Mini-Review

Blood pressure goals and patient-reported outcomes in patients with hypertension

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Abstract: Hypertension is very common among the adult population in the United States of America (29.0%), especially among individuals aged greater than 60 years (64.9%). The optimal blood pressure (BP) goal during treatment of hypertension has been controversial. Assessment of patient-reported outcomes (PRO), such as the health status, excellence of the life, and satisfaction with care, has important implications for BP guidelines in population. The previously published results of the Systolic Blood Pressure Intervention Trial (SPRINT) showed that among participants with hypertension and an increased cardiovascular risk, but without diabetes, the rates of cardiovascular events were lower among those who were assigned to a target systolic BP of less than 120 mmHg (intensive treatment) than among those who were assigned to a target of less than 140 mmHg (standard treatment). In addition, PRO among participants who received intensive treatment were similar to those among participants who received standard treatment, including among participants with decreased physical or cognitive function. The new recommendations modified the target goal BP for those with diabetes mellitus or renal diseases to <140/90 mmHg, regardless of age. In the future further studies of PRO in individual groups (such as the elderly, patients with diabetes mellitus or patients with chronic kidney disease) need to be evaluated.

Keywords: Blood pressure (BP); treatment; patient-reported outcomes (PRO)

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Hypertension is very common among the adult population in the United States of America (29.0%), especially among individuals aged greater than 60 years (64.9%). Approximately 1 billion adults around the world (1,2) suffer from hypertension. It is projected that by 2025, the total number of adults with hypertension will exceed 1.5 billion worldwide (1). Despite significant advances in pharmacotherapy, hypertension remains the leading public health problem due to adverse health effects. These effects include ischemic heart disease, chronic kidney disease, stroke, decompensated heart failure and decreased cognitive function (3,4). The Global Burden of Disease study reported hypertension as the leading risk factor, between 67 factors studied, for the life lost during 2010 (5).

Among persons older than 50 years of age, isolated systolic hypertension remains the most often form of hypertension (6,7) and systolic blood pressure (BP) come to be a more significant contributor than diastolic BP to coronary artery disease, stroke and renal disease (8-16). The meta-analysis of the 61 observational studies found a direct connection among an elevated baseline systolic BP and both vascular and all-cause mortality (13). In the group of 316,009 population, there was a direct relationship between increasing systolic BP and coronary artery disease mortality (17). Higher systolic BP is related to the higher risk of mortality across of all age ranges (18). It has been presented that every 20 mmHg increase above 115 mmHg among participants

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with age ranging from 40 to 69 years was related to the 2-fold increase in the cardiovascular events, including death; in participants with age ranging from 80 to 89 years, this risk greater than before by one third (13).

High BP is also a modifiable factor of the morbidity and mortality (19) and treating hypertension is one of a main therapeutic focuses of the last 50 to 60 years (20). Advantages of antihypertensive drug therapy first were confirmed in the end of 1950s in patients with the malignant hypertension, and above the next 30 years, similar benefits were found in the most of other groups of persons with hypertension, together with those with mild or severe diastolic BP or isolated systolic BP hypertension. Today, there is an evidence indicating that the treatment of elevated BP can lead to reduction in the occurrence of cardiovascular diseases unrelatedly of patients' age, gender, and race or the severity of hypertension (21). The strongest evidence comes from clinical trials where patients with untreated systolic BP values of ≥160 mmHg had significant reductions in adverse cardiovascular endpoints when their BPs were reduced to <160 mmHg (9). The magnitude of benefit with antihypertensive medication is seen for incident stroke (from 35% to 40%), myocardial infarction (from 15% to 25%), and heart failure (rise to 50%) (8,22,23). There is a role for treatment of hypertension in the decreasing of the risk for adverse changes in a brain structure and function, such as dementia and decreased cognitive function (24-30). Today exists the capability to lower BP effectively and with relatively minimal adverse effects in most hypertensive persons. The focus now is questions such as the relative welfares and risks of individual antihypertensive medications, and their long-standing properties on cardiovascular illness and chronic renal disease outcomes, and the optimal BP goals of the therapy in the different clinical conditions. For the last 25 years, BP ≥140/90 mmHg has been the value with identifies of hypertension, and goals for BP control have focused on achieving BP <140/90 mmHg, not including the patients with renal diseases or diabetes mellitus, for whom the goal was <130/80 to 85 mmHg (8,31).

The optimal target for a systolic BP reduction is debated. Clinical trials with systolic BP <150 mmHg [Hypertension in the Very Elderly Trial (HYVET) (32) and Systolic Hypertension in the Elderly Program (SHEP) (33)] have confirmed reduction in the rates of cardiovascular events and incident stroke (32,33). Observational studies report a progressive growth in danger of the cardiovascular events as BP increases over 115/75 mmHg. But, decreasing of systolic BP to <120 mmHg may be dangerous or fail to create the benefits, and can be needlessly expensive and resource consuming (34–41). The presented evidence from randomized, measured trials only documents the advantage of the treatment to the attain a systolic BP target of <150 mmHg, with limited data regarding lower BP goals (5,10-16,23,32,33,42-45). Interpretation of the most optimal systolic BP goal in the course of treatment of hypertension is significant for the health of the overall population. In studies involving the patients with diabetes mellitus of 2 type, the degree of the main cardiovascular events was comparable with a systolic BP mark of <120 mmHg and the normally recommended goal of a <140 mmHg, however the rate of the stroke was lower with the target of <120 mmHg (46). A current randomized trial with patients with stroke to decrease systolic BP to <130 or 150 mmHg identified no important benefit of the lower target and another stroke occurrence but an important benefit was noted in the risk of hemorrhagic stroke (47).

On the foundation of the randomized trial statistics together with HYVET trial (32) and the SHEP trial (33,48,49), the American College of Cardiology Foundation/American Heart Association 2011 hypertension guiding principle (50), the European Society of Hypertension/European Society of Cardiology 2013 hypertension guiding principle (51), the American Heart Association/American College of Cardiology Foundation/American Society of Hypertension 2015 guiding principle on the treatment of arterial hypertension in adults with the coronary artery disease (52), and the 2014 American Society of Hypertension/International Society of Hypertension guiding principle (53), recommended to reduce BP to less than 140/90 mmHg in adults under 80 years old and up to 150/90 mmHg in adults aged 80 and older. Data from 9,787 adults in the Reasons for Geographic and Racial Differences in Stroke (REGARDS) also confirmed these recommendations (54).

The 2013 Eighth Joint National Committee (JNC 8) guiding principle for the controlling of hypertension recommended to reduce the BP in the persons aged 60 years old or older to <150/90 mmHg if they did not have diabetes mellitus or chronic kidney illness and to <140/90 mmHg if they had either diabetes mellitus or chronic kidney disease (55). The minority opinion from JNC 8 suggested lowering the BP in adult persons older than 60 years with arterial hypertension to <140/90 mmHg (56).

New guiding principles for the treatment of hypertension were influenced by the consequences from the SPRINT (57). SPRINT randomized 9,361 adult persons with the systolic

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BP of 130–180 mmHg and increased cardiovascular risk, but without diabetes mellitus, history of stroke or heart failure in the past of 6 months and an assessed glomerular filtration rate less than 120 mL/min/1.73 m^2 to a systolic BP goal of less than 120 or 140 mmHg. Of the 9,361 adult persons with age of 50 years or older, 2,636 (28.2%) were aged 79.9 years and older (57). The most important compound consequence of the myocardial infarction, another acute coronary syndrome, stroke, heart failure, or death from cardiovascular events decreased by 25% with intensive treatment of BP in the total group (57) and 34% in adults aged 75 years and older. All-cause of mortality was reduced by 27% by intensive BP treatment in the entire group (58) and by 33% in adults aged 75 years and older (58). The heart failure rate was reduced by an intensive BP treatment by 38% in the entire group (57) and by 38% in adult persons aged 75 years and older (58). Therefore, among the patients with a high risk for cardiovascular events but without diabetes mellitus, targeting a systolic BP of less than 120 mmHg, as compared with less than 140 mmHg, resulted in lower rates of fatal and nonfatal main cardiovascular events and death from any reason, while higher rates of hypotension, syncope, electrolyte abnormalities and acute kidney injury, but not of injurious falls, were observed in the intensive-treatment group (57).

The 2016 Canadian view similarly recommends a systolic BP target of less than 120 mmHg in these high-risk individuals (59). New data from 204,103 patient—years of follow-up presented that BP goals of <120 and 130 mmHg classified No. 1 and No. 2 as the most efficient mark, while BP marks of <140 and 150 mmHg graded No. 1 and No. 2 as the safest target for the consequence of the adverse effects. So, a systolic BP mark of <130 mmHg had the finest sense of balance among efficiency and safety (60).

The SPRINT results are not appropriate to the patients who have diabetes mellitus, persons with a history of stroke, or established elderly people, all of them were left out from the study. Professional judgment has to be recommended to determine the optimal BP goal for persons with hypertension that were not included in the SPRINT study (61).

Patients that have diabetes mellitus were excluded as they had already been studied in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) (40) BP trial (46), which did not identify a cardiovascular advantage of intensive reduction of systolic BP (<120 mmHg) *vs.* standard BP (<140 mmHg) that although there was a reduction in the risk of the stroke (62). A recent meta-analysis of 49 trials, that included 73,738 patients with diabetes mellitus, reported that antihypertensive treatment reduced mortality and cardiovascular morbidity as long as systolic BP remained higher than 140 mmHg (63). If on-treatment systolic BP reduced to <140 mmHg, the risk of death from cardiovascular events is greater than before, and no benefits were observed (64).

The Secondary Prevention of Small Subcortical Strokes (SPS3) (47) trial, that compared a systolic BP goal of <130 mmHg with the goal of 130 to 149 mmHg in patients with a new lacunar stroke, identified a non-significant decrease in stroke recurrence in the group with lower systolic BP goals (65). There are no conclusive data from the studies in patients aged <50 years without other comorbidities and predominantly elevated diastolic BP (63).

The renal function in patients with hypertension is best preserved with systolic BP from 130 to 139 mmHg. Higher or lower BP goals are related to the worsening of the renal function (66). The new recommendations also increased the target of BP for those with diabetes mellitus or renal diseases to <140/90 mmHg, regardless of age (18).

The main goal of the effective BP control is to prevent or delay the cardiovascular morbidity and mortality that are related with hypertension, with a resultant increase in the quality and duration of the healthy life (67). The previously published results of the SPRINT trial which presented that among participants with hypertension the rates of cardiovascular events were lower between those with the target systolic BP of less than 120 mmHg (intensive treatment) than between those with the target of less than 140 mmHg (standard treatment) supports this goal. The ultimate goal of all clinical trials is to implement their results into the practice although hindered by concerns regarding its effect on the patient-reported outcomes (PRO), such as the health status, excellence of the life, and satisfaction with care (68,69). Thus, assessment of PRO obviously has important implications for BP guidelines in population.

With the growing the importance of involving patients in their care, assessing outcomes based on the patient's perspective using the PRO measures, are increasingly accompanied by traditional methods of measuring health and the consequences of patient treatment. It became common to measure the patients' perspective of their symptoms and their influence on their everyday life as a device for the evaluating the result of the selected treatment (70-72). How the patients observe their health and the impact of their treatment on their life can provide perception to clinicians previously unavailable (73-75). Collection of the PRO data has allowed development of the care management for the helping providers understand not just whether a clinical importance is within traditional

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endpoints but the influence of treatments on patients' lives. This approach can improve communication and patient engagement by the highlighting patients' involvement with a disease and its treatment, together with feelings, impressions, perceptions, and attitudes and may eventually result in a higher patient satisfaction, increased adherence, and better overall consequences (76-80).

The patient is considered as a center for any healthcare system. Currently there is growing understanding for the patient-centered healthcare system (81). That is why the results of a clinical intervention received by the patient, i.e., PRO may be more important in the future than any other results of clinical, physiological or caregiver-reported outcomes (82). According to studies, improved adherence to treatment and results can be reached by paying attention to patient feedback about the health outcomes and behavior changes of the patient (82).

As the prevalence of hypertension increases, there is a growing interest in understanding the health-related quality of life (HRQOL) of these patients (83). Most of the studies have shown that hypertension impairs vitality, social functioning, mental health, mood and psychological functioning (83). The question about hypertension and its treatment affecting HRQOL is important since HRQOL may affect long-term independence and commitment to therapy (84). Despite the fact that hypertension is often perceived as asymptomatic, it is associated with impaired HRQOL due to complications or concomitant diseases, awareness of the diagnosis and side effects from anti-hypertensive drugs (85). Lower rates of cardiovascular events related to intensive treatment can lead to improvement in health status, but serious adverse events related to reduced end-organ perfusion, including symptomatic hypotension, syncope, electrolyte abnormalities, and acute kidney injury, are more prevalent among trial participants who were randomized to intensive treatment (57). Patients adherence to antihypertensive medications is often poor (86,87) possibly because the diseases in most cases is asymptomatic, while the treatment can cause symptoms (88) and thus affect HRQOL of the patient. Additional therapy required to achieve the lower BP goal may be associated with additional side effects from the medication (20) Intensive treatment usually leads to the use of additional drugs. Participants with a target systolic BP of <120 mmHg received on average one additional antihypertensive drug (57). Such medications can be linked to both physical and mental side effects (89). Therefore it is important to assess the effect of intensive treatment for hypertension, not only on the frequency of cardiovascular events and death, and the results that are important for the perception of patient well-being and satisfaction (89). The decrease of cerebral blood flow, especially in elderly patients who have hypertension as well as physical and cognitive impairment, can lead to dizziness, confusion and depression (84,89-91). However, some studies have shown that long-term antihypertensive therapy leads to an increase in cerebral blood flow, auto regulation in maintained and reducing orthostatic hypotension in elderly persons with hypertension (92,93).

Hypertension significantly affects the quality of life from the point of view physical and mental health. Co morbidity further deteriorates HQOL among people with hypertension. Thus, it is important for the prevention and treatment of co-morbidities associated with hypertension (94). Studies of the influence of one or more co-morbid diseases on HRQOL showed that greater number of co-morbid diseases are associated with reduced HRQOL (85). Prevention of complications of hypertension, including cerebrovascular disease, which are associated with even greater reduction in HRQOL among these patients (85) is very important. Thus, intensive BP lowering leads to lower rates of cerebrovascular events (for the results SPRINT), and may improve the quality of life of patients of this group.

The controversy surrounding benefits and risks of antihypertensive therapy is in elderly patients and patients with physical and cognitive disorders (56,95). Observational studies have shown that impaired physical and cognitive function affects the association between high BP and adverse outcomes (96,97). The analyses from the trial showed that among participants aged 75 years and older, the positive effect of intensive treatment compared to standard treatment in lowering the rates of cardiovascular events and death was similar across frailty and gait-speed subgroup (59). In the recent study the authors show that on the basis of PRO, intensive treatment was associated with fewer side effects across the spectrum of physical and cognitive function that were included in the study (89).

In this study, the researchers also evaluated the well-proven PRO, which ascertained the physical and mental HRQOL, depressive symptoms, and adherence to BP drug (89). In the study, patients outcome indicators included results of Physical Component Summary (PCS) and Mental Component Summary (MCS) of the Veterans RAND 12-Item Health Survey, which describes the physical and mental HRQOL (98), the Patient Health Questionnaire 9-item depression scale (PHQ-9) (99), patient satisfaction from their pressure care and BP medications, and compliance with BP drugs (100-102). The authors found that, the benefits seen with the intensive

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BP intervention in relation to cardiovascular events and death was not accompanied by worse physical function, mental function, or depressive symptoms, as perceived by the participants (89). Mean PCS, MCS, and PHQ-9 scores were relatively stable, on average, from 3 years, no significant differences between the two treatment groups. No significant differences between treatment groups were noted, participants were stratified according to baseline measures of physical or cognitive function. Satisfaction with BP care was high in both treatment groups, and we found no significant differences in adherence to BP drugs (89). Thus, the authors concluded that PRO among participants who received intensive treatment, which is aimed systolic BP of less than 120 mmHg, was similar to those among participants who received standard treatment, including among participants with reduced physical or cognitive function (89).

This study adds important new information to the growing body of literature on the treatment of hypertension. At the same time, further studies are needed to address many clinically relevant questions. In the future, PROs in individual groups (such as the elderly, patients with diabetes mellitus or patients with chronic kidney disease) need to be evaluated. Patients with diabetes mellitus who participated in the ACCORD study, intensive treatment with a standard treatment showed no significant differences between groups with respect to the PHQ-9 scores and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) (103) MCS scores (103). In addition, the optimal target for diastolic BP should be evaluated, comparing different antihypertensive treatments with assessment of PRO. Clinicians should also consider treatment with non-pharmacologic options, including weight loss, dietary changes and increased physical activity, initially or concurrently with pharmacologic treatment (95).

The implementation of results of clinical trials remains difficult. Because, as mentioned above, before patients and doctors accept lower BP target in clinical practice, they must be sure that intensive treatment not only reduces the risk of cardiovascular events and death, but also lead to few side effects, as shown in patients assessments. The results from current studies shed light on a solution to this issue and provide additional evidence that confirms the main conclusions of the SPRINT trial.

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Footnote

Conflicts of Interest: The authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/amj.2018.01.14). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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