

Blood Pressure Remote Patient Monitoring for Management of Arterial Hypertension

Background

Remote patient monitoring (RPM) and telemedicine have been available for patient care for decades but have taken a more prominent role in patient management since the onset of COVID-19. In addition, recent advances in technology including enhancements in wireless data handling and speed, have improved the availability, affordability, and ease of use of RPM.

The management of hypertension has improved over many decades due to the widespread recognition of the condition, ease of diagnosis through blood pressure (BP) measurement, availability of numerous medications (many of which are now generic), and widely accepted management guidelines. Yet hypertension continues to place a substantial socioeconomic burden globally. Deficiencies in key areas such as adherence to lifestyle and medication recommendations, precision of office-based BP monitoring, data regarding magnitude of hypertension in the ambulatory environment and integration of corroborating physiologic data (e.g., central aortic BP waveform and associated cardiovascular parameters) all contribute to the suboptimal management of hypertension and hypertension-related disorders (e.g., cardiac dysfunction, chronic renal failure, stroke, hypertensive disorders of pregnancy).

An increasingly important management tool is RPM. The objective of this document is to briefly outline the role of RPM in hypertension. The document also identifies the availability of non-invasive central aortic pressure measurement that should be considered when deciding on systems for RPM.

Definition of Remote Patient Monitoring (RPM)

RPM involves the collection, transmission, and analysis of physiologic data (e.g., blood pressure, heart rate, heart rhythm) that are used to develop and manage a disease treatment plan. RPM, which is a subset of telehealth (or telemedicine) that uses the latest advances in information technology to collect and transmit patient data outside of standard healthcare settings (i.e., hospitals, ambulatory clinics). RPM enables patient monitoring as well as transfer of patient health data to a health care provider. The key objectives are to improve outcomes (end-organ damage, health-related quality of life) and reduce the costs of health care. Additional important objectives are to empower patients with their own health data with the hopes of increasing adherence, and a patient's sense of control.

RPM involves the collection, transmission, and analysis of physiologic data (e.g., blood pressure, heart rate, heart rhythm) that are used to develop and manage a disease treatment plan.

Key features of RPM include display and analyses of the parameters collected, trend analysis of physiological parameters, early detection of deterioration and confirmation of the positive effects of a treatment plan, which may reduce emergency department visits, hospitalizations, and the duration of hospital stays.

RPM positively impacts disease management; however, variability in the degree of effectiveness should be recognized. RPM is highly dependent on the individual's motivation to manage their health and how a healthcare professional uses the data. Although costs have dramatically decreased, cost is still a limitation to widespread use. Another issue is widespread incorporation of RPM into national and international disease guidelines for when and how to use RPM.

RPM and Hypertension Guidelines

The 2017 report of the American College of Cardiology/American Heart Association task force guideline for the prevention, detection, evaluation, and management of high blood pressure in adults concludes that telehealth strategies can be useful adjuncts to interventions shown to reduce blood pressure for adults with hypertension.¹ The report describes subsets of telehealth strategies, such as telemedicine, digital health ("eHealth"), and use of mobile computing and communication technologies ("mHealth").

The report notes the following:

"Meta-analyses of randomized controlled trials of different telehealth interventions have demonstrated greater systolic blood pressure (SBP) and diastolic blood pressure (DBP) reductions and a larger proportion of patients achieving BP control than those achieved with usual care without telehealth. The effect of various telehealth interventions on BP lowering was significantly greater than that of BP self-monitoring without transmission of BP data, which suggests a possible added value of the teletransmission approach."¹

An international hypertension expert position paper was published in 2020.² The authors wrote that

"The best proposed healthcare model for telemedicine in hypertension management should include remote monitoring and transmission of vital signs (notably blood pressure) and medication adherence plus education on lifestyle and risk factors, with video consultation as an option. The use of mixed automated feedback services with supervision of a multidisciplinary clinical team (physician, nurse, or pharmacist) is the ideal approach. The indications include screening for suspected hypertension, management of older adults, medically underserved people, high-risk hypertensive patients, patients with multiple diseases, and those isolated due to pandemics or national emergencies."

These experts highlighted the benefits of telemedicine in the management of hypertension as well as acknowledging some of the barriers to implementation in addition to the importance of continued research into telemedicine.

The guidelines and expert opinions clearly highlight the potential positive impact of hypertension as well as identify the need for continued understanding of the optimal delivery of RPM. Advances in RPM have rapidly advanced since the 2017 guidelines document in a manner that addresses many of the uncertainties.

Selected Peer-Reviewed Publications Supporting the Use of RPM for Hypertension

Substantial research in RPM has been published over the last decade. It should be acknowledged that the research publications are lagging the rapid advances in technology but provide the rationale for RPM support and integration into patient care. The next section of this overview highlights several relevant publications in the area of hypertension with a specific subsection on the use of RPM in hypertensive disorders of pregnancy.

a) Trials of RPM of Blood Pressure in the Management of Hypertension

Several trials with different methodology have been performed that document the utility and cost-effectiveness of RPM in BP management of hypertension. A sample of the literature has been selected for review based on the clinical relevance, study design and robustness of the data.

One of the key issues in home blood pressure monitoring (HBPM) use is the critical importance of healthcare provider proactive BP monitoring recommendations as it is likely that the majority of hypertensive patients will not spontaneously purchase and know how to use home BP monitors. Tang and colleagues examined whether HBPM use with a physician recommendation would be associated with lower BP and greater medication adherence.³ Data from 6,320 adults with hypertension in the National Health and Nutrition Examination Survey (NHANES) 2009-2014 was used to characterize the association of (a) provider recommendation for HBPM and (b) HBPM use on measured BP and medication adherence. Among adults with hypertension, 30% reported a physician recommendation for HBPM, of whom 82% reported using HBPM. For those who did not report a physician recommendation for HBPM, 28% used HBPM. For individuals who received a physician recommendation to use HBPM, mean SBP/DBP was 3.1/4.5 mm Hg lower in those who used HBPM than those who did not. Those who reported having a physician recommendation and used HBPM were more likely to report hypertension medication adherence (odds ratio 2.9; 95% confidence interval (CI): 2.0, 4.4). The authors concluded that HBPM use was associated with lower BP and higher medication adherence, especially when HBPM was initiated based on a physician recommendation. These results support physician HBPM counselling and the clinical impact of HBPM in BP management.

Data from NHANES involving over 6,000 adults with hypertension, demonstrated that HBPM use was associated with lower BP and higher medication adherence.

The clinical impact noted in the aforementioned publication is corroborated by the study reported by McManus et al (2021).⁴ The investigators performed a randomized controlled trial in the United Kingdom examining the effects of a digital intervention for hypertension management by combining self-monitoring of BP with guided self-management. A total of 622 people from 76 practices with treated but poorly controlled hypertension (>140/90 mm Hg) were enrolled. Subjects were randomized to BP self-monitoring with a digital intervention (n=305) or usual care (routine hypertension care), with appointments and drug changes made at the discretion of the general practitioner (n=317). The digital intervention provided feedback of BP data to patients and healthcare professionals with "optional lifestyle advice and motivational support". One-year follow-up data was high with data available from 552 participants (88.6%). Data for the remaining 70 participants was imputed. BP declined from 151.7/86.4 to 138.4/80.2 mmHg in the intervention group and from 151.6/85.3 to 141.8/79.8 mmHg in the usual care group (mean difference in systolic BP = -3.4 mmHg (95% CI: -6.1 to -0.8 mmHg, mean difference in DBP = -0.5 mmHg (95% CI: -1.9 to 0.9 mmHg)). Within trial costs showed an incremental cost effectiveness ratio of £11 (95% CI: £6 to £29) per mmHg BP reduction. The

data support the conclusion that digital intervention for the management of hypertension by using self-monitored BP results in improved BP control after one year compared to usual care with low incremental costs.

An early report by Lee et al in 2013 proposed that “Although nothing can replace the tried and tested doctor-patient relationship in the office, telemonitoring of home BP will be an important tool for treating hypertension in the future.”⁵ As support for their conclusion, a table using data from Margolis et al (Table 1) was displayed.⁶ The data was from a randomized trial with 12 months intervention and 6 months post-intervention follow-up involving 450 adults with uncontrolled hypertension from 16 clinics in the USA. Randomization was to either usual care or telemonitoring (home BP telemonitors with data transmitted to pharmacists who adjusted antihypertensive therapy accordingly).

Table 1. Composite and BP control by telemonitoring intervention or usual care.⁶

	Telemedicine Monitoring		Usual Care		Difference*	
	n	% (95% CI)	n	% (95% CI)	% (95% CI)	p-value
Composite BP control						
At 6 and 12 months	113	57.2 (44.8–68.7)	58	30.0 (23.2–37.8)	27.2 (13.4–40.0)	0.001
At 6, 12, and 18 months	96	50.9 (36.9–64.8)	42	21.3 (14.4–30.4)	29.6 (13.1–46.0)	0.002
BP control						
At 6 months	148	71.8 (65.6–77.3)	89	45.2 (39.2–51.3)	26.6 (19.2–33.1)	
At 12 months	141	71.2 (62.0–78.9)	102	52.8 (45.4–60.2)	18.4 (7.9–27.0)	0.005
At 18 months	135	71.8 (65.0–77.8)	104	57.1 (51.5–62.6)	14.7 (7.0–21.4)	0.003

*Study group difference for composite BP control and at each individual time point.

The authors concluded that BP telemonitoring and pharmacist case management achieved hypertension control relative to usual care during 12 months of intervention with persistent benefits for at least 6 months post-intervention. The data provided early convincing evidence of the potential of RPM in improving BP control.

Sheppard and colleagues performed a meta-analysis of studies to determine if self-monitoring can reduce clinic BP in patients with hypertension-related co-morbidities.⁷ Randomized controlled trials of self-monitoring of BP were selected and individual patient data were requested. Contributing studies were prospectively categorized by whether they examined a low/high-intensity co-intervention. Low intensity was based on minimal additional contact or automated feedback/support following initial education and instructions. High intensity incorporated an active intervention (i.e., regular classes) or individually tailored support from a health care professional (i.e., checking BP, medication, education/lifestyle counseling). Change in BP and likelihood of uncontrolled BP at 12 months were examined according to number and type of hypertension-related co-morbidity. A total of 16 trials were identified where individual patient data for the primary outcome was obtained (6,522 participants). Self-monitoring was associated with reduced clinic systolic BP compared to usual care at 12-month follow-up, regardless of the number of hypertension-related

co-morbidities (-3.12 mm Hg, [95% confidence intervals -4.78, -1.46 mm Hg]; p value for interaction with number of morbidities = 0.260). Intense interventions were more effective than low-intensity interventions in patients with obesity (p < 0.001 for all outcomes), and possibly stroke (p < 0.004 for BP control outcome only), but this effect was not observed in patients with coronary heart disease, diabetes, or chronic kidney disease. However, the likelihood of hypertension control was higher (i.e., lower risk of uncontrolled hypertension) in these disease states in the high intensity group.

Table 2: Likelihood of uncontrolled BP by patient group.⁷

	Likelihood of Uncontrolled BP [OR (95%CI)]		
	Low Intensity	High Intensity	Combined
All Patients	*	*	0.71 (0.58,0.87)
1 Comorbidity	*	*	0.68 (0.52,0.87)
2 Comorbidities	*	*	0.74 (0.58,0.95)
3 Comorbidities	*	*	0.72 (0.58,0.87)
Coronary Artery Disease	1.25 (0.54,2.92)	0.56 (0.34,0.94)	0.70 (0.45,1.08)
Stroke	1.14 (0.74,1.76)	0.37 (0.19,0.70)	0.66 (0.37,1.17)
Diabetes	0.95 (0.65,1.38)	0.62 (0.48,0.81)	0.71 (0.58,0.89)
Chronic Kidney Disease	2.07 (0.25,17.3)	0.56 (0.21,1.49)	0.75 (0.27,2.10)
Obesity	1.12 (0.82,1.53)	0.49 (0.38,0.63)	0.70 (0.54,0.91)

OR (95%CI): Odds ratio (95% confidence interval). Low values (<1) indicate reduced risk for uncontrolled hypertension.

*Data not provided in publication (presumably due to lack of relevant interaction of intensity with effect size)

The authors concluded that self-monitoring lowers BP regardless of the number of hypertension-related co-morbidities but may only be effective in conditions such as obesity or stroke when combined with high-intensity co-interventions.

Another meta-analysis that was more recently published evaluated the overall effects of remote blood pressure monitoring (RBPM) for hypertensive urban-dwelling patients who had healthcare that was highly accessible to healthcare.⁸ A total of 32 high-quality studies were selected for the meta-analysis. Primary outcomes were changes in office SBP and DBP following RBPM. The total number of patients for the analysis was in the 5,666 usual care group and 5,729 in the RBPM group. Compared with a usual care group, there was a decrease in SBP and DBP in the RBPM group (weighted mean difference [WMD] 4.464 mmHg, p < 0.001) and 2.075 mmHg, p < 0.001), respectively). The secondary outcome was the BP control rate, which was based on BP normalization data defined in each study (available in 16 studies, 2,655 patients in the usual care group, 2,816 in the RBPM group). The RBPM group had a higher BP control rate based on a relative ratio (RR) of 1.226 (1.107-1.358, p < 0.001). Of note, the frequency of remote BP transmission influenced the results. The WMD was 5.88 mmHg (p<0.001) for daily transmission, 4.02 mmHg (p<0.001) for weekly transmission, 3.94 mmHg (p<0.001) for biweekly transmission, and 1.80 mmHg (p=0.08) for monthly transmission. A decrease in the magnitude of effect was associated with the duration on RBPM (WMD for 3, 6, and 12 month duration was 6.2

($p < 0.001$), 4.5 ($p < 0.001$) and 3.4 ($p = 0.003$) mmHg respectively. The authors concluded that RBPM is effective in reducing BP and in achieving target BP levels for urban-dwelling patients with hypertension.

Two recently published meta-analyses provide objective data supporting the use of home-based remote patient monitoring of BP for improvement of BP control.^{7,8}

While research continues to show the clinical benefit of HBPM for the treatment of hypertension, an additional issue is whether payers have assessed the data to indicate a positive cost-effectiveness. Arrieta and colleagues developed a decision-analytic model for a cost-benefit analysis from the perspective of the insurer.⁹ Model inputs were derived from the 2008 to 2011 claims data of a private health insurer in the United States, from 2009 to 2010 National Health and the Nutrition Examination Survey (NHANES) data, and from published meta-analyses. The model simulated the transitions among health states from initial physician visit to hypertension diagnosis, to treatment, to hypertension-related cardiovascular diseases, and patient death or resignation from the plan. The investigators used a model to estimate cost-benefit ratios and both short- and long-run return on investment for HBPM compared with clinic BP monitoring. The data indicated that reimbursement of HBPM appeared to be cost beneficial from an insurer's perspective for diagnosing and treating hypertension. Depending on the insurance plan and age group categories considered, estimated net savings associated with the use of HBPM range from \$33 to \$166 per member in the first year and from \$415 to \$1,364 in the long run (10 years). Return on investment ranged from \$0.85 to \$3.75 per dollar invested in the first year and from \$7.50 to \$19.34 per dollar invested in the long run.

Table 3: Cost-benefit analysis results: return on investment (ROI) by health plan type and age group.⁶

Plan/Age Group	Investment Horizon			
	Year 1	Year 3	Year 5	Year 10
Employee Plan: 20-44 years				
Net Savings (\$)	\$33.75	\$155.11	\$245.36	\$414.81
ROI	0.94	4.34	5.52	8.37
Employer Plan: 45-64 years				
Net Savings (\$)	\$32.65	\$161.79	\$255.32	\$439.14
ROI	0.85	4.2	4.98	7.50
Medicare: >65 years				
Net Savings (\$)	\$166.17	\$557.00	\$846.86	\$1,364.27
ROI	3.75	12.59	13.83	19.34

Return on investment (ROI) is expressed as the ratio of net savings to costs.

In summary, the overall benefit of RPM in hypertension has been positive in terms of moving towards the targeted outcome (BP control) and cost-benefit of the intervention.

Analyses of large databases, including NHANES and a United State private health insurer show the cost-benefit of remote patient monitoring of BP in patients with hypertension.⁹

(b) Hypertensive Disorders of Pregnancy

Subsets of hypertension provide intriguing insights into the potential of HBPM due to the ability to refine the specific populations under study. As well, such an approach allows for definition of populations where the most impactful benefit to risk profile or highest cost-effectiveness ratio can be defined. One such category is hypertensive disorders of pregnancy.

An initial question is whether hypertensive pregnant women would be willing to self-monitor their BP and adhere to a regular schedule of monitoring. A study was performed to assess the feasibility of a BP self-monitoring intervention for managing pregnancy hypertension in a randomized controlled trial comparing HBPM to usual care for the management of pregnancy hypertension.¹⁰ Women with chronic or gestational hypertension were randomized (2:1) to HBPM or usual care. HBPM was requested to be performed daily with the data entered into a diary or telemonitoring. Clinicians were invited to use the home readings in clinical and antihypertensive titration decisions. The primary outcomes were recruitment, retention, adherence, and persistence with the intervention. A total of 158/222 (71%) of those approached agreed to participate (86 with chronic and 72 with gestational hypertension) of whom outcome data were available from 154 (97%). The median (interquartile range) number of days with home BP readings per week were 5.5 (3.1–6.5) for those with chronic hypertension and 6.1 (4.5–6.7) with gestational hypertension. Participants persisted with the intervention for 80% or more of their time from enrolment until delivery in 86% (43/50) and 76% (38/49) of those with chronic and gestational hypertension respectively. Recorded clinic and study BPs were similar for both groups. The data indicated that HBPM is feasible, acceptable, and associated with high adherence in women with hypertension disorders of pregnancy.

A study performed at St. George's Hospital, University of London sought to determine whether HBPM reduces visits to antenatal services and is safe in pregnancy using a case-control study of 166 hypertensive pregnant women.¹¹ Patients were included if they had chronic hypertension, gestational hypertension, high risk of developing pre-eclampsia, no significant proteinuria, and normal biochemical and hematological markers. Women with SBP > 155 mm Hg or DBP > 100 mm Hg, signs of severe pre-eclampsia, or significant mental health concerns were excluded. Pregnant women in the HBPM group were taught how to measure and record their BP at home and came to clinic every 1-2 weeks for assessment depending on the clinical need. The control group was managed as per the local protocol prior to implementation of HBPM. The two groups were compared with respect to number of visits to antenatal services and outcome. There were 108 women in the HBPM group and 58 in the control group. There was no difference in maternal age, parity, body mass index, ethnicity, or smoking status between the groups, but there were more women with chronic hypertension in the HBPM group compared with the control group (49.1% vs 25.9%, $p=0.004$). A lower number of outpatient visits per patient were reported in the HBPM group compared to the usual care group (6.5 vs 8.0, $p=0.003$). The significant difference persisted in favor of the HBPM group even with adjustment of differences in duration of monitoring (0.8 vs. 1.6 outpatient visits per week, $p<0.001$). The data gathered by the authors indicates that HBPM in hypertensive pregnancies can lower the number of clinic visits required by patients.

While clinical outcomes are of primary importance, the determination of cost-effectiveness is often required prior to acceptance and funding of interventions whether the intervention is a new drug therapy, a therapeutic device, or a monitoring system. In a recent study from the University of Wisconsin, Nui and colleagues determined the cost-effectiveness of telehealth with RPM for postpartum hypertensive disorders

from the hospital's perspective.¹² A decision tree was developed using results from a non-randomized controlled trial comparing telehealth to standard outpatient BP monitoring. At discharge, postpartum women with a hypertensive disorder received a Bluetooth tablet, BP monitor, and scale to submit vital signs daily for 6 weeks. Women were managed and treated with a standard protocol. A cost-effectiveness threshold was set at \$100,000/quality-adjusted life year (QALY). The data demonstrated that telehealth monitoring significantly reduced postpartum readmissions (3.7% (8/214) vs. 0.5% (1/214)) and resulted in higher QALYs. Average cost of telehealth per patient was \$309 and was cost-effective to a cost of \$420 per patient. Telehealth monitoring remained cost-effective down to an admission cost of \$10,999 compared to their baseline-estimate for the average admission cost of \$14,401. Telehealth monitoring also was cost-effective when the postpartum readmission rate was 3.0% or higher with standard monitoring. Based on an estimated 333,253 hypertensive pregnant women per year in the USA and a cost saving of \$93 per patient, telehealth could reduce health care costs by ≈\$31 million/year. The analysis demonstrates that telehealth monitoring can be cost-effective and produces cost-savings.

In summary, published data from different trial designs support the desirability of expanding RPM of BP for managing hypertensive disorders of pregnancy.

Home BP monitoring in hypertensive pregnancies can lower required clinic visits, produces cost saving and can be cost-effective.^{11,12}

Incorporating Central Aortic Blood Pressure into RPM

The role of non-invasively measuring and monitoring central blood pressure has been described in several reports sponsored by ATCOR that can be accessed through the ATCOR website (www.atcormedical.com). The details will not be reiterated in this brief report. However, several key points are highlighted:

- Elevated central aortic pressure predicts cardiovascular events and mortality in addition to structural changes (e.g., left ventricular hypertrophy, carotid intima-media thickness and reduced glomerular filtration rate). The risk of adverse CV outcomes is associated with elevated central pressures and these risks have been shown in multiple studies to be superior, and in others, at least as high than that associated with brachial pressures. A recent meta-analysis, which incorporated multiple baseline factors including brachial systolic pressure, demonstrated that central systolic pressure is independently predictive of cardiovascular events and therefore provides additional risk information.
- Based on the extensive published data on prediction of risk, the correlations of central and brachial systolic pressures, the improvement of health outcomes resulting from lowering elevated brachial systolic pressure, it is clinically appropriate to conclude that lowering of elevated central systolic pressures will reduce the risk of cardiovascular events and mortality.
- Threshold values for the diagnosis of elevated central arterial pressures have been defined and have been referenced to the threshold values for the diagnosis of hypertension based on brachial pressures and for target goals of treatment.
- Measurements of central arterial pressures can be incorporated into the current approaches to hypertension management as the dual arterial pressure SphygmoCor XCEL device, the only FDA cleared medical device for non-invasive measurement of central arterial pressure waveform analysis for all adults, can provide both brachial and central aortic pressures in the same clinic setting.

Conclusion

Although it is intuitive that RPM with home BP monitoring, whereby patients can self-monitor their health and have feedback of data to health care professionals, should improve health outcomes, data is still needed to provide justification for the investment into telehealth and self-monitoring interventions. This brief report has summarized several publications that support the need to provide such services to patients with hypertensive disorders. A specific subset of hypertensive disorders (pregnancy related) is indicative of the potential of RPM to improve health as well as reduce health care costs. Current technology is available to combine both peripheral and central BP monitoring, thereby allowing dual BP monitoring and a broader suite of variables to monitor vascular health.

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Abbreviations

BP	Blood Pressure
CI	Confidence Interval
DBP	Diastolic Blood Pressure
HBPM	Home Blood Pressure Monitoring
NHANES	National Health and Nutrition Examination Survey
OR	Odds Ratio
QALY	Quality Adjusted Life Year
ROI	Return On Investment
RPM	Remote Patient Monitoring
RBPM	Remote Blood Pressure Monitoring
SBP	Systolic Blood Pressure
WMD	Weighted Mean Difference

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