

Feasibility of a Pilot Randomized Hypertension Screening Initiative in the Preoperative Setting.

Sofia Diaz (✉ sofia.diaz@yale.edu)

US Department of Veterans Affairs <https://orcid.org/0000-0002-4716-6003>

Luying Yan

Yale School of Medicine: Yale University School of Medicine

Feng Dai

Yale University School of Public Health

Bin Zhou

Yale University School of Public Health

Matthew M. Burg

Yale School of Medicine: Yale University School of Medicine

Robert B. Schonberger

Yale School of Medicine: Yale University School of Medicine

Research

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Abstract

Objectives: This pilot study sought to assess feasibility of a randomized trial of blood pressure intervention (home blood pressure monitoring vs counseling) in the preoperative clinic and the baseline rates of primary care follow-up after such interventions.

Methods: A prospective randomized pilot study was performed at Yale New Haven Hospital Preadmission Testing Clinic. A sample of 100 adults with elevated blood pressure, were recruited during their preadmission visit, and randomized 1:1 to receive brief BP counseling and an educational brochure versus additionally receiving a home BP monitor (HBPM) with a mailed report of their home readings. At 60-day post-surgery telephone follow-up, investigators asked whether participants had primary-care follow-up; had new/adjusted hypertension treatment and felt satisfied with the study.

Results: There were 51 patients in the counseling group and 49 in the HBPM group. Of 46 patients in the HBPM group who returned their monitors, 36 (78%) were hypertensive at home. At 60 days post-surgery, 31 (61%) patients in the counseling group and 30 (61%) in the HBPM group were reached by telephone with the remaining followed by EMR. 36 (71%) patients in the counseling group and 36 (73%) in the HBPM group had seen their Primary Care provider. 17 of 36 (47%) in the counseling group and 18 of 31 (58%) in the HBPM group received new or adjusted hypertension medications. 61 participants answered questions regarding their satisfaction with the study with 52 (85%) reporting that they felt moderately to very satisfied.

Conclusions: This pilot study suggests that interventional blood pressure trials in the preoperative clinic are feasible, but telephone follow-up leads to significant gaps in outcome ascertainment.

Trial Registration: Clinicaltrials.gov, NCT03634813. Registered 16 of August 2018, <https://clinicaltrials.gov/ct2/show/NCT03634813>

Introduction

Poorly controlled hypertension increases risk for cardiovascular disease (CVD) (1–3) and, other than COVID-19, remains the leading modifiable cause of death and disability-adjusted life years worldwide.(4) Despite continued efforts to address undertreated blood pressure elevation, approximately 22% of Americans with high blood pressure are unaware of the condition, and 32% are not taking anti-hypertensive medications.(5)

Several investigations have attempted to address this public health opportunity through hypertension screening outside of the traditional setting of the primary care office, including in both the acute care setting(6) and in the general community with notable success.(7)

Within the field of anesthesiology, the Merit Based Incentive Program (MIPS) included hypertension screening in its 2007 anesthesiology specific quality metrics, and subsequent literature established

plausible thresholds at which preoperative blood pressures appeared reasonably predictive of longitudinal blood pressure elevation.(8–10) Nevertheless, while isolated teams have attempted to bring hypertension screening and treatment into perioperative workflows,(11) randomized interventional studies based on these efforts have remained unexplored.

In the effort to assess the feasibility of a randomized blood pressure intervention in the preoperative period and to understand baseline rates of blood pressure follow-up following such intervention, we pursued a pilot randomized trial of blood pressure screening, education, and follow up with vs. without longitudinal home blood pressure measurement in a cohort of 100 patients who presented to our preoperative testing center with blood pressures in the hypertensive range. The endpoints of interest included the observed prevalence of post-operative primary care follow-up, patient perspectives on the study protocol, and the ability to execute the several aspects of the trial effectively including recruitment, randomization, home blood pressure monitoring, and follow-up.

Methods

Inclusion and Exclusion.

After approval by the Yale School of Medicine Institutional Review Board and registration on Clinicaltrials.gov (NCT03634813), a sample of 100 patients scheduled for surgery was recruited during their preadmission visit at Yale-New Haven Hospital between November of 2018 to November of 2019. Inclusion criteria included age > 18 years, the ability to understand English, and a clinic-measured blood pressure of at least 140mmHg systolic or 90mmHg diastolic calculated as the mean of two successive measurements five minutes apart. These blood pressures were measured using an automated oscillometric blood pressure device rather than manually by clinicians in accordance with literature demonstrating the superior reliability of such measurements for hypertension screening.(12) Participants who were unable or unwilling to independently operate a brachial artery home blood pressure monitor, those who could not give proper consent, or those for whom the date of surgery was within 48 hours of the preoperative visit, were excluded.

Randomization:

After informed consent was obtained, all participants were given a questionnaire that included measures of medication adherence previously validated on hypertensive patients.(13) Participants were then randomly assigned to one of two groups in a 1:1 fashion stratified by gender. The two groups were defined as follows: One group received brief counseling regarding their apparent hypertension and the importance of blood pressure follow up. They then received a follow-up letter and an educational pamphlet by mail published by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) entitled "Your guide on lowering blood pressure",(14) which includes advice regarding diet, exercise and lifestyle changes that can be implemented to improve blood pressure control. The second group received the educational pamphlet at the time of enrollment and was also fitted with a validated Omron MX3 model BP742 Home Blood Pressure Monitor (HBPM) (Omron, Schaumburg, IL) (15)

and instructed in its use. The HBPM stores timestamped results for up to 50 blood pressure measurements. Participants were sent home with the device and instructed to conduct resting measurements in the morning and evening of each day until the day of surgery and then to bring the device back to the investigators on the day of surgery. Since specific cut-offs for the interpretation of home blood pressure are controversial,(16) and per the 2017 American Heart Association guidelines, should vary based on cardiovascular disease risk assessment,(17) in the present trial we used mean systolic home BP \geq 135 mmHg or mean diastolic home BP \geq 85 mmHg as our HBPM cutoffs. A similar HBPM cutoff of 137/84 mmHg has previously been associated with a 10% increase in the adjusted relative hazard of mortality relative to ideal blood pressure. (18) HBPM participants received a summary report of their mean home blood pressure readings by mail. Unless patients demonstrated sustained normotension on HBPM readings, these letters encouraged follow up to discuss hypertension management with participants' primary care physician (PCP).

Outcome assessment:

60-days post-surgery, investigators attempted to reach participants via follow-up telephone call to a) determine whether the participant had been seen in primary-care follow-up; b) determine whether the participant had received new or adjusted hypertension treatment, and c) assess participants' satisfaction with the study interventions. See Fig. 1 for the list of telephone questions. For those participants who were not reached after three phone call attempts, investigators consulted the Electronic Health Record (EHR) to look for new or adjusted hypertension treatment.

Results

Cohort Characteristics:

A total of 100 participants, were successfully enrolled. Forty-nine participants were assigned to the HBPM group vs. 51 in the counseling group. Fifty-four (54%) were female and Forty-six (46%) male. 72 (76%) participants identified as white, 16 (17%) as Black or African American and Twenty (20%) as Hispanic. See Table 1 for a complete demographic description of the cohort stratified by randomized group.

Table 1. Demographics

	<i>Counseling (n = 51)</i>	<i>HBPM (N = 49)</i>	<i>Total (N = 100)</i>
<i>Female</i>	27 (53%)	27 (55%)	54 (54%)
<i>Male</i>	24 (47%)	22 (45%)	46 (46%)
<i>Hispanic Or Latino</i>	9 (18%)	11 (22%)	20 (20%)
<i>Asian</i>	1 (2%)	0 (0%)	1 (1%)
<i>Black/African American</i>	11 (22%)	5 (11%)	16 (16%)
<i>White/Caucasian</i>	33 (66%)	39 (87%)	72 (72%)
<i>Other</i>	5 (10%)	1 (2%)	6 (6%)
<i>N/A</i>	1 (2%)	4 (8%)	5 (5%)

Blood pressures in the preadmission testing clinic were 154.22 (\pm 13.05) mmHg / 88.88 mmHg (\pm 10.03) in the counseling group, and for the HBPM group 158.10 mmHg (\pm 13.46) / 90.25 mmHg (\pm 11.15). Comparing the counseling group vs the HBPM group, 50 (98%) and 47 (96%) participants had an existing primary care doctor, respectively; 43 (84%) and 42 (85%) had seen their PCP in the last 6 months (of which 36 and 29 saw their PCP in the last 3 months), and 44 (86%) vs 40 (82%) were aware of a prior diagnosis of hypertension, respectively. The enrolled cohort in our clinic demonstrated higher baseline treatment as compared to prior literature(5) with 78% and 80% of each group, respectively, reporting that they were prescribed medications to control their blood pressure. Regarding medication adherence, it was similar amongst both groups. Out of 79 patients amongst both groups being treated for elevated blood pressure, a total of 64 (81%) agreed or strongly agreed with the statement that they took all their anti-hypertensive medications as prescribed. See Table 2 for more information regarding their hypertensive history.

Table 2. Hypertension History.

	<i>Counseling</i>	<i>HBPM</i>	<i>Total</i>
<i>Diagnosis of Hypertension?</i>	n = 51	n = 49	n = 100
Yes	44 (86%)	40 (82%)	84 (84%)
No	7 (14%)	7 (14%)	14 (14%)
No Answer	-	2 (4%)	2 (2%)
<i>Time since diagnosis</i>	n = 43	n = 42*	n = 85
0-6 months	12 (28%)	7 (17%)	19 (22%)
6-12 months	3 (7%)	1 (2%)	4 (5%)
>12 months	28 (65%)	34 (81%)	62 (73%)
No Answer	8	7	15
<i>Have you been to the Emergency Department due to elevated Blood Pressure?</i>	n = 51	n = 49	n = 100
Yes	8 (16%)	6 (12%)	14 (14%)
<i>Are you being treated for Hypertension?</i>	n = 51	n = 49	n = 100
Yes	40 (78%)	39 (80%)	79 (79%)
<i>What type of Treatment?†</i>	n = 39	n = 39	n = 78
Diet changes	11 (28%)	12 (31%)	23 (29%)
Exercise	17 (44%)	13 (33%)	30 (38%)
Smoking cessation	5 (13%)	35 (90%)	6 (8%)
Medications	3 (8%)	36 (92%)	71 (91%)
Stress management	19 (49%)	3 (8%)	6 (8%)
HBPM	12		
No Answer			

		8 (21%)	27 (35%)
		10	22
<i>If taking medications, how many do you take?</i>			
		n = 38	n = 33 n = 71
1		15 (39%)	13 (39%) 28 (39%)
2		13 (34%)	13 (39%) 26 (37%)
= or > 3		10 (26%)	7 (21%) 17 (24%)
No Answer		13	16 29

N equals available answers from questionnaires.

*2 patients in the HBPM group responded to this question, despite not answering positively to a diagnosis of hypertension.

+Multiple answers were permitted; hence percentages do not add to 100%.

Protocol Completion and Feasibility:

Out of 100 participants enrolled, 31 out of 51 (61%) patients in the counseling group and 30 out of 49 (61%) in the HBPM group were able to be reached for a follow up questionnaire. For the 39 participants who could not be contacted, a chart review in the EHR was performed to identify which patients had seen their PCP and had a change in their medication regime. If no information was found, they were coded as missing information. See Fig. 2.

Of the forty-nine home blood pressure monitors provided, 46 (94%) were returned, consistent with our prior experience of adherence to such monitoring among study participants in the preoperative population.(10) The median number of blood pressure readings among these participants was 26 (IQR = 16–46). 36 (78%) of the participants that returned the HBPM had elevated home BP (HBP), as defined by our a priori cut off of a mean systolic HBP \geq 135mmHg or mean diastolic HBP \geq 85 mmHg.(16–18) See Fig. 3.

Primary Outcomes:

Primary care follow-up 60 days after surgery was completed by 36 (71%) patients in the counseling group and 36 (73%) patients in the HBPM group. Of the 72 patients that visited their primary care physician post-operatively, 29 out of 36 (81%) in the counseling group reported discussing hypertension treatment with their PCP vs 32 out of 36 (89%) in the HBPM group.

Modification of hypertensive treatment took place in 17 out of 36 (47%) patients in the counseling group and 18 out of 31 (58%) in the HBPM group that answered this question. Figure 4. The changes in the counseling group included 4 (24%) patients with an increase in dosing, 7 (41%) patients who had a change in medications prescribed, and 9 (53%) patients that had medications added. In the HBPM group, these number were 6 (33%), 5 (28%) and 8 (44%), respectively. Out of the patients that were not on medications pre-operatively, 3 out of 13 (23%) in the control group and 3 out of 16 (19%) in the intervention group were started on medications.

Secondary Outcomes and Participant Acceptance of the Interventions:

Out of the 61 participants who we were able to reach for post-surgical follow-up, 30 belonged to the HBPM group and 31 to the counseling group. They were all asked several questions regarding satisfaction with the protocol participation, as listed in Fig. 1.

When asked if they remembered the NHLBI brochure and had put in practice any recommendations, 43 out of sixty-one (70%) of the participants answered that they did. The most common interventions cited by participants were diet changes, and exercise; endorsed equally by 61% of participants. See Table 3.

Table 3
Methods to lowering blood pressure implemented from the NIH brochure.

	<i>Counseling</i>	<i>HBPM</i>	<i>Total</i>
<i>Changes adopted from NIH brochure</i>	n = 24	n = 32	n = 56
<i>Diet changes</i>	17 (71%)	17 (53%)	34 (61%)
<i>Exercise</i>	17 (71%)	17 (53%)	34 (61%)
<i>Smoking cessation</i>	2 (8%)	2 (6%)	4 (7%)
<i>Medications</i>	11 (46%)	10 (31%)	21 (38%)
<i>Stress management</i>	3 (5%)	5 (8%)	8 (7%)
<i>Home blood pressure monitor – HBPM</i>	9 (13%)	11 (34%)	20 (36%)
<i>No Answer</i>	27	17	44
Multiple answers per patient allowed; therefore, columns do not add to 100%. N equals available answers from patients reached by phone, as well as chart reviews.			

Regarding protocol acceptance, participants were asked to rate their satisfaction with the study on several 5-point Likert scales ranging from 1 “not at all” through 5 “very much”. Overall, fifty-two out of 61 (85%) participants who answered, were moderately to very satisfied with their participation in the study. 49 out of 60 (82%) patients thought the NHLBI brochure was moderately to very helpful; and when asked about the follow up call, 44 out of 55 (80%) patients that answered ranked it as moderately helpful to very helpful. Of the patients in the HBPM group, 28 out of 30 (93%) that were reached found it moderately to

very easy to utilize, although total of 7 out of the 46 (15.2%) patients who returned the HBPM, expressed that adding the HBPM peri-operatively was an added stressor. See Fig. 5.

Discussion

Elevated blood pressure is a common, deadly, and modifiable cardiovascular disease (CVD) risk factor in patients presenting for surgery. Programs such as the Perioperative Enhancement Team (POET) at Duke University, have created multidisciplinary teams with the intention of reducing perioperative risk factors by sending their patients to subspecialized clinics for optimization with good results.(19–21) However, interventions focused on care coordination for newly diagnosed or uncontrolled hypertension have been more limited.(11) The present pilot study demonstrates that preoperative clinic blood pressure interventions are feasible and accepted by most participants, but their impact on blood pressure management is not established.

Several important results of the pilot deserve highlighting. First, while HBPM monitoring was successfully implemented in 94% of participants, it is not clear whether the marginal value gained from the relatively time-intensive process of instructing patients on HBPM use and tracking HBPM return carries sufficient pay-off over and above the simple intervention of a brief counseling session at the time of preoperative evaluation. Although HBPM has been shown to have a higher sensitivity and specificity for truly elevated blood pressure as compared to office measurements,(22–24) it is notable that almost 4 in 5 participants who were deemed to be hypertensive in the preoperative clinic indeed had the diagnosis confirmed in their home blood pressure readings. It is not clear whether the marginal improvement in diagnostic fidelity found in HBPM outweighs the practical benefits of a more widely acceptable brief counseling intervention for hypertensive presurgical patients.

Second, it is notable that the study cohort demonstrated significant changes in hypertension treatment at 60 days follow-up regardless of group assignment. The fact that 35 out of 100 patients in the trial had a change in hypertensive medication treatment at 60-days of follow-up may lend credence to the potential importance of preoperative counseling to encourage such follow-up.

Finally, given the finding that a large percentage of the overall cohort were not able to be reached by telephone at 60 days suggests that future pragmatic trials of larger scale blood pressure screening interventions in the perioperative period may benefit from greater reliance on EHR follow up to ascertain blood pressure treatment changes. While this would, of course, limit potential follow-up to patients within integrated EHR systems, the alternative of telephone follow-up itself carried with it a 39% failure to follow-up. As integrated electronic health records gain market penetrance, we suggest that the benefits of EHR follow-up are likely to increase.

In conclusion, our pilot study suggests that preoperative clinic blood pressure screening and intervention is feasible and accepted by patients. Given the accuracy of preoperative clinic blood pressure measurement for predicting longitudinally elevated blood pressures, it remains unestablished whether additional diagnostic accuracy obtained from home blood pressure monitoring in the preoperative period

is worthwhile. Future studies are required to delineate whether preoperative hypertension screening programs can have potentially long-term benefits for cardiovascular health among patients presenting for surgery.

Abbreviations

- CVD, Cardiovascular disease
- EHR, Electronic Health Record
- HBP, Home BP
- HBPM, Home Blood Pressure Monitor
- MIPS, Merit Based Incentive Program
- NHLBI, National Heart, Lung, and Blood Institute
- NIH, National Institutes of Health
- PCP, Primary care physician
- POET, Perioperative Enhancement Team

Declarations

Ethics approval and consent to participate

The Yale School of Medicine Institutional Review Board approved the study, and all participants provided written informed consent.

Consent for publication

The Yale School of Medicine Institutional Review Board approved the study, and all participants provided written informed consent.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

Dr. Schonberger reports owning stock in Johnson & Johnson. Dr. Schonberger reports that his institution receives funding from Merck, Inc. on a study with which he is involved.

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necessarily represent the policy or views of the NIH, NCATS, or the United States Government.

Authors' contributions

RS, SD and MB performed the study conception and design. SD and LY recruited and followed up with participants and acquired data. FD and BZ analyzed and interpreted the data collected. RS, SD, LY, and FD participated in the drafting of the manuscript. All authors read, performed critical revision and approved the final manuscript.

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Figures

60-Day Post-Operative Questionnaire

Have you seen your PCP after surgery?

Did you discuss treatment for your elevated BP?

Have you had any BP treatment changes after surgery?

- If yes, what changes?
 - Increase in dose
 - Addition of medications
 - Change in medications

If on no medications before surgery, have you received new treatment for elevated BP?

Did you follow the brochure recommendations?

- If yes, which ones? (all that apply)
 - Diet Changes
 - Exercise
 - Smoking Cessation
 - Medications
 - Stress Management
 - HBPM

Satisfaction Questions: Scale 1-5 (Unsatisfied to Satisfied)

How satisfied are you with your participation in this study?

How easy was it for you to take your BP at home with the HBMP?

How helpful was the brochure?

How helpful was the follow up letter with the BP values and phone-call after surgery?

Figure 1

Post-Operative Questionnaire. PCP, Primary Care Physician; BP, Blood Pressure; HBPM, Home Blood Pressure Monitoring.

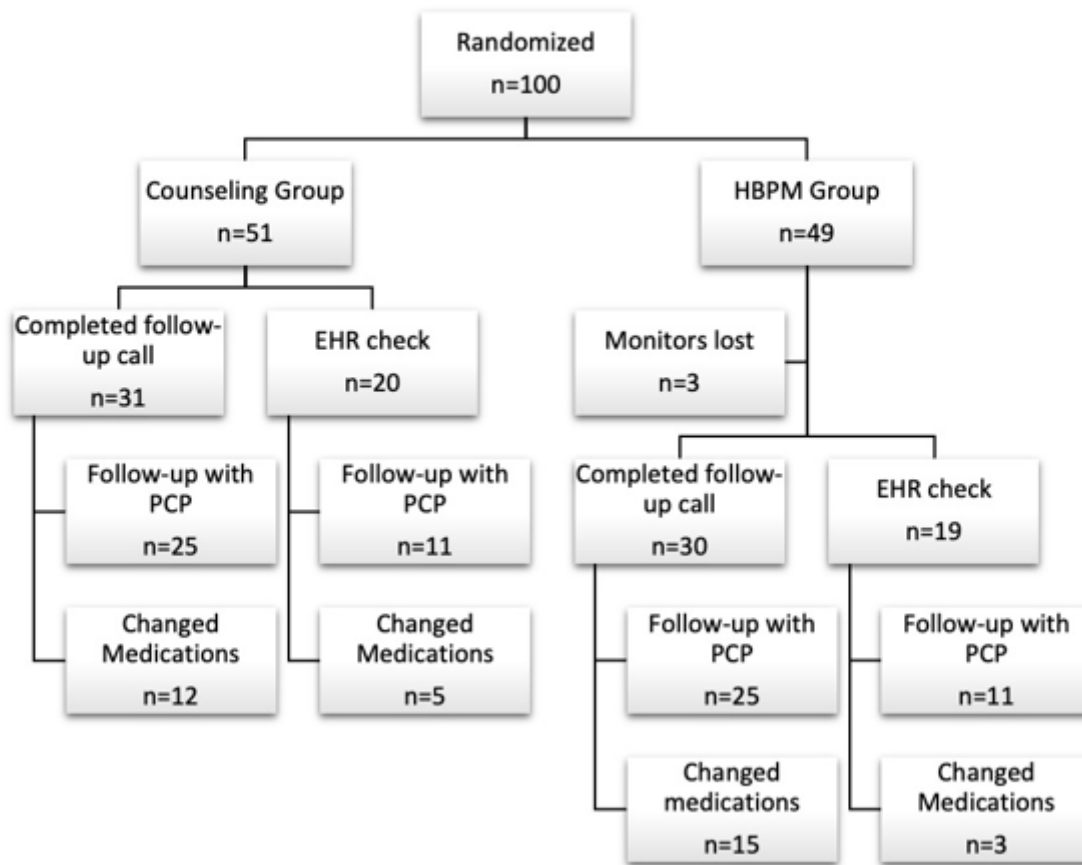


Figure 2

Flow chart depicting allocation of randomized participants and main results. HBPM, Home Blood Pressure Monitor; PCP, Primary Care Physician; EHR, Electronic Health Record.

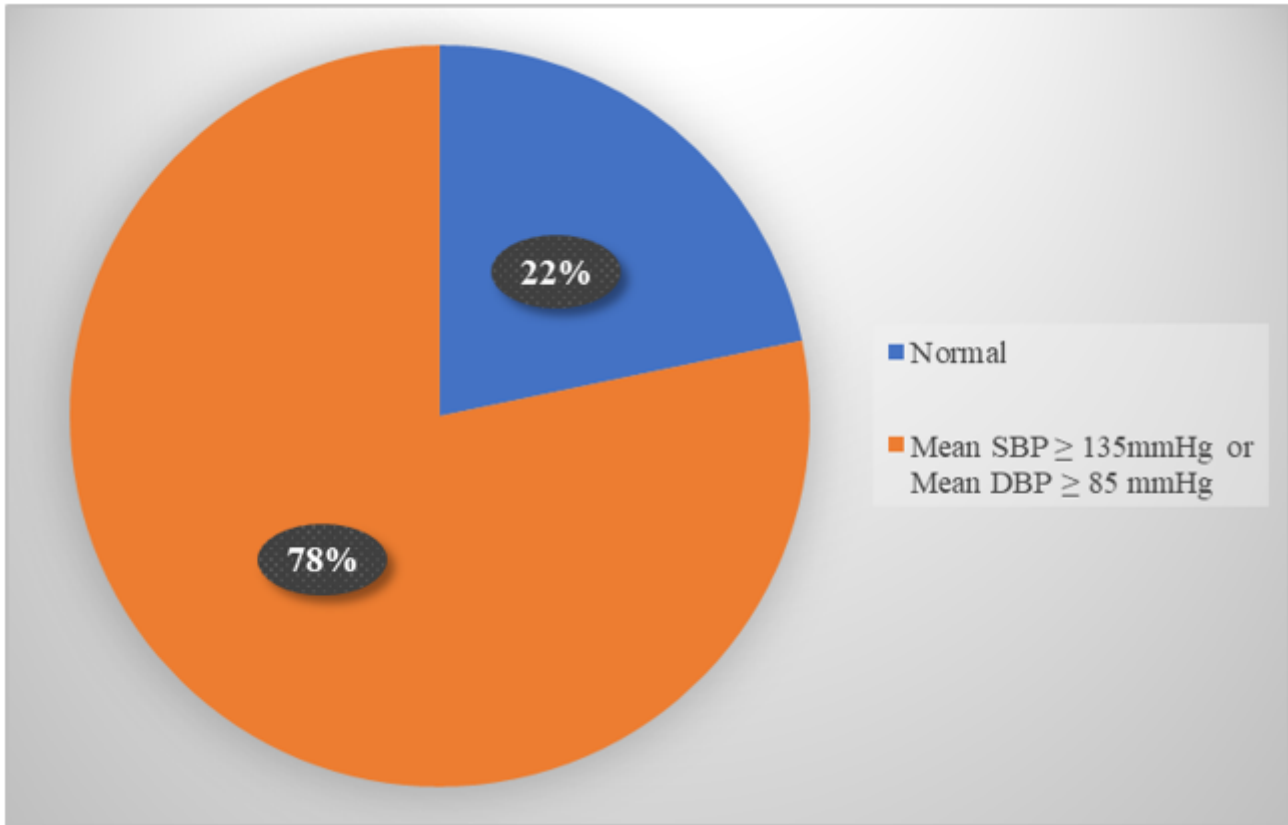


Figure 3

Home Blood Pressure Monitor cutoffs. Cutoff used was mean systolic HBP \geq 135 mmHg or mean diastolic HBP \geq 85 mmHg. HBP, Home Blood Pressure; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure.

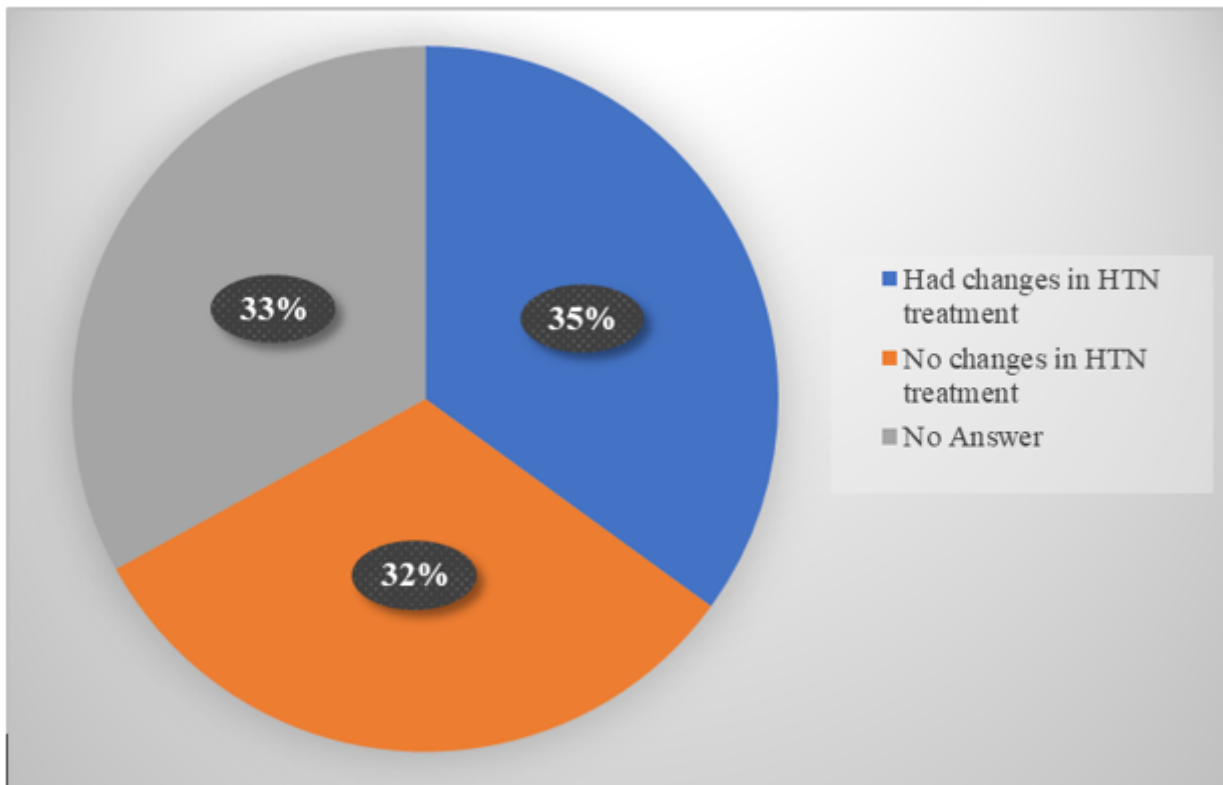


Figure 4

Percentage of patients with changes in their blood pressure treatment at 60 days of follow-up. Both the counseling and HBPM group had an even distribution regarding treatment. HTN, Hypertension. HBPM, Home Blood Pressure Monitoring Group.

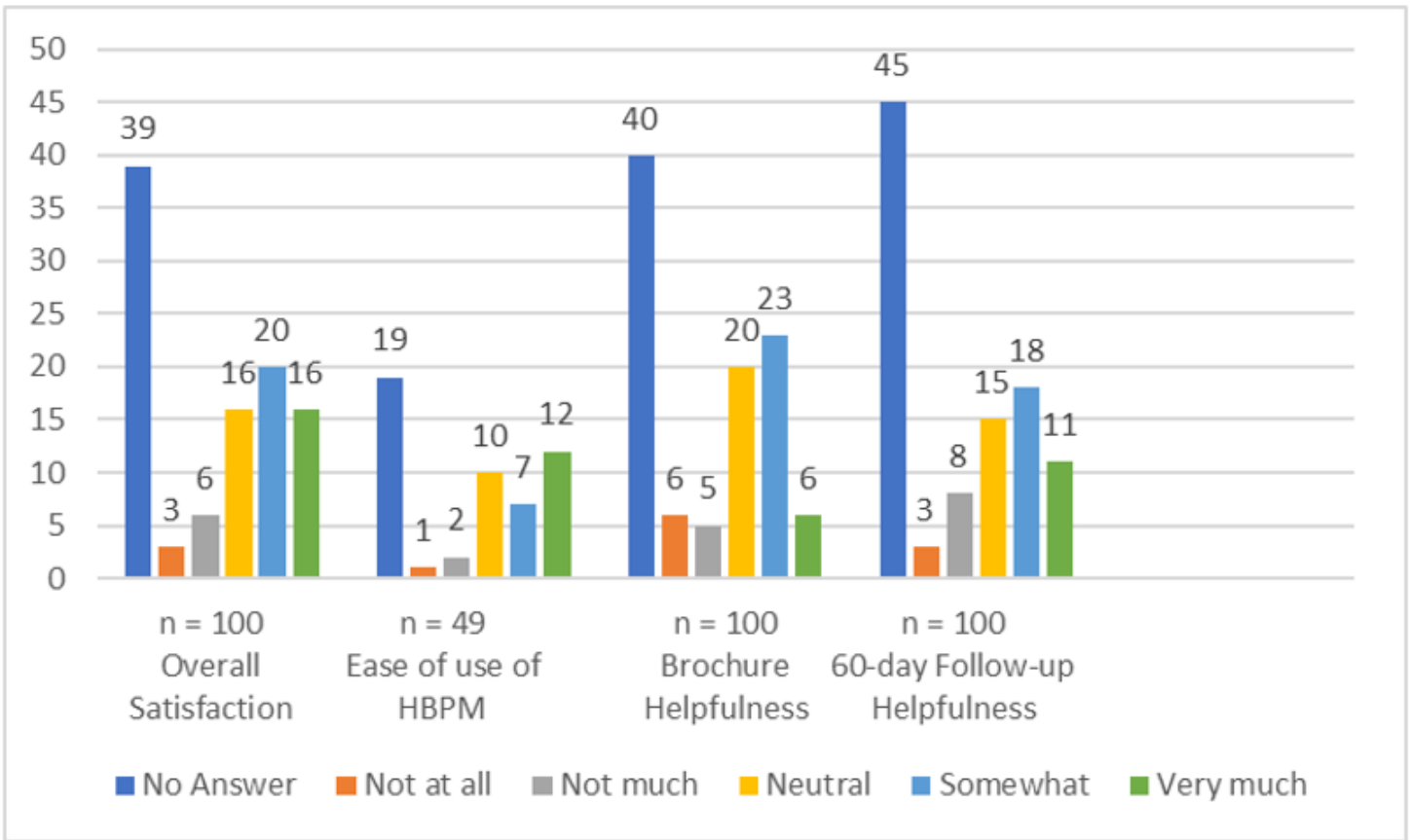


Figure 5

60-day follow-up satisfaction questionnaire. Satisfaction scores measured with a 5-point Likert scale. Values given in number of patients that answered each individual question. HBPM, Home Blood Pressure Monitor.