Variations in Hypertension Control in Indigent Rural Primary Care Clinics in North Carolina

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Objectives: To examine blood pressure control and prescribing practices in the treatment of hypertension, including the use of sample medications, in rural populations.

Design: Retrospective chart review of 296 hypertensive patients and surveys of primary care providers serving these patients.

Settings: Twenty-seven rural, primary care clinics in North Carolina.

Outcome Measure: Blood pressure control, with the practice site as the unit of analysis.

Results: An average of 29% of patients per clinic had blood pressures that were inadequately controlled. Wide variations existed between clinics in blood pressure control and medication costs. Thirty-two percent of all blood pressure medications used were either angiotensin-converting enzyme inhibitors or calcium channel blockers compared with 26% use of diuretics. Virtually all clinics used sample antihypertensive agents and reported that sample medications were an important source of free medications for their indigent patients. Reported sample use by practice was positively correlated with the mean daily hypertensive medication costs. Variations in blood pressure control were not explained by any measured variables, although the sample size was small.

Conclusions: Large variations exist within rural North Carolina primary care clinics in blood pressure control and medication costs. We need to study further the relationships of new antihypertensive agents, medication costs, and sample use with blood pressure control, health care costs, and other patient outcomes.

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Hypertension affects more than 60 million Americans. In 1992, almost $80 billion was spent treating hypertension and its sequelae of stroke and coronary heart disease. Medications alone account for approximately one third of the total costs of hypertensive care, an amount that is increasing as more patients who were previously undiagnosed begin to receive treatment. New antihypertensive medications are now available, many of which cost more than older agents. At the same time, the relative indications for choosing an agent for initial therapy have undergone major revisions, leading to uncertainty and controversy about preferred agents in various populations.

The widespread introduction and use of angiotensin converting enzyme (ACE) inhibitors and calcium channel blockers for antihypertensive therapy may make choices more costly and complex. Such agents are promoted as having improved safety profiles compared with many older antihypertensive agents, benefits proposed to increase patient compliance and decrease undesirable drug or metabolic interactions. Such benefits, if true, would likely lead to improved blood pressure control for patients.

National trends document a tremendous increase in the use of ACE inhibitors and calcium channel blockers during

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MATERIALS AND METHODS

SETTING

The North Carolina Office of Rural Health and Resource Development (ORHRD), in Raleigh, founded in 1973 by the North Carolina General Assembly, is a state agency designed to promote improved access to health care services for rural patients in North Carolina. Since its inception, the ORHRD has supported many rural practices through its financial and technical support services.

In 1990, the ORHRD, in conjunction with researchers from The University of North Carolina at Chapel Hill, developed a model quality-of-care assessment program to provide desired feedback to participating rural practices on adult health care maintenance needs and services. Participation in the quality assessment program is voluntary and occurs at no cost to the practice. In 1990-1991, 27 practices voluntarily participated in a quality of hypertension care audit and completed a survey on hypertensive medications used in the practices, including sample medications. The 27 practice sites represent approximately 85% of the practices that were supported by the ORHRD during the study period. The practice sites represent rural communities (most with populations of less than 2000) throughout North Carolina and include state-supported clinics, community and migrant health centers, and National Health Service Corps sites.

Clinics are supported by physicians, family-nurse practitioners, and/or physician's assistants. All physicians are primary care internists or family physicians, and physicians see patients in primary care settings. Patients are not referred by other physicians for special care. Most physicians see between 20 and 30 patients daily, almost half of whom could be defined as truly indigent. Many more have severely limited financial resources and pay very little based on sliding scale fee structures.

SURVEYS

We obtained data from the charts of patients, aged 20 through 70 years, who were receiving some sort of medical intervention for treatment of hypertension and who had visited the practice at least twice within the previous 2 years. Patients who were diagnosed as having congestive heart failure, angina, or coronary heart disease were excluded. Since most practices did not have computerized patient registries, charts were selected from patient registration logs where the patient's chief complaints and primary medical problems were listed. Each practice pulled their 10 most recent charts of patients who met the inclusion criteria above. By the same method, five additional charts were pulled for review for each additional full-time practitioner in the clinic. We audited 296 charts for this report.

From each chart, we collected demographic items, the antihypertensive medications used at the time of the audit, the blood pressure readings for the past year, and the number of clinic visits during the past 2 years. To evaluate the variables of hypertensive care in the rural practices, several measures were obtained, including annual measurements of serum creatinine level, serum potassium level (if the patient was receiving diuretics), and blood pressure readings. We defined inadequate blood pressure control as a diastolic blood pressure of greater than 95 mm Hg. For each practice site, we then calculated the mean percentage of visits in the past 12 months in which patients' diastolic blood pressure was greater than 95 mm Hg. All data abstractions were performed by a registered nurse (S.M.) employed by the ORHRD who had extensive experience in data abstraction and quality assessment.

We calculated hypertensive medication costs using the 1991 Drug Topics Redbook (Table 1). From the Redbook, we obtained an average wholesale price for each documented medication and dose listed in the patient's medical record and calculated the overall costs per day per patient for hypertension treatment. We treated all medications equally in assigning costs, regardless of whether medications were dispensed free of charge, either as samples or through free reimbursement programs. Such classification for analysis purposes is justified because we could not differentiate by chart audit the sample medications from nonsample prescriptions, and while samples may be used initially as a free medication, many patients eventually end up paying for such prescriptions.

Pharmaceutical sample utilization patterns were derived from an additional survey of each practice site. This survey asked providers to indicate the types and sources of medications generally used in the treatment of their hypertensive patients, their practice policies about sample medications, attitudes toward use of sample medications, how often patients used sample medications, and utilization of alternative antihypertensive medication reimbursement programs, i.e., "write-off" programs.

DATA ANALYSIS

All data were written onto standardized forms and entered into a microcomputer at the ORHRD. Data analysis was performed jointly by The University of North Carolina at Chapel Hill and the ORHRD staff, with the assistance of a statistical program (SYSTAT, version 5.0, Evanston, Ill). Descriptive statistics were used to examine distributions for all variables. Blood pressure control, medication costs, and questions on pharmaceutical samples were examined with means and SDs. Pearson correlation coefficients or χ2 statistics were used to examine bivariate relationships among variables. A two-tailed P value of .05 was used as the level of significance. We designed the study with the clinics themselves as the unit of analysis. No attempt was made to record or link individual physician characteristics to patient outcomes.
In the past 5 years, increases that have come at the expense of agents such as diuretics. Sample medications are almost exclusively limited to these newer antihypertensive agents, and pharmaceutical representatives rarely leave inexpensive antihypertensive sample medications.

Blood pressure control in populations with high numbers of indigent, minority, and/or uninsured patients is especially challenging. Despite having a greater overall prevalence of hypertension, such patients visit physicians' offices less frequently and use fewer health maintenance services. Antihypertensive medication costs are a major barrier to optimal utilization of health care resources for such patients. Indigent patients have a particularly difficult time affording expensive antihypertensive agents;

**In a mean of 29% of the audited charts reviewed . . . inadequate blood pressure control was found**

As a result, blood pressure control may suffer if compliance with medication regimens subsequently decreases. If clinicians in indigent care clinics have followed national prescribing trends, then an increased use of more expensive agents may be associated with no improvement or even a worsening in blood pressure control for their indigent patients. However, clinicians in indigent care clinics may use sample antihypertensive medications in an effort to offset their patient's inability to afford them.

At present, there is little research to suggest which antihypertensive medications rural primary care providers are prescribing to their patients, how well rural patients with hypertension have blood pressures under proper control, and if use of sample medications affects blood pressure treatment and control. In an exploratory attempt to look at such questions, we undertook a study designed to examine factors related to blood pressure control in this population.

**RESULTS**

**DEMOGRAPHICS**

Twenty-seven practice sites participated in the research project, and chart audits of 296 hypertensive patients were performed. Demographic analysis of these practice sites is shown in Table 2. Fifty-eight percent of the patients were women and the patient's mean age was 54 years.

**BLOOD PRESSURE CONTROL AND PRESCRIBING HABITS**

In a mean of 29% of the audited charts reviewed (range, 0% to 63%) (Figure), inadequate blood pressure control was found. The Figure also shows substantial variation in each clinic's mean medication costs per day. The use of more medications was not significantly correlated with higher mean blood pressures (r=.36, P=.08). Practices with higher mean medication costs (either because of more medications or more expensive medications) also were not linked with blood pressure control (r=.27, P=.18). All measured demographic variables were unrelated to blood pressure control (P>.25).

Thirty-two percent of the antihypertensive medications dispensed per clinic were either an ACE inhibitor or a calcium channel blocker (range, 12% to 85%). Diuretics composed an average of 26% of antihypertensive medications dispensed per clinic (range, 11% to 41%).

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**Table 1. Costs Per Dose of Common Antihypertensive Medications**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose, mg</th>
<th>Cost, *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochlorothiazide</td>
<td>25</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Reserpine</td>
<td>0.25</td>
<td>0.01</td>
</tr>
<tr>
<td>Propranolol hydrochloride</td>
<td>40</td>
<td>0.01</td>
</tr>
<tr>
<td>Hydralazine hydrochloride</td>
<td>50</td>
<td>0.02</td>
</tr>
<tr>
<td>Chlorothalidone</td>
<td>50</td>
<td>0.03</td>
</tr>
<tr>
<td>Verapamil hydrochloride</td>
<td>120</td>
<td>0.22</td>
</tr>
<tr>
<td>Diltiazem hydrochloride</td>
<td>30</td>
<td>0.33</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>10</td>
<td>0.34</td>
</tr>
<tr>
<td>Captopril</td>
<td>25</td>
<td>0.52</td>
</tr>
<tr>
<td>Atenolol</td>
<td>50</td>
<td>0.74</td>
</tr>
<tr>
<td>Enalapril malese</td>
<td>10</td>
<td>0.79</td>
</tr>
<tr>
<td>Diltiazem slow release</td>
<td>120</td>
<td>0.91</td>
</tr>
<tr>
<td>Nifedipine extended release</td>
<td>30</td>
<td>1.05</td>
</tr>
<tr>
<td>Verapamil slow release</td>
<td>240</td>
<td>1.07</td>
</tr>
</tbody>
</table>

*Average wholesale price estimates are derived from the 1991 Drug Topics Redbook, pharmacists' annual reference. Costs reflect generic prices or the lowest cost product if multisource products are available.

**Table 2. Demographic Analysis of Hypertensive Patient Chart Data From 27 North Carolina Rural Practice Sites**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>54±4</td>
</tr>
<tr>
<td>Sex, % female</td>
<td>58</td>
</tr>
<tr>
<td>Race, % white†</td>
<td>42</td>
</tr>
<tr>
<td>No. of providers</td>
<td>Physicians</td>
</tr>
<tr>
<td></td>
<td>Family nurse practitioners/physician's assistants</td>
</tr>
<tr>
<td>No. of hypertensive medications per patient</td>
<td>1.4±0.3</td>
</tr>
<tr>
<td>Average costs per day, $</td>
<td>1.00±0.29</td>
</tr>
<tr>
<td>Proportion of patients with diastolic blood pressure &gt;95 mm Hg</td>
<td>0.29±0.13</td>
</tr>
<tr>
<td>Proportion of patients with tests for serum creatinine levels ordered within last year</td>
<td>0.77±0.21</td>
</tr>
</tbody>
</table>

*Data are given as mean±SD except where noted.
†Only 15 practice sites recorded information designating race.
patients had in obtaining affordable medications, seven practices (26%) said that it was only a minor problem, 11 (41%) said that it was a moderate problem, and nine (33%) said that it was a severe problem. Eighty-two percent of all practices reported using one or more pharmaceutical-sponsored, special write-off programs for indigent patients. The use of write-off programs and the percentage of sample medications used per practice site were not related to blood pressure control.

**COMMENT**

Optimal blood pressure control remains the overall goal of hypertension treatment. In our 27 rural clinics, in almost one third of the audited charts, we found that blood pressure control was less than adequate. We also found substantial variation in blood pressure control and medication costs between rural practices. Improved blood pressure control was not related to higher overall medication costs per practice, the reported use of antihypertensive samples, or sponsored medication discount programs.

**Table 3. Reasons Why Practitioners at Rural Practice Sites Dispense Pharmaceutical Samples**

<table>
<thead>
<tr>
<th>Response</th>
<th>Mean±SD Score*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is indigent</td>
<td>2.9±0.38</td>
</tr>
<tr>
<td>Therapeutic trial of medication new to the patient</td>
<td>2.7±0.53</td>
</tr>
<tr>
<td>Trial of medication new to the practice</td>
<td>2.1±0.79</td>
</tr>
<tr>
<td>As a patient convenience</td>
<td>1.5±0.79</td>
</tr>
<tr>
<td>No pharmacy nearby</td>
<td>1.4±0.69</td>
</tr>
</tbody>
</table>

*1 indicates not important; 2, somewhat important; and 3, very important.

**SAMPLE MEDICATIONS**

Pharmacy survey results showed that all 27 practice sites reported dispensing free sample medications to their patients. Five practices (19%) reported using sample medications in less than 6% of patient visits, 12 practices (44%) reported using sample medications 6% to 25% of the time, nine practices (33%) reported using sample medications 26% to 49% of the time, and one practice (4%) reported using sample medications more than 50% of the time. Reported overall use of sample medications was significantly correlated (r=.48, P<.01) with mean daily hypertensive medication costs, independent of the number of medications used, suggesting that the sample medications used were more expensive agents.

Antihypertensive and nonsteroidal anti-inflammatory sample medications were reported as the most frequently used samples (data not shown).

Practices reported several reasons as to why practitioners at their facilities might dispense sample medications (Table 3). These rural practice sites reportedly use sample medications most frequently for indigent patients and as a therapeutic trial of a medication new to the patient. When asked to rank how much of a problem...
Committee on Detection, Evaluation, and Treatment of High Blood Pressure. In 1984, the Joint National Committee\textsuperscript{12} declared that initial pharmaceutical treatment of high blood pressure should begin with a diuretic or a \( \beta \)-blocker. However, by 1988, the Joint National Committee report\textsuperscript{13} indicated that ACE inhibitors and calcium channel blockers could also be acceptable first agents to initiate hypertension treatment. By 1992, the Joint National Committee\textsuperscript{14} listed six classes of drugs (diuretics, \( \beta \)-blockers, ACE inhibitors, calcium channel blockers, \( \alpha_1 \)-receptor blockers, and \( \alpha_\beta \)-blockers) as equally effective in reducing blood pressure, although the report notes that only diuretics and \( \beta \)-blockers have proven reductions with cardiovascular morbidity and mortality.

\textbf{Predictably}, pharmaceutical marketing and use of newer agents have expanded greatly. Sales of calcium channel blockers and ACE inhibitors increased from $422 million and $122 million, respectively, in 1985 to $2.5 billion and $1.77 billion, respectively, in 1991.\textsuperscript{15} Diuretics and \( \beta \)-blockers, on the other hand, went from $690 million and $1.12 billion, respectively, in 1985 to $740 million and $1.35 billion, respectively, in 1991.\textsuperscript{15} With more than 70 antihypertensive agents and at least 25 combination drugs now available to treat uncomplicated hypertension, scientific and economic controversy exists as to which agents are preferred and which are most cost effective.\textsuperscript{3,5,7,16-19} The use of more expensive antihypertensive agents can be justified if they provide convincing evidence of improved blood pressure control and improved patient outcomes.\textsuperscript{17} Our study did not show differences in blood pressure control for those patients who were using two of the newer class of agents, calcium channel blockers and ACE inhibitors.

One potential reason for the lack of improved blood pressure control seen with the use of sample agents in rural clinics may relate to how the agents are typically dispensed. Rural clinics often see a high percentage of indigent patients, in whom blood pressure control often remains inadequate for many reasons.\textsuperscript{9} Most practitioners believe that sample antihypertensive medications are an important component in the care of such patients and assume that indigent patients would forgo medication entirely without them, thereby exacerbating blood pressure control. However, based on the experiences of two of us (A.O.G. and T.S.C.) in caring for rural patients, there was concern that the use of sample medications with indigent hypertensive patients might not be leading to improved compliance in therapy. In practice, clinicians give indigent patients sample medications that are typically depleted within 1 or 2 months, since sample medications are not designed as a continuing source of medications for chronic conditions such as hypertension. When patients return for office visits, they may receive alternative sample agents if the original agent is not available. Different agents may be of a different class and may have different side effects or abilities to control blood pressure; increased office visits may create additional costs that negate sample cost savings. Some patients extend their sample medications by taking fewer doses or dividing their supply. Finally, when a sample medication is depleted, patients may get a prescription for a medication they cannot afford to buy. Unfortunately, compliance and actual use of sample medications were not recorded in the charts, so we could not support or refute this hypothesis.

Our results demonstrate that rural primary care clinics use and value sample medications and pharmaceutical-based discount programs for their indigent patients. While such clinicians believe that medication costs are a major barrier to optimal blood pressure control, they also use ACE inhibitors and calcium channel blockers for one third of their hypertensive medications, accounting for a greater overall percentage of prescriptions than diuretics. While such findings are not new,\textsuperscript{7} the fact that they are found in rural and indigent clinics demonstrates potential conflicting forces that may affect a patient's antihypertensive therapy. Since there was no documentation that linked individual patients to specific sample medications, we could not determine if increased use of newer agents is directly linked to experience with sample medications.

There are important limitations to consider in interpreting our results. Since the research was conducted in one southern state and in rural primary care clinics, the results may not be generalizable to other states or settings. More comprehensive measures of the case mix of patients per clinic and the severity of their underlying disease would also be desirable; however, there was little evidence and no systematic reasons to suppose that the severity of hypertension varied greatly among practice sites. More importantly, as a preliminary, hypothesis-generating study, we used the practice site as the level of analysis, since we were observing primarily treatment patterns, not the behavior of individual patients. However, to test several hypotheses generated from this study, individual practitioners and their patients are the optimal units of analysis. For instance, compliance with therapy is an important variable that was not measured. With the limited practice sites that we had available for study, we also had a greater likelihood of making a type II beta error, that is, assuming a relationship does not exist when it, in fact, does. A total of 52 practice sites would have been needed to give us an 80% chance of finding a difference of at least 10% in blood pressure control and related variables between practices.

\textbf{lack of improved blood pressure control seen with the use of sample agents in rural clinics}

ARCH FAM MED/VOL 3, JUNE 1994

518
Several types of selection bias could have influenced our results. For instance, because we selected patients from the practice logs and selected the most recent patients who also met other inclusion criteria, patients who visited the clinic more frequently were more likely to be selected for our sample. If such patients had blood pressure more difficult to control, we could have potentially overestimated the true proportion of a practice’s hypertensive population with inadequate blood pressure control. However, such bias would not have affected the amount of variation found between clinics in terms of blood pressure control. These variations could theoretically be related to practice style, if some practices in our sample chose to routinely see their hypertensive patients more or less frequently than other practices, thereby biasing the sample selection to healthier or sicker hypertensive patients. While this selection bias could have been in either direction, we have no evidence for its existence.

Another limitation involves the process of studying the use of sample medications and outcomes such as blood pressure control. In our study, the process proved very difficult because virtually all of the rural practices used sample antihypertensive medications, with little variation between practices. Few clinicians recorded when or how often sample medications were used, so we could not document which patients were seen, received sample antihypertensive medications, which products they received, how often they received samples, or how often they received different classes of sample medications at different visits. The validity of self-report use of sample medications as reported by the practice providers is unknown but is likely to have been underestimated. Finally, our survey was a cross-sectional one, and such research cannot establish causal relationships. All of these factors are important to assess in future studies looking at the use of sample medications and outcomes such as blood pressure control.

In conclusion, our results demonstrate large variations in blood pressure control, medication costs, and prescribing patterns within North Carolina rural primary care practices. Rural practices also report frequent use of antihypertensive sample medications. Future research should investigate the effects of such use of sample medications, discount medication programs, compliance with therapy, and changing practitioner prescribing practices on the costs and outcomes of hypertensive treatment.

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REFERENCES