

ORIGINAL RESEARCH

A New Device (Inferum NBP-050) to Correct Low Blood Pressure and to Improve Symptoms in Patients with Idiopathic Hypotension

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ABSTRACT

Background: Idiopathic hypotension is not uncommon among young individuals, yet it is not well studied. Hypotension could affect quality of life because symptoms are often accompanied by anxiety, depression, and low motivation. The aim of this study was to assess the effectiveness of the new Inferum NBP-050 device in correcting blood pressure in symptomatic hypotensive patients.

Results: The study included 43 symptomatic hypotensive patients. Demographics, symptom analysis and risk factors as well as office and ambulatory blood pressure measurements were assessed at baseline. Patients were instructed to use the Inferum device at home on the dorsal surface of their left wrist for 6 minutes, twice daily for 14 consecutive days. Symptoms and blood pressure were reassessed after 14 days and then after 3 months of using the device. At 14-days follow up, the median baseline office systolic and diastolic blood pressures had increased from 85 to 104.5 mmHg ($P<0.001$) and from 52 to 66.5 mmHg ($P<0.001$) respectively and the median baseline 24-hours ambulatory systolic and diastolic blood pressures had increased from 88 to 103 mmHg ($P<0.001$) and from 51 to 66 mmHg ($P<0.001$) respectively. Most patients (88.4%) claimed marked improvement or even disappearance of symptoms after 14 days of device use. Follow up after 3 months showed comparable results to the 14-days follow up visit.

Conclusions: The new device Inferum NBP-050 was effective in improving hypotension in symptomatic patients with idiopathic hypotension. The effect was apparent after 14 days of device use and it persisted for 3 months thereafter

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Introduction

Low blood pressure (hypotension) has never been considered a disease,¹ but rather a manifestation of a disease. Yet, it was noticed that some healthy, non-cardiac individuals, mostly young females, suffer from symptoms of low cardiac output associated with low blood pressure.

There is no absolute cut off levels below which hypotension is diagnosed, rather hypotension is considered when blood pressure drops below the accepted normal blood pressure values with levels below 100/60 mmHg were considered abnormally low. Hypotension is generally regarded as a benign condition and is only considered serious when it affects perfusion of the vital organs².

The scientific interest of hypotension is very old yet very little. Low blood pressure is usually associated with physical and psychological symptoms such as tiredness, weakness, dizziness and headache,³ and with sleep disturbances, anxiety and depression⁴. Some studies indicated that low blood pressure is associated with various somatic and psychological

symptoms that could influence quality of life and working capacity of humans, often in young age^{4,6}.

Due to non-specificity of complaints, absence of precise diagnostic criteria, as well as low referral of patients for medical care even in clinically manifested hypotension, actual prevalence of idiopathic hypotension is not clear.

Treatment of idiopathic hypotension involves many non-drug and drug approaches, yet none is specifically recommended. The absence of clear recommendations for patients with idiopathic hypotension invites the search for additional methods of blood pressure correction.

Transcutaneous electro-neurostimulation (TENS) is the application of low frequency electrical impulses through electrodes applied to the skin. It is considered a non-invasive, cheap technique used individually for pain relief⁷. TENS has variable effects on the hemodynamics depending on the intensity and the site of application. Inferum NBP-050 device is a new device based on the TENS technique and it is said to have a regulatory effect on vascular tone by means of a non-invasive, transcutaneous, electric current exposure (frequency range 9-77 Hz) on biologically active points MC-6

(on the inner part of the left wrist) and TE-5 (on the outer part of the left wrist) with an exposed zone diameter of 10 mm. The device has 2 programs; program number 1 that provides exposure on point MC-6 and it helps improve cenesthesia for patients with high blood pressure and program number 2 which provides exposure on point TE-5 and helps to improve cenesthesia for patients with low blood pressure. Manufacturers recommend using the device once or twice daily for 10-15 days and they claim that the effect is a long lasting with permanent improvement of the cenesthesia after the initial course of device treatment. The device has been registered as a medical device in Russia and in Europe⁸.

The aim of this study was to test the effectiveness of the new Inferum NBP-050 device in improving the low blood pressure in symptomatic hypotensive individuals.

Methods

This study is a prospective, interventional study that included 43 individuals with idiopathic hypotension (defined as low blood pressure (<100/60 mmHg) in absence of an underlying organic disease) who complained of symptoms of low cardiac output. Excluded from the study were individuals with intolerance to electric current, epileptic seizure and neoplasms of any etiology and location. Individuals were recruited over a period of 6 months from public as well as private clinics.

Oral recorded consent was taken from the recruited subjects and the study was approved by the local ethical committee.

Clinical history was taken including age, sex, risk factors assessment (diabetes, smoking, dyslipidemia) and presenting symptoms (headache, fatigue, palpitations, shortness of breath, etc.).

Office blood pressure (BP) was measured according to the standardized technique of blood pressure measurement using a commercially available semiautomated digital device. The systolic and the diastolic BP were measured, and the mean BP was calculated as follows: (mean BP = DBP + 1/3 PP) mmHg, where DBP is the diastolic blood pressure and PP is the pulse pressure which equals (systolic-diastolic BP).

A 24-hours ambulatory blood pressure monitoring was done to confirm the low blood pressure levels. The average daytime, nighttime and 24-hour systolic and diastolic blood pressure readings were reported.

The use of the Inferum device

The examining physician taught patients how to use the Inferum NBP-050 device at home. The device looks like a digital wristwatch, and it is worn on the left wrist with the electrodes facing the exposure point TE-5 on the outer part of the wrist. The device is light weight (weighs only 300 g) and is battery-operated (using 2 alkaline batteries type AAA). Individuals were taught to tighten the cuff of the device around their wrist and to turn on the device by pushing the proper button. The icon on the display should flicker white and this indicates that the device is working. The individuals were instructed to sit still until the flickering stopped, as this meant that the session had ended (the session lasted 6 minutes). When flickering stopped,

they were instructed to take the device off and to rest for 20-30 minutes after the session. This session was repeated twice daily for 14 consecutive days (a total of 28 sessions). The electrodes of the device were cleaned and sterilized after each session. Patients were not allowed to use the device after those 14 days.

Follow up symptoms, heart rate, office as well as ambulatory blood pressures were done after 14 days course of the device therapy and 3 months thereafter. Data of follow up and baseline visits were compared. The difference between paired values was calculated as the follow up value minus the preceding visit value.

Statistical analysis

The data were collected, tabulated, and delivered to an SPSS program (version 26) for data analysis. Categorical variables are presented as frequency and percentages and because of non-normality of data, continuous variables are presented as median and range of values. Comparison between paired data was done using a nonparametric Wilcoxon signed rank test. A p-value less than 0.05 was considered significant.

Results

This study included 43 hypotensive individuals, with median age 31 years (range 18-63 years). There were 38 females (88.4%), 1 diabetic patient, 1 current smoker and 6 patients (14%) with dyslipidemia. Analysis of the presenting symptoms showed that patients mainly complained of easy fatigability (n=13, 30.2%), headache (n=11, 25.6%), fainting attacks (n=9, 20.9%), palpitations (n=4, 9.3%), shortness of breath (SOB) (n=3, 7.0%) and others (n=3).

The baseline heart rate and blood pressure measurements are shown in table 1.

Patients were seen after 14 days of using the device and their symptoms were reassessed. Most patients claimed that their symptoms had improved (n=31, 72.1%) or even disappeared completely (n=7, 16.3%), while other patients complained of persistence of the presenting symptoms (n=5, 11.6%). All individuals were compliant to the 14-days device course and none of the patients complained of any device inconvenience.

The values of the office as well as the ambulatory BP after 14 days are shown in table 2. Almost all patients showed a significantly higher BP readings at follow up, except for 3 patients (2.3%) who showed lower office systolic and diastolic BP and 2 patients (4.7%) who showed lower 24-hours systolic and diastolic BP. The mean arterial blood pressure increased from a median of 63.3 mmHg at baseline to a median of 77.7 mmHg at follow up (p<0.001).

Follow up after 3 months of the single device course revealed persistence of BP improvement with no significant difference between the 14-days and the 3-months visits' readings, table 3. The mean arterial blood pressure insignificantly increased from a median of 77.7 mmHg at 14-days follow up to a median of 81.3 mmHg at 3-months follow up (p=0.166). Figure 1 shows the median of office and ambulatory BP readings at the 3 visits.

Table 1 Baseline HR and BP measurements (before using the device)

Variable	Median (Range)
Heart rate, bpm	87 (73-130)
Office BP	
Office SBP, mmHg	85 (76-100)
Office DBP, mmHg	52 (40-60)
ABPM	
Daytime SBP, mmHg	88 (75-104)
Daytime DBP, mmHg	52 (44-66)
Night-time SBP, mmHg	87 (79-104)
Night-time DBP, mmHg	51 (43-61)
24-hours SBP, mmHg	88 (76-99)
24-hours DBP, mmHg	51 (47-62)

BP, blood pressure; SBP, Systolic blood pressure; DBP, diastolic blood pressure; ABPM, ambulatory blood pressure monitoring

Discussion

Hypotension is a decrease in blood pressure below the normal values. There is not yet an accepted absolute cut off definition of low blood pressure, and most physicians diagnose hypotension when blood pressure drops suddenly or when blood pressure drop is associated with symptoms of low cardiac output.

Idiopathic hypotension should be distinguished from secondary and orthostatic hypotension. Secondary hypotension is diagnosed when low blood pressure represents a sign of a specific pathological condition as blood loss, cardiac problem, severe allergic reaction, severe infection, and after use of certain medications ⁹. In these cases, the treatment of the underlying disease should correct hypotension. Orthostatic hypotension is defined as a drop of at least 20 mmHg systolic and/or 10 mmHg diastolic pressure upon standing or with head-up tilt table test ¹⁰. It commonly affects elderly (prevalence may reach 30%) ⁹ and patients with autonomic dysfunction.

In contrast, idiopathic hypotension is not considered a disease by itself, ¹ and in absence of an underlying pathology, it is not considered a manifestation of another illness. Because of lack of clear diagnostic criteria, idiopathic hypotension is left undefined and poorly investigated and its prevalence is not yet known. A relatively old study by Owens et al ² used the ambulatory blood pressure monitors to detect hypotensive events in an Irish general population and found that 49% of the included subjects had hypotensive events. They described the profile of those individuals as being mostly females, underweight and with low body mass and low creatinine level.

Despite lack of evidence in literature, hypotension is a common clinical finding in daily practice.² Low blood pressure causes many symptoms that could be both annoying and incapacitating to patients. Headache, easy fatiguability, ¹¹ dizziness, syncope and poor perception of self-wellbeing ¹² are among the important symptoms of hypotension. When blood pressure is low enough, it could hinder proper perfusion of vital organs and could endanger patient's wellbeing.

Non-drug approaches for hypotension include modification of lifestyle (optimization of sleep/wake regime, balanced nutrition), psychotherapy, high intake of

common salt and sufficient amount of fluid, massage of cervical collar zone, acupuncture, physiotherapy (General body conditioning, balneotherapy, hydromassage, neck electrophoresis), physical exercises, wearing of compression stockings as indicated, etc. ⁹.

If the above-mentioned measures are insufficient, drug treatment is initiated: herbal drugs (magnolia vine, aralia, ginseng), midodrine-based drugs, cerebro-protective drugs, antioxidants, vitamin complexes, antidepressants, etc. ⁹. The absence of precise recommendations on management of patients with idiopathic hypotension invites the search of additional methods for BP correction, especially in clinically manifested patients. In this context, TENS is known to reduce the severity and incidence of hypotension¹³.

The inferum device has been recently released in the market and the manufacturers demonstrated that the device acts through a low-intensity electric current stimulation of peripheral receptors located at the outer surface of the left wrist. Excitation of these receptors leads to a cascade of neurologic stimulation that eventually lead to correction of an abnormal vascular tone and improvement of a low blood pressure. The device is accredited to use in Russia and Europe and is recently allowed in the markets of Egypt ⁸.

The aim of this study was to investigate the effectiveness of the new Inferum NBP-050 device in correcting hypotension and improving its associated symptoms. In this study, hypotension was defined as an office blood pressure less than 100/60 mmHg with low cardiac output symptoms, in absence of any secondary causes for low blood pressure and/or symptoms.

Forty-three eligible patients, were recruited and were given the device to use at home for 14 consecutive days. They were scheduled for a follow up visit immediately after those 14 days and their office as well as ambulatory blood pressures were compared between the 2 visits. Our results showed that 88% of the included patients were females, a finding that was similarly observed in the study by Owens et al ².

There was a significant improvement of office blood pressure measurements, with 17 mmHg median increase in office SBP and 14 mmHg mediana increase in DBP. Ambulatory blood pressure measurements showed a similar significant improvement at the follow up visit after 14 days of device use, with16 mmHg median increase in the 24-hours SBP and 13.5 mmHg median increase in the 24-hours DBP. The heart rate showed a significant reduction at follow up, denoting improvement of the hemodynamic mechanisms as well. Most patients (88.4%) claimed that their presenting symptoms had markedly improved or even completely disappeared with the use of the device.

Patients were scheduled for a second follow up after 3 months, without the device and without any treatment. The improvement in blood pressure persisted after 3 months of a single device use, with nearly similar blood pressure readings in the two follow up visits. Patients also claimed marked improvement in their quality of life with disappearance of disturbing symptoms of hypotension. These results proved that the device exerted its maximum effect on the first cycle of usage and that those effects were maintained on a short-term period.

Table 2 Comparison between HR and BP measurements at baseline and after 14 days of device use

Variable	Baseline	After 14 days	P-value	Difference
Heart rate, bpm	87 (73-130)	77.5 (74-103)	<0.001	-10 (-56 to 20)
Office BP				
Office SBP, mmHg	85 (76-101)	104.5 (74-131)	<0.001	17 (-18 to 50)
Office DBP, mmHg	52 (40-66)	66.5 (43-80)	<0.001	14 (-13 to 37)
ABPM				
Daytime SBP, mmHg	88 (75-104)	104 (88-127)	<0.001	18.5 (-8 to 39)
Daytime DBP, mmHg	52 (44-66)	67 (52-80)	<0.001	14.5 (-1 to 31)
Night-time SBP, mmHg	87 (79-104)	100.5 (85-126)	<0.001	13 (-5 to 40)
Night-time DBP, mmHg	51 (43-61)	64.5 (46-81)	<0.001	13 (-12 to 32)
24-hours SBP, mmHg	88 (76-99)	103 (87-127)	<0.001	16 (-2 to 40)
24-hours DBP, mmHg	51 (47-62)	66 (51-80)	<0.001	13.5 (-3 to 31)

Values are presented as median (range). SBP, Systolic blood pressure; DBP, diastolic blood pressure; ABPM, ambulatory blood pressure monitoring

Table 3 Comparison between the two follow up visits

Variable	After 14 days	After 3 months	P-value	Difference
Heart rate, bpm	77.5 (74-103)	77 (72-104)	0.404	2 (-20 to 27)
Office BP				
Office SBP, mmHg	104.5 (74-131)	105.5 (94-120)	0.500	1 (-34 to 11)
Office DBP, mmHg	66.5 (43-80)	69 (58-77)	0.189	0 (-20 to 14)
ABPM				
Daytime SBP, mmHg	104 (88-127)	103 (93-123)	0.681	-1 (-19 to 12)
Daytime DBP, mmHg	67 (52-80)	68 (60-78)	0.171	1 (-11 to 12)
Night-time SBP, mmHg	100.5 (85-126)	102 (90-115)	0.477	0 (-15 to 15)
Night-time DBP, mmHg	64.5 (46-81)	68 (57-77)	0.064	1 (-6 to 11)
24-hours SBP, mmHg	103 (87-127)	104 (92-117)	0.625	-1 (-11 to 13)
24-hours DBP, mmHg	66 (51-80)	67 (56-95)	0.536	1 (-8 to 29)

Values are presented as median (range). SBP, Systolic blood pressure; DBP, diastolic blood pressure; ABPM, ambulatory blood pressure monitoring

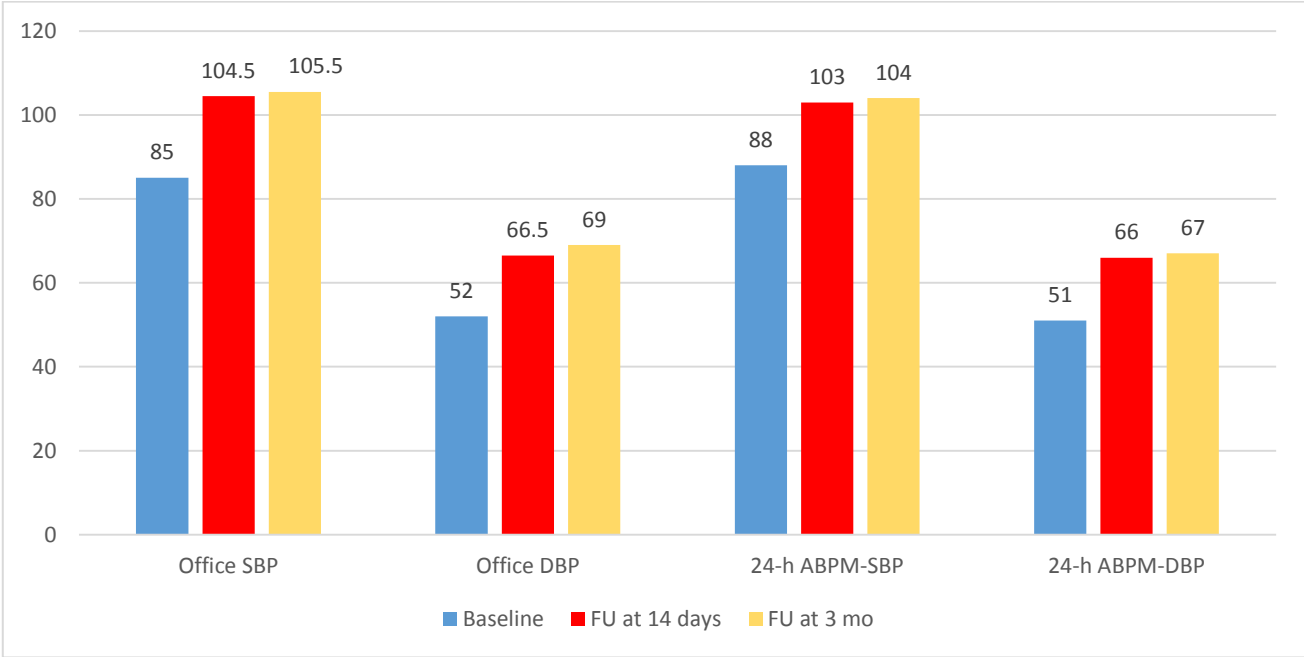


Figure 1 Comparison between the baseline and the follow up office and average ambulatory BP measurements
SBP, Systolic blood pressure; DBP, diastolic blood pressure; ABPM, ambulatory blood pressure monitoring

Limitations

In this study, we only assessed the short-term effects of the device on hypotensive patients (at 14 days and after 3 months of device use). The long-term effects on blood pressure need to be evaluated to validate the use of the device as a therapeutic tool in symptomatic hypotensive patients. It is not clear whether this device could be enough for correction of hypotension or if other drug and non-drug measures are still needed.

Conclusions

The new electrostimulation device (Inferum NBP-050) succeeded in correcting low blood pressure and improving low cardiac output symptoms in a group of symptomatic hypotensive individuals. The improvement in hypotension was apparent after a single course of device use for 14 consecutive days and the effects persisted for 3 months thereafter. The device was able to correct both the systolic and the diastolic blood pressures and the improvement could be detected by office as well as ambulatory blood pressure monitors. Further studies are needed for validation of these results.

Declarations

Ethics approval and consent to participate

The study was performed in accordance with the Declaration of Helsinki.

The study was approved by the ethics committee of the Faculty of Medicine, Cairo University.

All participants gave consent for participation in the study and for publication of data.

Competing interests

The authors declare that they have no competing interests.

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None.

Authors' contributions

S.G and H.S.G proposed the idea, H.A and M.M collected the data, R.T and G.Y did the statistical analysis, H.A wrote the first draft of the manuscript and G.Y finalized the draft and prepared the paper in its final form. All authors critically revised the manuscript and approved its final form.

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List of Abbreviations

BP: Blood pressure

DBP: Diastolic blood pressure

Hz: Hertz

SBP: Systolic blood pressure

SOB: Shortness of breath

TENS: Transcutaneous electro-stimulation

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