Surgeons, regardless of their specialty, and whether they practise in a community or academic institution, make decisions not only on the care of their patients but also on hospital and health care policy. Surgeons provide input to various committees in the hospital, to regional health districts and to national organizations that influence the adoption of new surgical innovations.

Clinical scenario

You are a general surgeon on the active staff of a community hospital. The last patient in your office is a 45-year-old automotive shop schoolteacher who has carpal tunnel syndrome. Your clinical examination and electromyographic and nerve conduction studies confirm the diagnosis. Since the anti-inflammatory agent and the splint previously prescribed by the patient’s family physician have not helped, you recommend carpal tunnel release. Your patient is a regular user of the Internet and he has researched carpal tunnel syndrome to such depth that his knowledge of the subject is startling. He requests that you perform the release endoscopically because he has read that the recovery from this method is faster than from the open method and he would like to return to his work as soon as possible. As the golfing season approaches he wishes to have the surgery with the technique that will cause less interference with his game. At the last conference you attended, a number of your colleagues were lauding this new technique (endoscopic carpal tunnel release) for its simplicity and stating that they can perform the procedure in 10 minutes. You make a request to the operating room committee that they purchase the endoscope because you intend to switch your practice from the open to the endoscopic method. The administrator of the hospital asks you to justify the cost.

The search

The ideal article addressing this surgical question would be one comparing endoscopic carpal tunnel release with the open method in which the costs and consequences were valued. From your office computer you enter the PubMed database (MEDLINE). In the Advanced Search field, the broadest term “carpal tunnel syndrome” is entered, and the articles published within the past 10 years are selected (i.e., filtered), generating 4060 citations. Next, the term “endoscopic release” is entered into the search field, generating 188 citations. Finally, the term “economic” is added to the search field, generating 12 citations. Of these, 3 articles discuss the clinical outcomes of endoscopic versus open carpal tunnel release, 4 articles describe the endoscopic technique, 1 article is a meta-analysis of endoscopic release as a method for treating carpal tunnel syndrome and 1 article is a letter to the editor on carpal tunnel syndrome. The remaining 4 articles deal with the question of cost-effectiveness. You print out the abstracts of these last 4 articles and carefully review them: 1 is published in a foreign journal and 1 does not compare the 2 procedures of interest. You obtain copies of the remaining 2 articles that deal specifically with the subject matter (“Endoscopic versus open carpal tunnel re-

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Introduction

When recommending the adoption of a new surgical intervention as opposed to maintaining the old one, surgeons need to consider the opportunity cost, which is the value of the forgone benefits because the resource is not available for its best alternative use. Therefore, the surgeon should weigh not only the benefits and risks of a surgical procedure but also consider whether the benefits provided by the new technique are worth spending the limited resources available to their institution. As the hospital budgets are fixed, resources expended on the new surgical technology are resources taken from another surgical program.

To make these decisions, surgeons can use economic analyses of surgical practices. Economic analysis is a set of formal, quantitative methods used to compare alternative strategies with respect to their resource use and their expected outcomes. Economic analyses can help to inform health care decision-makers on the best allocation of the limited resources.

There are 3 different types of full economic evaluation: cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis. In cost-effectiveness analysis the health outcomes are not valued but are reported in units such as life-years gained or cases successfully treated. Cost-utility analysis is a variant of cost-effectiveness analysis and is commonly encountered in studies originating from Canada and United Kingdom. The health improvement is generally measured in quality-adjusted life years (QALYs) and the results are expressed as cost per QALY gained. To calculate QALYs, the patient's utility score in various health states and the time spent in each health state needs to be measured. Utility is the preference or worth assigned to a particular health state on a scale for which 0 represents death and 1 represents perfect health. The utility scores are then transferred into QALYs. This transformation is beyond the scope of this article, and the reader is referred to other sources (D. Hong, C. Goldsmith, V. Tandan [tandanv@mcmaster.ca]: unpublished data, 2000). A cost-benefit analysis is the third type of economic evaluation. This type of analysis attaches a monetary value to the consequences of an intervention. Both cost-utility and cost-benefit analyses have an advantage over cost-effectiveness analysis because they permit a direct comparison of various programs, since both costs and consequences are reported in the same units (QALYs or dollars). The main criticism of cost-benefit analysis in health interventions is that it might show bias toward the rich, if their willingness to pay were higher than that of the poor.

The efficacy of a surgical intervention can usually be found in randomized controlled trials (RCTs) published in the surgical literature and accessed via MEDLINE. It is only recently that some RCTs have collected cost data concurrently. Surgical investigators can piggyback an economic evaluation into an RCT by collecting effectiveness data and costs simultaneously. This would be amenable to a stochastic analysis. However, such primary data are often not available, and investigators resort to performing economic analyses from secondary data obtained from previous RCTs or studies of lesser quality. Data for economic analyses can also be obtained by pooling data from multiple sources. When the costs and effectiveness are estimated from secondary data, the economic evaluation is called deterministic analysis. The main distinction between economic analyses and other studies is the explicit measurement and valuation of resource consumption and cost. When an economic evaluation is undertaken, the investigators measure the health outcomes and costs so that the 2 different surgical interventions can be compared.

This article is structured in the same format as previous articles in the evidence-based surgery series. The purpose of this article is to help you understand economic analyses when they are published in the surgical literature. It will explain how they are conducted and how to appraise their strengths and weaknesses. This article will apply the "User's guide to economic analysis of surgical practice" (Table 1) to both studies. If you intend to carry out economic evaluations, we would recommend additional sources that go into greater detail on the subject.

Are the results valid?

Did the analysis provide a full economic comparison of health care strategies?

Economic analysis compares 2 or more interventions. A full economic evaluation must consider both the costs and the outcomes or consequences. Often what we see in the literature are partial evaluations in which only the costs are compared. This is termed a cost analysis.

The study by Vasen and colleagues examined 2 outcomes—complications and return to work; however, these outcomes were only used to estimate costs. Owing to its lack of inclusion of explicit consequences, this study can be considered a partial evaluation or a cost analysis. This cost analysis is not ideal for comparing open and endoscopic carpal tunnel release and, therefore, will not be considered further in this article. On the other hand, the study of Chung and associates includes both costs and effects in terms of QALYs, making it a full economic evaluation.
Were relevant viewpoints considered?

A number of perspectives can be viewed in an economic evaluation, including the patient, the hospital, the primary payer or the societal perspective. When we consider costs and consequences, it is important that we are explicit as to which perspective we are using. The viewpoint chosen should depend on the question that is being asked. For example, in our clinical scenario (endoscopic carpal tunnel release) the relevant viewpoint would be that of the hospital. However, from the patient or societal perspective, the outcomes may be different. For example, from a patient’s perspective, a new surgical procedure that leads to an early discharge from the hospital may not be of benefit if the spouse must take time off work to care for the patient during convalescence. With the older surgical procedure the patient may have been hospitalized longer, but the spouse may have continued to work, thus costing the family less in the process. In contrast, from the hospital’s perspective the early discharge accomplished as a result of the new surgical technology may mean a lower cost to the hospital. There is a general agreement that a broader viewpoint, the societal perspective, is the most relevant for those who are concerned about the allocation of scarce health care resources.

The key methodologic features of the study by Chung and associates are presented in Table 2. This study stated that a societal perspective was used. However, careful review shows that the authors paid particular attention to the medical costs but less so to the indirect costs. For example, there was no explicit mention of the caregivers’ expenses in the article. The study used data from Transitions Systems Inc., a leading vendor of relational database software to the health care industry. According to Chung and associates “it is designed to allow integrated data analysis of cost and quality, using variables like direct and indirect costs...”. Also, Chung and associates did not provide information on the cost of productivity losses (wage loss); therefore, they took an incomplete societal viewpoint. The failure to account explicitly for the indirect costs is understandable as this study was based on secondary data. Data related to costs were not collected in the 2 randomized studies on which they based their economic evaluations.

Table 1

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<tr>
<th>Users’ Guide for Economic Analysis of Surgical Practice</th>
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<td><strong>Are the results valid?</strong></td>
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<td>• Did the analysis provide a full economic comparison of health care strategies?</td>
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<td>• Were relevant viewpoints considered?</td>
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<td>• Were all relevant clinical strategies compared?</td>
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<td><strong>Were the costs and outcomes properly measured and valued?</strong></td>
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<td>• Was clinical effectiveness established?</td>
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<td>• Were costs measured accurately?</td>
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<td>• Were data on costs and outcomes appropriately integrated?</td>
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<td>• Was appropriate allowance made for uncertainties in the analysis?</td>
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<td>• Are estimates of costs and outcomes related to the baseline risk in the treatment population?</td>
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<td><strong>What are the results?</strong></td>
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<tr>
<td>• What were the incremental costs and outcomes of each strategy?</td>
</tr>
<tr>
<td>• Do incremental costs and outcomes differ among subgroups?</td>
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<td>• How much does allowance for uncertainty change the results?</td>
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<td><strong>Will the results help in me caring for my patients?</strong></td>
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<tr>
<td>• Are the benefits worth the harms and the costs?</td>
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<tr>
<td>• Could my patients expect similar health outcomes?</td>
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<td>• Could I expect similar costs?</td>
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Table 2

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<th>Key Methodologic Features of the Study Reported by Chung and Associates</th>
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<td><strong>Feature</strong></td>
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<td>Overall study design</td>
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<td>Viewpoint for analysis</td>
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<tr>
<td>Alternatives compared</td>
</tr>
<tr>
<td>Benefit measure(s)</td>
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<td>Sources of effectiveness data</td>
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<td>Estimates of resource use</td>
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<td>Source(s) of cost data</td>
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<td>Discounting</td>
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<td>Sensitivity analysis</td>
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case the 2 RCTs. As it is widely known that recipients of workers' compensation benefits have pro-longed recovery and return to work, Chung and associates considered recipients and nonrecipients of workers' compensation benefits in their respective analyses.

**Were the costs and outcomes properly measured and valued?**

**Was clinical effectiveness established?**

The preferred economic evaluation comparing 2 surgical procedures is one in which economic data are collected alongside an RCT providing high internal validity. The weakness of such a study is the generalizability of the results. This type of study will have low external validity since the study subjects may not be typical of community practice owing to the very strict inclusion criteria set for the RCT. Pooling the results from many RCTs in meta-analyses helps to increase generalizability because the pooled estimate of effectiveness is derived from a wider spectrum of patients and uses a narrower confidence interval (CI). The number of RCTs and meta-analyses of surgical interventions is low, so health economists often utilize secondary data from studies with a lower level of evidence. Another problem that may arise in surgical studies is that the follow-up may be too short for the purposes of economic evaluation. Modelling studies that can make projections of long-term outcomes from short-term trial data relating to intermediate end points may be used to offset this problem of inadequate follow-up.

The study of Chung and associates was a cost-utility analysis, because the outcome was expressed as QALYs. As neither endoscopic nor open carpal tunnel release is expected to have an impact on the death rate, the interest is focused on how well the 2 surgical techniques improve the quality of life. In this study, the values of the health states were obtained from utilities provided by “experts” who were knowledgeable in the 2 interventions. By describing different scenarios corresponding to the various complications that can occur from the 2 surgical procedures, the “experts” were asked to mark on a vertical ladder from 0 (representing death) to 10 (representing perfect health). These utilities scores were then transformed into QALYs. There is evidence to support the premise that the utilities provided by “experts” correspond with utilities collected from real patients. However, this method is not ideal. Recently, there has been some dissenting opinion on this issue.

A preferable approach is to obtain utility scores directly from patients in the different health states by using a validated instrument such as the Health Utilities Index. The estimation of the costs and effects will depend on the perspective. In reporting costs, it is important to report the physical quantities of resources consumed or released by the surgical treatments separately from their prices. This is important as the price per quantity of an intervention varies among different locations, including provinces, states and countries. By such separation, an analyst in a different country can calculate the cost for the area of practice and reach a separate conclusion regarding cost-effectiveness of the new intervention.

Another difficulty with valuing costs is that published charges of a particular surgical intervention may differ from the actual costs, depending on the bargaining power of health care institutions, third-party payers and the profit margin in a for-profit health care system. If there is a significant difference between charges and costs, a charge-to-cost ratio may be used as a compromise. Chung and associates used surgical costs derived from Medicare and they justified these as the most accurate because they were obtained from Medicare’s Resource-Based Relative Value Units (RVUs) published in the Federal Register.

In addition, they considered surgical, anesthesia and hospital costs from a private non-profit hospital in Michigan in a sensitivity analysis.

**Were data on costs and outcomes appropriately integrated?**

On close scrutiny, some studies that purport to be cost-effectiveness analyses are not. A common error is to take the ratio of cost and effect of a surgical intervention and compare it to the ratio of the second intervention. When a comparison is made between 2 surgical interventions, we are interested in determining the extra benefit that is gained from the extra unit cost. This is called the Incremental Cost-Effectiveness Ratio (ICER).

The numerator of the ICER is the marginal difference of the mean cost of each intervention, and the denominator is the marginal mean difference of the effectiveness, as follows:

\[
\text{ICER} = \frac{\text{Cost}_{\text{experimental}} - \text{Cost}_{\text{traditional}}}{\text{Effect}_{\text{experimental}} - \text{Effect}_{\text{traditional}}}
\]

In general terms if one surgical intervention is both less expensive and more effective, then this procedure is dominant and is referred to as a win-win situation. There is no need to calculate an ICER in a win-win situation. Conversely, if it is more expensive and less effective, this is referred to as a lose-lose situation, and there is also no need to calculate an ICER.

In the article by Chung and associates, the endoscopic carpal tunnel release procedure was more effective, but it cost more both when the Medicare RVU calculations and private sector data were used. The marginal effectiveness was quite small, varying from 0.021 QALYs gained for the 65-year age group in the data published in the Federal Register, to 0.235 QALYs gained for the 25-year age group using the trial date of Brown and associates. Because of...
the small difference in effectiveness, change in the relative cost will have a large impact on the cost-effectiveness ratio. The private sector cost data from the United States are an overestimate of the true costs, in contrast to the Medicare costs, which may be more realistic. For example, the ICER was calculated and found to be US$237 per QALY gained for a 35-year-old patient using Medicare costs in the U.S. Chung and associates concluded that using this value, the endoscopic carpal tunnel release appeared to be cost-effective.

Discounting is another important issue that needs to be considered in an economic evaluation. Discounting is the valuation of costs and consequences over time. It is generally accepted that we prefer to obtain the benefits of an intervention sooner and postpone the costs for the future. In economic evaluations it is normally acceptable to discount costs and benefits occurring in the future to present values. The general agreement on the discount rate varies between 3% and 5%. In the study of Chung and associates, which was not necessary to discount the costs since the RCTs from which the data were obtained were less than a year in duration. Discounting is unnecessary in economic evaluations if the duration of the study is less than 1 year.

**Was appropriate allowance made for uncertainties in the analysis?**

If an RCT compared 2 surgical procedures and economic data were obtained simultaneously, then the sampled data could be subjected to statistical analysis obtaining means and variances. These calculations would permit an analyst to perform a sensitivity analysis by considering a range of estimates in both costs and effects and determine how the ICER is affected. For example, one may consider the costs to be 1 or 2 standard deviations from the means, and so forth. If the results obtained by considering different ranges of valuations in costs and effects produce the same answer, then one can conclude that the findings of the economic evaluation were robust and defensible.

Often the data available to the analyst are secondary, not obtained from RCT’s but from studies of lesser evidence value. In such a situation the uncertainty in the estimation of both costs and consequences is problematic. The conventional way of tackling this problem is again through a sensitivity analysis. In this case, in contrast to sampled data, we do not have means and variances. Instead, the probabilities of certain variables in both costs and effects are altered in a 1-way (varying one variable at a time) or 2-way sensitivity analysis (varying 2 variables at the same time). The choice in the variation of the probabilities needs to be defended by the authors. If the results of the ICERs are similar despite the sensitivity analyses, then one can conclude that the results of the study are robust and therefore believable.

Chung and associates performed a 1-way sensitivity analysis by using 2 different cost estimates: the Medicare costs and costs from a private hospital. In considering the 2 cost structures, they demonstrated that endoscopic carpal tunnel release was more expensive than the open method but was still cost-effective considering other procedures. A 2-way sensitivity analysis, varying both the QALYs and costs, was also performed. This calculation demonstrated that the cost-effectiveness ratio was highly dependent on the difference in the effectiveness data. The endoscopic carpal tunnel release is less cost-effective because of the small marginal effectiveness of endoscopic carpal tunnel release over the open method, the former having a higher incidence of a major complication such as median nerve transection. They identified that increasing the inadvertent transection of the median nerve by 1% made the endoscopic carpal tunnel release less cost-effective.

Economists are frequently criticized for not reaching firm conclusions. The reason for this is the uncertainty that accompanies the cost and effect estimates. The conclusions can be only as firm as the accuracy of the cost and effect estimations.

**Are estimates of costs and outcomes related to the baseline risk in the treatment population?**

The costs and outcomes of a surgical intervention are related to the baseline risk of the condition under scrutiny. Patients who are at high risk will generally benefit more from a procedure than those at low risk. Certain subgroups (age, sex) of patients may have a higher risk of a condition and are more likely to benefit from the new surgical intervention. Therefore, the ICERs may be dependent on the patient’s ability to benefit from the surgical intervention.

Chung and associates considered 5 different age groups in the ICER: 25, 35, 45, 55 and 65 years. The ICER increased with age, suggesting that this new surgical intervention was more cost-effective for the younger patients.

**What are the results?**

**What were the incremental costs and outcomes of each strategy?**

The first step we need to take is to look at the tables in the article that list the costs and outcomes of each surgical intervention. The costs considered in an economic analysis are the quantity of a resource used multiplied by its unit price. Therefore, these costs should be clearly identified so that a reader is able to calculate the costs or translate the costs in a particular setting. The upfront costs should include the surgeons’ fees, nursing time, anesthesia time, surgical supplies and operating room time. The downstream costs should include any future costs attributable to the surgical procedure such as removing a plate from a fractured ra-
dias 1 year after plate fixation. Depending on the perspective of the economic evaluation, there may be other downstream costs to society and the patient. Using the same example, downstream costs to society may include productivity losses for the patient during recovery from the second operation (plate removal), and downstream costs for the patient may include physiotherapy and medications (if not covered by private insurance) during the same period.

Chung and associates did not quantify the resources consumed as they chose a decision analytic model for their economic evaluation. However, they provided tables comparing the surgery, anesthesia and hospital costs for the 2 surgical techniques. They also provided the probabilities of the health states associated with some key complications of the 2 techniques as well as the utilities of these health states. The marginal costs and marginal effectiveness are summarized in their Table IX of their article (page 1096). In this table, the authors included the marginal costs separately from Medicare and private practice and used the costs from 2 different RCTs. The utilities transformed into QALYs are shown in their Table VIII. In both tables they also subdivided the findings into the 5 age groups previously mentioned. Finally, the authors integrated the data into their Table X with calculated ICERs. Using the data from the RCT by Brown and associates, the ICER (in US dollars) for a 35-year-old patient was $237/ QALY for the Medicare and $3983/ QALY for private sector care. When the data from the other RCT were used, the ICER for a 35-year-old patient was $940/ QALY for Medicare and $30 999/ QALY for private sector care.

Do incremental costs and outcomes differ among subgroups?

As you go carefully over the results summarized in Table X of Chung and associates’ paper, you immediately notice that the ICER varies with age. The ratio increases progressively from age 25 to 65 years. The same trend applies to both RCTs and also to the different settings (Medicare and private sector). The message you get from this is that the new technology, endoscopic carpal tunnel release, looks to be more cost-effective for the younger than the older patient.

How much does allowance for uncertainty change the results?

Chung and associates demonstrated that the cost-effectiveness ratio was highly dependent on the differences in the effectiveness data. The small marginal effectiveness of endoscopic carpal tunnel release over the open method and a higher incidence of a major complication such as median nerve transection will make the endoscopic carpal tunnel release less cost-effective. Unfortunately, they have not tabulated the results of these sensitivity analyses. Clearly one must be very cautious in applying results from studies in which a small change in an outcome measure can result in a change in direction of the ICER (i.e., from a cost-effective state to a non-cost-effective state).

Will the results help me in caring for my patients?

The next step is to interpret the ICER in decision-making and to ascertain the extent to which the costs and effects from the study of Chung and associates can be applied to your practice setting.

Are the treatment benefits worth the harms and costs?

When one surgical treatment is compared to another, there are 9 possible outcomes (Table 3). This 3 x 3 matrix shows clearly these 9 possibilities, which consider whether a treatment may be more costly, the same or less costly and more effective, the same or less effective.

In cell 1, a new surgical intervention will be less expensive and more effective than the standard treatment. This surgical intervention is said to be dominant and provides strong evidence to adopt it. There is no need to go any further with ICER calculation in such a case. In cell 2, a new surgical intervention costs more and is less effective than the traditional treatment. This represents strong dominance in favour of rejecting the new surgical intervention. Cells 3 to 6 all indicate comparative cost and effectiveness combinations that provide evidence of strong or weak dominance. Cells 8 and 9 require further analysis. Our interest lies in cell 7, which represents the most commonly encountered situations with the introduction of new technologies, such as the one we are exploring. The study of Chung and associates falls clearly in cell 7 as the endoscopic technique is more effective than open carpal tunnel release but is also more expensive.

Chung and associates estimated an ICER of $237/ QALY by using the data from the RCT of Brown and associates and the Medicare costs. How then can we interpret this ratio? Is $237 an acceptable price to pay for an additional year of life? The answer

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<td>Incremental effectiveness</td>
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is not simple. The interpretation of ICERs and the opportunity costs need to be considered.

Quantitative thresholds for cost per QALY gained have been proposed by Laupacis and associates on review of economic evaluations and previously published guidelines by Kaplan and Bush. Laupacis and associates suggest that if a new program is more effective and more costly than the existing one and costs less than $20,000 per QALY gained, there exists strong evidence for adoption of the new program. Similarly, $100,000 per QALY gained provides moderate evidence for adoption of the new program. Similarly, $100,000 per QALY gained provides weak evidence for adoption and strong evidence for rejection. According to these thresholds, the cost–utility analysis of Chung and associates, using the $237 per QALY gained (data from the Brown and associates RCT and Medicare costs) shows strong evidence for adoption of endoscopic carpal tunnel release.

**Could my patients expect similar health outcomes?**

Once you understand the results of the study, you need to determine how they apply to your surgical practice. There are 2 issues that need to be resolved. The first issue is whether the evidence of the 2 RCTs used by Chung and associates forms the basis for the estimated treatment effect and whether this can be applied to any jurisdiction. The second issue is the extent to which the observed effect and cost data are transferable to other jurisdictions. To assess whether patients in your practice can expect the same outcomes you should consider the following: Are your patients similar to those mentioned in the 2 RCTs, and is the surgical treatment of your patients similar to that in the 2 RCTs? If, on careful review of the 2 RCTs from which the outcome data were taken, you find no deviation in exclusion and inclusion criteria, then you can be assured that your patients are likely the same as those in the study.

**Could I expect similar costs?**

One should remember that the cost of a surgical intervention is the summation of the product of physical resources consumed (surgery, nursing time, tests) and their unit prices. Cost data may not be transferable from one jurisdiction to another. For example, the estimated costs assembled by Chung and associates are not applicable to a Canadian surgeon whose carpal tunnel release has one fee, which is a fraction of the equivalent surgical fee in the US. The multiple third-party payers in the US make American economic evaluations more complex than Canadian economic evaluations where there is only one party payer — the provincial ministry of health. Therefore, it is important that authors of economic evaluations articles report resource use and costs separately so that readers will be able to ascertain whether practice patterns and prices apply to their own setting.

Chung and associates reported their costs and effects separately, which made it feasible to substitute Canadian costs in place of American data. This substitution enables us to recalculate the ICER and consider it in our setting.

The means by which we could apply the study data to our own setting was manageable in the present study, but it can cause some problems when the data are obtained from RCTs spanning different countries with different cultures. Variation in the prices of surgical interventions can threaten the validity of cross-country inferences.

**Resolution of the scenario**

Returning to the original scenario, and based on what we have learned so far, we are ready to make a decision. It is evident by now that endoscopic carpal tunnel release, a new surgical technology is more expensive but also more effective (Table 3, cell 7).

The sources of the costs for each procedure are provided by Chung and associates. However, all of the costs are based on the US health care system and are meaningless to you (a Canadian surgeon). You can identify the costs for the physician fees, surgical fees, hospital costs and physiotherapy costs in Canadian terms from the provincial schedule of benefits for each province. Additionally, the direct hospital costs can be obtained from individual hospital finance departments. Patient and caregiver costs should also be estimated if you are using a societal viewpoint. The costs values can then be added into a decision analytic model. You then calculate the ICER. If the results are less than $20,000 per QALY gained, then there is strong evidence to adopt the new (endoscopic) procedure. However, you are cautious in accepting the results because the cost-effectiveness ratio was highly dependent on the differences in the effectiveness data in the sensitivity analysis. Therefore, a small change in an outcome measure can result in a change in direction of the ICER (i.e., from a cost-effective state to a non-cost-effective state). You are also aware of the limitations of the study that were previously mentioned.

You inform the hospital administrator about the economic analysis you reviewed and the calculation of the ICER in a Canadian context. You and the committee, however, are aware of the opportunity costs from introducing this technology in your hospital. After reviewing the sensitivity analyses and the resulting variation in the ICER in different age groups, you and the operating room committee agree to reserve the endoscopic carpal tunnel release for patients under the age of 45 years and continue using the open method for the older patients. You will continue to monitor the literature for future economic evaluations comparing the...
2 techniques of carpal tunnel decompression that may provide stronger evidence for or against endoscopic tunnel release.

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