Simvastatin also affected the other outcomes evaluated in this study, significantly decreasing the risk of a coronary event (relative risk = 0.73) and the likelihood of undergoing coronary artery bypass surgery or angioplasty. There was no significant effect on non-MI acute CHD events. The drug was judged to be well tolerated, based on the similarity of adverse effects and the rate of patients discontinuing therapy between the two groups. Subgroup analysis revealed that elderly patients (>60 years) benefited to the same extent as younger patients, although mortality in women (as a group) was not decreased.

To help interpret these results, a useful measure of clinical significance (not reported in the study) is the "number needed to treat" (NNT), which is the number of patients who would have to be treated for one of them to achieve the goal of therapy. Calculating the NNT for this trial reveals that about 135 people would have required treatment for 1 year, or 25 patients for 5 years, for one death to be prevented. By comparison, only 81 people would need to be treated with a beta-blocker for 1 year following an MI to prevent one death.[1]

Recommendation for clinical practice. This trial provides the first evidence that patients with documented CHD are less likely to die if treated with a cholesterol-lowering agent. Therefore, physicians should recommend simvastatin to their hyperlipidemic patients with CHD. Three cautions, however, are warranted.

First, simvastatin is the only agent that has been convincingly shown to decrease all-cause mortality. A meta-analysis that combined the results of previous cholesterol-lowering trials has shown that only patients at highest risk benefit from therapy, and that patients at low risk may actually be harmed.[2] As a result, it is risky to extend the results of this trial to include other drugs. Second, all patients in this study already had evidence of CHD. Patients without CHD are at much lower risk of cholesterol-related mortality. Using lipid-lowering agents to treat these patients may not be beneficial and may actually be harmful. Finally, no significant benefit to patients occurred for the first several years of therapy, which underscores the importance of continuous treatment.

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EFFECT OF EPIDURAL ANESTHESIA ON LABOR

TITLE: The effect of epidural anesthesia on the length of labor
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Clinical question. Does the use of epidural anesthesia increase the length of the second stage of labor?

Background. Several studies have shown that women who receive epidural anesthesia have a longer second stage of labor than women who do not. Because these trials were not randomized, however, the observed difference in the duration of labor may be related to factors other than the epidural anesthesia itself. That is, women who elected to receive epidural anesthesia or whose physician recommended it may have been different in some other way (such as having a greater incidence of cephalopelvic disproportion), which also may have affected the duration of the second stage of labor. In the state of Tennessee, a change in the state's insurance program for the indigent resulted in a sudden decrease in the use of epidural anesthesia among patients at a family practice clinic, setting the stage for the "natural experiment" observed by the authors.

Population studied. The study included all women under the care of residents and faculty of the Bristol Family Practice Residency in Bristol, Tennessee, over a 1-year period from July 1, 1993, to June 30, 1994. Women who had a precipitous delivery for which the length of the second stage could not be accurately measured and women whose infants were delivered by cesarean section were excluded from measurement of the second stage of labor.

Study design and validity. This was a nonrandomized (or quasi-experimental) trial that used a pretest-posttest design. That is, the length of the second stage of labor and other outcome variables were measured in a sample of patients for a 6-month period, known as the pretest period. Then, after the insurance coverage for this group of

women changed on January 1, 1994, another set of measurements was made. This second 6-month period is called the posttest period. The validity of the study rests on the assumption that the decrease in the use of epidural anesthesia was related to the insurance coverage alone, and not to any other factor or factors associated with the length of the second stage of labor.

The most important threat to the validity of this study design is the possibility that there may have been some other change in the management of labor that could have affected the length of the second stage of labor. In this case, the authors point out that there was no change in "hospital or hospital policy, nursing staff, nursing staff education, medical staff, physicians, anesthesiologists, or percentage of primiparous women" during the study period. This study could have been strengthened by observing a control group of privately insured women from the same hospital for the same 12-month period, for whom no change in the rate of use of epidural anesthesia (and therefore, the length of the second stage of labor) would be expected. Such a design is known as a pretest-posttest design with nonequivalent control group (*Cook TD, Campbell DT. Quasi-experimentation: design and analysis issues for field settings. Boston, Mass: Houghton Mifflin Co, 1979:99–102).* A randomized trial would have been the strongest study design but it may not have been ethically feasible in this case.

Outcomes measured. The primary outcome was the length of the second stage of labor. Secondary outcomes included the number of forceps deliveries and the number of cesarean sections. Possible confounding variables measured included maternal age and race, parity, and birthweight.

Results. The average length of the second stage of labor decreased from 84 minutes in the pretest period to 46 minutes in the posttest period among primiparous patients, and from 40 minutes to 17 minutes among multiparous patients. Both differences were statistically significant at a level of $P<.001$. The rate of cesarean sections decreased from 24% in the pretest period to 18% in the posttest period, and the number of forceps vaginal deliveries decreased from 14 to 1. The authors write that the small number of patients precluded analysis of these data; however, I calculated the probability that these results occurred by chance alone and found that whereas the difference in the number of cesarean sections was not statistically significant (Pearson chi-square, $P=.82$), the difference in the number of forceps vaginal deliveries was significant (Fisher's exact test, $P=.001$).

Recommendation for clinical practice. Although inconclusive, this study provides evidence that the use of epidural anesthesia lengthens the second stage of labor. Physicians should discuss this with their patients before the onset of labor so that the patients can make an informed decision regarding the risks and benefits of epidural anesthesia. More study is needed to confirm the finding that increased use of epidural anesthesia is associated with a greater incidence of forceps vaginal deliveries and to measure the impact of epidural anesthesia on patient-oriented outcomes, such as neonatal outcome and the number of postpartum infections.

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