

When should hypertension be treated? The different perspectives of Canadian family physicians and patients

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Abstract

Background: Hypertension guidelines from different organizations often specify different treatment thresholds, and none explicitly state how these thresholds were chosen. This study was undertaken to determine the treatment thresholds of family physicians and hypertensive patients for mild, uncomplicated essential hypertension. A subject's treatment threshold can be determined by eliciting the minimum reduction in cardiovascular risk that he or she feels outweighs the inconvenience, costs and side effects of antihypertensive therapy (the minimal clinically important difference [MCID]).

Methods: The study subjects consisted of a random sample of family physicians and a consecutive sample of hypertensive patients without overt cardiovascular disease from Ottawa and Edmonton. To determine participants' MCIDs, we used a survey employing hypothetical scenarios (each depicting a different baseline cardiovascular risk) and a probability trade-off tool.

Results: Of 94 family physicians and 146 patients approached for the study, 72 and 74 participated respectively. There was marked variability in the MCIDs of both groups. In general, patients were less likely to want antihypertensive therapy than physicians, particularly when baseline cardiovascular risks were low: 49% v. 64% ($p = 0.06$), 68% v. 92% ($p < 0.001$) and 86% v. 100% ($p = 0.001$) for 5-year cardiovascular risks of 2%, 5% and 10% respectively. Moreover, patients expressed larger MCIDs (i.e., wanted greater benefits before accepting therapy) than physicians. However, a subgroup of patients (15% to 26%, depending on the scenario) wanted treatment even if there was no anticipated benefit. Multivariate analysis showed that no sociodemographic factors strongly predicted the MCIDs of either group.

Interpretation: Guidelines that set treatment thresholds on the basis of physician or expert opinion may not accurately reflect the preferences of hypertensive patients. There is a need for patient decision aids and attention to patient preferences when initiation of antihypertensive therapy is considered for the prevention of cardiovascular disease. Further research is needed to define treatment thresholds for other chronic conditions and in other groups.

The efficacy of antihypertensive therapy is well established, and various bodies intermittently produce evidence-based clinical practice guidelines for the management of hypertension;¹⁻³ however, these guidelines often disagree about treatment thresholds for patients with mild, uncomplicated essential hypertension (140–159/90–99 mm Hg).⁴ Given that the blood pressure of most hypertensive people is within this range, these discrepancies have important implications (Table 1).⁵⁻⁸ However, the process by which treatment thresholds are chosen is rarely explicit and, because there is a direct relation between diastolic or systolic blood pressure and the risk of cardiovascular end points, the clinical trial literature does not illuminate a specific threshold separating those who will derive benefit

Research

Recherche

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[Return to August 22, 2000 Table of Contents](#)

from therapy from those who will be harmed. There have been calls to incorporate the opinions of front-line clinicians and patients when setting treatment thresholds in guidelines,^{5,9,10} but little research has been done to define the preferences of either group.

The preferences of physicians and patients can be elicited by determining the smallest amount of benefit that they perceive as outweighing the inconvenience, cost and side effects of antihypertensive therapy; this is known as the minimal clinically important difference (MCID).¹¹ Probability trade-off tools can be used to elicit MCIDs: background information is presented about the disease, the treatment options and the potential outcomes, and subjects are asked to choose between not accepting the therapy (given the baseline risk of an adverse outcome) and accepting the therapy (given a reduced risk of the adverse outcome but also incurring the inconvenience, cost and side effects associated with that therapy).⁹ The hypothetical benefits of therapy are varied until the lowest absolute risk reduction that the subject feels outweighs the inconvenience, cost and side effects is found; this is the MCID.

The purposes of this study were to develop a tool to elicit from family physicians and patients their MCIDs for antihypertensive therapy and to evaluate the MCIDs of both groups for the treatment of mild, uncomplicated essential hypertension under various assumptions of baseline risk.

Methods

A survey of practising family physicians and patients with mild, uncomplicated essential hypertension was carried out in Ottawa and Edmonton from November 1997 to May 1998.

Ottawa-area family physicians were randomly selected from among those who spent more than 25% of their work week in direct patient care and who saw hypertensive patients in their practices. A consecutive sample of adult patients (18–60 years of age) with mild essential hypertension but without overt cardiovascular disease (International Classification of Diseases, 9th revision [ICD-9],¹² codes 401, 402, 403, 404 and 437.2), seen over a period of 3 months by 5 family physicians and 4 general internists in Ottawa and Edmonton, were approached to participate in the study. Initial contact (in the form of a mailed letter) was made by the patient's usual physician, and interested patients were asked to contact the

study centre to schedule an interview time. Patients who did not respond to the letter were not contacted by the investigators.

The study protocol was approved by the research ethics committees of the Ottawa Civic Hospital, Ottawa, and the University of Alberta, Edmonton.

A questionnaire presenting 6 hypothetical scenarios with different baseline cardiovascular risks was developed. The scenarios detailed cardiovascular risks (coronary death and fatal and nonfatal myocardial infarction or stroke) of 2%, 5% and 10% at 5 years and 15%, 30% and 50% at 20 years. These risks were derived by means of the previously validated Cardiovascular Disease Life Expectancy Model⁶ and correspond to the estimated risks for patients with the average cardiovascular risk profile of Canadian hypertensive patients⁷ and sustained blood pressures of 150/90 mm Hg, 160/95 mm Hg and 170/100 mm Hg respectively. The questionnaire provided descriptive and probabilistic information on hypertension, myocardial infarction and stroke (derived from cohort studies^{13–16} and consultation with experts in the field). In addition, the inconvenience, cost and possible side effects of antihypertensive drugs were described (as derived from randomized clinical trials and a survey of Canadian pharmacies^{17–19}). To simplify the presentation, distinctions were not drawn between different classes of antihypertensive drugs, and only mean data were presented (see questionnaire, available in *eCMAJ*, www.cma.ca/cmaj/vol-163/issue-4/pdf/pg403_a.pdf).

Patients were interviewed face to face by specially trained interviewers or the lead author (F.M.), who followed a script; probabilities were presented both numerically and graphically (using 100 stick-figure icons to show percent frequencies; see questionnaire, available in *eCMAJ*). Physicians were interviewed by telephone and received the same information in numeric form only. The same 6 scenarios were presented to all subjects, and all probabilities were presented in both negative and positive wording.

For each of the 6 scenarios, a series of hypothetical situations was described, each of which had a different probability of cardiovascular events with antihypertensive therapy. For each hypothetical situation, the subject was asked to decide whether he or she would accept or prescribe drug treatment. A subject's MCID for a given scenario was the smallest benefit (expressed as absolute risk reduction) for which he or she would choose to accept or prescribe treatment.⁹ For example, if a subject chose to prescribe or accept therapy when the cardiovascular risk was reduced with treatment from 10% to 1%, 2% or 3% but not when the risk was reduced with treatment from 10% to 4%, his or her MCID was 7% for this scenario.

Responses from completed surveys were entered into a statisti-

Table 1: Implications of different treatment thresholds for patients with uncomplicated essential hypertension

Diastolic blood pressure, mm Hg	Risk of cardiovascular event,* %		NNT to prevent 1 cardiovascular event†		% of population eligible for treatment
	In 5 yr	In 20 yr	In 5 yr	In 20 yr	
90	2	15	200	27	25
95	5	30	80	13	14
100	10	50	40	8	8

Adapted from McAlister and Laupacis.⁵

Note: NNT = number needed to treat.

*Cardiovascular risks were calculated from the Cardiovascular Disease Life Expectancy Model,⁶ assuming patient is 45 years old and has the average risk factor profile seen in Canadian hypertensive patients⁷ (risks for men and women were averaged).

†Assuming that treatment results in relative risk reduction of 25% for any cardiovascular event.⁸

cal database for analysis. The Kolmogorov–Smirnov test was used to assess whether responses for all 6 scenarios were normally distributed. The MCIDs of physicians and patients were compared by means of the nonparametric Mann–Whitney test; the mean MCIDs and 95% confidence intervals were compared with Student's *t*-test. Multiple linear regression was used to determine if any factors were associated with the size of specified MCIDs. The

proportions of physicians and patients choosing treatment in each case were compared with the χ^2 test. For all tests, the α level for statistical significance was 0.05.

Results

The participation rate was 77% for family physicians (72 from a random sample of 94) and 51% for patients (74 from a consecutive sample of 146). Physician participants (Table 2) were similar to the national population of Canadian family physicians (1995 Royal College of Physicians and Surgeons of Canada Work Force Study, unpublished data). In addition, their reported practice features were consistent with those of respondents to another recent Canadian survey.²⁰ Patient participants (Table 2) were similar to hypertensive subjects in recent population surveys,^{21,22} although a higher proportion were taking antihypertensive medication. Seventeen (23%) of the patients had been first diagnosed with hypertension within the 12 months preceding the study interview. None of the 26 untreated patients had previously received antihypertensive drugs.

In general, patients expressed larger mean and median MCIDs than physicians (Table 3). These differences were even more pronounced after adjustment for age and sex differences between the 2 groups. In other words, patients generally required more potential benefit than physicians to offset the inconvenience, cost and side effects of antihypertensive drugs. Furthermore, physicians were more likely to prescribe antihypertensive therapy than informed patients were to want it, particularly when the absolute risks were low (Fig. 1).

Responses were not normally distributed for either physicians or patients. For example, 3 groups of patients were evident: those who were willing to take therapy even if there was no benefit (15% to 26% [median 22%] of patients, depending on the scenario), those who were unwilling to take therapy regardless of benefit (0% to 51% [median 15%]) and those for whom the decision was sensitive to the magnitude of potential benefit (35% to 74% [median 63%]). Although no patients (or physicians) stated that they

Table 2: Characteristics of respondents

Characteristic	No. (and %)*
Physicians	
No. participating	72
Mean age (and SD), yr	45 (7.6)
Female	28 (39)
Years in practice, mean (and SD)	18.4 (7.3)
In solo practice	41 (57)
With hospital affiliation	50 (69)
With academic appointment	16 (22)
No. of hypertensive patients seen per month, median (and range)	50 (7–200)
Patients	
No. participating	74
Mean age (and SD), yr	49.4 (8.0)
Female	39 (53)
Median duration of hypertension (and range), yr	4.5 (0.2–32)
Currently taking antihypertensive medication	48 (65)
Total no.	48 (65)
No. who have missed taking medication one or more times†	28 (58)
Relative or close friend with stroke	66 (89)
Relative or close friend with MI	70 (94)
Education	
<6 yr	2 (3)
6–12 yr	21 (28)
>12 yr	51 (69)

Note: SD = standard deviation, MI = myocardial infarction.

*Except as indicated otherwise.

†Percentage calculated on basis of number taking antihypertensive medication.

Table 3: Minimal clinically important differences (MCIDs) of physicians and patients for the initiation of antihypertensive therapy in mild, uncomplicated essential hypertension

Scenario*	Group; mean MCID (and 95% CI)		<i>p</i> for difference	Group; median MCID (and 25th and 75th percentiles)	
	Physicians	Patients		Physicians	Patients
1 (2% risk in 5 yr)	1.7 (1.6–1.8)†	1.5 (1.3–1.7)†	0.08	2 (1, never treat‡)	Never treat‡ (1, never treat‡)
2 (5% risk in 5 yr)	2.7 (2.3–3.0)†	2.8 (2.3–3.3)†	0.64	2 (1, 5)	3 (1, never treat‡)
3 (10% risk in 5 yr)	2.6 (2.2–3.1)	4.0 (3.2–4.9)†	0.005	3 (1, 3)	2 (1, 7)
4 (15% risk in 20 yr)	5.1 (4.2–6.0)†	6.1 (4.8–7.4)†	0.24	5 (2, 7)	5 (1, 10)
5 (30% risk in 20 yr)	4.9 (4.0–5.8)	7.8 (6.0–9.7)†	0.006	5 (3, 6)	6 (1, 13)
6 (50% risk in 20 yr)	4.5 (3.6–5.3)	9.8 (7.1–12.6)	<0.001	4 (1, 5)	6 (0, 15)

Note: CI = confidence interval.

*Scenarios are described in detail in the questionnaire, available in eCMAJ (www.cma.ca/cmaj/vol-163/issue-4/pdf/pg403_a.pdf).

†Respondents who indicated that they would never prescribe or accept treatment in a given scenario were assigned the maximum possible MCID (2, 5, 10, 15 and 30 in scenarios 1, 2, 3, 4 and 5 respectively) and were included for the purpose of this analysis.

‡Respondents indicated that they would never prescribe or accept treatment at that level of risk, irrespective of the amount of potential benefit.

would refuse therapy in all scenarios, a subgroup of 11 patients (no physicians) did choose therapy for all scenarios, even when told that the treatment would not confer any benefit.

Multivariate regression analysis failed to reveal any factors that consistently predicted physician responses. However, it did show that patients with prior exposure to antihypertensive drugs were more likely to accept therapy than patients not taking antihypertensive drugs (odds ratios ranged from 4.4 to 14.4 in the 6 scenarios). Also, among those who chose therapy, patients not taking antihypertensive drugs expressed significantly larger MCIDs than those who were taking antihypertensives at the time of the interview (mean MCIDs for the 20-year scenarios 9.9% v. 5.9%, $p = 0.03$). However, this variable only explained between 6% and 18% of the variability in patient decision-making for each scenario.

Interpretation

We have developed and tested a research tool for determining the MCIDs for antihypertensive therapy of patients and family physicians. Our key findings were that variation among respondents in expressed preferences was marked, that patients were generally more conservative in their treatment choices than physicians (fewer were willing to accept drug therapy and those who were willing to accept such therapy expressed larger mean MCIDs) and that no sociodemographic or clinical factors consistently predicted responses. The mean 5-year treatment thresholds of physicians and patients were similar to those set out in guidelines that specify absolute risk thresholds. For example, the New Zealand Guidelines²³ explicitly specified a risk threshold of

10% in 5 years (which, given the expected 25% relative risk reduction with therapy, corresponds to a 5-year MCID of 2.5%). However, merely comparing the mean (or median) treatment thresholds with those published in guidelines ignores the substantial variations in patient preferences identified in this study. For instance, one-third of our patient respondents decided against drug therapy when presented with risk profiles that would qualify for treatment under the Canadian Hypertension Society Guidelines³ (scenario 3), and almost half wanted therapy when presented with a risk profile that was not felt to warrant treatment under these same guidelines (scenario 1).

There has been little research comparing the MCIDs of physicians and patients. Although one study²⁴ suggested that Canadian patients with atrial fibrillation had smaller MCIDs for warfarin therapy than those embodied in current guidelines, another study²⁵ revealed that many British patients with atrial fibrillation qualifying for treatment under the same guidelines would refuse warfarin therapy when given information about their individual risks and benefits. Our finding that sociodemographic characteristics do not accurately predict a subject's MCID is also consistent with the literature.²⁶⁻²⁸ It appears irrational that a substantial minority of patients were willing to accept antihypertensive therapy even when told that it would have no impact on the risk of cardiovascular events, whereas others were unwilling to take therapy even when told that it would reduce their personal risk to zero. However, this pattern has been documented in previous projects eliciting MCIDs^{24,29} (H.A. Llewellyn-Thomas, J.M. Paterson, J.A. Carter, A. Basinski, M.G. Myers, G.D. Hardacre: unpublished data, 2000) and suggests that some patients have unrealistic expectations of therapy. This emphasizes the impor-

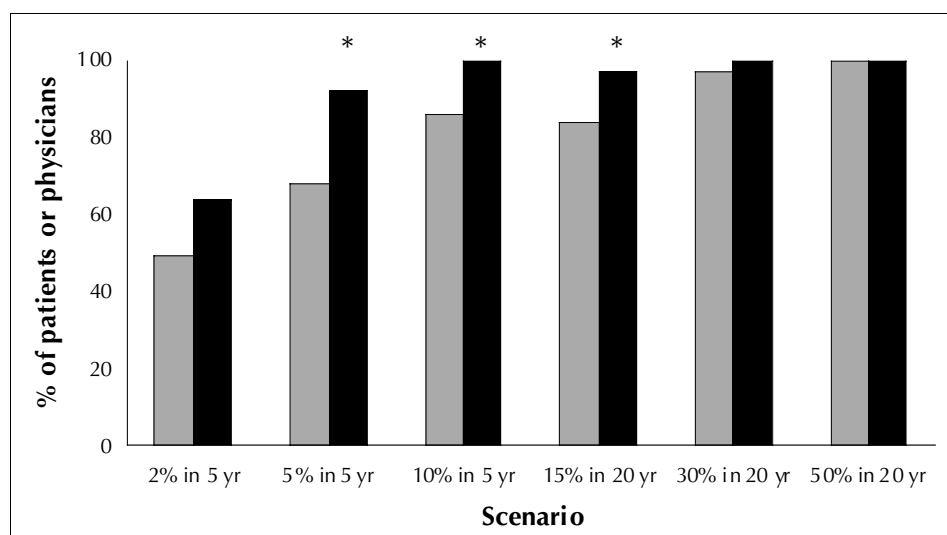


Fig. 1: Percentage of respondents (grey bars = patients, black bars = physicians) who would prescribe or accept therapy in each scenario. Data were determined by grouping all subjects who would eventually prescribe or accept therapy for each scenario (irrespective of the degree of benefit they required before prescribing or accepting therapy). Asterisk indicates $p < 0.01$ for the comparison between patient and physician respondents.

tance of patient education and supports an increased role for patient decision aids.²⁶

There were a number of potential limitations to our study. It may have been subject to selection bias, in that we recruited only hypertensive volunteers who were currently receiving care from physicians; in contrast, most hypertensive people are not under medical care.^{1,21} However, our finding that patients are more conservative than physicians in terms of treatment decisions is, if anything, likely to underestimate the true relation, since hypertensive people who pursue medical care and volunteer for a study are probably more favourably disposed to therapy than those who do not undertake such activity. Second, the method of presenting probabilities can affect subject responses; however, we employed a standard, well-validated method in this study and presented the outcome data in formats previously shown to be most comprehensible to clinicians and patients (baseline risks and absolute risk reductions, with visual displays of frequency for patients).³⁰⁻³² Third, we interviewed each subject only once; however, previous projects^{24,27,33} have suggested that a person's MCIDs are relatively stable over time. Fourth, there is conflicting evidence³⁴ on how well responses to hypothetical scenarios predict actual behaviour; however, recent studies suggest that physician responses to clinical vignettes on hypertension do serve as reasonable proxies for their actual practice behaviours.^{22,35,36}

Because of the nature of our study, the following limitations were unavoidable and highlight areas for future research. First, we did not include policy-makers or the non-hypertensive public in our study and, given that these groups may express different treatment preferences than our subjects did, their views should be sought; the probability trade-off tool we have developed is ideally suited to this task. Second, we described an average cost and side-effect profile for antihypertensive drugs, but because physician and patient treatment thresholds may be sensitive to these factors, it is possible that different cost and side-effect profiles would be associated with different treatment thresholds. Third, we did not describe the possible impact of some antihypertensive agents on coexisting conditions (such as the benefits of α -blockers for prostatism), which might affect physician and patient decision-making in specific situations. Finally, it remains to be determined whether the presentation of outcome data in both numeric and graphic form as opposed to numeric-only form might influence responses.

This study has established that patient preferences for antihypertensive therapy vary widely and that their correlation with physician preferences (and the thresholds specified in current guidelines) is less than ideal. While the movement toward risk-based guidelines and the individualization of treatment decisions should obviate the need to specify treatment thresholds,⁵ guideline developers will probably continue to set such thresholds to provide some anchor points for decision-making. In that case, we believe that future guidelines must go beyond clinical

trial evidence and expert opinion in establishing these thresholds.

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