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The Role of Telemedicine in Hypertension Management: Focus on Blood Pressure Telemonitoring

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Abstract This review aims at updating and critically assessing the role of telemedicine, and in particular, of home blood pressure telemonitoring (HBPT), in the management of the hypertensive patient. Result from several randomized trials suggest that HBPT represents a promising tool for improving blood pressure (BP) control of hypertensive patients, in particular, those at high risk. Most studies documented a significant BP reduction with regular HBPT compared to usual care. HBPT interventions showed a very high degree of acceptance by patients, helped improving the patients' quality of life, and were associated with lower medical costs than standard care, even though such costs were offset by those of the technology, thus reducing the overall cost-effectiveness of HBPT. The high heterogeneity of the technologies, study designs, and type of patients in the various studies suggest that further well-designed, large cohort, prospective studies are needed to identify key elements of HBPT approach to be able to give impact on specific outcomes. Likely, patients who need a constant monitoring of multiple vital signs and a tight BP control, such as high risk patients with chronic diseases (ischemic heart disease or heart failure, diabetes, etc.), as well as non-adherent patients, may particularly benefit from HBPT. In general, HBPT can be an advantageous choice when a network among healthcare professionals (doctors, nurses, and pharmacists) is needed to improve the screening and management of hypertension and related comorbidities and to achieve an effective prevention of cardiovascular diseases in the community.

This article is part of the Topical Collection on *Blood Pressure Monitoring and Management*

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Introduction

The term telemedicine commonly refers to the use of medical information exchanged from one site to another via electronic communications in order to improve a patient's clinical health status. Formally, telemedicine includes a growing variety of applications and services using two-way video, phone calls, e-mail, the Internet, smart phones, wireless tools, and other forms of telecommunications technology [1].

Telemedicine was first introduced in hospitals approximately 40 years ago, with the aim of extending care to patients in remote areas, and since then, its use has spread rapidly. Although poor implementation, low reimbursement levels, and lack of physician support have represented and still represent important barriers slowing down diffusion of telemedicine in daily practice, this tool is becoming an integral part of healthcare, being more and more often integrated into the ongoing operations of hospitals, specialty departments, home health agencies, private physician offices as well as consumers' homes and workplaces. According to the most recent survey from HIS technologies, the number of patients using telemedicine services is projected to reach 7 million in 2018, from less than 350,000 in 2013 [2].

Telemedicine positively affects all branches of medicine offering to healthcare professionals and patients a tool for improving disease management. For this reason, more and more often telemedicine has become synonymous of telehealth, a definition encompassing a wide range of remote healthcare services. Patient consultations via video

conferencing, transmission of still images, website for patients, remote monitoring of vital signs (so-called telemonitoring), continuing medical education, consumer-focused wireless applications, and nursing call centers, among other applications, are all considered part of telehealth [1].

At variance from health information technology, which more commonly pertains to electronic medical records and related information systems, telemedicine refers to the actual delivery of remote clinical services using information technology. A branch or specific application of telemedicine is represented by telemonitoring, defined as the use of information technology to monitor patients at a distance.

Telemonitoring allows remote data transmission of main vital [e.g., blood pressure (BP) and heart rate] and non-vital parameters, from the patient's living site to the doctor's office. It is a technology applying particularly well to patients with chronic illnesses or conditions, such as arterial hypertension, diabetes, chronic obstructive pulmonary disease, heart failure, etc.

Specifically considering arterial hypertension, a telemonitoring application which is becoming more and more popular among doctors and their patients is the home blood pressure telemonitoring (HBPT), which is based on electronic automated BP monitors storing and forwarding BP readings to a remote computer where they are reviewed by the referring physician for treatment adjustments [3].

In this review, we aim to update the reader on the role of telemedicine in hypertension management, focusing in particular on the recent data regarding the clinical efficacy of HBPT interventions compared to usual care.

Telemedicine Technologies and Services for Hypertension Management

During the recent years, growing interest regarding the impact of telemedicine in reducing the burden of chronic cardiovascular diseases led to an increasing number of randomized as well as pragmatic trials aimed at evaluating the clinical effectiveness of telemedicine for the primary and secondary prevention of cardiovascular diseases [4•, 5]. A particular focus on telemedicine is being dedicated to arterial hypertension due to the burden of suboptimal BP: telemedicine may represent a useful tool to improve BP control and reduce the long-term social costs related to increased frequency of cardiovascular events when hypertension is not controlled, both in terms of clinical outcomes and increased social and healthcare costs. As a matter of fact, suboptimal BP cost 370 billion US dollars (approximately 282 billion euros) globally in 2001; this represents about 10 % of the world's overall healthcare expenditures. It has been estimated that over a 10-year period, high BP may cost nearly 1 trillion US dollars (762 trillion euros) globally in health spending, if current BP levels persist. Indirect costs could be as high as 3.6 trillion US dollars annually (274 trillion euros) [6]. Nowadays, the technological outbreaks have made available several different tools which can be used to deliver services to both healthcare professionals and hypertensive patients through telemedicine, by creating a healthcare network centered around the patient. Some of the most common services currently provided to hypertensive patients and doctors are listed in Table 1.

The availability of high-speed normal landlines and the Internet represents a unique opportunity for easily creating networks between hospitals and community health centers in rural or suburban areas, without the need of expensive ad hoc technologies. Live interactive video or store and forward transmission of diagnostic images, vital signs, and/or video clips along with patient data may be used by the primary care physician in order to allow a consultation with a patient or a specialist assisting the primary care physician in rendering a diagnosis. Web-based monitoring centers may be used for monitoring patients' vital signs, such as BP, heart rate, respiratory function, and adherence to antihypertensive therapy at home or providing them care services. Tools for remote patient's BP or other vital sign monitoring at home, supplemented by visiting nurses and telephone calls, may be used to remotely collect and send data to a home health agency or a remote diagnostic testing facility for interpretation and distribution to the referring physicians. Point-to-point connections using private high speed networks may be required by hospitals and clinics in order to deliver dedicated services to other hospitals and to outsource specialty services or independent medical service providers. Web-based e-health patient service sites may provide direct consumer outreach services over the Internet and may be used to forward medical and health information to the patients and to promote on-line discussion groups, providing peer-to-peer support. Finally, telemedicine may be used to supply medical education and update to physicians in charge of hypertension management and to organize online medical education seminars for targeted groups in remote locations.

Table 1 Typical services which can be provided to healthcare professionals and hypertensive patients through telemedicine

- Electronic health records
- Remote consultation and diagnosis (via videoconference)
- Monitoring of health parameters (e.g., blood pressure)
- Monitoring of patient's adherence to treatment
- Transmission of diagnostic images
- Web-based health information (interactive education programs on lifestyle and behavior) and on-line discussion groups for patients
- Continuing medical education for healthcare professionals

Advantages and Benefits of Telemedicine in Hypertension Management

The application of telemedicine to hypertension care brings several important advantages, which are shared with many other chronic conditions currently managed through telemedicine technologies (Table 2) [7, 8]. A main advantage of telemedicine is to establish and build an enduring and long-term relationship with patients, a particularly important feature in case of hypertension, a lifetime condition needing continuous medical supervision. More in general, the use of telemedicine may help empowering hypertensive patients, influencing their attitudes and behaviors, and improving their medical condition. Telemedicine allows physicians and health facilities to expand their reach, beyond their own offices, and to easily provide service to an increased number of patients, in both rural and urban areas. With telemedicine much of the current time demands on physician could be eliminated because care may be the net result of shared management between patients and doctors. The number of patients served by a single physician may thus be consistently raised. Increased doctor-patient contact entails increased awareness about patient's needs and medical history, thereby expanding the access to health facilities for hypertension screening and detection, and providing continuous and superior care with reduced costs. Although some observers fear that telemedicine may minimize the patient–physician relationship, increasing the risk that the hypertensive patients, after a period of acquaintance to technologies, may self-manage their condition, this seems to be unlikely. Instead, telemedicine can reinforce and empower the physician-patient relationship, may even try to individualize it, and thus improve BP and cardiovascular risk control. As a matter of fact, clinicians might be able to spend more time with the patients who need them most and may benefit of a diagnostic support by expert colleagues even in absence of specific knowledge on the disease management [9].

Table 2 Advantages of telemedicine in the hypertension management

- Establishment of a tight relationship between the patient and the referring physician
- Empowerment and reinforcement of the physician-patient relationship
- Possibility for the physician to reach underserved areas and their population
- Increase in the number of patients to be served
- Reduction in travel time and related stresses for the patient
- Assessment of data in real time
- Acceleration of the delivery of best practice
- Improvement in the quality of care and in the health outcomes
- Potential cost efficiency: long-term reduction of social and healthcare expenditure
- Access to medical services or diagnostic procedures not available otherwise

Although many are convinced that remote patient's management through information technology may reduce the quality of the delivered care, there is strong evidence that the quality of healthcare services provided via telemedicine to hypertensive patients is as good as that given in traditional in-person consultations [4•]. Telemedicine allows hypertensive patients to easily and rapidly communicate to their doctors the occurrence of acute symptoms or sudden BP raises. It also enhances the monitoring, tracking, and communication of various biometric information, as we will discuss later in this paper, enabling greater engagement and partnership in their care, and reducing the patient stress. Telemedicine services offer hypertensive patients the access to diagnostic procedures (e.g., ambulatory BP or ECG monitoring) that might not be available otherwise, without the need to travel long distances. In fact, there is established evidence that demand of telemedicine is increased among patients, their family and their community. And many studies have documented patient satisfaction and support for telemedicine services, particularly those based on mobile technologies [10].

In the case of hypertensive patients, mobile health technologies may provide a more flexible platform to enhance patient self-care activities, which can play a major role in achieving good BP control. As a matter of fact other electronic health systems like those requiring wired connections and a personal computer, and an Internet access may reduce access for many older patients, as discussed later [11].

Home Blood Pressure Telemonitoring

As mentioned above, HBPT is a particular application of telemedicine. Basically, it consists in a process of automatic BP data transmission from the patient's home to the doctor's office or to a clinic. HBPT is generally based on the use of electronic automated upper arm or wrist BP monitors storing BP values obtained at patient's home. Several systems are available on the market, which are characterized by the different modalities of data collection, transmission and reporting, and by additional features such as reminding facilities for BP measurement to be performed and/or for medication intake, and automatic data reporting. Among the available technologies, wireless systems, at present mostly based on bluetooth or near field communication technology, seem to be particularly promising because they are user-friendly and not limited by the patient's appliances: they also minimize disruption due to additional wiring. Such technologies allow linking the medical devices to interfaces with built-in mobile telephone-based transmission systems (e.g., smartphones or tablets) or to Wi-Fi access points more and more often available in many users' dwellings. Data are then forwarded to a remote computer

(server) of the telemedicine provider through a telephone line (wired or wireless), by a modem or an acoustic coupling system, or, as done in most of the more recent systems, through the Internet. Data transmission is usually achieved through a landline broadband or cellular network and security is ensured by encryption protocols (S-HTTP or S-FTP). When data are received at the central telemedicine server they are stored and automatically analyzed. Reports are generated, including graphic display of time variations in the monitored parameters and their averages over the recording period. Case managers may review the data before they are presented to the reporting physician and interact with the patient. At the end of this process, a medical report is forwarded to the patient and referring primary physician through a website, via e-mail or through dedicated smartphone apps (Fig. 1) [3].

HBPT shares the same advantage of home self-BP monitoring: the lack of alarm reaction during the measurement and the potential to obtain several reproducible BP measurements over several days under daily-life conditions. Moreover, HBPT has additional advantages for patients and doctors; in particular, HBPT encompasses the assessment of data in real time and the accelerated delivery of best practice when combined to decision-making strategies [12]. A list of the main advantages of HBPT is summarized in Table 3 [3, 13]

Table 3 Advantages of the combination of home blood pressure monitoring with the data teletransmission for patients and doctors

Advantages of HBPT
• No alarm reaction to blood pressure measurement
• Several and highly reproducible blood pressure measurements over time
• Evaluation of blood pressure during daily life
Advantages of HBPT for patients
• Active patient's involvement in the disease management (particularly important for critically ill patients)
• Increase in patient's compliance to treatment
• Reduced visits and costs of management
• Optimization of therapy
• Better individual blood pressure level estimation and control
Advantages of HBPT for doctors
• Teletransmission of blood pressure readings with feedback to ensure a quick update of doctor on patient's health status
• Strict patient's monitoring
• Centralized automatic analysis (no need of local software or specific computer skills)
• Detailed medical report
• Active support to medical decision
• Saving of doctor's time
• Simplification of the doctors' intervention
• Promotion of counselling between general practitioners and specialists, and more in general healthcare operators (including community pharmacists)

Feasibility and User Acceptability of Home Blood Pressure Telemonitoring

Making services usable and acceptable by patients is vital if telemedicine technologies and services are to be taken up and to be successful in practice. Interestingly, HBPT seems to be well accepted by hypertensive patients. In most studies, patients showed a high degree of adherence to telemonitoring programs and a regular use of these technologies, probably

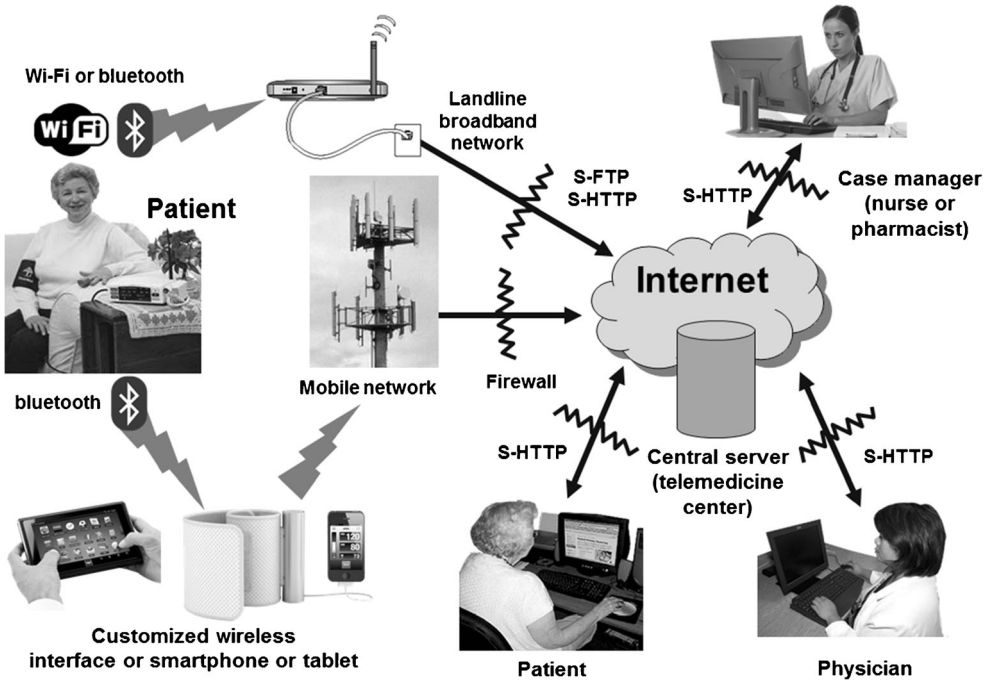

Fig. 1 Example of a typical home blood pressure telemonitoring system. *S-FTP* Secure File Transfer Protocol, *S-HTTP* Secure Hyper Text Transfer Protocol

because of the greater predisposition of hypertensive patients to use electronic BP monitors at home. The studies showed also a very high degree of acceptance of these techniques by patients. A summary of the main studies currently available on such aspects of HBPT is reported in Table 4.

Such a positive feedback from patients on the use of HBPT services is mostly related to the recent technological advances, and in particular on the release of mobile systems, which turned into practical benefits such as ease to use, reliability, and improved human–technology interactions. However, to allow uptake of telemedicine technologies, some of the current barriers need to be overcome in the future and the systems should have basic requirements as those proposed in Table 5. People should easily interact with and easily configure the devices and software according to their own needs: the importance of such feature has been highlighted in the IDEATel Study [30], which was based on a rather old technology. In this study, many participants found learning how to use the computer challenging and support was needed in many cases. This was consistent with the very low level of computer literacy and educational status of the study population, which is common to most long-term longitudinal studies. Advances in mobile health technology for telemonitoring had developed more versatile products and flexible enough to easily support self patient management of the facility. Most studies on hypertensive patients with such technologies have shown improvements in system usability and acceptability [15, 16, 19, 22, 23, 29].

The selection of educated patient groups and pre-set instructions may all be key success factors to improve ability to HBPT. Given that the patients with a chronic disease targeted in home telemonitoring applications do not all have the same level of technological skill and education, the same professional constraints, or the same lifestyle, and that some may have a slight visual or motor deficit, it would be preferable for application providers to ensure that patients have the technological device best suited to their specific needs [31].

A recent qualitative study has attempted to identify factors facilitating or hindering the effectiveness of HBPT and those influencing its potential translation to routine practice [32]. The study enrolled 25 high risk hypertensive patients in 6 primary care practices. Patients were asked to use a system made-up of a validated electronic home BP monitor and a mobile phone used to transfer the BP readings via SMS to a secure website accessible to the user and their doctor or nurse. The BP monitor was linked to the mobile phone wirelessly, via bluetooth. Both patients and clinicians considered that a BP measurement based on the average of multiple readings

Table 4 Degree of adherence to the HBPT program and acceptance of the technology by patients enrolled in different trials

Author, year [ref.]	Transmission type	No. of patients	Type of hypertensive patients	Adherence to HBPT (%)
Denolle, 1999 [3]	Telephone	55	Pregnancy	90
Bondmass, 2000 [3]	Telephone	33	Uncomplicated	88
Artinian, 2001 [14]	Telephone	26	Uncomplicated	67
Omboni, 2004 [3]	Telephone	195	Uncomplicated	90
Scherr, 2006 [15]	Mobile phone	20	Cardiac decompensation	83
Bobrie, 2007 [16]	Mobile phone	33	Diabetes	83
McCant, 2009 [17]	Telephone	441	Uncomplicated	75
Wakefield, 2011 [18]	Telephone	195	Diabetes	70
Logan, 2012 [19]	Mobile phone	55	Diabetes	65
Kerby, 2012 [20]	Telephone	213	Uncomplicated	73
Kerry, 2013 [21]	Telephone (vocal)	168	Stroke	48
McKinstry, 2013 [22]	Mobile phone	200	Uncomplicated	89
Rifkin, 2013 [23]	Mobile phone	28	Chronic kidney disease	78
Author, year [ref.]	Transmission type	No. of patients	Type of hypertensive patients	Acceptance of the technology (%)
Friedman, 1996 [24]	Telephone (vocal)	276	Uncomplicated	69
Rogers, 2001 [25]	Telephone	121	Uncomplicated	96
Omboni, 2004 [3]	Telephone	195	Uncomplicated	96
Scherr, 2006 [15]	Mobile phone	20	Cardiac decompensation	100
Bobrie, 2007 [16]	Mobile phone	33	Diabetes	81
Logan, 2007 [26]	Telephone	22	Diabetes, pneumopathy, cardiopathy	73
Santamore, 2008 [27]	Internet	161	High risk patients	92
McManus, 2010 [28]	Telephone	234	Uncomplicated	71
Neumann, 2011 [29]	Mobile phone	30	Uncomplicated	97
Rifkin, 2013 [23]	Mobile phone	28	Chronic kidney disease	96

Table 5 Desirable features for the uptake of telemedicine solutions among hypertensive patients

- Practical design of the device
- Easy interaction (user-friendly)
- System readily configurable
- Minimal or no technical assistance during a prolonged use
- Personalization and customization
- Compliance with ethical, privacy and safety requirements
- User acceptability
- Affordable costs (ideally reimbursable service)

from HBPT system was trustworthy and could be used in usual care settings. The technology increased patient's engagement in the management of their condition, but professional time for maintaining telemetry support and greater patient engagement increased workloads and demanded service organization, limiting its diffusion among general practitioners.

Older patients are among the less technologically skilled patients and may particularly need user-friendly appliances. In a recent randomized, controlled study enrolling 43 veterans with stage 3 or greater kidney disease and uncontrolled hypertension, the use of a web-based HBPT facility was associated with a high compliance to the monitoring schedule (29 transmitted BP readings per months, corresponding to a 96 % compliance rate) and with 78 % of the patients continuing to regularly use the device. The low-cost wireless monitoring strategy applied in this study was likely responsible for a greater data sharing between patients and clinic and a very high adherence to the study protocol [23].

Thus, according to the evidence collected so far, it is reasonable to infer that among the main conditions limiting a successful HBPT program stand the educational level and features of the patients targeted by the telemonitoring intervention, the complexity of the technology employed, the characteristics of the telemonitoring program and workflow organization [33].

Impact of Home Blood Pressure Telemonitoring on Blood Pressure Control and Other Patients' Outcome

One of the main established advantages of HBPT is the potential for improvement of hypertension control and associated healthcare outcomes. In a recent meta-analysis, we conducted in more than 7,000 hypertensive patients enrolled in 23 selected high quality randomized controlled studies, office BP was reduced significantly more in the telemonitoring group than in patients receiving usual care. Across the studies, the mean office SBP and DBP reductions were larger in the HBPT group by nearly 5 and 2 mmHg, respectively (Fig. 2)

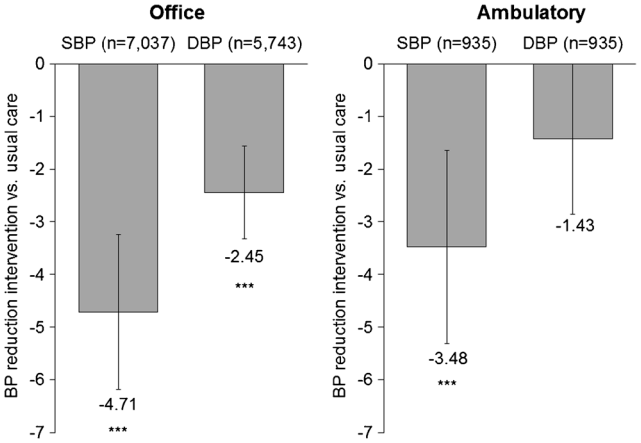

Fig. 2 Weighted mean differences (and 95 % confidence intervals) in office and ambulatory systolic (SBP) and diastolic blood pressure (DBP) changes between patients randomized to home blood pressure telemonitoring (HBPT) and patients followed by their healthcare givers in the usual clinical setting. The *asterisks* refer to the statistical significance of the difference (HBPT vs. usual care): ***$p<0.001$ [redrawn from 44 by permission]

[34••]. The level of heterogeneity among studies was high, though a sensitivity analysis did not significantly alter the study results, the range of weighted mean differences being very similar to the overall random effect. A significantly ($p<0.001$) larger proportion of patients achieved office BP normalization (BP target: <140/90 mmHg for non-diabetic patients and <130/80 mmHg for diabetic patients) in the intervention group [RR and 95 % confidence interval: 1.16 (1.04, 1.29)] than in the control group.

In the five comparison studies assessing intervention effect on ambulatory BP, its reduction was smaller than that for office BP, although still greater in the HBPT group for both SBP and DBP (Fig. 2). Interestingly absence of heterogeneity was demonstrated for the studies based on ambulatory BP, suggesting that such an endpoint might be a more robust predictor of intervention effectiveness than office BP.

The number of antihypertensive drugs used by patients at entry was similar in the HBPT and usual care group (1.8±1.6 for both, $p=0.954$) in the eight studies (2,691 subjects) reporting on this parameter. However, at the end of the study the HBPT group had a significantly ($p<0.001$) larger prescription of antihypertensive medications [+0.40 (+0.17, +0.62)] than the control group. Adherence to treatment was high and did not differ ($p=0.481$) between the intervention (91.8 %) and usual care group (89.8 %) in the three studies (773 subjects) evaluating this parameter. The number of office consultations during the study was slightly smaller in the intervention group, the difference being nearly statistically significant vs. the control group [0.18 (0.37, +0.00), $p=0.055$].

In the same systematic review, adverse events were reported in 205 of the 1,362 patients randomized to HBPT (13.1 %) versus 184 of the 1,563 assigned to usual care (11.8 %) over a median follow-up period of 24 weeks. There was no between-

group statistically significant (p=0.263) difference in the relative risk of adverse events [1.22 (0.86, 1.71)]; however, the few studies (four) included in the meta-analysis were not designed or powered to detect reduction or increase in mortality or differences in clinical events. Moreover, in these studies adverse events were not homogeneously quantified and not always appropriately assessed [34••]. The number of medications, but not the level of adherence to treatment, the number of office visits and the rate of adverse events presented a high and significant heterogeneity across the studies.

Few randomized studies also assessed another clinically relevant outcome of intervention: quality of life. The evaluation was based on the Short Form (SF)-12 and SF-36 instruments, which proved to be useful and valid for patients with chronic diseases, including hypertension. Although only four studies (1,262 subjects) assessed the impact of HBPT on quality of life, the results may have a statistical robustness due to the homogeneity of the effect sizes among the studies. Quality of life was improved in patients using HBPT in the physical domain; the physical component summary (PCS) was significantly better in the HBPT group (+2.78, p<0.001), whereas mental component summary (MCS) did not significantly differ between group (−0.11, p=0.890; Fig. 3) [34••].

We concluded that HBPT allowed to achieve a better BP control in hypertensive patients respect to usual care and that this was reasonably due to a more intensive treatment received by the patients in the intervention group, as adherence to hypertension medications and number of office visits were both comparable between the two study arms [34••].

Other meta-analyses demonstrated the effectiveness of HBPT for improving BP control in hypertensive patients [4•, 31, 35–39]. However, all of them reached the same conclusion that given the high level of heterogeneity of studies, future well designed, large-scale, prospective, controlled trials will be needed to understand the long-term benefit of such technologies, in particular their actual cost-effectiveness and their benefit beyond BP control. These two issues will be dealt in depth in the next two sections.

Home Blood Pressure Telemonitoring: Cost-Effectiveness

Cost-effectiveness analysis for HBPT as a strategy for hypertension management is difficult to interpret due to the variety of factors involved in the different studies, such as levels of risk factors, comorbidities, costs of personnel, telemedicine devices, communication, and data management infrastructures. Costs of technologies and social insurance systems across the countries are extremely different as well. Notably, the cost assignment shows a great variability: most studies considered only overall healthcare costs, whereas only few others provided a more comprehensive evaluation. Therefore a cost-effectiveness analysis of HBPT should take into account the different healthcare systems and settings.

In our meta-analysis [34••], based on the available data from six studies (4,227 subjects), in the HBPT group, along with a clear benefit in terms of greater BP reduction, the overall costs were significantly higher (+662.92 euros, p<0.0001) than in the usual care group (Fig. 4) [34••]. In other words, HBPT was more clinically effective but cost more; however, the medical costs (technology excluded) were only +12 euros higher with HBPT. Additionally, when expenses were corrected for the BP lowering magnitude, the average incremental cost-effectiveness ratio (ICER)—that is the cost per additional 1 mmHg of BP reduction—was 406 euros for SBP and 829 euros for DBP over a median follow-up period of 4 years, which means 100–200 euros per person per year per 1 mmHg of BP reduction. Considering only medical costs HBPT proved to be rather cost-effective, with a mean ICER of +32 euros for SBP and +25 euros for DBP. Unfortunately, medical costs were offset by those of the equipment and technologies, which contributed to the overall healthcare costs

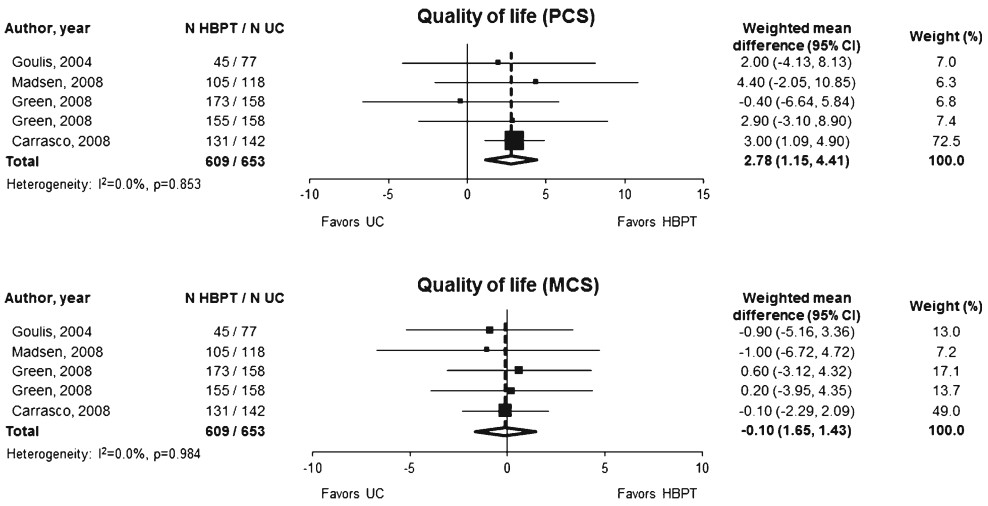

Fig. 3 Weighted mean difference (95 % confidence interval, CI) in mean Short Form (SF)-12 or SF-36 physical component (PCS) and mental component (MCS) at study end between patients of the home blood pressure telemonitoring (HBPT) and usual care (UC) group [from 44 by permission]

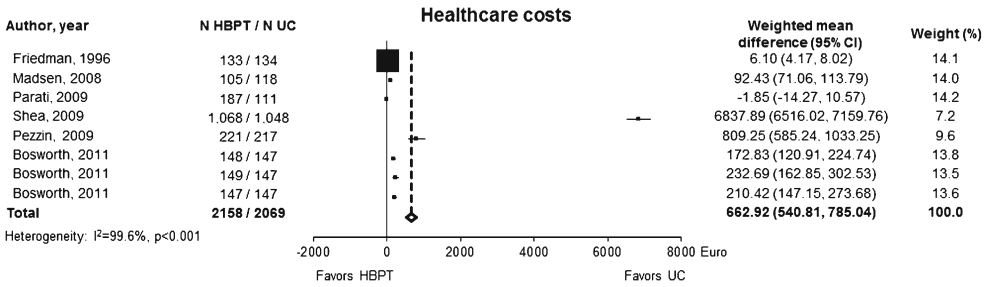

Fig. 4 Weighted mean difference (95 % confidence interval, CI) in the healthcare costs during the study (in euros) between the home blood pressure telemonitoring (HBPT) and usual care (UC) group [from 44 by permission]

increase. [34••]. If these costs are compared with a cost-effective intervention in cardiovascular diseases as estimated by NHS (approximately 12.500 euros for life saved-year), HBPT seems to be rather cost-effective [40]. However, it seems straightforward that in the future attention should be paid to the development of cheaper telemonitoring technologies in order to improve the cost-effectiveness ratio in favor of HBPT, making it a promising alternative to existent clinical practice.

The finding of the economic evaluation of the HINT S study [41, 42] suggests that, to optimize the investment in home and telephone-based interventions, it is critically important for health systems to consider applying interventions to specific subpopulations of patients that are most likely to benefit from intensive home-based monitoring and self-management efforts. Furthermore, implementation should also consider whether intervention generates other patient-centered outcomes or efficiencies in other aspects of medical care saving such as slowing progression of the chronic disease [42].

In a recent post hoc economic evaluation on data of a pragmatic randomized controlled trial involving 401 primary care patients with uncontrolled day-time ambulatory BP, during the 6 months of follow-up HBPT resulted significantly more effective in terms of BP reduction, but also significantly more expensive than usual care (the mean difference per patient was 115.32 pounds, equivalent to approximately 145 euros; $p<0.001$ vs. usual care) [43•]. Increased costs were due to telemonitoring service costs (70.77 pounds, approximately 90 euros), patient training and additional general practitioner and nurse consultations (approximately one additional general practitioner consultation and a half a practice nurse consultation). The mean cost of SBP reduction (ICER) was 25.60 pounds/mmHg (32 euros/mmHg): this indicated that HBPT was both more costly, but also more effective than usual care. The author concluded that if such clinical gains are maintained, the additional costs of HBPT might be compensated for by reductions in the cost of future cardiovascular events. Nevertheless, in the future, studies allowing longer term modeling of costs and outcomes are required to fully analyze the cost-effectiveness implications of HBPT.

Home Blood Pressure Telemonitoring Needs a More Robust Evidence on its Efficacy

Objectively it must be admitted that in the light of the studies published so far evidence on HBPT clinical efficacy and economic benefit is incomplete. Available randomized studies do show a high heterogeneity of the main effect, due to variety of technologies of data transmission, measuring devices, frequency of monitoring, endpoints, interface with different types of healthcare professionals to review and act on measurements, frequency of patient-to-healthcare provider contacts, duration of study, and more in general, type of patients and study designs. Some secondary outcomes (cost, adherence to treatment, feasibility, etc.) have not been evaluated systematically, and strong evidence on the clinical and economic impact of HBPT is definitely still lacking.

Although several meta-analyses and systematic reviews on HBPT interventions for patients with chronic diseases, including arterial hypertension, have been published, most of them appear to lack in optimal scientific rigor due to intrinsic methodological issues. A recent study tried to evaluate this issue by assessing the quality of the major systematic reviews and meta-analyses, making use of the R-AMSTAR (Revised Assessment of Multiple Systematic Reviews) instrument. The authors pointed out that the methodologies to proper conduct systematic reviews and meta-analyses, and eliminate potential risks of bias, have not yet fully integrated in the area of HBPT [44]. Moreover, the high level of heterogeneity of published studies suggests that well-designed, large-scale, randomized, controlled studies are needed to prove the clinical usefulness of HBPT [34••, 35, 44]. To definitely demonstrate the usefulness of HBPT more objective study endpoints should be considered. For instance office BP should be replaced by a more robust and objective estimation of BP control, such as ambulatory BP. Studies should try to compare, possibly in the same subjects, the different impact of conventional HBPM, based on diary logbooks periodically showed to the doctors, versus that of a regular HBPT with nurse- or pharmacist-led support and personalized recommendations on life style. Probably studies focusing on particularly high risk patients, for whom an optimal BP control is particularly difficult to achieve, should be planned.

Is Home Blood Pressure Telemonitoring Better than Conventional Self Home Blood Pressure Monitoring?

Compared with conventional self HBPM, HBPT may enhance the quality of data reporting and ease its interpretation by doctors. As a matter of fact, it is well known that HBP readings may be unreliable due to the elevated risk of over- or under-reporting with logbook manual entries of HBP measurements [45]. Even in case of memory-equipped devices, doctor's feedback is not immediate and evaluation may be time-consuming and inaccurate.

The evidence originating from randomized studies suggests that HBPT may positively affect BP control to a greater extent than conventional HBPM, particularly in the long term. A recent meta-analysis including 52 prospective studies assessed the impact of self HBPM with or without additional support (including telemonitoring) vs. usual care [46••]. Self HBPM alone (without additional support) was associated with statistically significant average reductions in both SBP and DBP of 3.9 and 2.4 mmHg at 6 months (10 studies). These changes were smaller and no longer statistically significant at 12 months of follow-up (1.5 mmHg for SBP and 0.8 mmHg for DBP, 8 studies). For self HBPM plus additional support (including telemonitoring), high strength evidence supported a lower BP as compared to usual care with reductions ranging from 3.4 to 8.9 mmHg for SBP and from 1.9 to 4.4 mmHg for DBP at 12 months in 5 good quality studies. Thirteen trials directly compared the effectiveness of self HBPM with additional support versus self HBPM without additional support (or with less intensive additional support). Groups differed in the type of support, with some studies including electronic transmission of BP measurements. Overall, the evidence was rated by the authors of the meta-analysis as low-strength and failed to support a difference between the two approaches in terms of office BP lowering.

Thus current studies seem to support a clinically relevant impact of hypertension management of self HBPM with some form of additional support compared with usual care. However, further direct comparative studies are needed to verify whether in the same subjects HBPT may have some additional advantage as compared to self HBPM alone, particularly to provide sustainability and long-term clinical effectiveness of this approach.

Home Blood Pressure Telemonitoring for High Risk Patients

Hypertension is frequently associated with other chronic diseases or cardiovascular risk factors, which makes adequate BP control often difficult to achieve. The effectiveness of telemedicine intervention based on HBPT for high risk patients was examined in few randomized studies.

The IDEATeL randomized, controlled, longitudinal study enrolled 1,665 elderly, ethnically diverse, medically underserved hypertensive diabetic patients which were randomly allocated to intervention or usual care, and monitored over 5 years of follow up [30]. The intervention consisted of a home telemedicine unit with a web camera for videoconferencing between the patient and the nurse in charge of single case management. The study results revealed that patients in the intervention group had an office BP reduction larger [4.3 (1.9, 6.7) mmHg for SBP and 2.6 (1.5, 3.7) mmHg for DBP, $p<0.05$ and $p<0.001$] than those assigned to the usual care group: such differences present at 1 year were maintained over 5 years of follow-up.

Patients with chronic diseases, and particularly diabetics, are engaged in self-care activities, whose effectiveness requires reliable information and healthcare provider collaboration. A randomized controlled study demonstrated the effectiveness of HBPT combined with self-care support as compared to conventional self HBPM in reaching BP target in diabetic patients with uncontrolled systolic hypertension [19]. The telemonitoring system provided self-care messages on the smartphone of 244 hypertensive diabetic patients after each reading. The primary endpoint of the study was the mean ambulatory SBP, which significantly ($p<0.001$) decreased at 1-year follow-up only in the intervention group by 9.1 mmHg. Furthermore, 51 % of the subjects receiving the intervention achieved recommended target of <130/80 mmHg compared with 31 % in the control group ($p<0.05$; Fig. 5). These improvements were obtained without medication intensification or additional clinic visits to physicians. Thus HBPT with automated self-care support reduced the BP in diabetic patients with uncontrolled systolic hypertension and improved hypertension control.

Another randomized controlled pilot trial enrolled 137 hypertensive patients with type 2 diabetes, at risk of renal disease

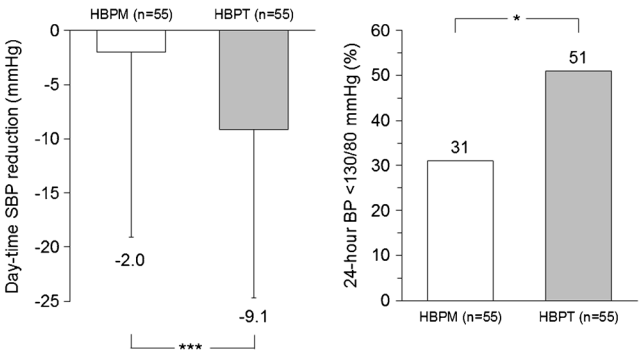

Fig. 5 Reduction of day-time systolic blood pressure (SBP) and percentage of diabetic patients with uncontrolled hypertension who reached the target of 24-h average BP <130/80 mmHg, in the group randomized to home blood pressure monitoring (HBPM) and in that randomized to home blood pressure telemonitoring (HBPT). The *asterisks* refer to the statistical significance of the between-group difference (***$p<0.001$; *$p<0.05$) [redrawn from 19 by permission]

progression [47]. In the intervention group, patients' home blood glucose and BP readings were transmitted to a smartphone and then to the central server; whereas in the control group, patients were assigned to usual care. In the intervention group SBP decreased significantly after 6 months of follow-up (6.5 mmHg, $p=0.027$), whereas it was unchanged in the control group (+2.1 mmHg, $p=0.570$). Patients who achieved a SBP of <120 mmHg had lower average blood glucose than those with higher readings.

The importance of targeting specific types of intervention to specific patient severity groups has been highlighted in a randomized controlled trial focused on 845 patients with stage 2 uncontrolled hypertension receiving home-based post-acute care. Nurse-led intervention, providing additional medication review and patient self-management support during post-acute care period, significantly improved BP control in these high risk patients. [48].

The TASMIN-SR is an ongoing trial set out to investigate whether self-management is effective and cost-effective also in a subpopulation of high risk patients (with diabetes, stroke, or other conditions) previously enrolled in the TASMINH2 trial [49]. If successful, this model may be applicable for hypertension management in these high risk patients.

Finally, the TELEBPMET study is another ongoing open label, parallel group, randomized controlled trial which aims to assess the superiority of HBPT versus usual care in high-risk hypertensive patients with the metabolic syndrome. This study will also study and compare patient's personality traits as predictive factors of adherence to antihypertensive treatment between randomization groups. The impact of HBPT on additional and economic outcomes will be further investigated on a relative long-term follow up of 12 months [50].

Home Blood Pressure Telemonitoring and Telehealth Networks

A key point for a successful BP management by HBPT is the networking among healthcare providers and, in particular, the counseling between doctor and pharmacist or nurse, namely a new model of care based on telephone/web services for BP control whose effectiveness was indeed showed in a number of trials.

One of the first studies to address this specific model of telemedicine service in the hypertension management was the Electronic Communications and Home Blood Pressure Monitoring (e-BP) Study. This was a randomized controlled trial, which enrolled 778 participants with uncontrolled essential hypertension and Internet access. The main outcome measures were the percentage of patients with controlled BP (<140/90 mmHg) and changes in SBP and DBP at 12 months. Participants were randomly assigned to usual care, HBPM and secure patients web site training only, or HBPM and secure web site training plus clinical pharmacist care management delivered through web communications [51]. Adding web-based pharmacist care to HBPM and web training significantly increased the percentage of patients with controlled BP compared to HBPM and web training only and usual care (Fig. 6, left panel). BP benefits occurred mainly in patients with more severe hypertension at baseline (SBP≥160 mmHg) with web-based pharmacist team patients almost twice as likely to have controlled BP (54 vs. 20 % usual care at 12 months, $p<0.01$) [51, 52]. Interestingly, the web-delivered pharmacy team care resulted in greater reductions in SBP and improved BP control also 1-year after the completion and discontinuation of the interventions (Fig. 6, right panel). However, similar to previous studies [53••, 54] the control group under usual care continued to improve, and differences between groups narrowed. Also at 1-year after intervention, the largest benefit occurred in those patients with more severe hypertension at baseline followed by the web-based pharmacist team (56 % of BP control vs. 34 % usual care group and 23 % web only group, $p=0.05$ and $p<0.005$ respectively) [52].

Another randomized controlled trial enrolled 450 patients with uncontrolled BP, including patients with comorbidities (obesity, diabetes, chronic kidney disease, or a history of cardiovascular disease) and severe hypertension, with a baseline mean SBP of 148 mmHg and DBP of 85 mmHg [55]. Patients were allocated to receive a telemonitoring intervention (telemonitors and transmission of BP data to pharmacists who adjusted antihypertensive therapy accordingly) or usual care. The intervention lasted 12 months: after this period patients discontinued HBPT, returned to the care of their primary physicians, and no longer received support from a study pharmacist, though were followed-up for additional 6 months. At both 6 and 12 months the proportion of patients with BP

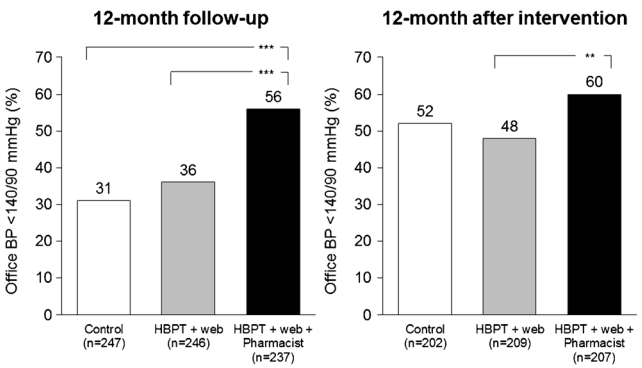

Fig. 6 Percentage of patients with controlled (<140/90 mmHg) office blood pressure (BP) in three different settings: usual care only (control), usual care plus home blood pressure telemonitoring (HBPT) and web site training, usual care plus HBPT, and web site training plus web-based pharmacist care. Data are shown at 12 months of follow-up (*left panel*) and at 1-year after discontinuation of the intervention (*right panel*). The *asterisks* refer to the statistical significance of the between-group difference (***$p<0.001$; **$p<0.01$) [redrawn from 51 and 52 by permission]

control (<140/90 or <130/80 mmHg in patients with diabetes or chronic kidney disease) was significantly (p=0.001) greater in the telemonitoring group (57 %) than in the usual care group (30 %). SBP decreased more from baseline among patients in the telemonitoring intervention group at 6 months [10.7 (14.3, 7.3) mmHg, p<0.001], at 12 months [9.7 (13.4, 6.0), p<0.001], and at 18 months [6.6 (10.7, 2.5) mmHg, p= 0.004]. Thus the synergy between HBPT and pharmacist case management of high risk hypertensive patients allowed a better BP control compared with usual care during the 12 months of intervention, extended by 6 months of post-intervention follow-up [55].

The general practitioner-pharmacist counseling may have a crucial role for hypertension screening and management of follow-up. The TEMPLAR study (TEleMonitoring of blood Pressure in Local phARmacies) is the first ongoing Italian Registry on 24-h BP telemonitoring in community pharmacies, aiming at verifying the level of BP control in treated and untreated patients undergoing 24-h BP monitoring in pharmacies upon general practitioners' prescription. Preliminary study results seem to support the role of community pharmacies for the improvement of the detection of high BP in the population [56].

Combined intervention of telemedicine also with nurse-led care showed to improve hypertension management in large randomized controlled trials that enrolled hypertensive high risk patients [41, 57]. Thus clinical experiences that combined electronic technologies with team care have had the most positive results. However, the studies show a high degree of heterogeneity and there are still shortcomings regarding cost-effectiveness, long-term benefits of technology enhanced by team interventions which need further investigation in the future [53••].

Conclusions

In summary, HBPT seems to be a promising tool for improving BP control among hypertensive patients, particularly those at high risk. In the majority of studies regular HBPT yielded greater BP reductions and a larger proportion of patients achieving BP normalization than usual care. The most plausible cause of such outcome was that patients in the intervention group usually received a more intensive treatment. In terms of quality of life, HBPT did not adversely affect health status assessed by a generic validated scale. Indeed, the physical component of quality of life was improved by the intervention, a finding that may have positive implications in long-term hypertension management. From the perspective of cost-effectiveness, HBPT was associated with lower medical costs, which were, however, offset by those of the equipment and technologies. Unfortunately, the impact of the technology in terms of cost is difficult to assess because in the various studies, published over the last 20 years, old and outdated technologies were compared to more recent and advanced ones. Hence, further studies are needed to identify specific key elements of HBPT approach able to impact on specific outcomes.

On the basis of what is known from studies published so far HBPT is likely to represent a realistic strategy to improve hypertension management when a particularly tighter BP control is needed, such as in high risk patients, elderly, diabetics, etc. HBPT may be used when a support to the doctor is appropriate for a closer and continuous monitoring of the patients, as in case of high risk patients, but also of non-adherent patients or subjects living in remote areas. Besides, HBPT can be an advantageous choice in situations requiring monitoring of multiple vital signs (e.g., cardiac patients, diabetics, etc.). HBPT and, more in general, a telemedicine approach is the only option when a network among healthcare professionals needs to be established in order to improve the screening and management of hypertension and related comorbidities, and consequently achieve an effective prevention of cardiovascular diseases in the community.

Compliance with Ethics Guidelines

Conflict of Interest Stefano Omboni reports personal fees from Biotechmed Ltd and Microlife. Rossella Ferrari declares no conflict of interest.

SO has received consultancy fees from Biotechmed Ltd., provider of telemedicine services, and from Microlife, manufacturer of blood pressure measuring devices. RF has no conflict of interest to declare.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance

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also underlined that further research is needed to explore the specific impact and relative value of the different elements of telemonitoring interventions.

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