ABSTRACT

Hypertension remains the leading atherosclerotic risk factor leading to premature death. The management of hypertension remains problematic, despite its ease of diagnosis, the simplicity of blood pressure monitoring and the wide availability of a number of effective antihypertensive drugs with excellent safety profiles. Based on these considerations, self care of hypertension - both in terms of monitoring and treatment would seem to be a feasible option. Further, self care models are becoming the norm for many of the other major factors leading to atherosclerosis. This brief review examines the key considerations underlying the feasibility of a self care model for the diagnosis, monitoring and management of hypertension. Monitoring of blood pressure (as opposed to taking antihypertensive therapy in the absence of baseline blood pressure assessment) still appears to be a required step in the diagnosis and management of hypertension. Over the counter (OTC) availability of antihypertensive drugs would need to be based on the assessment of the safety of these agents and probably be limited to those with self-evident adverse effects (i.e., not requiring laboratory monitoring). Alternatively, the availability of low dose single pill combinations might be advantageous in this setting given the greater effectiveness and better safety profile of these formulations of antihypertensive drugs. Overall, self care models for the management of hypertension remain attractive but unproven in the management of hypertension.

Key words: Hypertension management, single pill combinations, blood pressure

INTRODUCTION

Hypertension is a very significant health risk globally. Hypertension remains the most common risk factor leading to atherosclerotic vascular disease (cardiac, cerebrovascular and renal) and remains one of the top risk factors for premature death in both industrialized and developing countries\(^1\). Further, despite recent advances in some jurisdictions in hypertension control rates, globally, blood pressure control in general populations falls far short of what is achievable in controlled clinical trials\(^2\).

Notwithstanding the global importance of hypertension as a crucial atherosclerotic risk factor, the management of this disease remains challenging. Hypertension management would seem,
at least superficially, as amenable to management strategies which include self care. Self care strategies have been utilized effectively for other atherosclerotic risk factors (e.g., diabetes), although the self management of dyslipidemias remains problematic (see below). The diagnosis of hypertension is relatively straightforward and requires rudimentary technology. Notably, both the diagnosis and ongoing monitoring of blood pressure control can be performed by patients with minimal medical supervision. With regard to the treatment of hypertension, there are a number of effective non drug-based therapies that do lower blood pressure, including weight reduction, aerobic exercise regimens and dietary salt reduction. Further, there are dozens of effective antihypertensive drugs with few side effects and wide therapeutic indices, many of which are well-established and available as lower-priced “generic” formulations. Additionally, there are an increasing number of single pill drug combinations available which offer opportunities for more effective blood pressure control with fewer overall side effects (see below), although potentially presenting a greater risk of adverse drug interactions, especially in older patients. However, despite the simplicities inherent in the management of hypertension, control rates remain frustratingly low. Based on these considerations the objective of this article is to examine the basis for and limitations of a self care model for the management of hypertension.

SELF CARE MODELS FOR ATHEROSCLEROTIC RISK REDUCTION

Hypertension is only one of a number of atherosclerotic risk factors that predispose to atherosclerotic disease. The others include several “metabolic” diseases, i.e., diabetes mellitus and hypercholesterolemic dyslipidemias, tobacco addiction as well as a range of other “lifestyle” factors including obesity and lack of physical activity. Many of these risk factors are highly amenable to self care strategies. Self care treatment plans are readily available for management of obesity, sedentary lifestyles and to a limited extent smoking cessation. Although the effectiveness of self care models for the management of these lifestyle diseases may be questioned, there is little to suggest the superiority of conventional medical management for these disorders, at least in terms of safety or effectiveness of treatment.

GLOBAL ATHEROSCLEROTIC RISK REDUCTION

Acetyl Salicylic Acid (ASA) is probably the only drug-based anti-atherosclerotic therapy available OTC that is readily accessible on a global basis. ASA at an anti-atherosclerotic dose (81 mg) is available OTC without the requirement of any assessment by a health care professional. ASA self-prescription could be well-justified based on its clear effectiveness in those with pre-existing atherosclerotic disease (for secondary prevention) and for those patients at higher risk for atherosclerosis (e.g., in patients with hypertension). However, its wide-spread use in patients without pre-existing atherosclerotic disease and in those with diabetes has been questioned. Further, whether its use for an anti-atherosclerotic indication is really based on a self-care model is unclear. More likely the use of ASA for atherosclerosis risk reduction reflects a ‘collaborative care’ model, where a patient acquires ASA OTC following the advice of
a health care professional. Whether taken as part of a self-care or a collaborative care model, the use of low-dose ASA in properly self-selected patients on an OTC basis must be viewed as an effective anti-atherosclerotic treatment associated with a low incidence of adverse effects most of which are self-evident (e.g., dyspepsia).12

SELF-CARE MANAGEMENT OF INDIVIDUAL ATHEROSCLEROTIC RISK FACTORS

Of the “disease-associated” atherosclerotic risk factors (i.e. diabetes mellitus, hypercholesterolemic dyslipidemias and hypertension), self-care and collaborative care based management models have been implemented to a varying extent for both diabetes mellitus and hypercholesterolemic dyslipidemias. The diagnosis of diabetes and the choice and prescription of drug therapy regimens with hypoglycemic drugs are not easily amenable to fully autonomous models of self care. However, many of the aspects of monitoring and titration of hypoglycemic therapy have been shown to be as, or more, effectively implemented by a patient-directed model of care. Thus, improved blood sugar control has been reported in some but not all studies examining the effectiveness of self-monitoring and self-adjusted insulin doses.13 With the availability of OTC statins in some jurisdictions, the management of hypercholesterolemia has been undertaken under self-care patterns of management with minimal health care supervision. In the UK, simvastatin 10 mg has been available without a physician’s prescription since 2004 although there remain barriers to its acceptance by patients and health care practitioners.14, 15 It should be appreciated that this use of statins cannot be viewed as entirely self-care. The availability of this drug to consumers is based on “behind-the-counter” accessibility and requires an initial assessment by a pharmacist. The availability of simvastatin without a prescription was based on the safety of this class of agents, their wide therapeutic indices and the self-evident nature of their major adverse effects (primarily myopathic complications). Further, with properly constructed labeling of this class of drugs, appropriate consumers of these agents can be self-selected. Notably, in the US, the FDA did not accept this premise in the course of their deliberations regarding the non-prescription availability of statins. This was despite the evidence that the availability of non-prescription statins would potentially have significant beneficial public health benefits, even accounting for inappropriate self-selection of patients for therapy (i.e. low risk individuals) as well as for failure of higher risk individuals to receive more aggressive therapy.17 However, in aggregate, one can conclude that there are some prior precedents for the use of self-care or minimalist collaborative care models in the management of atherosclerotic risk factors.

SELF CARE MODELS FOR THE MANAGEMENT OF HYPERTENSION

Based on the considerations noted above, it is reasonable to conclude that most of the other atherosclerotic risk factors can be managed to some extent based on self-care models. However, how do these paradigms apply to the management of hypertension? To appreciate the opportunities and risks inherent in a self care model for the management of hypertension we need to examine whether an individual can:

1. self-diagnose hypertension
2. self-select the optimal antihypertensive drug in an OTC setting

3. self-monitor and advance/step-down an antihypertensive drug regimen

Or alternatively conclude that assessment by a health care professional would be integral at each of these steps in the management of hypertension.

Is it reasonable to proceed with self-treatment of hypertension in the absence of baseline blood pressure measurement?

As an alternative to mandating awareness of one’s blood pressure prior to proceeding with self-treatment, there are several reasons to justify self-treatment with antihypertensive drugs even in the absence of a reliable determination of baseline blood pressure. Firstly, elevated blood pressure is common, especially in the middle-aged and elderly. Secondly, even at levels of blood pressure that would only qualify as barely above the median (i.e., greater than 120 mmHg), hypertension-related complication rates rise progressively. This might suggest benefit for antihypertensive therapy even for patients with “normal” blood pressure. Further, concerns about excessive blood pressure lowering (needlessly) for those with normal blood pressures are mitigated by the observation that the extent of blood pressure reduction for almost all antihypertensive drugs is directly proportional to the baseline elevation of blood pressure. Thus, for individuals with “normal” blood pressures the antihypertensive effect of using antihypertensive drugs needlessly would be minimal. In practice, drugs with antihypertensive effects are used in a range of conditions in individuals who are normotensive. This would include the use of beta adrenergic blockers for patients with migraine headaches and essential tremor, and the use of Angiotensin-Converting Enzyme (ACE)-inhibitors and Angiotensin Receptor Blockers (ARBs) for patients with diabetes and renal disease. Further the phosphodiesterase inhibitors used for erectile dysfunction therapy have significant hypotensive effects and are used safely in normotensive individuals. Lastly, antihypertensive drugs have been suggested as components of so-called polypill formulations, ie. single pill combinations proposed to be given to higher risk patients irrespective of baseline levels of blood pressure and/or LDL cholesterol.

However, there are several important reasons for NOT considering self-care with antihypertensive drugs in the absence of a baseline blood pressure assessment. Firstly, for patients whose blood pressures are below accepted targets (i.e., 140/90 mmHg in the general population and 130/80 mmHg in those with chronic kidney disease and with diabetes mellitus), there is no compelling evidence supporting the use of antihypertensive drugs. Further, there are potential risks associated with excessive reduction in diastolic blood pressure (to less than 70 mmHg) with treatment of even elevated systolic blood pressures in those with underlying coronary artery disease (the so-called J-curve hypothesis). Lastly, even if the initiation of antihypertensive therapy without a blood pressure determination could be justified, in the absence of blood pressure determination, the titration of antihypertensive therapy would be impossible. Thus, notwithstanding the relative safety of these drugs and the observational data...
supporting risk of hypertension-related complications even in the normotensive range, initiation of antihypertensive therapy under any conditions in the absence of a valid determination of baseline blood pressures would seem unwarranted.

Can an individual diagnose/monitor blood pressure in an unsupervised setting?

A diagnosis of hypertension can be readily made based either on measurements taken in a health care professional’s office or by an individual themselves. In fact the blood pressures derived from so-called self monitoring have been shown to be more predictive of hypertension-related complications than those taken in physician’s offices. Further, blood pressure measurements are often readily available in public settings e.g., in pharmacies. Thus, equipped with only a minimal appreciation of the threshold between a diagnosis of normal blood pressure and hypertension, an individual might reasonably be expected to be able to self-diagnose hypertension.

Several caveats should be appreciated however. Most errors in blood pressure measurement lead to over-estimation of blood pressure (and hence tendency to over-treatment). Further, the risk of errors in measurement would be expected to be significantly higher with either measurement in public settings (e.g. pharmacies) or blood pressures taken by an individual with minimal education in measurement techniques. Instructions on blood pressure measurement are readily available from internet sources. However, the accessibility of these instructions from a reputable source of internet information, for the majority of people who would be likely to utilize a self-care model of hypertension treatment, has yet to be determined. Given the small but finite risks of excessive blood pressure lowering with inappropriate self treatment of hypertension and concerns regarding the precision of blood pressure measurements taken by an inadequately educated individual, establishing a diagnosis of hypertension would still seem to require a health care professional.

Is it reasonable to expect an individual to be able to effectively self-select the optimal antihypertensive drug in an OTC setting?

If one assumes that it is reasonable to self-initiate drug therapy, which medicine(s) should be available on an OTC basis? There are 5 major classes of drugs currently indicated for first line therapy in the management of hypertension and multiple other classes that have been used as alternates. All first line drugs have wide therapeutic indexes. What are the factors that would differentiate them in consideration of OTC availability? Important factors might include: self-evident side effects, no (or minimal) requirement for ancillary monitoring, and effective blood pressure lowering across a broad range of hypertensive populations. Thus diuretics (at least as monotherapy), although the foundation of many antihypertensive drug regimens, might not be preferred given that their side effects, except perhaps at very low doses, primarily require drug monitoring. Alternatively, beta blockers, although somewhat less widely used for hypertension, might be a more attractive OTC choice because of their self-evident side effects.
(CNS effects and bradycardia) and gradual onset of action. Other preferred choices based on these criteria would include calcium channel blockers, ARBs and ACE inhibitors.

Beyond monotherapy choices, one might speculate that the best choice for OTC antihypertensive offerings might also include single pill combinations based on considerations of more “universal effectiveness” than any single drug\(^{25,26}\) and a more favorable side effect incidence than a single drug taken at a “standard dose”\(^{27}\). Thus although in a self care setting it would not be reasonable to make available all of the antihypertensive drugs currently available by prescription, the use of a restricted menu of agents might be a reasonable option.

**Is it reasonable to expect an individual to self-monitor and advance/step-down an antihypertensive drug regimen?**

Regardless of the basis of diagnosis, self care of hypertension treatment would require ongoing blood pressure monitoring both to advance as well as to step-down care. Notably, the use of self-directed management of hypertension based on a patient-specific algorithm developed by a health care professional, coupled with self blood pressure monitoring, has been shown to be as or more effective than conventional clinic-based care\(^3\). Recently, the use of more universal algorithms for drug therapy applicable to the vast majority of hypertension patients (and featuring the early use of single pill combination therapies) has been shown to be more effective than individualized antihypertensive drug choices\(^{28}\). Thus, in the light of results from these studies, it would be reasonable to hypothesize that a self care management plan combining self blood pressure measurement with a simplified algorithm for advancing/stepping down therapy, and featuring the use of low dose fixed dose combinations, would be a potentially feasible (but as yet entirely unproven) approach to care. However, in the setting of failure to reach blood pressure targets, access to a health care professional would need to be an integral part of even a self-management plan for hypertension.

**What else would be required to implement a predominantly self care model of hypertension management?**

Beyond an assessment of the feasibility of educating patients on how to monitor their blood pressure outside of a traditional clinic model of care and the availability of appropriate low dose single pill combinations with which to treat hypertension, what else might be required or at least preferred to implement a self care program on a public health basis? Could medical supervision be replaced and/or substituted for? Notably there a number of programs (generally associated with the prescription of specific antihypertensive drugs) which assist patients with the ongoing monitoring of blood pressure and help with interpretation of blood pressure assessments. If these were made available on a more general basis in conjunction with OTC antihypertensive drugs they might be valuable adjunctive support. Beyond that, more intensive educational efforts either from health care professionals and/or via public health agencies on both the importance of blood pressure control and the mechanics of self-
management would be required next steps towards the implementation of a self-care model in hypertension management.

Table 1: Critical determinants in the implementation of a self-care model in the management of hypertension: a feasibility analysis.

<table>
<thead>
<tr>
<th>Considerations supporting feasibility</th>
<th>Barriers to implementation of an entirely self-care based management plan.</th>
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<tr>
<td>Hypertension self-diagnosis</td>
<td>Widespread availability of precise automated blood-pressure measuring devices.</td>
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<td>Greater predictive accuracy of hypertension-related CV risk based on home blood pressures.</td>
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<tr>
<td>Anti-hypertensive drug self-selection</td>
<td>Most of the first-line drugs have “self-evident” adverse effects, detectable without lab tests.</td>
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<td>Wide therapeutic indices of all first line drugs.</td>
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<td>Availability of low dose single pill combinations with minimal side effects and broad range of dosing.</td>
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SUMMARY

Increasingly the prevention of atherosclerotic disease/treatment of atherosclerotic risk factors will be based on a self-care model of management. The development of newer, simplified, and accurate technologies for blood pressure assessment and the increasing appreciation of the safety and effectiveness of simplified algorithms utilizing single pill combinations offer real opportunities to improve both blood pressure control and reduce the development of hypertension-related complications for expanding populations of individuals. Despite their potential for improved blood pressure control and reduced cardiovascular complication rates, self-care models for the management of hypertension remain, as yet, unproven. However, a collaborative care model is a feasible alternative. This approach, featuring health care professional interventions to establish the initial diagnosis of hypertension, and to development a drug therapy algorithm and selective follow-up in the event of adverse effects or failure to reach targets, is feasible. A collaborative care model featuring much greater patient
responsibility could be more widely adopted and would be an important interim step en route to self-care for patients with hypertension.

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