Point/Counterpoint:

Debating the Cost-Effectiveness of a Glaucoma Surgical Device

This technology does not merit the extra cost.

BY STEVEN KYMES, PHD

In a recent presentation for the American Glaucoma Society, Hennen and colleagues reported results from a retrospective cohort study of 353 patients. They found that the use of the Ex-Press Glaucoma Filtration Device (Alcon) added $784 to the cost of glaucoma surgery for patients undergoing a single procedure (ie, incisional surgery alone) and $495 when the glaucoma surgery was performed in combination with phacoemulsfication.[1] This represents an increased cost in excess of 15% to be borne by US taxpayers, as most glaucoma patients are Medicare beneficiaries. Approximately 25,000 trabeculectomies are performed in the United States every year.[2] Transitioning all of these to the use of the Ex-Press would place a burden of $10 to $30 million on the already overburdened US financing system. Although this is a "drop in the bucket" within the $1.5 trillion health care system, it is an expenditure that should give pause to the responsible clinician or health policymaker.

Employing appropriate methods of economic evaluation, Hennen et al found that use of the Ex-Press was "dominated" by traditional trabeculectomy. Specifically, her team reported that surgery with the Ex-Press was more expensive but less effective than trabeculectomy

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Assessments need to account for more than the cost of the implant.

BY LEON W. HERNDON, MD

Ever since the FDA cleared the Ex-Press Glaucoma Filtration Device (Alcon) in 2002, the glaucoma community has debated the implant's appropriate use.

RESEARCH ON COST

At the 2014 annual meeting of the American Glaucoma Society, Stella Hennen, MD, presented the results of a retrospective chart review with 3-year post-surgical outcomes for 343 patients who underwent placement of the Ex-Press with or without cataract surgery compared to trabeculectomy procedures with or without cataract surgery.[1] She and her fellow investigators calculated the cost-effectiveness of the procedures by comparing the incremental cost-effectiveness ratio to the policymaker's willingness to pay to determine quality-adjusted life years. Dr. Hennen and colleagues concluded that the device was not a cost-effective alternative to trabeculectomy.

Last year, Yvonne Buys, MD, published an economic analysis comparing surgery using the Ex-Press to trabeculectomy in Canada. Dr. Buys stated that the significantly greater cost of Ex-Press surgery would likely be the main barrier to the procedure's widespread adoption.[2]

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in all outcomes: IOP, visual acuity, and mean deviation. Why, then, would a clinician choose to perform a procedure with the shunt? Two advantages are often presented by Ex-Press advocates: (1) patients who receive the device have a shorter recovery time than after standard trabeculectomy surgery and (2) use of the implant improves surgical productivity by reducing procedural time for the surgeon and facility compared with trabeculectomy. If the Ex-Press were costless, either of these points would justify its widespread use, but of course, that is not the case.

RECOVERY TIME

In their retrospective study, Hennen and colleagues found that, at 36 months postoperatively, visual outcomes favored the traditional trabeculectomy. Let us assume that both Hennen, who found statistical equivalence at 3 years, and advocates of the Ex-Press, who claim early advantage for the device, are correct. Traditionally, economic evaluation is carried out by means of cost-utility methods, which use quality of life as the measure of effectiveness.[3] According to this method, an intervention is considered to be cost-effective if the cost per quality-adjusted life year is less than $100,000.[4] If we assume this to be the case, the $784 increase in cost associated with the shunt would be justified if it resulted in an improvement in quality of life sufficient to meet this standard. The difference in quality of life between mild and severe glaucoma is 0.06 quality-adjusted life years.[5] Based on this, we estimate that the added expense of the Ex-Press would only be justified if recovery occurs, on average, 83 days earlier with the device (for the phacoemulsification group, recovery would have to be 60 days earlier). No report has claimed a difference of this magnitude.

SURGICAL TIME

Dispensing with the argument that the additional cost of the Ex-Press is justified by shorter surgical times does not require complicated economic analyses. As noted earlier, in the United States, most people who undergo glaucoma surgery are Medicare beneficiaries. The higher cost of the Ex-Press procedure, therefore, is only justified if the benefit of this expenditure accrues to the beneficiaries and taxpayers who fund the Medicare Trust Fund. To the contrary, while the cost of the Ex-Press is borne by the American taxpayer, the benefit of greater efficiency accrues to the surgeon and surgical center that are able to increase throughput due to shorter surgical times—leading to higher revenues and profit. If a surgeon believes that the Ex-Press improves surgical efficiency, then the device should be paid for by the surgeon or the surgical center out of their increased profit, not by the patient or health insurance plan.

CONCLUSION

Technological innovation has provided miracles that preserve or restore the vision of patients who previously would have been consigned to live in darkness. If all are to enjoy the benefits of technology, we must use health resources wisely. There is no evidence that the widespread adoption of the Ex-Press creates value for society or for glaucoma patients. It should not enjoy the support of the vision community.

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1. Hennen SN, Lambert D, Stwalley DL, et al. Comparison of cost-effectiveness of Ex-Press shunt and trabeculectomy. Paper presented at: American Glaucoma Society 24th Annual Meeting; February 27, 2014; Washington, DC.
2. Ramulu PY, Corcoran KJ, Corcoran SL, Robin AL. Utilization of various glaucoma surgeries and procedures in Medicare beneficiaries from 1995 to 2004. *Ophthalmology*. 2007;114(12):2265-2270.
3. Kymes SM. An introduction to decision analysis in the economic evaluation of the prevention and treatment of vision-related diseases. *Ophthalmic Epidemiol*. 2008;15(2):76-83.
4. Gillick M. Medicare coverage for technological innovations: time for new criteria? *N Engl J Med*. 2004;350(21):2199-2203.
5. Lee BS, Kymes SM, Nease RF Jr, et al. The impact of anchor point on utilities for 5 common ophthalmic diseases. *Ophthalmology*. 2008;115(5):898-903 e894.

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BEYOND THE DEVICE

When evaluating the cost of any new technology, the assessment must include more than the cost of the device. It must also consider the cost to the provider and to the patient. For the former, it must weigh opportunity costs such as length of the procedure and the time involved in postoperative visits. In my experience, the difference in procedural time between standard trabeculectomy surgery and trabeculectomy with the Ex-Press is negligible. I find that the number of postoperative visits, however, is considerably lower for patients who receive the device than for those who undergo standard trabeculectomy surgery. This means more time in a typical clinical day for revenue-generating visits.

With regard to the patient, the main costs relate to postoperative visits and recovery. Most published studies support my clinical experience of fewer postoperative visits for patients who receive the implant. This means

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less potential income lost and lower transportation expenses for the patient and any caregivers.

One area in which the Ex-Press appears to be consistently superior to standard trabeculectomy is the rate of visual recovery after surgery. In a comparative study, Beltran-Agullo et al showed that, at any time point, eyes that underwent trabeculectomy were more likely to lose more than 2 Snellen lines of visual acuity. They also reported that the Ex-Press eyes recovered visual acuity faster.[3] In a retrospective study comparing surgery with the Ex-Press to standard trabeculectomy, Good and Kahook found that patients in the former group returned nearly to baseline levels of visual acuity by the 1-week postoperative visit versus 1 month for trabeculectomy patients.[4] In a randomized, prospective trial comparing the two surgical procedures, Netland et al found that the Ex-Press patients had returned to baseline visual acuity by the 1-month visit but that the standard trabeculectomy patients had not returned to baseline visual acuity until the 3-month visit.[5]

Although most studies show no difference in long-term outcomes between surgery using the Ex-Press and trabeculectomy, they demonstrate a smoother early postoperative course favoring the device.[3-6] The significance of this finding should not be underestimated. Certainly, quicker visual recovery is crucial in a monocular patient, but I would argue that all patients would choose the surgery that allows them to resume their activities of daily living sooner.

CONCLUSION

I agree with Arthur Sit, MD, that the Ex-Press is a sustaining rather than a disruptive technology, so the decision whether or not to use the device is based on the individual doctor-patient relationship.[7] To those who argue that the device is not cost-effective, however, I would suggest that the ability to function sooner after glaucoma surgery is priceless. If you required glaucoma filtration surgery and had to choose between standard trabeculectomy and Ex-Press device surgery, which one would you choose? ■

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1. Hennen SN, Lambert D, Stwalley DL, et al. Comparison of cost-effectiveness of Ex-Press shunt and trabeculectomy. Paper presented at: American Glaucoma Society 24th Annual Meeting; February 27, 2014; Washington, DC.
2. Buys YM. Trabeculectomy with ExPress: weighing the benefits and cost. *Curr Opin Ophthalmol*. 2013;24:111-118.
3. Beltran-Agullo L, Trope GE, Jin Y, et al. Comparison of visual recovery following Express versus Trabeculectomy: results of a prospective randomized controlled trial [published online ahead of print June 25, 2013]. *J Glaucoma*.
4. Good TJ, Kahook MY. Assessment of bleb morphologic features and postoperative outcomes after Ex-Press drainage device implantation versus trabeculectomy. *Am J Ophthalmol*. 2011;151:507–513.
5. Netland PA, Sarkisian SR, Moster MR, et al. Randomized, prospective, comparative trial of Ex-Press glaucoma filtration device versus trabeculectomy (XVT Study). *Am J Ophthalmol*. 2014;157:433-440.
6. Marzette L, Herndon LW. A comparison of the Ex-Press mini glaucoma shunt with standard trabeculectomy in the surgical treatment of glaucoma. *OSLI Retina*. 2011;42:453-459.
7. Sit AJ. Evaluation and adoption of new technology in glaucoma surgery. *Am J Ophthalmol*. 2014;157:263-265.