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Recommendations for treating hypertension and what are the right goals and purposes?



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1. Introduction and epidemiology

Worldwide, hypertension affects around a billion individuals. In the United States (US), 1 in 3 individual adults over the age of 40 years have high blood pressure (BP) defined as BP greater than 140/90 mmHg. Due to its prevalence, hypertension is a leading cause for myocardial infarction (MI), stroke, vascular disease, congestive heart failure (CHF), atrial fibrillation (AF). It is also the *number one* reason in the U.S. for hospitalization, contributing to almost a half of million admissions each year. Hypertension is a very large problem for Indians as well, with prevalence rates nearly that seen in the US, though rates very among studies depending on definitions, population survey in rural versus urban.

2. Hypertension: critical questions and importance

Some important clinical questions about hypertension (HTN) are

- When and where to treat it?
- What threshold should one begin treating high BP, and should that vary depending on a patient's age or their risk factor profile?
- What is the treatment goal?

- Does goal also varies by a person's age, and various risk factors?
- What drugs to use as our first, second and third-line agents and does this vary depending on one's race or one's genetic profile?
- Who should be managing blood pressure? Should it be the primary care physician, subspecialist, a nurse or pharmacist or the patients themselves?

Importance of high blood pressure lies in that number of different epidemiologic studies that have shown direct correlation between higher blood pressure and risk for mortality or alternatively risk for stroke seen in every decade of life.

3. Benefits of treating HTN

Treating HTN could make a marked difference in the outcomes for patients with 50% lowering in heart failure cases, 40% lowering in stroke, and 20% reduction in overall CV risk. Even on a population basis, small changes in BP such as changes in diet, etc. could result in relatively large differences in ultimate outcome in terms of ischemic heart disease events or overall stroke events in populations. Thus evidence from these epidemiologic as well as intervention studies shows that BP - lower was better (Fig. 1).

4. Hypertension guidelines: conflicts and concerns

JNC-7 guidelines (2003) were relatively straightforward, talked about when and where to treat blood pressure and the goals of blood pressure treatment. In general, goal was below 140/90 mmHg and a little more aggressive (<130/80 mmHg) in those who had renal disease as well as diabetes. In addition, those who had aortic disease or aortic aneurysms were

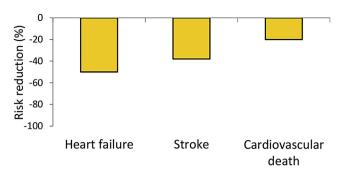


Fig. 1 – Benefits of treating hypertension.

included in the same more aggressive treatment category. A decade later JNC-7, JNC-8 (2014) recommendations were published as a standalone article. These guidelines were not endorsed by any of the major professional societies. This guideline, raised the threshold for patients over the age of 60 years to above 150 or 90 mmHg and target to treat BP below 150/90 mmHg. Threshold for patients with diabetes or renal disease was above 140 or 90 mmHg. This is much more lenient relative to JNC-7. Amongst drugs, choice of first and secondline agents varied depending on the race of the patients with preference to thiazide-diuretic or calcium channel blocker (CCB) as first line agents in African-American populations. The controversy stirred up around these "long waited guidelines". A dissenting view was published in an alternative journal. So what is all the evidence around for which there is this controversy?

5. Do we have an "answer" amidst guidelines controversy?

The controversy around JNC-8 was related to the methods used by the authors. Evidence available from the published randomized clinical trials only was used in preparing guidelines. It is difficult to see how little is actually known about what is the right threshold in randomized clinical trials.

Clinical evidence in patients above years

INVEST (INternational VErapamil SR Trandolapril) study

INVEST study included patients aged 60 years or above with baseline systolic BP > 150 mmHg. At achieved BP, it was observed that with lower blood pressures results generally tend to be better, but in fact this is the degree to which a patient is being treated using a randomized comparison (Fig. 2).

Better BP reduction achieved in a patient in part may reflect about the vascular health of that individual much more than the effectiveness of therapy in lowering the blood pressure to a given number.

6.2. JATOS (The Japanese trial to assess optimal systolic blood pressure in elderly hypertensive patients) study

This study looked the patients over the age of 60 in 2200 patients with baseline BP 170/90 mmHg targeted to below 150 (mild-treatment group) and below 140 (strict-treatment group). Efonidipine was baseline drug and rest were add-on to achieve targeted BP. Patients were followed for up to 2 years. The overall results of that study showed no differences in outcome between the two groups (Fig. 3). The issues here are short follow-up of two years, and small number of the total number of events (86 in each group).

6.3. VALISH (VALsartan in elderly Isolated Systolic Hypertension) Study

This trial included elderly (70–84 years) patients with isolated systolic HTN (sitting SBP 160–199 mmHg). Patients randomized to either strict control (1545 patients) and moderate control (1534 patients) groups were followed up for 3 years. The primary end point of this study was a composite of cardiovascular events. Given the minor differences actually achieved in terms of BP control, there were limited differences though results slightly favour strict control group (Fig. 4).

While interpreting evidence from these randomized clinical trials in the patients over the age of 60, the trouble is that they were in selective population, the follow-up was short, they used non-standard BP medications, and there was limited statistical power and small actual difference between the two treatment groups.

7. Clinical evidence in patients below 60 years

For patients under the age of 60 years, unfortunately there is no randomized clinical trial data that has evaluated whether a SBP of 150 or 140 provides better outcomes. In this regard, does the absence of evidence leads to the conclusion of evidence of absence? For people under 60 years of age, JNC-8 said there is no RCT evidence and thus the existing guidelines retained.

8. Impact of BP goal change

These changes in goal can have huge impact on treatment of patients. Based on National Health and Nutrition Examination Survey (NHANES) data, there would be slightly less populations that would end up being treated particularly in those over the age of 60 in part because of the movement upwards on the guidelines in terms of the diabetics and renal disease patient populations. On the other hand, the percentages of those who were considered actually controlled would rise (Fig. 5).

Current guidelines have changed remarkably from those earlier days of general recommendations to being evidence from randomized clinical trials. Impact of these changes in terms of BP management depending on whether one adopts JNC7 or JNC8 can be devastating. Overtreatment of older

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