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Do Better Treatments Save Money?
(or Do They Just Produce More Patients?)

Even the most nihilistic physicians would have to acknowledge the development of new clinical strategies that are more easily tolerated by patients. Imaging tests are now less invasive, drugs have fewer side effects, and an increasing number of surgical procedures now entail only small puncture wounds instead of long incisions. There can be little doubt that these new clinical strategies have helped some patients lead better lives.

Proponents of these new strategies frequently argue that they have yet another benefit—saving money. The general argument is simple: Better tolerated interventions require less monitoring and create fewer complications. If either the monitoring or the treatment of complications is typically done in the hospital, the savings should be significant. Finding good evidence for this argument, however, is often difficult. In this issue of **ecp**, Pearson and colleagues[1] provide such evidence for one new clinical strategy: low-molecular-weight heparin for deep venous thrombosis (DVT).

Low-molecular-weight heparin has real advantages over conventional heparin (which is a much more heterogeneous mixture of heparins with different molecular weights). Because low-molecular-weight heparin rarely binds to extraneous proteins, it is almost completely available to exert its primary action—anticoagulation. This pharmacologic effect has important clinical implications. First, patients can be anticoagulated effectively with a subcutaneous injection instead of the continuous intravenous infusion that is typically required when conventional heparin is used for DVT. Second, the therapeutic response to a given dose of the drug is more predictable than with conventional heparin. These two advantages combine to produce a third: Patients do not have to be hospitalized to receive therapy. It seems axiomatic that strategies that obviate hospitalization must save money. But as with many axioms, reality may not be so simple.

To estimate the true effect of low-molecular-weight heparin on the cost of treating patients with DVT, Pearson and colleagues had to avoid several pitfalls. They could not assume that the cost of the drug was the only cost of the

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new strategy. Visiting nurses administered low-molecular-weight heparin twice a day because most patients did not want to perform the subcutaneous injection themselves; some even preferred to be treated in the urgent care clinic. In addition, the initiation of oral anticoagulation (with warfarin) required drawing daily blood samples for monitoring. In fact, one of the main contributions of the Pearson study is the description and costing of the infrastructure required to implement a strategy of outpatient treatment for DVT.

Another possible pitfall would have been to assume that patients who are eligible for outpatient DVT therapy represent DVT patients in general. The Pearson study uses a before–after design, which always raises concerns about validity (*see* **Primer**). In this case, the most common mistake would have been to compare the cost of treating *all* patients with DVT before the program (the before group) with the cost of treating the *selected* patients with DVT who were enrolled in the program (the after group). This approach would ignore the patients who were deemed ineligible for the program, a subset that is bound to be sicker than the patients enrolled in the program. In fact, the authors found that these patients had longer and more costly hospital stays. Failing to include these sicker patients in the after group would have created a powerful selection bias. However, because these patients were included in the after group, we can be much more confident about the study's main finding—that is, that the outpatient low-molecular-weight heparin program at Harvard Pilgrim Health Care reduced the average cost of treating patients with DVT.

But another pitfall may need to be considered: Does a simpler therapy lead to lower diagnostic and treatment thresholds for the disease? More specifically, does a well-designed, smoothly functioning program that supports outpatient therapy for DVT make physicians more likely to identify a borderline case as one that requires treatment? Is it possible that Harvard Pilgrim has lowered the average cost of treating DVT patients but is now treating more patients? Could low-molecular-weight heparin raise the total cost of treating DVT? (Or are these just knee-jerk reactions of a medical skeptic?)

Unfortunately, the work by Pearson and coworkers does not shed light on these questions. In fact, neither would the typical randomized trial. The diagnostic threshold of a trial is set through the eligibility criteria, and then the patients are randomly assigned to various treatment strategies, essentially making the treatment threshold irrelevant. The ran-

domized trial provides no information about what happens to treatment thresholds in practice and cannot determine whether more patients will ultimately be treated. To learn about the effect of new clinical strategies on diagnostic and treatment thresholds, we need to examine population-based rates across time. In this case, what we would like to know is whether the observed incidence of DVT (or the treatment rate) has increased after the introduction of low-molecular-weight heparin.

The question of whether better treatments increase volume is not simply academic, as is exemplified in the case of laparoscopic cholecystectomy. Laparoscopic technology was clearly a quantum leap for surgery. In the case of cholecystectomy, the new technology has shortened the length of the procedure, the length of hospitalization, and the time to full recovery. More important, it made the procedure safer—the operative mortality rate (e.g., deaths per 1000 operations) for the new approach is substantially lower. Not surprisingly, the laparoscopic approach quickly diffused into clinical practice, and in some settings, cholecystectomy volumes soared, thereby implying that the diagnostic and treatment thresholds for cholelithiasis had been lowered.[2] Because more procedures are being done, the total number of cholecystectomy deaths may have stayed the same or even increased, despite the advent of a safer procedure (total deaths = operative mortality $\times$ volume).[3, 4]

Unless we pay close attention to how frequently clinical strategies are used, safer strategies may ultimately cost more—both in dollar and human terms. Paying attention to diagnostic and treatment thresholds is the key to ensuring that new clinical strategies represent a genuine improvement.

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