of 80% and acceptability of 80%. In some body positions...
participants felt uncomfortable while mobile but suggested changing the body position for the better mobility, finally chest or upper back side was comfortable for the users. Operating the device was found to be difficult, especially switch on and off using the external magnet and its exact timings.

Table 2 - Evaluation of selected medical devices for mobility (M), usability (U), comfort (C) and acceptability (A)

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Table 3 - Comparison of similar Blood Pressure monitoring devices in clinical context

<table>
<thead>
<tr>
<th>Name/Device</th>
<th>Model</th>
<th>Purpose</th>
<th>Evaluation type</th>
<th>Number of Participants</th>
<th>Result</th>
<th>Limitations</th>
</tr>
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<tbody>
<tr>
<td>Takayuki et al. [42]</td>
<td>Jentow, Japan</td>
<td>Arterial Tonometry</td>
<td>Accuracy</td>
<td>30</td>
<td>Almost equal</td>
<td>Movement artefacts</td>
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<td>Shennan et al. [43]</td>
<td>SpaceLabs 90207</td>
<td>Use in Pregnancy</td>
<td>Accuracy</td>
<td>122</td>
<td>Reasonably accurate</td>
<td>Arm cuff too tight</td>
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<td>Nakano et al. [44]</td>
<td>Microlife WatchBP O3</td>
<td>Self-usage</td>
<td>Acceptability</td>
<td>37</td>
<td>86% feels very easy</td>
<td>Uncomfortable</td>
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<td>Used here</td>
<td>Boso-medicus prestige blood pressure monitor [34]</td>
<td>Vital sign Monitoring</td>
<td>Acceptability</td>
<td>30</td>
<td>70%</td>
<td>Low mobility</td>
</tr>
</tbody>
</table>

Table 4 - Comparison of similar Pulse Oximeter devices in clinical context

<table>
<thead>
<tr>
<th>Name/Device</th>
<th>Model</th>
<th>Purpose</th>
<th>Evaluation type</th>
<th>Number of Participants</th>
<th>Result</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fisher et al. [45]</td>
<td>Pulse Oximeter Tester (POT)</td>
<td>Arterial Tonometry</td>
<td>Simulation</td>
<td>-</td>
<td>2 SD difference</td>
<td>Faulty sensor</td>
</tr>
<tr>
<td>Ibáñez et al. [46]</td>
<td>biox 3700 pulse oximeter</td>
<td>vasoactive therapy</td>
<td>Accuracy</td>
<td>24</td>
<td>4% difference</td>
<td>Not reliable</td>
</tr>
<tr>
<td>Kathryn Aughey et al. [47]</td>
<td>Baxter ASAT pulse oximeter</td>
<td>Pre-hospital Care</td>
<td>Accuracy</td>
<td>30</td>
<td>100%</td>
<td>Lack of depth</td>
</tr>
<tr>
<td>Used here</td>
<td>Nonin’s Onyx II Pulse Oximeter [35]</td>
<td>Vital sign Monitoring</td>
<td>Acceptability</td>
<td>30</td>
<td>80%</td>
<td>-</td>
</tr>
</tbody>
</table>

Evaluation of medical devices and systems is important to achieve a high level of acceptability. Tamura et. al [48] conducted a home healthcare system trial to monitor blood pressure at two different locations for about one year, the 42% and 55% of participants at each location continuously monitored their blood pressure. BP was measured with a commercially available BP monitor (CH-462E, Citizen Japan), and a modified semiautomatic oscillometric device was used for data communication and all data were automatically transmitted to the healthcare centre via a home gateway. It is reported that many participants could not understand user manual, find the system cumbersome and troublesome which discourages them from participating. Freund et al. [49] conducted the research study in hospital for investigating the failure of pulse oximetry at four different hospitals. Bitterman [50] surveyed the monitoring devices form a home prospective, where special focus was given to the patients’ need in their home for designing the patient acceptable home monitoring system. Bergmann and McGregor reported that the successful design of healthcare system is only possible when medical professional as well as patient are consulted at every stage of the system design and development. Sixsmith [51] evaluated an intelligent home monitoring system in terms of user acceptability and usability and reported that the system achieved 50% acceptance form the users.

5. Conclusion

The proposed system is evaluated with 30 individuals for mobility, usability, users’ comfort and users’ acceptability. The crucial aspect is the configuration of different medical devices in one system (set-top box), which collects and transmits the patients’ physiological data in real time. In addition, the collected data is diagnosed and alert/warning for any potential
abnormal signals will be sent to medical professional in real-time. We focuses to address the current limitations of this technology, such as: interoperability, complexity, high cost and user acceptability using the proposed solution [52]. The proposed solution can be implemented at home - as remote and continuous home monitoring or in hospital - as point of care technology with remote access of the patient’s physiological data with audio/video connectivity or even in an emergence situation (e.g. ambulance or accident site) as a portable and wireless monitoring device.

Medical devices could play an important role in the ever-growing telehealth care by providing advanced, cutting-edge and state-of-the-art telehealth care solutions. The main focus is to address the current challenges and limitations reported in the literature and implement an advanced telehealth care system to benefit the overall healthcare sector. Special emphasis has been given to medical device evaluation and their use in clinical settings. Medical devices have been addressed to a great extent with advanced features for both medical professionals as well as patients (users).

6. Acknowledgments
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7. Conflicts of Interest
The authors declare no conflict of interest.

8. References


