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ANALYSIS

TOO MUCH MEDICINE

Mild hypertension in people at low risk

Stephen A Martin assistant professor¹, Marcy Boucher assistant professor¹, James M Wright co-managing director², Vikas Saini president ³

¹Department of Family Medicine and Community Health, University of Massachusetts Medical School, 151 Worcester Road, Barre MA 01005, USA; ²Therapeutics Initiative, University of British Columbia, Vancouver, Canada; ³Lown Institute, Brookline, Massachusetts, USA

Measurement of blood pressure is an iconic part of modern medicine. Over the past century, life insurers, public health organisations, and prospective studies, including the Framingham Heart Study, have established the relation between increased blood pressure and long term morbidity and mortality. About 40% of adults have hypertension globally; the prevalence is highest in the African region. In the United States, hypertension is the most common diagnosis at a medical visit. Complications of hypertension may account for nearly half of global deaths from cardiovascular disease, though this proportion is the subject of debate. The scale of the problem has resulted in large scale interventions and national and international plans for action, such as the 2013 World Health Day. 5-9

Antihypertensive drugs have an important role in the treatment of malignant hypertension, secondary prevention of cardiovascular disease, and primary prevention for people at high risk: those with moderate to severe hypertension (≥160/100 mm Hg), diabetes, or chronic kidney disease. Debate continues, however, about the level at which treatment should begin and the appropriate targets for treatment (see supplementary box on bmj.com). The greatest uncertainty surrounds mild hypertension (140-159/90-99 mm Hg), which accounts for over 60% of those with hypertension² or 22% of the global adult population. Evidence suggests no net benefit from drug treatment of mild hypertension in people without the higher risks of diabetes or chronic kidney disease. ¹0 Nevertheless, most people with mild hypertension are treated with drugs. In this article, we examine the overdiagnosis and overtreatment of mild hypertension.

Changing definitions and treatment thresholds

Over time, hypertension has been diagnosed at progressively lower blood pressures (table 111). In 2003, the seventh US Joint National Committee (JNC) guidelines introduced the category of "pre-hypertension." This term was removed in 2013 by JNC

8¹²; both reports define mild hypertension as 140-159/90-99 mm Hg. The JNC 8 authors explain that for the first time their guidelines were derived from evidence rather than expert consensus.

Treatment thresholds have similarly decreased, though JNC 8 raised the systolic blood pressure treatment threshold to 150 mm Hg for those aged 60 and older and from 130 mm Hg to 140 mm Hg for people with diabetes and kidney disease.

The new JNC guidance has been controversial because contemporaneous guidelines from the American Heart Association, the American College of Cardiology, the Centres for Disease Control and Prevention, and guidelines by the American and International Societies of Hypertension¹³ ¹⁴ essentially endorse the status quo. Five members of JNC 8 issued a separate report advocating that the threshold of 140 mm Hg be maintained for people aged 60 years or older. ¹⁵ Differences also exist between US and Canadian, European, and UK guidance. ¹⁶⁻¹⁸ Patients and clinicians have been left confused. ¹⁹ ²⁰

Rationale for change

Changes in a surrogate marker, such as blood pressure, may correlate with or even cause a decline in health (see animation on bmj.com). However, treatment to modify a surrogate marker does not necessarily result in health improvements and can lead to overly aggressive intervention.^{21 22} Although raised blood pressure is correlated with cardiovascular disease in observational studies, we cannot assume the logical reverse—that antihypertensives should prevent disease at an individual or population level.

If lowering blood pressure is beneficial, for example, then partial exsanguination should be worthwhile. However, the harm from bloodletting shows that not all techniques or agents that reduce blood pressure also reduce cardiovascular risk. Similarly, α blockers, mmediate release calcium channel blockers, summediate release calcium channel blockers, and renal denervation and its sham all reduce

Correspondence to: S A Martin stmartin@gmail.com

Box showing changing views on hypertension (as supplied by the author) (see http://www.bmj.com/content/349/bmj.g5432?tab=related#datasupp)

Summary box

Clinical context—Up to 40% of adults worldwide have hypertension, complications of which may account for up to 9.4 million deaths annually from cardiovascular disease

Diagnostic change—Recommendations for drug treatment have decreased from diastolic pressure of >115 mm Hg to ≥140/90 mm Hg. A new category, prehypertension (120/80-139/89 mm Hg), has also been introduced

Rationale for change—Patients with even mildly raised blood pressure may have increased cardiovascular risk

Leap of faith—Lowering threshold blood pressures will lead to increased diagnosis and treatment, which will decrease mortality

Impact on prevalence—22% of adults worldwide have mild hypertension (systolic pressure 140-159 mm Hg) and 13.5% have a systolic pressure ≥160 mm Hg

Evidence of overdiagnosis—Use of a uniform threshold (140 mm Hg) to mark hypertension risk ignores evidence that risk varies by individual and includes many people who will not benefit from drug treatment

Harms from overdiagnosis—Studies suggest over half of people with mild hypertension are treated with drugs even though this approach has not been proved to decrease mortality or morbidity. Overemphasis on drug treatment risks adverse effects, such as increased risk of falls, and misses opportunities to modify individual lifestyle choices and tackle lifestyle factors at a public health level

Limitations of evidence — Lack of randomised trials that use hard outcomes and compare drugs with lifestyle interventions and placebo in patients with mild hypertension

Conclusion—Lowering definitions of hypertension has led to identification and drug treatment of larger populations of patients despite lack of evidence that drugs reduce morbidity or mortality

blood pressure but are inferior choices for long term treatment of hypertension.

These findings reinforce the need for randomised controlled trials to show whether each antihypertensive drug reduces morbidity and mortality. A recent example shows that we have ignored this lesson. The US Food and Drug Administration approved aliskiren, a new type of antihypertensive (renin inhibitor) in 2007; it was prescribed to nearly half a million US patients within four years. However, the drug has not been shown to reduce cardiovascular disease, only to reduce blood pressure. It had this effect in a recent trial, but the study was stopped early as the drug caused harm without benefit.

Further debate surrounds how much drug should be given and whether blood pressure should be treated to a target. Evidence is lacking that the benefits outweigh the harms of such targets. ³² ³³ US guidelines for patients 65 years and older acknowledge the 140/90 mm Hg target is based only on expert opinion. ³⁴ Nonetheless, the push to lower blood pressure to a "normal level" continues. ³⁵ This language of hypertension has become broadly influential in medicine, with terms such as "good control," "poorly controlled," and "at goal" now readily associated with other conditions. These terms have powerful effects on physicians, payers, employers, governments, and patients. For many patients, such control of hypertension is challenging; indeed, targets were not achieved in up to 40% of participants in closely monitored trials. ³⁶ Table 2 || summarises the most effective interventions for each range of blood pressure.

Rise in treatment

The trend has been to expand the indications for drug treatment alongside the definitions of hypertension. In the US, for example, when a definition of stage 1 (mild) hypertension was introduced in1977 drug treatment was not indicated; a conditional indication for treatment was added in 1984 and full indication in 1993 (table $1 \Downarrow$). Now having hypertension is virtually synonymous with taking a medication for it. While over 60% of Americans with hypertension have stage $1,^{43}$ surveys find from 62.6% to more than 90% of Americans with hypertension report being prescribed a medication for the condition. 44 Among people aged 65 years or older with hypertension, 94% take an antihypertensive. 45 This conflation has turned the diagnosis of mild hypertension into a proxy for its overtreatment with drugs.

In addition, use of a sharp, uniform blood pressure threshold to define risk from hypertension ignores evidence to the contrary.

Reassessment of Framingham data has found, for example, that the levels at which systolic blood pressure is related to increases in all cause and cardiovascular disease mortality vary with age and sex. 39 A substantial proportion of the population with a systolic pressure ≥ 140 mm Hg are therefore at no increased risk.

Uncertainty of evidence

Even if mild hypertension is accurately diagnosed, evidence of epidemiological risk is not supported by corresponding data that drug treatment reduces that risk. A 2012 Cochrane review used individual patient meta-analysis to identify all patients with mild hypertension studied in randomised trials and suitable for primary prevention. This review found that compared with a placebo, treatment with an antihypertensive drug did not reduce any outcome, including total mortality (relative risk 0.85, 95% confidence interval 0.63 to 1.15), total cardiovascular events (0.97, 0.72 to 1.32), coronary heart disease (1.12, 0.80 to 1.57), or stroke (0.51, 0.24 to 1.08). It therefore remains uncertain whether treatment is beneficial, neutral, or harmful for this population.

The Cochrane review exposed how studies of more severe hypertension are used to buttress more diffuse treatment. When guidelines claim support for drug treatment for mild hypertension, they tend to do so by citing studies that focused almost exclusively on either moderate to severe hypertension or secondary prevention. JNC 8, for example, opens with "abundant evidence" of benefit for drug treatment and cites three studies, each of which studied moderate to severe hypertension. 12

Guidelines for the UK, Canada, and Europe recognise the insufficient evidence for drug treatment of mild hypertension in people at low risk. 16-46 The 2013 European guidelines conclude that drug treatment of mild hypertension is "still open to question." The 2011 UK National Institute for Health and Care Excellence (NICE) and 2013 Canadian Hypertension Education Program (CHEP) recommendations encourage drug treatment only if there is a significant comorbidity such as diabetes.

How blood pressure is measured is important

A further concern is that the way blood pressure is measured can lead to overdiagnosis of hypertension (table $3 \parallel$). Traditional, office based measurements by doctors may be

incorrect. Switching to automated office blood pressure cuff measurements, being wary of recent patient nicotine or caffeine use, allowing five restful minutes before the first check, repeating the measurement at least once, and excluding physician measurements all improve accuracy. ^{49 50} Perhaps routine office measurement of blood pressure should be abandoned altogether. Home blood pressure is prognostically superior to office based blood pressure readings ⁵¹⁻⁵³ and identifies the roughly 20% of the hypertensive population who have white coat hypertension. NICE and CHEP guidelines both advise diagnostic confirmation with ambulatory or home blood pressures, ^{16 17} and home monitoring has been recommended as the new standard of care. ⁵⁴

Costs to patients and systems

The cost of drug treatment of mild hypertension in the US has been estimated at \$32.1bn (£19bn; €24bn) a year. This corresponds to more than 1% of annual healthcare costs and more than one third of US total national expenditures on public health. ^{55 56}

Analyses of absolute cardiovascular risk show that drug treatment based on blood pressure alone is likely to have little individual effect in low risk patients with mild hypertension.⁵⁷ 58 In addition, nearly half of cardiovascular events in a primary care population occur in a small subset of those with previous cardiovascular events. 59 60 Rather than focusing substantial healthcare efforts on low risk individuals with unclear benefits, targeting efforts at high risk patients —with severe hypertension, diabetes, chronic kidney disease, and previous cardiovascular events—would be less costly and yield patient centred outcomes such as reduced cardiac events or improved quality of life. 60-62 For patients with mild hypertension, the focus on drug treatment reduces emphasis on lifestyle changes. Unlike drug treatment, lifestyle changes are free of side effects and provide benefits beyond reduced blood pressure. 63-65 The health benefits of lifestyle interventions have been known for decades,³⁷ yet the medical system does not adequately support these approaches. Comments are often made about lack of adherence to advice about behaviour change, but 50-80% of patients are non-adherent with antihypertensive drugs.⁶⁶

Proved harms from antihypertensive drugs include hip fracture, drug related hospital admissions, and poorer self rated physical and mental health. ⁶⁷⁻⁶⁹ Even in high risk groups, stricter systolic pressure targets have been associated with increased mortality. ^{70 71} In general, harms have not been sufficiently measured in clinical trials of antihypertensive medication. ⁷²

How to do better

Blood pressure must be measured more accurately to ensure patients are correctly identified. Consideration should be strongly given to home measurement as the default. ⁵⁴ For patients with mild hypertension doctors should be open about the lack of known benefit for drug treatment ¹⁰ and the benefits of lifestyle improvements (box). Payers, quality organisations, and healthcare organisations will need to promote and reward lifestyle care in meaningful ways. This is likely to require transfer of resources from medical care to public health.

Use of global outcome scores⁷³ rather than blood pressure thresholds could also improve the approach for individual patients. Pay for performance metrics that increasingly compel patients, at all ages and levels of risk, to lower their blood pressure must also be revised. These metrics may incentivise

medication of patients with mild hypertension while those with severe hypertension are relatively ignored.^{74 75}

The optimal blood pressure target for an individual patient with hypertension remains unclear. ³² Systematic reviews show benefit from average blood pressure decreases of 10 mm Hg systolic and 5 mm Hg diastolic. ⁷⁶ ⁷⁷ Targets are a crude method to reach a "sweet spot" on the harm-benefit gradient, ⁷¹ ⁷⁸ and risks iatrogenic harm such as falls, decreased quality of life, and increased mortality. For those aged 90 or older a target of 160/90 mm Hg has recently been suggested in light of available data. ⁷⁹ The innumerable hours of patient, clinician, and administrative time to reach current targets add up to a substantial opportunity cost.

Conclusion

Fifteen years ago, Jeremiah Stamler advised tackling hypertension at the population level rather than pursuing catch-up in the medical system. He cautioned that, "The high-risk strategy of the last 25 years—involving detection, evaluation, and treatment (usually including drug therapy) of tens of millions of people with already established high BP [blood pressure]—useful as it has been, has serious limitations: It is late, defensive, mainly reactive, time-consuming, associated with adverse effects (inevitable with drugs, however favourable the mix of benefit and risk), costly, only partially successful, and endless. It offers no possibility of ending the high BP epidemic." ³⁷

Nonetheless, this medicalised strategy remains the default policy of most healthcare systems. In its dilution of effort, it fails people at high risk, who need more clinical attention. In diverting resources, it fails the many more that would benefit from a population based public health approach that tackles the structural drivers of hypertension such as cheap and empty calories, excess sodium and sugars, tobacco and heavy alcohol use, and inadequate physical activity. ³⁸ As healthcare systems grow and adopt a "big data" approach, the idea that medical care can substitute for population based strategy has become an irresistible temptation.

Disagreements among experts reveal cracks in the guideline enterprise. In the US, the American College of Cardiology and American Heart Association plan to publish a new guideline in 2015 for clinicians to follow as "the national standard." The idea that heated controversies in 2014 can be turned into a national standard in 2015 seems impossible, unless, as others advise, our decisions about treatment acknowledge uncertainty and defer to the preferences of patients. Only with this acknowledgment can we best use the past century's understandings to inform the right care for the individual and public alike.

This article is part of a series on overdiagnosis looking at the risks and harms to patients of expanding definitions of disease and increasing use of new diagnostic technologies.

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Contributors and sources: SAM is a family physician and faculty member with research experience in prevention, overtreatment, and health systems. MB is a family physician and faculty member with experience in hypertension quality improvement. JMW is co-managing director of the Therapeutics Initiative and coordinating editor, Cochrane Hypertension Review Group. VS is president of the Lown Institute and co-convener of the Right Care Alliance, a lecturer at Harvard Medical School, and visiting scientist at the Harvard School of Public Health. All authors cowrote the article. SAM had the idea for the article and is the guarantor.

Better management

- Accurate measurement of blood pressure—resting for at least five minutes, at least two measurements, preferably at home—is crucial
- Encourage lifestyle changes to treat hypertension including weight loss, smoking cessation, decreased alcohol consumption, and increased exercise
- Ensure patients are aware that drug treatment of mild hypertension in low risk people has not been proved to reduce cardiovascular disease
- · Abandon unproved and unrealistic blood pressure targets

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Tables

Table 1| Changing recommendations for categorisation and treatment of systolic blood pressure < 160 mm Hg from US Joint National Committee and comparison with other national recommendations

Recommendation	Blood pressure range (mm Hg)				
(year)	Diastolic	Systolic	Term provided	Drug treatment indicated	
JNC 1 (1977)	_	140–159	No term given	No	
JNC 2 (1980)	90–104	_	Stratum I (mild)	No	
JNC 3 (1984)	<85	_	Normal	No	
	85-89	_	High normal	No	
	90-104	_	Mild hypertension	Yes*	
	<90	<140	Normal	No	
	<90	140-159	Borderline isolated systolic hypertension	No	
JNC 4 (1988)	<85	_	Normal	No	
	85-89	_	High normal	No	
	90-104	_	Mild hypertension	Yes†	
	<90	<140	Normal	No	
	<90	140-159	Borderline isolated systolic hypertension	No	
JNC 5 (1993)	<85	_	Normal	No	
	85-89	_	High normal	No	
	90-99	_	Stage I (mild)	Yes	
		<130	Normal	No	
		135-139	High normal	No	
	_	140-159	Stage I (mild)	Yes	
JNC 6 (1997)	<80	<120	Optimal	No	
	<85	<130	Normal	No	
	85-89	130-139	High normal	No‡	
	90-99	140-159	Stage I (mild)	Yes	
JNC 7 (2003)	<80	<120	Normal	No	
	80-89	130-139	Pre-hypertension	No§	
	90-99	140-159	Stage 1 hypertension	Yes	
JNC 8 (2013)¶12	<80	<120	Not indicated for drug treatment	No	
	80-89	130-139	Not indicated for drug treatment	No	
	>90	> 140	Indicated for drug treatment if <60 years old if systolic or diastolic pressure above threshold. For people ≥60 treat if systolic >150 or diastolic >90	Yes	
NICE (2011) ¹⁷	> 90	> 140	Stage 1 hypertension If target organ damage present of year cardiovascular risk > 20'		
CHEP (2013) ¹⁶	>90	>140 (averaged across five office visits)	e Stage 1 hypertension Guided by individual global cardiovascular risk assessmer		
European (2013) ¹⁸	>90	>140	Grade 1 hypertension	When total cardiovascular risk is high because of organ damage, diabetes, cardiovascular disease, or chronic kidney disease; or with low to moderate risk if repeatedly in this range despite lifestyle measures	

 $^{^{\}star}$ >95 mm Hg. If non-drug measures not effective, potentially indicated for 90-94 mm Hg.

^{† &}gt;95 mm Hg or ≥90 mm Hg if "high risk."

[‡] Drug treatment if heart failure, diabetes, or renal insufficiency.

 $[\]$ Drug treatment if a "compelling indication": chronic kidney disease or diabetes.

 $[\]P \ \text{Not recognised by the American Heart Association or American College of Cardiology}.$

ANALYSIS

Table 2| Blood pressure ranges and supported interventions in low risk individuals

Blood pressure (mm Hg)	Global prevalence (%)²	Risk of cardiovascular disease	Individual risk assessment helpful?	Drug treatment (unselected risk)	Supported interventions ^{37 38}
120/80-139/89	36.8	Uncertain ³⁹ or increases ⁴⁰	Uncertain	No evidence of benefit ⁴¹	Public health > lifestyle
Stage 1: 140/90- 159/99	22	Uncertain ³⁹ or increases ⁴⁰	Yes ^{16 17 42}	Uncertain benefit ¹⁰	Lifestyle + public health
Stage 2/3: ≥160/100	13.5	Increases	Yes ^{16 17}	Evidence of benefit	Lifestyle + medication + public health

Table 3| Errors in measurement of blood pressure

Type of error	% Affected	Notes
Natural variation	≥14%	After two clinic visits, a person with a true systolic pressure of 130 mm Hg will have a 14% chance of an average above 140 mm Hg. After 10 visits, the risk of this average (and potential misdiagnosis) increases to 64%. In healthy adults < 35 years, the probability of misclassification exceeds that of accurate diagnosis ⁸³
Incorrect measurement technique	>60%	63% of physicians and nurses were found to be out of range in blood pressure measurement (false increases or reductions); none followed the American Heart Association's recommendations. 4894 Single measurements are unreliable for assessing any individual's level of control. 85 86 Simply using proper technique compared with usual care has been shown to double the number of patients considered at goal 87
White coat hypertension	20%	White coat hypertension is more common in elderly people and is generally associated with a relatively benign prognosis 5388
		Doctors consistently obtain higher readings than nurses ⁸⁹
Office based measurement	~100%	Home blood pressure is superior to office blood pressure and should be the standard of care 52.54
Global cardiovascular risk not assessed	l ~100%	People with established cardiovascular disease or at high risk are approached the same as those with low risk. Equal focus on all patients dilutes the impact of scarce resources ^{59 60}