Letters to the Editor

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TERAZOSIN FOR BPH

To the Editor:

I read with dismay a recent article in *The Journal* concerning treatment of hypertension and symptomatic benign prostatic hyperplasia (BPH) with terazosin.[1]

In this study, over 700 primary care physicians throughout America were "recruited" to enroll patients, but we are not told *how* they were recruited. Since the study was funded by the manufacturer of terazosin, one wonders if financial incentives were involved that could have biased the trial. Such studies, termed "seeding trials," are routinely employed by pharmaceutical companies to gain exposure and increase the use of their product without producing any useful information.[2]

Open-label enrollment was used: there was no placebo control group, and the study was not blinded. While this is not always inappropriate, the study of BPH demands a more scientific approach. The lack of a placebo group is an especially glaring problem in a BPH treatment study. Previous investigators have demonstrated that patients with BPH who receive placebo often show considerable improvements in symptom scores.[3,4] Thus, contrary to the author's assertions, I do not find an asset of this study to be the "power of numbers." Without a placebo control group this amounts to nothing more than a large case series,[5] and conclusions regarding the safety and efficacy of terazosin from the data presented are unfounded.

We are given no information on what defines "hypertension," and no delineation of the "run-in" period required to make the diagnosis. This is a pertinent concern because "regression to the mean" in hypertension treatment trials is well recognized.[6]

Authors, publishers, and readers must share responsibility for what appears in the medical literature.

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The preceding letter was referred to Dr Guthrie, who responds as follows:

Dr Jerant raises two specific points and a general philosophical question that I will address.

First, the physicians who provided the research were recruited by the sales force for Abbott Laboratories in North Chicago, Ill. This is a traditional mechanism for recruitment of physicians in large-scale clinical trials such as this. However, this was *not* a "seeding trial" or "demonstration project," which have been used by pharmaceutical companies in the past to encourage physicians to use newly developed products.

Terazosin had been on the market for hypertension for a number of years, and this project was developed as a large-scale Phase IV project to investigate a variety of questions about terazosin. The project involved proper informed consent and Institutional Review Board approval consistent with all legitimate research projects. The physicians were paid $60.00 per patient, a modest amount considering the amount of work involved, which included the cumbersome gathering of scores from the Boyarsky scale, in use at that time to detect symptomatic BPH.

In a second point, Dr Jerant questioned the open-label design, an issue with which I thought I had dealt in the manuscript, particularly since we both referenced the same study by Dr Lepor, which had provided data on placebo effect in treatment of symptomatic BPH. I am confident that the improvement seen, which was more than twice the level of placebo effect seen in Dr Lepor's study, is significant. I do think that the study is a valuable addition to the double-blind data that have been accumulated by other investigators in the use of terazosin and other alpha$_1$ blockers.

This was the first large-scale trial utilizing alpha blockers to treat symptomatic BPH in the primary care office setting. All the other trials have been conducted in academic urological offices (medical schools), and one can question their relevance regarding how patients would respond in the typical primary care office. Therefore I think that this type of trial is *extremely valuable* in documenting that these agents, which have clearly been shown to be safe and effective in double-blind trials in academic urological offices, were also safe and effective in the very practice setting where they will be predominantly used. While the open-label design is not perfect, I think this type of large community-based study provides legitimate supplementary data to the double-blind data accumulated in other investigations.

Dr Jerant questions the definition of hypertension. The trial was originally developed to look at a multitude of issues in patients who were either documented as hypertensive in the office or currently treated with antihypertensive medications, with that being accepted as the definition of hypertension. For a variety of reasons, I did not feel that the other data they attempted to accumulate beyond the BPH data were valuable, and those data were therefore discarded. This report was developed to document the very positive effects on the *subset* of patients who had symptomatic BPH. The hypertension data were presented not to document the efficacy of alpha-blockers in treating hypertension. The design did not allow for that type of accurate documentation, and that issue has been documented in a large number of other studies in the past. It was included simply to provide reassurance to practitioners that patients who had normal blood pressures and received alpha-blockers as treatment for their BPH did so without becoming significantly hypotensive. The hypertension data are therefore included fundamentally as a safety issue.

The issues raised by Dr Jerant appear to

be basically philosophical, concerning what should constitute family medicine research. In the early days of our specialty, our research background was provided by nonclinicians who were brought into our specialty from a variety of other research backgrounds, such as social sciences and statistics. This background has produced what I think is an inappropriate concern with academic structure inside our research community. System- or structure-oriented rather than clinically oriented research projects are dominating family medicine research. Rarely do we see landmark clinical research conducted by family physicians, and rarely do we see original research from our literature referenced by specialists in other fields. This has also meant that the evolution of clinical knowledge that is relevant to family physicians has, for the most part, been conducted by physicians in other specialties and published in literature outside family medicine. A more flexible approach, stressing the clinical value of our research efforts, would serve our specialty better in the future.

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FAMILY PRACTICE PROCEDURES

To the Editor:

Eliason et al deserve credit for studying the diagnostic and therapeutic skills of family practice.[1] These data constitute a "snapshot" of 325 Wisconsin family physicians in the spring of 1993. The "quit ratio" is defined as the number of physicians who have quit the procedure divided by the number still providing the procedure. This concept is a real contribution. However, additional perspective is available from other published studies.[2,3] Family physician investigators have been tracking the gradual transfer of tertiary care technology into primary care specialties such as family practice for many years. For example, prior to 1980, flexible sigmoidoscopy training was not available. Unfamiliar with the diagnostic benefits of this procedure when performed by family physicians, some even opposed flexible sigmoidoscopy by family physicians.[4,5]

Political opposition against family physicians performing procedures such as esophagogastroduodenoscopy (EGD) and colonoscopy has been strong.[6–10] Therefore, a high quit ratio might not reflect the value of the procedure as much as it reflects unavailable role models, inadequate training, and political resistance.

In the area of obstetric (OB) ultrasound, data by Wadland et al[11] suggest that among family physicians who practice maternity care, 53% of OB-capable family physicians have unrestricted OB-ultrasound privileges in their hospital practice. The 4.3% described in the Eliason study is distinctly different. Connor et al[12] found that over 60% of family practice residency programs are teaching OB ultrasound.

Each year, the American Academy of Family Physicians (AAFP) tracks the percentage of family physicians performing a variety of procedures. Prior to 1992, EGD and colonoscopy were not tracked because they were not viewed as family practice procedures. More family physicians, however, are acquiring these skills each year.[13–15]

In summary, a high quit ratio for procedures that are becoming obsolete is appropriate. However, in analyzing quit ratios for new procedures, additional data will be needed to confirm these trends over time. With each year, family practice role models become more prevalent and

training becomes more available. For such things as obstetric ultrasound, maternity care, colonoscopy, and esophagogastroduodenoscopy, the technology becomes easier to use and less costly. Public access via the medical specialty of family practice is another important consideration.

Where appropriate, tertiary care technologies will improve and transfer into primary care. Access to training, family physician–faculty role models, political resistance, and the time (20 years) required to train a generation of technically literate family physicians will be confounding variables in studying which technologies "stick and stay" in family practice.

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The preceding letter was referred to Dr Eliason, who responds as follows:

The comments by Rodney and his leadership and encouragement for family physicians to learn and perform a variety of procedures are recognized and appreciated.

Our data represent a "snapshot" of Wisconsin family physicians, and the procedures they were performing in the spring of 1993.[1] We also agree that additional data over time will confirm whether family physicians will adopt and utilize new procedures such as OB ultrasonography, colonoscopy, and esophagogastroduodenoscopy.

Our data showed for all three of these procedures that <5% were performing the procedure and <3% planned to learn any one of them, indicating a limited interest at this time. We agree that for these procedures, the quit ratio is not as relevant because of the newness of the procedures and the small number of physicians currently performing them.

Rodney's comments on OB ultrasound deserve a further response. Our finding that 4.3% of all family physicians are performing OB ultrasonography is similar to that of the survey by Phillips[2] of physicians in the state of Washington in 1989. Phillips found that 4% performed OB ultrasonography and 3% interpreted the results. The study of Wadland et al[3] which reported that 53% of family physicians are doing ultrasonography included only family physicians who provide maternity care. The current data on practicing family physicians indicate that approximately 25% of all family physicians provide maternity care.[3] Wadland's data would extrapolate to indicate that about 13.5% of all family physicians perform OB ultrasonography. Connor's[4] article on teaching obstetrical ultrasonography in family practice residencies seems to indicate that over 60% of the respondents used ultrasonography in their practices and that 53.2% of programs desired to have training in OB ultrasonography, not that over 60% of programs are teaching residents to perform OB ultrasonography.

We agree that where transferable, appropriate tertiary care technology will be adapted by family physicians. Patient safety, medical marketplace economics, community needs, physician interests, adequate training, and practice volume to maintain skills also will remain important issues.

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