surgeries is five times higher than in the United Kingdom and three times higher than in Sweden.

Prolonged rest does not improve outcome and promotes deconditioning

Once radiculopathy and serious causes of acute back pain have been ruled out, there are four general principles to follow.

Get the patient out of bed. Prolonged rest does not improve outcome and promotes deconditioning.[4,5]

Encourage physical activity, instead of passive therapies such as massage or ultrasound treatments. Exercise programs are available, but patients may fare just as well by continuing their normal activities, with appropriate caution.

Give nonnarcotic analgesics as needed so that patients can resume their physical activities. The role of muscle relaxants is at best marginal and short-term.

Educate the patient as to what is appropriate in the diagnostic approach (eg, that magnetic resonance imaging does not show the cause of the pain in most cases) and what he or she can expect from treatment. Explain that the source of the pain is often not clear and that imaging findings have questionable significance.

WHAT IF THE PATIENT DOESN'T GET BETTER?

If a patient does not get better within 1 month, it is time to ask oneself:

- Was the initial diagnosis correct?
- Are additional diagnostic studies now appropriate?
- Was therapy appropriate, or was it too passive?
- Are there previously unrecognized psychosocial barriers to recovery? If the patient has been in bed for 4 to 6 weeks and has not gone back to work, there may be some underlying psychosocial or secondary gain issues. Whatever the reason, such passivity can clearly delay recovery and needs to be addressed.

Rehabilitation should be considered in persons who do not make progress as you would expect in 4 to 6 weeks. Also make an effort to sort out the psychosocial issues. Some patients may benefit from a sports-medicine approach, with aerobic exercise and weight training.

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Is intensive glycemic control worth the expense?

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IN 1993 THE LANDMARK Diabetes Control and Complications Trial (DCCT) demonstrated that patients with type I diabetes could delay the onset of complications by carefully controlling their serum glucose levels.[1]

However, such a regimen is expensive, since it requires more physician visits, patient education, and health status monitoring than

standard care. Is the benefit of intensive glycemic control of type I diabetes worth the cost? And perhaps even more important, is strict glycemic control cost-effective for patients with type II diabetes, who make up 90% to 95% of the people with diabetes?

The cost implications of these questions are immense. Care for people with diabetes consumes almost 15% of the health care expenditures in the United States, almost $100 billion annually.

Even though the DCCT did not study people with type II diabetes, intensive glycemic control is as cost-beneficial as many other medical interventions that are routinely funded. Thus it makes sense for the United States health care system to fund the more expensive monitoring and treatment necessary to achieve tight glucose control in people with type I and type II diabetes.

COST-EFFECTIVENESS: TYPE I

The DCCT found that strict glycemic control reduced the occurrence of severe nonproliferative and proliferative retinopathy by 47%, reduced clinical nephropathy by 54%, and reduced the incidence of neuropathy by 60%.[1]

The intensive treatment regimen's goal was to achieve levels of blood glucose as close to normal as possible. This was accomplished by more frequent self-monitoring of blood glucose levels (4 times a day vs once daily in the standard treatment group), administration of 3 or more insulin injections or use of an insulin pump rather than standard therapy of 1 or 2 injections per day, and monthly visits with a diabetes treatment team.

A subsequent cost-benefit analysis[2] estimated that if intensive glycemic control was implemented for all 120,000 Americans with type I diabetes who met the DCCT criteria (that is, who were between the ages of 13 and 39 and had no complications or were in the early stages of developing complications), it would result in the gain of 920,000 years of sight, 691,000 years free from end-stage renal disease, 678,000 years free from lower extremity amputation, and 611,000 years of additional life.

This cost-benefit analysis assumed that the patients would maintain a hemoglobin A_{1C} of 7% — the equivalent of a blood sugar level of 150 mg/dL — for life. This is an optimistic scenario, since the support services and supplies necessary to achieve this level of compliance are not paid for by most insurers. However, treatment that achieves a HbA_{1C} of 8% remains cost-effective, assuming that the cost of supplies and services is proportional to the effect on HbA_{1C}.

Certainly routine use of more intensive glycemic control would be expensive. In the DCCT trial, the cost of usual treatment was $1,666 a year, while the cost of caring for patients in the intensive treatment group was $4,545 a year.

Extended to all 120,000 in the type I population meeting the DCCT criteria, a regimen of intensive glycemic control would add $4 billion to health care costs over the lifetime of the population. That equates to an expenditure of $28,661 per year of life gained. If this is adjusted to account for the improvement in the patient's health-related quality of life, the cost falls to just under $20,000 per year of life gained.

Intensive glycemic control is well within the realm of what is considered cost-effective

Intensive control compares favorably with other common treatments

Treatments that cost the health care system $20,000 per year of life gained (such as the treatment of hypertension) are generally available to patients, and even treatments that cost as much as $100,000 per year of life gained, like liver transplants, are often available. Even though intensive glycemic control does not actually save money, these cost figures indicate that it is well within the realm of what is considered cost-effective.

COST-EFFECTIVENESS: TYPE II

For intensive glucose control to be cost-effective in type II diabetes, glucose must be the culprit in the complications of that disease, just as the DCCT trial demonstrated it is in type I diabetes. Current expert opinion, buttressed by several recent studies, is that hyperglycemia has certain toxic effects, whether the elevated glucose levels are caused by type I or type II diabetes.

One study[3] of diabetic retinopathy found that the relationship between complication

rates and hemoglobin A_{1C} levels was about the same, regardless of whether the patients had type I or type II diabetes. A study in Japan similar to the DCCT trial, except studying men who had type II diabetes, found a benefit from intensive control similar to the DCCT results.[4]

Granted, glucose is not the only factor that causes the complications of diabetes: genetic predisposition, hypertension, and smoking also play a role. Nonetheless, a fairly large part of the variance in microvascular complications is explainable by glucose, and that is correctable with intensive control. All of these factors support the concept that people with type II diabetes will benefit from intensive glycemic control.

CALCULATING COST-BENEFIT

We published a detailed model predicting the complications of type II diabetes with standard care and intensive glycemic control.[5] We also analyzed the health benefits and cost-effectiveness of treating type II diabetes patients with a goal of normoglycemia.[6]

Our analysis demonstrated that for the standard treatment for type II diabetes, the average lifetime cost per person (discounted 3% over time for the cost of money) was $62,769, while with intensive glycemic control, the cost increased to $76,922.

Under our analysis, the cost of managing intensive control almost doubled the cost of treatment over a lifetime, but that increase was offset somewhat by the decreased costs of complications (notably a reduction in end-stage renal disease). The net effect was a cost-effectiveness ratio of $16,000 per quality-adjusted life year gained.

A number of factors can affect this average calculation for a specific individual. For instance, the younger a person is at diagnosis, the more cost-effective is intensive therapy. On the other hand, if a person is 75 years old at the time of diagnosis of type II diabetes, then it becomes very expensive to treat that person aggressively, since with a life expectancy of five years or less, few complications can develop.

This may seem paradoxical, since a younger person has to be treated with a very expensive regimen over a longer period of time. Nonetheless, because prolonged intensive treatment is more likely to prevent severe and expensive complications, it is more cost-effective the earlier in life it is started.

Likewise, ethnicity can have a big effect on the cost-benefit calculation. African-Americans, Hispanic-Americans and Native Americans tend to get diabetes earlier, live with it longer, have greater hyperglycemia, and have greater hypertension and more comorbidities. As a result, the cost of intensive control in treating a member of one of these groups is much lower per year of life gained, about $4,000 to $5,000.

Finally, our cost-benefit analysis was conservative. It did not take into account any savings for a reduction in acute hospitalizations, peripheral vascular disease, the effects of macrovascular disease, and complications such as neuropathy-related sepsis. Nor did it consider cost savings from reduced disability payments for blindness, renal failure, or amputations.

WILL WE PAY THE ADDITIONAL COSTS?

These cost projections are very important as health care payers begin to look at the costs and benefits of diabetes treatment. If payers look at the cost of an intensive glycemic control regimen, which can be an extra $2,000 to $3,000 a year, they will see that this increased cost may not save them money for 20 years. This may not seem attractive to insurers, since many patients will have moved away or be on another health plan by the time the cost savings occur.

So why should health plans fund this preventive care if it is only going to cost them money? The point is, over the long run, it will save society morbidity and mortality. We have to take the societal perspective into account if we are going to do any preventive therapy. We currently take this perspective in treating hypertension and in coronary disease prevention, but we don't do it for diabetes. In fact, treatment of hypertension and coronary disease prevention may increase the population burden of microvascular complication by decreasing cardiovascular disease mortality.

I believe payers will choose to pay the increased cost of intensive glycemic control. It is a quality of care issue, and in any case, they

I believe payers will choose to pay the increased cost of intensive glycemic control

are paying now, although mostly for care of end-stage complications. In addition, a recent study[7] has shown that increases in worker productivity may offset the increase in the cost of providing intensive glycemic control.

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CORRECTION

The special supplement "Clinical practice guidelines: renal cell carcinoma"[1] contained an error. On page SI-29, a dosage of rHuIFN-α cited from preliminary results of a study by S. Negrier et al[2] was reported as 6×10^6 IU SC three times each week for both monotherapy and combination therapy. While this was the correct dosage for rHuIFN-α in combination with rHuIL-2, the correct dosage of rHuIFN-α as monotherapy should read 18×10^6 IU SC three times each week.

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