The Duke Primary Care Tailored to You (TTY) Blood Pressure Control Pilot Study

Document Date: 06/14/2022

NCT05141175

The Duke Primary Care Tailored to You (TTY) Blood Pressure Control Pilot Study

Research Summary

Research Abstract

Suboptimal blood pressure (BP) lowering therapy is a key reason for failing to reach hypertension control targets. Both clinical inertia and patient adherence contribute to suboptimal BP-lowering therapy. Impedance cardiography (ICG) is a simple, noninvasive method to assess a person's hemodynamic state and the pathophysiology contributing to high BP. Armed with such an understanding, a clinician can tailor medication selection to the individual patient. In this pilot study, we will test a protocol and procedures designed to investigate the clinical utility and feasibility of ICG-based hypertension therapy in the primary care setting. Twenty patients with uncontrolled hypertension (office BP≥140/90 mm Hg) who are taking at least one BP-lowering medication will be enrolled in this study and followed for four-months. Participants will undergo ICG in the office setting during their clinic visit, and ICG assessment will be used to guide medication selection. Follow-ups with repeat BP measurement and ICG-guided medication titration will occur monthly until BP is controlled or four-months have passed. Outcomes (at four months) will be percent of patients who attain controlled BP and mean BP achieved as well as feasibility outcomes (enrollment and completion rates). This study is low-risk, carrying the same risks as standard care for patients with hypertension. Participants' BP will continue to be monitored in the standard manner in addition to ICG assessment.

Primary study objectives: To test procedures and gather preliminary data on the potential efficacy of incorporating impedance cardiography (ICG) into the assessment of patients with hypertension in the primary care setting to provide the clinician guidance on individualizing therapy to improve blood pressure (BP) control. Potential efficacy will be assessed as percentage of participants in whom BP control is attained.

Secondary study objectives: Collect preliminary data for informing a larger study.

Objectives & hypotheses to be tested

To assess feasibility and potential effectiveness of incorporating impedance cardiography (ICG) assessments into the care of patients with uncontrolled hypertension. As a pilot study, we will not be testing a hypothesis.

Background & Significance

Control of high blood pressure (BP) is one of the most important strategies for prevention of stroke and cardiovascular diseases. In addition to the adoption of appropriate lifestyle modifications, from a clinical standpoint, achieving BP control requires several steps that culminate in choosing antihypertensive medication that is effective for the patient. In practice, BP-lowering medication is chosen empirically or based on clinical judgment taking into consideration clinical factors such as age, lifestyle and comorbidities. Ideally, however, BP-lowering medication should be matched to the patient's underlying

pathophysiology. Our central hypothesis is that hypertension control can be improved by addressing this gap.

In fact, a suboptimal medication regimen is the most common reason for uncontrolled BP. Some medications may simply not be effective for certain patients, and some medications can even cause a paradoxical BP increase. As opposed to the current strategy of choosing BP-lowering medications largely arbitrarily, measurement of hemodynamic parameters using impedance cardiography (ICG) may allow a better alignment of medication choice with a patient's underlying hypertensive pathophysiology. ICG provides information on vascular resistance and thoracic fluid status in addition to resting heart rate. A systematic review and meta-analysis of five studies suggested that ICG may be valuable as an adjunct to therapeutic decision-making in the treatment of hypertension.(Ferrario C, et al. 2010.) The review identified two randomized controlled trials (total 268 patients) of ICG-guided treatment with patients randomized to ICG-guided therapy about twice as likely to achieve BP control. However, both trials are dated, and baseline control rates were low (33% in one trial and 27% in another). Duke Primary Care, which uses the attached hypertension medication algorithm, currently has an overall 75.1% BP control rate. Our goal is to determine whether a tailored approach using ICG can facilitate an even greater proportion of our population attaining control of their BP, thereby reducing their risk for untoward cardiovascular events. This pilot study represents a first step in this line of research and quality improvement.

Design & Procedures

The purpose of this pilot study is to test procedures and gather preliminary data on the potential effectiveness of incorporating impedance cardiography (ICG) into the assessment of patients with hypertension in the primary care setting to provide the clinician guidance on individualizing therapy to improve blood pressure (BP) control. ICG is not an experimental or investigational device; it is a low-cost, noninvasive technology that easily measures a person's hemodynamic phenotypic profile.

This pilot study will take place in the South Durham Duke Primary Care Clinic. The clinic serves approximately 15,700 patients, with an estimated hypertension diagnosis prevalence of 28.3%. As a pilot study, this will be a non-randomized, single-arm, prospective study. BP and ICG data will be recorded in a REDCap database. Data on BP-lowering medications will be collected by abstracting data from the EHR and entering it into the REDCap database.

The ICG system provides a printed report that indicates whether a person's hemodynamic state is predominantly one that is vasoconstricted, hyperdynamic, or mixed. The participating clinicians will have received teaching on the reports via a presentation delivered by one of the study investigators. Participating clinicians can refer to a separate table that provides a list of medication options suited to address each of these states based on their mechanism of action. The table was developed by MediSync for their MedEngine algorithm that is configured to align medication choices based on the hemodynamic findings from the ICG readings. This decision support tool was created so as to organize these medications based on their mechanism of action and is consistent with the evidence-based treatment of hypertension. In other words, the table is simply a way to organize BP-lowering medications matched to hemodynamic state according to their mechanism of action. The table lists appropriate standard of care medication options. The clinician can use the information to guide selection of the next BP-lowering medication. The ultimate decision on therapy rests with the patient's clinician. ICG data will not be put into the Duke SOC process. ICG data will not be incorporated in the DPC hypertension algorithm.

Participating clinicians will use clinical judgment, informed by ICG data and a table of standard of care BP medications for different hemodynamic states, to adjust medications.

For participants whose office BP is controlled prior to the 4-month visit, we will conduct a chart review to assess last clinic BP obtained, which will be entered into REDCap.

We will conduct anonymous surveys with both patients and providers who participated in the study to better understand acceptability and feasibility. These will be administered using REDCap and will include a short implied consent statement.

Selection of Subjects

We will recruit 20 patients (18 years or older) for this pilot feasibility study assessing ICG-guided hypertension management as an alternative to standard algorithm-based care (see Hypertension Medication Algorithm provided as an attachment) for improving BP control. Patients will be eligible if they have a documented diagnosis of hypertension (ICD 401.XX) and their most recent office systolic BP average measured using automated office BP (AOBP) is ≥140 mmHg systolic or ≥90 mmHg diastolic and they are currently prescribed at least one BP-lowering medication. All patients will already be under the care of a primary care clinician. AOBP is already the standard form of BP assessment in Duke Primary Care.

Subject Recruitment and Compensation

Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

Study staff will attend clinic days. Eligible patients of participating clinicians will be identified and informed about the study by the medical assistant. On study days, eligible patients of participating clinicians (who will have been trained on protocol) will be approached consecutively until the end of the clinic day or until target enrollment is complete. A study coordinator will work with the scheduled study clinician(s) and their medical assistant(s) to identify patients who may be eligible before the start of the clinic session. During the vital signs check-in procedures, the medical assistant will inform potentially eligible participants about the study if their check-in BP is ≥140 mmHg systolic or ≥90 mmHg diastolic. If an eligible patient is interested in participating, the medical assistant will introduce the patient to the study coordinator who will provide more information and obtain informed consent. Based on the number of patients with hypertension, it is estimated this pilot study will reach target enrollment in 5 or fewer study enrollment days. There is no compensation provided to participants. The ICG assessment will be provided free of charge.

Study Interventions

If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

If a patient approached by the medical assistant is interested in participating, the medical assistant will "hand-off" the patient to a study coordinator. The study coordinator will obtain informed consent and enter study information into a secure Redcap database. An in-office ICG assessment will then be performed by either the study coordinator or a trained clinic nurse. The procedure uses four electrodes (2 electrodes on the right ankle and 2 electrodes on the left wrist) and takes approximately 5 minutes to perform while the participant lies on an exam table. It is painless and completely noninvasive (does not even require chest to be bare). The ICG report will be printed and presented to the participant's clinician, who will then see the patient. The report will contain a recommendation for therapy based on the result. Participating clinicians will have all been trained about ICG and how to interpret the report.

Participating patients will be seen in a hypertension follow-up visit 1-month later and have repeat AOBP measured in the office. If BP is <140/90 mmHg, they will continue the current BP-lowering medication regimen and follow-up per usual care. If AOBP average is ≥140/90 mmHg, the participating patient will have repeat ICG and therapy adjustment as above with another one-month follow-up. The four-month visit AOBP average will be used as the endpoint for this pilot study. For participants whose office BP is controlled prior to the 4-month visit, we will conduct a chart review to assess last clinic BP obtained, which will be entered into REDCap.

Data Analysis

As this is a pilot study for feasibility, our main outcomes will be enrollment and completion rates. Nonetheless, we will assess improvement in BP control (both percent at goal <140/90 mmHg as well as average mmHg reduction in BP) at 4-months. For participants whose office BP is controlled prior to the 4-month visit, we will conduct a chart review to assess last clinic BP obtained, which will be entered into REDCap. Characteristics of participants will be tabulated by simple means and percentages. We will also tabulate number and categories of anti-hypertensive medications participants are prescribed.