Telemedicine Applications in Sleep Disordered Breathing

Thinking Out of the Box

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KEYWORDS

• Telemedicine • Sleep disordered breathing • Technology • Monitoring

KEY POINTS

- Telemedicine encompasses the use of information and communication technology (telephone, video, Internet, satellite, cloud) to deliver health care at a distance.
- Diagnostic telemedicine applications include telemonitored polysomnography, long-term polygraphic monitoring, and remote continuous positive airway pressure (CPAP) titration.
- Telemedicine allows clinicians to remotely monitor CPAP adherence and compliance and fine-tune CPAP settings.
- Patient counseling, as well as therapy reinforcement by combining and integrating psychoeducational interventions and telemonitoring, is feasible.
- Barriers like patient's and physician's cooperation, privacy concerns, financial barriers, technological barriers, and quality concerns have to be overcome.

INTRODUCTION

The popularity of technology is increasing in nearly every field, and sleep medicine is no exception. Telemedicine as a means of remote patient-physician interaction is growing and virtual consultations with sleep specialists are feasible.[1] The potential benefits of telemedicine include improved access to health care, reduced waiting time for appointments, and increased adherence to chronic illness treatment plans.[2] Because many sleep disorders, particularly sleep apnea, are chronic conditions, and require a continuous treatment and monitoring of therapy success, telematic communications and new information technologies could be useful to establish diagnostic and therapeutic strategies. It is important to install cost-efficient technologies for an initial simple diagnosis, rapid treatment initiation, and for long-term monitoring of treatment adherence and compliance, providing the possibility for patients to avoid traveling.[3] A substantial proportion of patients are willing to consider telemedicine as an option for their care. In such settings, in case of insufficient adherence or compliance, device dysfunction, or subjective problems, alerts can be generated and sent to the health professional, who can react rapidly and focus on the patient's needs.

In this article, telemedicine solutions in sleep disordered breathing are reviewed, with emphasis on adherence and compliance monitoring:

- Diagnostic telemedicine applications: telemonitored polysomnography, long-term polygraphic monitoring.
- Remote continuous positive airway pressure (CPAP) titration.

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- Monitoring of CPAP adherence and compliance:
  - Standard care
  - Remote monitoring and fine-tuning therapy
- Patient counseling and therapy reinforcement by combining and integrating the most promising elements of both psychoeducational interventions and technological innovations.
- Barriers in the implementation of telemedicine are also highlighted.

DIAGNOSTIC TELEMEDICINE APPLICATIONS

Telemonitored Polysomnography

Telemonitored polysomnography (PSG) is designed to overcome the disadvantages of home recordings and could provide an organizational solution to the overloading of specialized sleep centers. Dedicated technicians regularly verify, at a distance, the quality of the PSG recordings by means of periodic access to the PSG monitoring device. From a telemonitoring control panel, they are able to insert comments in the recording; adjust transducer gain; and, in the event of an artifact or an undesirable accident, inform the patient by telephone.[4] However, evidence on the efficacy of telemonitored PSG is weak. Gagnadoux and colleagues[5] reported that PSG performed in a local hospital and telemonitored by a sleep laboratory was clearly superior to unattended home PSG. Kristo and colleagues[6] proposed a telemedicine protocol for the online transfer of PSG data from a remote site to a centralized sleep laboratory, which provided a cost-saving approach for the diagnosis of obstructive sleep apnea (OSA). Their system was based on the transmission of data using an Internet file transfer protocol (FTP), which is the conventional system for file transfer. Kayyali and colleagues[7] presented a new compact telemetry-based sleep monitor, consisting of a 14-channel wearable wireless monitor and a cell phone–based gateway to transfer data, including video, in real time from the patient's home to a remote sleep center. The monitor can easily be worn and transported, and it offers reliable recordings. The receiver is a separate unit connected with the back of the display. Internal Bluetooth receivers, usually included in laptops, can also be used instead of a dedicated external Bluetooth receiver. A major problem encountered with home sleep studies is the potential loss of data in about 4.7% to 20% of the cases, which results in lower than expected cost savings.[8] Using Sleepbox technology (Medatec, Brussels, Belgium), a wireless system able to communicate with the polysomnograph and with Internet through a WiFi/3G interface, and communicating via Skype, the investigators were able to deliver recordings with excellent quality in 90% of the cases.[9] This finding suggests an interesting way to decrease the failure rate of home sleep studies, although it is still problematic, and some technical aspects need to be improved. Pelletier-Fleury and colleagues[10] comparatively evaluated the cost and effectiveness of PSG telemonitoring and PSG by conventional unsupervised home monitoring, and showed that remote telemonitoring made the procedure clearly superior from a technical point of view and was preferred by the patients. The cost of PSG telemonitoring was US$244, whereas the cost of PSG with conventional unsupervised home monitoring was US$153. The health care infrastructure savings have to be taken into account as well. For example, by adding up the working days that the patients did not lose and the round-trip travel costs they avoided, it can be estimated that the real cost would be similar or lower than that of conventional PSG.[3] Masa and colleagues[11] compared the costs made between device transportation and telematic transmission of data, with comparable results. Having devices moved by a transportation company or sent telematically as raw data proved cost-effective and equally beneficial. This finding opens the possibility of application among patients who live a long way from the hospital or those with limited mobility. Fields and colleagues[12] showed the feasibility of a comprehensive, telemedicine-based OSA evaluation and management pathway compared with a more traditional, in-person care model. They combined video consultation for intake with home sleep testing using a type 3 portable monitor with remote download, and automatic CPAP (autoCPAP) titration with wireless modem technology. Patient satisfaction, CPAP adherence and compliance, and improvement in quality of life were similar in both groups.

Long-Term Polygraphic Monitoring

In clinical practice, the use of PSG is a standard procedure to assess sleep disordered breathing. However, PSG is not suitable for chronic monitoring in the home environment. New telemedicine applications have become available using a home appliance as a precautionary measure for monitoring snoring and OSA. Seo and colleagues[13] developed a nonintrusive health-monitoring home system to monitor patients' electrocardiogram (ECG) results, weight, motor activity, and snoring. Choi and colleagues[14] proposed a ubiquitous health-monitoring system in a bedroom, which monitors the ECG, body movements, and snoring with nonconscious sensors. Böhning and colleagues[15] evaluated the feasibility of nighttime pulse-oximetry telemedicine to screen patients at risk for OSA. They concluded that the technique seemed to be suitable and cost-effective, with high sensitivity and specificity. This approach can be applied in a telemedicine referral network for early diagnosis of OSA, and the reading could be transmitted to the relevant sleep laboratory, examined, and the results returned to the referring physician.[16]

THERAPEUTIC TELEMEDICINE APPLICATIONS

Remote Continuous Positive Airway Pressure Titration

An exploratory study was set up to perform real-time titration of domiciliary CPAP.[17] The novelty of this approach is that a telemetry unit is connected to a commercially available CPAP device to allow a low-cost, 2-way communication channel in real time between the sleep laboratory technician and the CPAP device in the patient's home. The approach requires no special telemedicine approach, nor does it require the patient's active cooperation or any kind of communication infrastructure (computer or the Internet) in the patient's home.

Monitoring of Continuous Positive Airway Pressure Compliance and Adherence

Continuous positive airway pressure adherence and compliance

Because CPAP is a self-administered treatment, its efficacy is critically dependent on the patient's willingness to use the device and apply the nasal mask during sleep, regardless of how well a CPAP machine corrects apnea. In this context, the term adherence is used to describe continued use of the machine (ie, uptake), whereas compliance expresses the use of CPAP for a certain amount of time.[18] However, these terms are often inadequately used and interchangeable. A user is defined as a patient who uses the device for greater than 4 hours per night. Commonly used definitions of adequate compliance are usage of greater than 4 hours per night for 70% of days or greater than 4 hours per night for more than 5 d/wk.[19,20] Different studies have shown that the rates of CPAP use are between 30% and 60%. Note that patients who become nonadherent in the first days of CPAP treatment generally remain nonadherent.[21] Without optimal CPAP use, patients fail to achieve the full cardiovascular and symptomatic benefits of therapy.

Hence, compliance for CPAP should be regarded as the main determinant for success.[18] Self-reports are an inaccurate tool to determine compliance with CPAP therapy for OSA. Trying to estimate daily use time by simply questioning how many hours a night the patient uses the device generally results in a considerable misestimation of mean treatment time per night, because the patient is likely to provide the number of hours of CPAP use solely for the nights it was worn. Including the question about the number of nights on CPAP per week makes self-reports of CPAP use more accurate. This discrepancy may be attributed to not using the machine when traveling, during episodes of upper airway infection, or during self-prescribed treatment vacations from time to time. Another explanation is that many patients do not reestablish CPAP after the first awakening in the morning. Altogether, a more objective approach is mandatory. At present, CPAP usage is assessed by using time meters or more sophisticated devices that measure both run time and pressure delivery. It is increasingly accepted in sleep medicine that good compliance consists of 4 hours or more of CPAP per night and 70% of the nights, and that this is needed to achieve optimal symptom control.[22,23] The literature shows that between 29% and 83% of patients do not meet the criteria for good compliance because of removing CPAP early in the night and/or discontinuing use. Patients' perceptions of CPAP within the first weeks of using the machine affect the long-term results of CPAP adherence and compliance.[24] Objective compliance can be obtained from the average number of hours of running of the machine per 24 hours, calculated from the built-in time counter of the device, but, preferably, effective compliance is assessed based on the time spent at the prescribed effective pressure per night, using a pressure monitor coupled with a microprocessor.[25] Microprocessors use an algorithm for the detection of mask-on pressure. The variable component of the pressure signal given by the pressure transducer is analyzed in order to determine whether the patient is breathing into the mask. Reductions in therapeutic pressure greater than 2 to 5 cm and lasting longer than 10 seconds can be documented as mask-off events. Thus, the duration of therapeutic pressure delivery per day (also referred to as mask time) and number of missed days of use can be determined. From these data, several parameters can be calculated (percentage of days when CPAP was used; percentage of days when CPAP was used for >4 hours; mean daily use; mean daily use on days CPAP was used), including mean delivery pressure and residual apnea-hypopnea index (AHI). This approach is usually described as CPAP adherence tracking, although the term

CPAP compliance tracking might be more applicable.[26] Modern CPAP devices can be interfaced with a computer in the physician's office or home setting to download data. Newer modems can interface with the CPAP unit and the integrated chip to facilitate the reporting of remote data and reduce the need for face-to-face visits.[27] These modems may be used as augmentation to therapy for adherent patients or to identify and assist nonadherent patients. In addition, smart cards can be inserted into slots in the CPAP devices to imprint the data. These cards are then transported to the appropriate professional in a variety of ways, including the use of mail carriers or other modes, to reduce the need for direct patient travel for routine compliance and adherence reporting. These cards track usage hours, mask leak (liters per second), pressure, snoring, and AHI, and may assist sleep technicians, specialists, and home care providers with feedback on efficacy data to determine effective therapy and to measure outcomes. AHI measurements by some machines have been shown to be highly correlated with the measures recorded by PSG.[28] However, there are known problems with loss of data and failure of recording systems (primarily smart cards).[26,29] An evolutionary development in the collection and reporting of adherence and compliance data is wireless and Internet technologies to transmit clinical data to remote sites.[27] The powerful ability to track daily CPAP use facilitates rapid detection of decreased compliance, nonadherence, or suboptimal apnea correction to reduce the burden and risks and ensure cost-efficacy.

Standard follow-up

The patient should be seen by a qualified sleep professional to assess CPAP usage (hours of use and hours of application), to check the machine settings, and to ensure the interface (mask, pillows, and so forth) is in good condition. Short-term and long-term follow-up are crucial to adherence and compliance, but monitoring efficacy is also critical to adherence, compliance, and successful therapy. The results of the hours/usage monitor should be discussed and the need to be adherent to the prescribed treatment reinforced. An annual office visit should also be scheduled to check all the equipment and the hours/usage and to replace masks. Changes in the patient's overall condition may warrant a change in CPAP pressure (ie, weight gain may allow a higher CPAP setting or vice versa). In one study, compliance monitoring, including consistent follow-up, troubleshooting, and feedback to both patients and physicians, achieved good CPAP compliance rates ($\geq$4 hours per night) of greater than 80% over 6 months.[30] In contrast, close follow-up has not been consistently shown to improve compliance, but is worth doing.[31] Even more effective is to establish adherence and compliance patterns early in treatment initiation, which can help to resolve problems in a timely manner and is essential in the effort to establish a pattern of treatment adherence and good compliance.[21] Intervention early in therapy may improve the patient's early response to CPAP therapy and increase the likelihood that the patient will become a regular and compliant user, thereby enhancing clinical outcome.

Remote continuous positive airway pressure monitoring and fine-tuning

Remote monitoring of health status is one of the objectives of telemedicine.[32–34] It allows clinicians to remotely download previously recorded data.[35–39] Patients can also transmit data on a daily basis into a database (eg, the Encore Anywhere database, Philips; ResTraxx database, ResMed), where data extraction takes place. Next, the data can be analyzed against a set of preestablished criteria or filters. The data set can be scanned for multiple criteria and compared with thresholds for adherence and compliance, trends, AHI, periodic breathing, occurrence of central apneas, and mask leaks.[40] Automatically triggered clinical actions can then be scheduled. An additional goal of such a platform is to proactively identify and address issues that can negatively influence CPAP adherence and compliance. By providing patient data early in the course of CPAP treatment, it is thought that this technology will be extremely useful in improving compliance and acceptance of the device in patients with sleep apnea.[27,35,36,38,40–43] All that is needed is a personal computer, an Internet connection, and the proprietary software. Detailed reports can be generated to show usage information and then forwarded electronically to referral laboratories or physicians without generating additional paperwork. A modem connected to a CPAP unit in the patient's home automatically dials into the server each evening. The compliance server analyzes the data and notifies the physician of any patients with poor CPAP usage. Patient confidentiality is secured through a password and login-protected system that provides protection for the patients' information. Such systems provide accurate, thorough, and advanced information to clinicians and ensure that each patient is receiving the maximum benefit from CPAP therapy. Wireless applications have become available that transmit adherence and compliance data to a central server on a daily base, eliminating the need for data cards, home telephone lines, and frequent patient visits. Clinicians can check their patients at a glance with physician summary reports. Color-coding allows the caregiver to easily identify patients who require attention. Remote setting changes are available to fine-tune therapy and optimize patient management. Historical data can be searched at any time to retrieve data that were not transmitted via the monitoring schedule. As a provider extender, telemedicine support for patients initiating CPAP therapy may allow greater practice efficiency while maintaining quality of care. Roles, expectations, and responsibilities of providers involved in the delivery of such services should be defined and communicated, including those at originating sites and distant sites.[44] The assumptions that parties may have in such encounters and roles should be explicitly documented. In general, the standards for supervision should follow the same general guidelines as those for technicians, respiratory care practitioners, and nurses working with physicians in the live setting. All providers involved have to review their facilities' and institutions' bylaws and human resource documents. Moreover, relevant regulatory documents related to the provision of care are to be followed, and organizations and providers are to ensure that such care is consistent with policies regarding scope of practice and state licensing laws of all involved parties.[44] However, it is questionable whether service providers could be allowed to fine-tune CPAP settings independently, because changing treatment regimens has been the privilege and responsibility of physicians for centuries. To overcome this problem, physicians must be available by telephone to provide assistance and direction if needed. Telemedicine could be readily used to augment general supervision, and asynchronous methods could be used.[44] However, in some countries, CPAP fitting and troubleshooting are not eligible for reimbursement when performed via telemedicine by respiratory therapists and sleep technologists.[44] Nevertheless, study results suggest that the use of telemonitored CPAP compliance and efficacy data seems to be as good as standard care in its effect on compliance rates and outcomes in new CPAP users.[38] Stepnowsky and colleagues[38] showed that a telemonitored clinical care group had a compliance rate of 4.1 hours per night after 2 month, which represents a 46% increase in compliance compared with the mean compliance level of the standard clinical care group (2.8 hours per night). There were some concerns regarding the potential loss of data through wireless transmission. However, the loss was negligible and, once the wireless unit was properly connected, data from previous nights stored on the flow generator device could be retransmitted and obtained wirelessly. Anttalainen and colleagues[45] compared a group of wireless telemonitored CPAP users with a usual-care group, after CPAP titration. They found equal CPAP compliance and residual AHI at 1-year follow-up. Median nursing time was 39 minutes in the telemonitored group and shorter than the 58 minutes per patient in the usual-care group.

Challenges for therapy monitoring

Telemedicine monitoring of sleep apnea therapy is currently limited to CPAP and related ventilator support devices. However, alternative treatment modalities are becoming available. One such option is mandibular advancement devices, which are used to optimize upper airway patency by forcing the mandible into a forward position. It has been shown that these devices can be objectively monitored by in-built thermosensors, with wireless transmission of adherence and compliance data.[46] Also, the data from CPAP devices have to be incorporated with the data regarding the physical status of the patients into the e-Health sleep record. At a later stage, other aspects of digital technology will most likely be incorporated. Among them, integration of relevant health-related data collected from everyday apparel, wearable sensors, and household appliances, and increased interactivity between patients and health care providers, will improve the anticipation and thus, it is hoped, the prevention of the worsening of medical disease states based on validated algorithms.

PATIENT COUNSELING, THERAPY REINFORCEMENT

The use of telemedicine, defined as the use of information and communication technology to deliver health care at a distance, can have a substantial impact on health care use, strengthen the sleep professional–patient interaction, and enhance self-management skills.[47] It has the ability to quickly collect, transmit, and incorporate data, making it a swift and viable means of communication between patients and their providers.[48] These features have a significant potential for the management of patients with OSA, particularly for education and counseling, optimizing CPAP adherence and close monitoring of effective compliance. This type of intervention also has the added potential benefit of fostering patient empowerment. Patients who take ownership, who are involved in their own care, and who possess the knowledge and skills to manage their disease are more likely to comply with lifestyle modifications and treatment regimens, which in turn improves clinical outcomes.[49]

Patient Counseling and Personalized Feedback (Video and Teleconferencing)

Video and telephone contacts provide both direct and indirect benefits to patients. Direct benefits include decreased waiting time and increased physician availability. Indirect benefits include avoidance of barriers to in-person visits, such as the cost and time associated with travel or missed work.[2] Video visits could accommodate chronic routine follow-up appointments. Patient-specific data, such as diaries for insomnia and CPAP machine downloads for OSA, could be reviewed at such visits, as could routine challenges with equipment or medications.[2] A concern could be that the doctor might need to perform some physical examination. However, in sleep medicine it may be that stable patients could be adequately assessed without performing a physical examination that requires the physician to be present in the same room. In addition, certain elements of the examination, such as weight or blood pressure measurement, could be performed at home or by the family physician. In a series of 90 patients with OSA, 56 were seen by a physician at the sleep center and 34 by videoconference. Satisfaction did not differ between the groups.[1]

Promotion and Reinforcement of Patients' Adherence and Compliance

Maximizing adherence and compliance is one of the most important challenges sleep experts face. Telemedicine has been used in various studies to promote and reinforce CPAP treatment.[50–53] In most of them, a cognitive behavioral intervention was applied by telephone,[27,35,41,54,55] the Internet,[35,55] and videoconference.[1,36,56]

Telephone

DeMolles and colleagues[41] used a daily computer-based telephone system to monitor patients' self-reported compliance behavior and provided automated counseling through a structured dialogue. The impact of the intervention was not significant compared with standard care. However, the findings suggest that concurrent education and reinforcement during the initial and early treatment period are effective countermeasures to patient-reported attenuated compliance. Sparrow and colleagues[42] applied an automated telemedicine intervention system, based on an algorithmic interactive voice response system designed to improve CPAP adherence and compliance. The system monitors CPAP-related symptoms and patients' self-reported behavior and provides feedback and counseling through a structured dialogue to promote CPAP usage. The monitor uses digitized human speech to speak to the patients and the patients communicate via the touch-tone keypad of their telephones. Each call began with an assessment of the self-reported duration and frequency of CPAP usage during the past week, followed by one of several motivational counseling modules. If participants reported excessive side effects or OSA symptoms, the system then recommended the patients to contact their physicians to discuss the problems. The computer system called the patients if they did not make a call at the expected times. Routine printed reports were sent to the participants' physicians biweekly during the first month and the month thereafter. This telemedicine approach resulted in a median CPAP usage that was 0.9 hours per night (at 6 months) and 2.0 hours per night (at 12 months) higher than that of an attention control group.[42] Chervin and colleagues[37] performed a randomized controlled trial (RCT) among 33 patients of 2 interventions to improve compliance: one group received weekly telephone calls to uncover any problems and encourage use, a second group received written information about OSA and the importance of CPAP adherence, and a third group served as a control group. Intervention improved CPAP compliance and the effect was especially strong when intervention occurred during the first month of CPAP treatment. Isetta and colleagues[57] found in a series of 50 consecutive patients with OSA that most of them were satisfied with the teleconsultation method, and 66% agreed that the teleconsultation could replace more than half of their CPAP follow-up visits. In addition, Coma-Del-Corral and colleagues[3] found that the level of good CPAP compliance was 85% at 6 months in patients attending the sleep center for a face-to-face meeting, and 75% in the teleconsultation arm.

Sedhaoui and colleagues[58] performed an RCT in 379 patients with OSA, comparing standard support completed or not within 3 months of coaching sessions, based on telephone-based counseling by competent staff. Sixty-five percent of the patients in the standard group showed a compliance rate of greater than 3 hours per night, versus 75% for the coached group. The mean CPAP usage was 26 minutes longer in the coached group versus the standard group.

Internet

Taylor and colleagues[35] used computers to provide daily Internet-based informational support and feedback for problems experienced during CPAP usage. Questions related to CPAP use, hours of sleep, and quality of sleep were sent to the participants via a computer. The patients' responses were monitored by the sleep medicine practitioner, and the patient telephoned if deemed necessary. There were no significant differences between the telemedicine intervention and standard-care group at 30 days in patient functional status and satisfaction with CPAP. This intervention only provided self-reported data to the health care provider, whereas objective compliance and detailed physiologic information may have been more useful in effectively troubleshooting problems and may have improved CPAP compliance.[35,56,59] Furthermore, in an RCT, Fox and colleagues[55] showed improved CPAP compliance with a Web-based telemedicine monitoring system. An autoCPAP machine transmitted physiologic data (residual AHI, air leak, compliance) daily to a Web site that could be reviewed. In case problems were identified from data from the Web site, patients were contacted by telephone as necessary. After 3 months, the mean compliance rate was significantly greater in the telemedicine arm (191 min/d), compared with the standard arm (105 min/d). In contrast, 67 minutes of technician time were spent on the patients in the telemedicine arm compared with the standard approach. In addition, Kuna and colleagues[60] found in an RCT that providing patients with daily Web-based access to their positive airway pressure (PAP) usage improves compliance (4.7 ± 3.3 hours in the usual-care group, 5.9 ± 2.5 hours and 6.3 ± 2.5 hours in the Web access groups with and without financial incentive, respectively). Inclusion of a financial incentive in the first week had no additive effect in improving compliance. These findings are consistent with a similar study evaluating the effect on compliance when an interactive Web site providing PAP data to both patients and providers is used.[61]

Video

Smith and colleagues[36] tested a teleconferencing approach in which a nurse visually assessed mask fit and patients' CPAP procedures and provided counseling and reinforcement to patients who were trying CPAP again after an initial 3-month period of poor compliance. Although the patient education materials supplied during the initial period did not affect adherence rates, the nurse teleconferencing sessions during the second trial period substantially improved the adherence of the intervention group (9 of 10 patients vs 4 of 9 in the placebo intervention group), suggesting that intensity of one-on-one counseling and feedback by a care provider is a relevant variable.[36] Isetta and colleagues[57] performed an RCT in which 20 patients with OSA received standard face-to-face training, whereas another 20 received the training via videoconference. Patients showed comparable knowledge about OSA and CPAP therapy, and performance of practical skills was also similar between the two groups. In another study of the same group in 139 patients with OSA, similar levels of CPAP compliance, and improved daytime sleepiness, quality of life, side effects, and degree of satisfaction, were found in a telemedicine-based CPAP follow-up strategy (televisits via video conference based on Skype, e-mail, Web tool support) compared with face-to-face management.[62] Note that the telemedicine group made more extra visits than the face-to-face group, but most of them were non–OSA related.

Integration of Questionnaires, Rating Scales, and Diaries

Questionnaires, rating scales, and diaries can be useful for tracking short-term and long-term results, provided that baseline information is collected. Subsequent data can then be used to monitor symptomatic improvement. Among others, the Functional Outcomes of Sleep Questionnaire (FOSQ) is a popular and well-validated, self-reporting measurement to assess disease-specific health-related quality of life, based on multiple activities of daily living.[63] The FOSQ consists of 32 questions and is available with selected Philips (Murryville, PA) CPAP machines. Data can be remotely downloaded or can be completed or uploaded on a Web-based platform, and can be integrated in the electronic patient record. For patients with comorbid insomnia, telemedicine also provides opportunities to exchange and automatically process sleep diaries and smartphone applications of sleep-wake data, and follow online programs related to cognitive behavior therapy (CBT).[64–66] In this way, the insomnia field can probably be transitioned from evaluating more basic, noninteractive online programs to personalized, interactive online programs. For example, Espie and colleagues[65] used a virtual therapist to help deliver a Web-based CBT-i (CBT for insomnia) program. Such approaches may have more important roles in managing insomnia in the future. Apart from insomnia, it has been shown that the CBT approach is also effective in the context of OSA to improve CPAP adherence.[67] In cases of inadequate sleep hygiene, platforms can be programmed with automated messages to encourage behavioral change, without direct interaction with the sleep provider.[68,69] Clinician and patient satisfaction can be assessed using questionnaires that include visual analog scales and open-ended questions. Patients can be asked to rate their likelihood of continuing to use CPAP, their concern about being monitored, and their overall satisfaction with care. The CPAP self-efficacy scale is a 5-item self-report scale that was developed by Stepnowsky and colleagues.[70] The list of opportunities is almost unlimited. Online platforms will facilitate the movement from disease-based care into patient-based medicine. Such asynchronous tools may provide important diagnostic and therapeutic information. The information from these tools should be easily accessible to sleep providers.[44]

BARRIERS IN THE IMPLEMENTATION OF TELEMEDICINE

Telemedicine aligns with the shift in national focus from technology being used in isolation to technology being the means to both expand the reach of health care and to integrate health care services across patients and organizations. Its adoption has been hampered by a multitude of barriers.

Receptiveness and Willingness of Health Care Providers and Patients

At present, expansion of telemedicine into all aspects of sleep disorder management is limited by the willingness of physicians, patients, and health care organizations to accept telemedicine as an alternative to in-office care.[44] The settings from which patients and physicians originate may influence the perception or acceptance of telemedicine.[1] Croteau and colleagues[71] showed that physicians in urban areas tend to be unwilling to dedicate time to learning how to use new telemedicine equipment. However, if the technology is easy to use, the correlation between ease and implementation is positive. In a study of rural communities, Campbell and colleagues[72] found that physicians are more likely to adopt telemedicine technology if they perceive an increased capability of telemedicine to accommodate the constant advance of technology. In both rural and urban areas, perceived usefulness had the most significant impact on the decision by health care providers to adopt telemedicine. As long as telemedicine can be proved to be a useful tool for health care, the willingness of physicians to use telemedicine technology remains positive. Nevertheless, clinicians' feedback should be further assessed and their involvement promoted as main factor in guaranteeing a successful telemedicine implementation.[73,74] In general, research indicates that telemedicine has been well received by patients with OSA,[1,36] as well as by patients with other medical conditions.[75,76] The greatest advantages of telemedicine that have been identified are more convenience and decreased travel burden.

Privacy Concerns and Confidentiality

Systems need to be developed to protect patient privacy when CPAP adherence and compliance data reports are reviewed and maintained on servers. A significant current problem in the monitoring of CPAP performance is the ability to track patients with the location data that are transmitted. This ability would violate the right for privacy for the patients being treated. Also, a service provider who monitors not only the usage time but also the flow pattern can provide a diagnosis of the reoccurring sleep apnea as well; for example, it may be caused by a worsening of the disease over time. The patient could be alerted to contact the sleep center, or the applied CPAP pressure could be adjusted remotely. Legal issues may arise, because this is comparable with a medical intervention, such as changing a medication dosage, and such an approach is not allowed in all health care systems.[44] Also, integration of the telemonitored data in the patient sleep record by the home care provider is limited by privacy issues. In France, all these privacy concerns have now led the courts to conclude that there are no legal grounds to allow telemonitoring. Therefore, a robust level of information security for transmission, storage, and access of the data and at the platform in which the data reside is mandatory to implement telemedicine acceptably. This security encompasses strong authentication, data encryption (for both live and stored information), nonrepudiation services, audit logs, a common security policy, and controlled contracts between partners.

The American Academy of Sleep Medicine (AASM) also explicitly describes the following requirements: muting availability; passphrase requirement to access device on which patient data are stored; inactivity timeout function requiring reauthentication with timeout not exceeding 15 minutes; protected health information and confidential data only stored on secure data storage locations; provider knowledge on how patient data are stored and ability to answer patient questions regarding storage of protected health information; access granted only to authorized users; data streamed directly to storage to avoid accidental or unauthorized file sharing.[44] All these requirements are based on American Telemedicine Association guidelines.[77] To encounter security requirements, different data (interchange) standards have been developed.[78] These standards include the primary clinical messaging format standards (eg, the Health Level Seven

[HL7] series) for clinical data messaging; Digital Imaging and Communications in Medicine for medical images; National Council for Prescription Drug Programs script for retail pharmacy messaging; Institute of Electrical and Electronics Engineers (IEEE) standards for medical devices; and Logical Observation Identifiers, Names, and Codes for reporting of laboratory results.[78] Encryption algorithms have been developed for the encryption of electronic data, like the Data Encryption Standard (DES), but the DES was shown to be insecure, because the algorithm was broken in 1993.[79] In addition, the Needham-Schroeder protocol was proved to be insecure more than a decade after its publication.[80,81] More up-to-date encryption standards are the Advanced Encryption Standard (AES), DES-X, GDES, and Triple DES standards, which have been shown to be secure.[82] Alternatives for the DES standard are several replacement algorithms (RC5, Blowfish, IDEA, NewDES, SAFER, CAST5, FEAL, GOST 28147–89, RC6, Serpent, MARS, and Twofish, among many others) with higher security and faster operation.[82,83] For image transfer, specific algorithms have been developed, like the Joint Watermarking-Encryption, which offers confidentiality, integrity, authenticity, and traceability functionalities,[84] and newer algorithms that combine traditional image encryption and image hiding with chaos theory, with improved processing.[85] Nonrepudiation implies that a person cannot deny responsibility for a certain transaction. This principle is important to maintain in audits because a person implicated by an audit should not be able to repudiate responsibility.[79,86,87] Data-access standards for electronic health records (EHRs) are also increasingly being implemented, such as the Fast Health Interoperability Resources, and the Substitutable Medical Applications Reusable Technologies (SMART) Health IT apps interface.[88] From the patient perspective, patient-powered networks are asking for easy download and exchange of their EHR data. Some (unsuccessful) technologies for this purpose were the Consolidated Clinical Document Architecture and the Blue Button.[89] The requirement for certified EHR technologies to provide an application programming interface will enable patients to get access to their EHR data in a timely fashion.[88] Legal liability can be avoided by providing policies and standards for health care providers to observe, like the Health Insurance Portability and Accountability Act (HIPAA) and HL7, which are the standard for encrypting communications and storing medical data in the United States and the United Kingdom.[90–92] Nonrepudiation is necessary to comply with HIPAA, and thus needs to be addressed by all telemedicine systems targeted toward the United States.[87] Also, clear contingency plans are required in the event of loss of communications.[90,91] In addition, controlled contracts between partners are recommended. Such measures are feasible between hospital organizations, and hence for physician-physician contacts, but raise concerns over the ability to develop secure patient-to-physician (or vice versa) data transfer. By only transmitting data relevant to the problem in question, using storing and transmission methods where confidentiality and security are guaranteed, and obtaining informed consent from the patient are ways in which these concerns can be minimized.

Financial Barriers

Although telematic transmission of CPAP adherence and compliance data is the future, a major problem with wireless systems is having the additional resources to retrieve the data,[44] and to cover the costs for providers' services, transmission modules, home installation, licensing fees, telephone charges, security, and additional work by the sleep professionals.[93] These costs should be anticipated by the health care authorities before introducing these technologies. Moreover, despite the evident potential of telemedicine-based interventions, the precise benefits, risks, and costs of this method to deliver health care remain unclear.[94] In a systematic review, telemedicine and telecare services were found to be no more cost-effective than standard health care strategies.[95] In one sleep medicine study, the cost of the interventions, including material costs, was lower than the same number of face-to-face visits,[36] whereas another study reported lower total costs because of savings on transport and less lost productivity (indirect costs).[62] Therefore, a telemedicine-based approach could be especially advantageous if applied to the working population and to residents in medically underserved areas. However, it is important to target and customize these interventions to patients who are most likely to benefit from them. Ultimately, clinicians should also carefully select the appropriate outcomes that telemedicine strategies seek to effect.[96] For example, telemedicine encompasses expanded patient access to quality sleep health care.[97–99] Moreover, protocols need to be developed that describe the roles, expectations, and responsibilities of health care providers, hospitals, physicians, and patients involved in the delivery of sleep telemedicine, because it is not clear when, how, and who should monitor the wireless transmissions. In addition, long-term studies with cost-effectiveness analyses are needed.

Technological Barriers

There are other barriers to incorporating wireless transmission systems routinely in clinical practice. If hospitals make use of different CPAP brands, they will be urged to switch to a single brand in order to control the telemedicine costs. The lack of standardization also precludes interoperability with existing electronic patient records, and data profiles are not standardized between the different providers. Moreover, current electronic patient records are not configured for this type of data management. In addition, there is also the potential for network complications when using a telecommunications network, latency, as well as disconnection. This concern is legitimate, because the potential for complications is a reality.[100] A general concern for telemedicine application includes the lack of reliable Internet access outside of large cities and inadequate bandwidth for high-resolution images or videoconferencing.[101]

Future Platforms

In the older platforms, the organization and management of data were based on a centralized server operating through a call center, with several inherent financial and legal aspects between hospitals and providers.[51] With low-cost miniature integrated circuits now available, new devices have been developed that enable a decentralized communications architecture, whereas the patient's home no longer has to be equipped with any telecommunications infrastructure. Also, smartphone applications are now checked for their diagnostic value, in addition to just monitoring sleep behavior. These developments are rarely validated against medical standards and the diagnostic value is unknown. However, because they allow the transmission of data to the cloud, or even a personal Web page, this is another area in sleep telemedicine that is being realized.[102] However, tracking of patients may also be an issue when using SIM (Subscriber Identity Module) cards, which allow tracking through the wireless transmission cell structure. When the user changes locations, it stores the Location Area Identity number to the SIM and sends it back to the operator network with its new location.[103] Security here is also an issue, particularly when SIM cards use the DES, which is, despite its age, still used by some operators. Cards using the more recent AES or Triple DES standards are secure.[104] Nevertheless, at the moment, these smartphone applications are gadgets in the framework of quantifying an individual, but are not medical supportive tools.[105] It is expected that a full combination of biomedical sensors and mobile phones will also help to incorporate telemedicine into routine practice. However, in a group of 107 high-cardiovascular-risk patients with OSA, telemonitoring of self-measured home blood pressure, physical activity, and CPAP compliance based on smartphone intervention failed to improve adherence or blood pressure. The investigators speculated that it is possible that telemedicine could be perceived as an additional burden associated with the self-management of blood pressure and CPAP.[106]

Quality Concerns

As recommended by the AASM, clinical standards for telemedicine services should mirror those of live office visits, including all aspects of diagnosis and treatment decisions as would be reasonably expected in office-based encounters.[44] Inherently, physical examination is not possible as it is performed in a face-to-face visit, but is not critical in a sleep medicine setting. Therefore, clinical judgment is mainly based on anamnesis and detailed metrics and analytics. Resources should be made available to reimburse these facilities in a manner competitive or comparable with traditional in-person visits and this will make it feasible to promote a care model in which the different parties involved collaborate and interact, resulting in a better value of health care delivery in a coordinated fashion. Consecutively, this also means that appropriate technical standards have to be upheld through the complete telemedicine care delivery process. Therefore, quality assurance processes have to be introduced as well, to ensure the optimal level of patient outcomes, process measures, and user experience. Quality improvement based on data management and quality processing should also be recognized and financially appreciated. Such programs should encompass process measures, patient-centered outcomes, overall provider experience and satisfaction, technical ease, and encryption of communications and storage. Strict application of the highest professional and ethical standards is required, with the aim of improving overall patient access, quality, and value of care. Such an approach benefits from financial transparency throughout the process.[44]

Legal Concerns

Apart from patient privacy, confidentiality, and security concerns, other legal obstacles could arise that focus on the licensure of physicians. It is a universal requirement that physicians practicing within a country must be licensed in that country, whereas in telemedicine, physicians deliver medical treatment across state lines and, possibly, international borders.

Furthermore, the legalities surrounding virtual medical services can sometimes be inconsistent and vague, and can increase liability concerns. Some countries do not allow controlled substances (eg, sedative hypnotics) to be prescribed to patients whom the provider has not seen in a face-to-face encounter. Also, as discussed earlier, data protection and data security are the number 1 issue in any telemedicine application. The EU Directives on the Processing of Personal Data and the Protection of Privacy in the Electronic Communication Sector describe several specific requirements relating to confidentiality and security that telemedicine services have to meet in order to safeguard individuals' rights.[107–109]

If such security can be guaranteed, telemedicine can easily be performed, because any form of communication that does not relate to an identified or identifiable natural person is not subject to the multitude of data protection laws.[107,109] Other European legal achievements related to e-Health are the E-Commerce Directive, the Medical Device Directive, and the Directive on Distance Contracting. These directives are not adopted especially for e-Health applications, but are indirectly important. For store-and-forward encounters that may use digital images of patients for the purpose of rendering a diagnosis or medical opinion, without the presence of the patient, this has been proved feasible for some specialties, like radiology (teleradiology), pathology (telepathology), and dermatology (teledermatology).[110,111] Sleep electroencephalography and polysomnography can also have the interpretation performed remotely.[44] However, in telemedicine with more complex patient/physician encounters using electronic communication and electronic patient records with personally identifiable data, this will be a less achievable goal. Nevertheless, the confidentiality of telemedicine is affected by the inherent risk of third parties intercepting the communication. For example, if a confidential communication is disclosed to a third party, it is not deemed to be confidential, and therefore the physician-patient privilege does not apply.[100] In France, the concept of telemedicine was formalized in the 2009 Hospital, Patients, Health Territories national law and the 2010 decree through which it was applied.[112] Since then, doubts have remained, and, less than 5 years later, sleep telemedicine and remote CPAP compliance monitoring were put on hold, because of privacy concerns. Cloud applications are now being used in some ambitious health care applications, drawing together huge amounts of data from disparately located computers, which implies data sharing across jurisdictions and the sharing of responsibilities by a range of different data controllers.[113] This process could be said to be opening Pandora's Box.

SUMMARY

Various methods are available to assess adherence and compliance with nasal CPAP at home. Objective data can be obtained by either downloads from the memory card of the CPAP device or by direct interrogation of CPAP devices that do not have memory cards. Telemedicine applications can be useful to monitor and motivate patients on a large scale. There are emerging mechanisms for supporting virtual visits and remote monitoring if they can be shown to be financially competitive. Inclusion of sham telemedicine control arms might determine whether increased adherence might have been caused by the perception of monitoring by the patients, or by the more prompt institution of clinical interventions. As this new frontier is explored, it is of paramount importance to be aware of how to use this technology safely, and within the health care system's current legal confines. In addition, careful telemedicine management will provide a more seamless communication flow, to the benefit of medical providers, the global health care system, and ultimately for patients.

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