Managing Hypertension in Patients with or without Comorbidities in a Teaching Hospital Outpatient Setting

Shan Wang, PharmD, RPh, Nicholas Berbari, MD, David Choi, DO, James McNamara, PharmD
Candidate, Martin Feuerman, MS, Kathryn Bucci, PharmD, and Brian Malone, MS, RPh

ABSTRACT

Objective. According to the findings of the most recent National Health and Nutrition Examination Survey (NHANES), 50 million citizens in the U.S. have hypertension, and only about 30% of these patients are at their goal for blood pressure control. A more serious problem is evident when these patients present with comorbidities such as diabetes, hyperlipidemia, and renal insufficiency. At Winthrop University Hospital’s Internal Medicine Outpatient clinic, we wanted to evaluate how hypertensive patients, with or without other comorbidities, were being managed and whether they were achieving recommended goals for blood pressure, glycosylated hemoglobin (HbA1c), and low-density lipoprotein-cholesterol (LDL-C) levels if they also had diabetes and hyperlipidemia.

Methods and Study Population. We conducted a cross-sectional, observational study from June 2004 to March 2005 and enrolled 167 adults with hypertension, with or without diabetes, hyperlipidemia, and renal insufficiency. (Moderate-to-severe renal insufficiency was defined as a creatinine clearance of less than 30 ml/minute.) During the study period, we compared blood pressure, HbA1c values, and LDL-C levels with the treatment goals set by guidelines from the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7); the American Diabetes Association (ADA); and the National Cholesterol Education Program Adult Treatment Panel (ATP III).

Results. Sixty-two percent of patients seen by our hospital’s physicians met their blood pressure goal, compared with the national benchmark of 31% (P < .0001). Thirteen percent of patients with diabetes achieved their blood pressure, LDL-C, and HbA1c goals at a rate that was four times better than the national benchmark (P = .005). The national benchmark for achieving LDL-C and hypertension goals in hyperlipidemic patients is less than 10%; at our hospital, this figure was 32% (P < .0001). Compliance with medication in our study was about 20% higher than the national average (90% vs. 71%, respectively, P < .0001).

Conclusion. Winthrop physicians successfully managed hypertensive patients with or without comorbidities, and these patients were in compliance with current JNC 7, ADA, and ATP III recommendations. The authors believe that success resulted, in large part, because of strict adherence to the national guidelines by physicians. An emphasis on patient education was also thought to play a role.

INTRODUCTION

Hypertension is a common cause of morbidity in the U.S. The prevention and treatment of hypertension are major public health concerns, because patients initially display no overt signs or symptoms of disease. Untreated or uncontrolled hypertension may increase the risk of heart disease, stroke, end-stage renal disease, and peripheral vascular disease. Today, approximately one in five adults, or 50 million individuals, in the U.S. have hypertension.1

The National Health and Nutrition Examination Survey (NHANES) is conducted every year by the National Center for Health Statistics to survey the dietary habits and health of U.S. residents. The most recent data from NHANES have shown that the prevalence of hypertension increases with age.2 Hypertensive patients with coexisting conditions such as hyperlipidemia, diabetes, or renal insufficiency tend to have more serious medical problems because of the increased risk of cardiovascular disease and, subsequently, of morbidity and mortality. The literature reports that 20% to 60% of diabetic patients also have hypertension.3 Furthermore, 55% of hypertensive patients in the U.S. also have hyperlipidemia; fewer than 10% of these patients have achieved both blood pressure and low-density lipoprotein-cholesterol (LDL-C) goals.1

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) is a cornerstone guideline for health care professionals in the management of hypertension.1 Table 1 illustrates the different classifications of hypertension according to JNC 7.

The primary treatment of pre-hypertension is lifestyle modification. Examples include weight reduction and adoption of the Dietary Approaches to Stop Hypertension (DASH) food plan. The plan recommends eating foods rich in potassium and

Disclosure: Kathryn Bucci is a Pfizer employee. Nicholas Berberi has received honoraria from Pfizer for speaking engagements on topics not related to this study.
calcium, reducing dietary sodium, increasing physical activity, and consuming only moderate amounts of alcohol. Lifestyle modification is important not only for the pre-hypertensive stage but also for patients at any stage and for those with other comorbidities.

Tables 2 and 3 illustrate risk factors for hypertension and cardiovascular disease, and Table 4 summarizes evidence-based indications for individual hypertensive drug classes. Antihypertensive therapy effectively decreases the incidence of cardiovascular complications when patients reach a goal blood pressure of below 140/90 mm Hg and when patients with diabetes or renal disease achieve a goal of less than 130/80 mm Hg.

The American Diabetes Association (ADA) defines a blood pressure goal for diabetic hypertensive patients as below 130/80 mm Hg. The organization also states that antihypertensive drugs are effective in decreasing the incidence of microvascular disease, including nephropathy, neuropathy, and retinopathy in diabetic patients.

The ADA recommends an angiotensin-converting enzyme (ACE) inhibitor, an angiotensin-receptor blocker (ARB), a beta blocker, or a diuretic as a first-line therapy in patients with both diabetes and hypertension. According to the ADA, behavioral therapy is also important in improving hypertension in diabetic patients. Examples include weight reduction or sodium restriction in conjunction with laboratory monitoring of:

- glycosylated (glycated) hemoglobin (HbA1c), below 7%
- LDL-C, below 100 mg/dl
- triglycerides, below 150 mg/dl
- high-density lipoprotein-cholesterol (HDL-C), above 40 mg/dl
- non–HDL-C, below 130 mg/dl

The Third Report of the National Cholesterol Education Program Adult Treatment Panel III (ATP III) is a guideline for health care professionals when selecting cholesterol testing and management strategies. ATP III states that the optimal LDL-C level should be less than 100 mg/dl for patients with coronary heart disease (CHD) or a CHD risk equivalent; total cholesterol should be below 200 mg/dl; and HDL-C should be between 40 and 60 mg/dl.

Recent clinical trials have shown that LDL-C–lowering therapy reduces mortality in patients with CHD. The same goal should be applied to patients with CHD risk equivalents such as diabetes, symptomatic carotid artery disease, peripheral arterial disease, abdominal aortic aneurysms, and multiple risk factors that confer a 10-year risk of more than 20%.

Table 5 illustrates the major characteristics of current therapeutic agents that affect lipoprotein metabolism.

The JNC 7, ADA, and ATP III guidelines emphasize the importance of controlling hypertension to prevent complicated cardiovascular disease. Combined risk factors increase the chances of developing CHD. In patients with CHD, conventional risk factors such as hypertension, diabetes, cigarette smoking, and hyperlipidemia were prevalent at much higher rates. If risk factors are prevented and well managed, the incidence of CHD would be significantly less.
Managing Hypertension in an Outpatient Setting

Table 4  Indications for Hypertensive Drug Classes

<table>
<thead>
<tr>
<th>High-Risk Condition with Compelling Indication</th>
<th>Diuretic</th>
<th>Beta Blocker</th>
<th>ACE-Inhibitor</th>
<th>ARB</th>
<th>Calcium-Channel Blocker</th>
<th>Aldosterone Antagonist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High risk for coronary heart disease</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent stroke prevention</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACE = angiotensin-converting enzyme; ARB = angiotensin-receptor blocker.

Table 5  Classification of Lipid-Lowering Drugs

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Lipid and Lipoprotein Effect</th>
<th>Side Effect</th>
<th>Contraindication</th>
<th>Result of Clinical Trial</th>
</tr>
</thead>
</table>
| HMG-CoA reductase inhibitors (statins)* | LDL ↓ 18%–55%  
HDL ↑ 5%–15%  
TG ↓ 7%–30% | Myopathy; elevated liver enzymes  
Absolute: active or chronic liver disease  
Relative: comitant use of certain drugs | Reduction in major coronary events, CHD deaths, need for coronary procedures, stroke, and total mortality |
| Bile acid sequestrants†             | LDL ↓ 15%–30%  
HDL ↑ 3%–5%  
TG no change or increase | Gastrointestinal distress, constipation, decreased absorption of other drugs  
Absolute: dysbetalipoproteinemia; TG above 400 mg/dl  
Relative: TG above 200 mg/dl | Reduction in major coronary events and CHD deaths |
| Nicotinic acid‡                     | LDL ↓ 5%–20%  
HDL ↑ 15%–35%  
TG ↓ 20%–50% | Flushing; hyperglycemia; hyperuricemia; upper gastrointestinal distress; hepatotoxicity  
Absolute: chronic liver disease or severe gout  
Relative: diabetes, hyperuricemia, peptic ulcer disease | Reduction in major coronary events and possibly total mortality |
| Fibric acids§                       | LDL ↓ 5%–20%  
(may be increased in patients with high TG levels)  
HDL ↑ 10%–20%  
TG ↓ 20%–50% | Dyspepsia; gallstones; myopathy; unexplained non-CHD deaths in WHO study  
Absolute: severe renal disease or severe hepatic disease | Reduction in major coronary events |

CHD = coronary heart disease; HDL = high-density lipoprotein; HMO-CoA = 3-hydroxy-3-methylglutaryl coenzyme A; LDL = low-density lipoprotein; TG = triglyceride; WHO = World Health Organization.

Key: ↓ = decrease; ↑ = increase.

* Lovastatin (e.g., Mevacor), 20–80 mg; pravastatin (Pravachol), 20–40 mg; simvastatin (Zocor), 20–80 mg; fluvastatin (Lescol), 20–80 mg; atorvastatin (Lipitor), 10–80 mg; and rosuvastatin (Crestor), 5–40 mg.
† Cholestyramine (4–16 g); colestipol (Colestid), 5–20 g; and colesevelam (Welchol), 3.6–3.8 g.
‡ Immediate-release (crystalline) nicotinic acid (1.5–3 g), extended-release nicotinic acid (1–2 g), and sustained-release nicotinic acid (1–2 g).
§ Gemfibrozil (Lopid), 600 mg twice daily; fenofibrate (Tricor), 48 mg or 145 mg once daily; and clofibrate (Atromid-S), 1–2 g/day in two to four divided doses.

Managing Hypertension in an Outpatient Setting

continued from page 34

THE HYPERTENSION STUDY AT WINTHROP UNIVERSITY HOSPITAL

Winthrop University Hospital, a 591-bed teaching hospital in Mineola, New York, is a regional health care resource that has provided health care for more than a century. The hospital offers several inpatient and outpatient services, with an added focus on medical education and research.

Winthrop’s Internal Medicine Program provides an academic learning environment for patient care, scholarship, and research in internal medicine and its subspecialties. The hospital provides tertiary subspecialty care and is also a teaching affiliate of the State University of New York, Stony Brook School of Medicine. As of this writing, 82 internal medicine residents were participating in the program. All outpatient clinics are located in the same building and are equipped with an in-house laboratory.

Objectives

Our goals were to evaluate the following:

- the treatment of hypertension in patients with or without comorbidities (e.g., hyperlipidemia, diabetes, and renal insufficiency) by internal-medicine faculty physicians and medical residents in an outpatient setting
- patient adherence to drug therapies based on JNC 7, ATP III, and ADA guidelines
- the efforts of physicians to implement these guidelines

Methods and Study Population

This cross-sectional, observational study was approved by the hospital’s institutional review board. We collected data for all patients with a diagnosis of hypertension, with or without other comorbidities, who were seen by physicians at Winthrop Internal Medicine Associates (WIMA) for a total of nine months (from June 2004 to March 2005). Those subjects participating in the study had been patients at WIMA for years.

A total of 167 outpatients were typically seen every three months during the study period. However, only the first appointments of these 167 patients from June 2004 to March 2005 were considered for data collection; we wanted to ensure that no patient data were repeated twice, because these were all well-established patients.

Information on the data-collection form included the following:

- age, sex, comorbidities (e.g., coronary artery disease, diabetes mellitus, congestive heart failure, hyperlipidemia, chronic kidney disease, status after myocardial infarction, cerebrovascular accident or transient ischemic attack, and pulmonary vascular disease)
- blood pressure on the day of the visit (the average of two readings)
- current antihypertension medications along with any recent changes
- therapy prescribed for lowering LDL-C and lipid levels
- HbA1c concentrations for diabetic patients
- A self-reported assessment of medication adherence that included two questions asked by the physician:
  - How many days last week were you able to take your medication as prescribed? (Patients’ responses ranged from 0 to seven days.)
  - Did you take all of those medications as prescribed yesterday? (Patients responded yes or no.)

Statistical Methods

The mean and range were used to express continuous variables. The binomial test was used to evaluate whether rates of our study differed significantly from those of the national benchmarks. We used version SAS 9.1 (SAS Institute, Cary, N.C., for Windows) to perform all calculations. We considered the results statistically significant when the P value was less than .05.

Baseline Demographics

A total of 167 patients enrolled in the study: 85 women (51%) and 82 men (49%) with an average age of 60 years (range, 29 to 92 years). Of these hypertensive patients, 55% also had hyperlipidemia, 28% had diabetes, 15% had coronary artery disease, 16% were smokers, and 6% had renal insufficiency. (Moderate-to-severe renal insufficiency was defined as a creatinine clearance of less than 30 ml/minute.) Each patient could have more than one comorbidity.

RESULTS

Table 6 presents the results of the study.

The average blood pressure among the 167 patients was 135/78 mm Hg, and 62% of these patients met the blood pressure goal defined as below 140/90 mm Hg (P < .0001, compared with the national benchmark of 31%). Fifty-four percent of the patients took two or more antihypertensive medications. About 49% of the patients used ACE-inhibitors or ARBs, 37% took beta blockers, 37% used calcium-channel blockers, and 41% took diuretics. Each patient could be using more than one blood pressure medication.

Among 47 patients who had comorbid diabetes, 30% of these patients achieved their blood pressure goal of below 130/80 mm Hg; 45% achieved their LDL-C goal of less than 100 mg/dl; and 36% had HbA1c concentrations below 7%. Of the 47 patients, 13% met all three goals, compared with the national benchmark of 3% (P = .005).

Ninety-two patients had comorbid hyperlipidemia, and 67% of these patients were taking LDL-C–lowering medications. Of the 92 patients, 62% met the LDL-C goal of below 100 mg/dl, and 32% reached both blood pressure and LDL-C goals (P < .0001, compared with the national rate of 10%).

Ten patients with comorbid renal insufficiency achieved an average blood pressure of 118/77 mm Hg, and 80% (n = 8) of the patients met their blood pressure goal of less than 130/80 mm Hg. One hundred fifty patients (90%) claimed to be adherent to medications, compared with the national rate of 71% (P < .0001).

DISCUSSION

In this study, physicians at Winthrop University Hospital successfully managed hypertensive patients, with or without comorbidities, at a rate that was twice that of the national benchmark of 31%; that is, 62% of the patients met their blood pressure goals (P < .0001). In addition, 13% of comorbid diabetic patients achieved their blood pressure, LDL-C, and HbA1c goals at a rate that was four times better than that of the national benchmark of less than 3% (P = .005).
Managing Hypertension in an Outpatient Setting

Table 6  
Results of Hypertension Study at Winthrop University Hospital

<table>
<thead>
<tr>
<th>Total No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of patients</strong></td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
</tr>
<tr>
<td>• Female (%)</td>
</tr>
<tr>
<td>• Male (%)</td>
</tr>
<tr>
<td>• Mean age (range)</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
</tr>
<tr>
<td>• Lipid disorder</td>
</tr>
<tr>
<td>• Diabetes mellitus</td>
</tr>
<tr>
<td>• Coronary artery disease</td>
</tr>
<tr>
<td>• Smoking</td>
</tr>
<tr>
<td>• Renal insufficiency</td>
</tr>
<tr>
<td><strong>Blood pressure</strong></td>
</tr>
<tr>
<td>• Average reading (mm Hg)</td>
</tr>
<tr>
<td>• No. of patients with BP 140/90 mm Hg or higher</td>
</tr>
<tr>
<td><strong>Use of antihypertensive drugs from more than one class</strong></td>
</tr>
<tr>
<td>• ACE-inhibitors or ARBs</td>
</tr>
<tr>
<td>• Beta blockers</td>
</tr>
<tr>
<td>• Calcium-channel blockers</td>
</tr>
<tr>
<td>• Diuretics</td>
</tr>
<tr>
<td>• Two or more medications from any class</td>
</tr>
<tr>
<td><strong>Comorbid diabetes (n = 47)</strong></td>
</tr>
<tr>
<td>• Patients taking ACE-inhibitors or ARBs</td>
</tr>
<tr>
<td>• BP below 130/80 mm Hg</td>
</tr>
<tr>
<td>• LDL-C below 100 mg/dl</td>
</tr>
<tr>
<td>• HbA₁c in last 12 months</td>
</tr>
<tr>
<td>• HbA₁c below 7%</td>
</tr>
<tr>
<td>• Average HbA₁c and range</td>
</tr>
<tr>
<td>• Met all three goals (BP, LDL-C, HbA₁c)</td>
</tr>
<tr>
<td><strong>Comorbid hyperlipidemia (n = 92)</strong></td>
</tr>
<tr>
<td>• Receiving pharmacotherapy</td>
</tr>
<tr>
<td>• At LDL-C goal (below 100 mg/dl)</td>
</tr>
<tr>
<td>• At BP and LDL-C goals (below 140/90 mm Hg and below 100 mg/dl)</td>
</tr>
<tr>
<td><strong>Comorbid renal insufficiency (n = 10)</strong></td>
</tr>
<tr>
<td>• Average BP</td>
</tr>
<tr>
<td>• No. of patients with BP below 130/80 mm Hg</td>
</tr>
<tr>
<td><strong>Adherent with therapy</strong></td>
</tr>
</tbody>
</table>

ACE = angiotensin-converting enzyme; ARB = angiotensin-receptor blocker; BP = blood pressure; HbA₁c = glycated hemoglobin; LDL-C = low-density lipoprotein-cholesterol; mm Hg = millimeters of mercury.

Table 7 illustrates LDL-C goals and recommendations on when to initiate lifestyle modifications and drug therapy, according to ATP III.

The national benchmark for achieving LDL-C and hypertensive goals in hyperlipidemic patients is less than 10%; at Winthrop University Hospital, this figure was 32% (P < .0001).

We assessed patients’ self-reported adherence to medication using two questions adapted from previously standardized instruments. With this method, we determined patients’ adherence to the medication regimen to be about 20% higher than the national average (90% vs. 71%, respectively; P < .0001). Although there is no standard for assessing medication adherence, self-reported adherence is widely used and has been demonstrated in the literature to be a commonly accepted specific measure of non-adherence, with a sensitivity of 55% and specificity of 87%, compared with pill counts.

We concluded that the physicians at Winthrop successfully managed patients with hypertension, with or without comorbidities, and were in compliance with current JNC 7, ADA, and ATP III recommendations. The patients achieved goals for blood pressure, cholesterol, and control of diabetes. Although the physicians did work within the guidelines, we suggest that it was the strict adherence to these guidelines that was the key to the patients’ success.

In a conventional outpatient setting or private practice, physician visits can be very short and uninformative for patients. Because of a lack of time in the office, many physicians in these settings do not tell patients everything they need to know about their drug therapy. In our study, both attending and resident physicians spent significantly more time with each patient than would be spent in a standard outpatient setting. Depending on whether a patient saw only an attending physician or an attending and a resident physician, office visits could last from about 45 minutes to an hour and 15 minutes.

At every visit, patients were seen by a multidisciplinary team consisting of a physician, a nurse, and a dietitian. The team was responsible for keeping the patient informed about all the different aspects of their treatment. The visits centered on medication use, adherence, with special emphasis placed on lifestyle modifications. In standard outpatient care, these lifestyle changes tend to take a back seat to prescription therapy in the later stages of the disease. However, according to all of the aforementioned guidelines, lifestyle modifications are recommended in every stage of every disease state.

A diabetic education center at Winthrop also played a major role in this success. The center is supervised by registered nurses and dietitians who teach patients how to manage their blood glucose levels to achieve the optimal effect. In addition, medication use, blood glucose and blood pressure monitoring, proper diet, and exercise are addressed.

Our hospital also has a diabetic nurse educator on staff in the outpatient Internal Medicine Clinic who ensures that patients are aware of their scheduled appointments. Patients are notified by telephone and mail about all upcoming laboratory and physician visits as well as appointments with any specialists (e.g., neurologists, nephrologists, cardiologists, podiatrists, and ophthalmologists).

As a teaching hospital, Winthrop has 82 internal medicine residents on staff. The attending physicians on staff reinforce the
principles of current guidelines and keep the residents updated by giving frequent morning and noon lectures on new or changing guidelines. Drug utilization evaluations (DUEs) are often reviewed with the residents by the pharmacy department to see how their patients are responding to prescribed therapy and how compliant they are, compared with the rates proposed by the national guidelines. The DUEs also identify areas that need to be improved for appropriate management of patient disease states.

We attribute the high success rate of our study to the greater involvement of the physician and nursing staff with the patients and to the staff’s implementation of all aspects of the treatment guidelines for hypertension and its comorbidities. When physicians and staff members spend more time with patients, therapy has a better chance of being properly implemented. Because the patients enrolled in this program were more informed than standard outpatients, we believe that they will be more likely to adhere to their medication regimens and to participate in the necessary lifestyle modifications that are essential in managing hypertension and its comorbidities.

LIMITATIONS OF THE STUDY

Because our study was observational, there might not have been total control over the quality of the data. The study also lacked a control group. An ideal control group would have consisted of patients in a similar population as the study group but who received treatment from a normal outpatient setting. The control group would not have had access to multidisciplinary teams, diabetic education centers, and other resources.

CONCLUSION

Physicians at Winthrop University Hospital were successful in implementing the standards of care outlined in the JNC 7, ADA, and ATP III guidelines. They were effective in their management of hypertension, hyperlipidemia, and diabetes, particularly when compared with the goals set forth in the national guidelines.

Acknowledgments. The authors would like to thank the Winthrop Internal Medicine residents for assisting in the data-collection process.

REFERENCES


Table 7 Low-Density Lipoprotein-Cholesterol (LDL-C): Levels at Which Lifestyle Changes and Drug Therapy Should be Implemented

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>LDL-C Goal</th>
<th>LDL-C Level at Which to Initiate Therapeutic Lifestyle Changes</th>
<th>LDL-C Level at Which to Consider Drug Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD or CHD risk equivalents (10-year risk of above 20%)</td>
<td>&lt; 100 mg/dl</td>
<td>≥ 100 mg/dl</td>
<td>≥ 130 mg/dl (100–129 mg/dl: drug optional)*</td>
</tr>
<tr>
<td>More than two risk factors (10-year risk of 20% or below)</td>
<td>&lt; 130 mg/dl</td>
<td>≥ 130 mg/dl</td>
<td>10-year risk 10% to 20% ≥ 130 mg/dl 10-year risk less than 10% ≥ 160 mg/dl</td>
</tr>
<tr>
<td>0–1 risk factor</td>
<td>&lt; 160 mg/dl</td>
<td>≥ 160 mg/dl</td>
<td>≥ 190 mg/dl (160–189 mg/dl: LDL-C–lowering drug optional)</td>
</tr>
</tbody>
</table>

CHD = coronary heart disease. 