Is it worth €739m to avoid one case of bilateral endophthalmitis? Economic case made for same-day bilateral cataract surgery, but patient safety concerns remain

ASK a surgeon why cataract surgery shouldn’t be done on both eyes in one session and you’re likely to hear that it’s a necessary precaution to avoid blinding a patient due to bilateral endophthalmitis, or possibly toxic anterior segment syndrome (TASS).

Yet over the past 30 years only four cases of bilateral endophthalmitis have been reported in the medical literature, and all of them were linked to documented sterilization problems, Steve Arshinoff MD, Ontario, Canada, told a symposium at the XXVI Congress of the ESCRS. However, one case of bilateral endophthalmitis using a sterile technique that did not result in a poor visual outcome has recently been reported in the UK. Not a single case of bilateral TASS has yet been reported, Dr Arshinoff added.

Dr Arshinoff, who claims he may be the loudest, if not the most prominent, proponent of simultaneous bilateral cataract surgery (SBCS), says that in 3,000 consecutive patients, on whom he has performed SBCS since 1996, he has not observed a single bilateral presentation of any serious complication. He says the same was true for about 30,000 additional cases he gathered information on through an informal survey of surgeons performing bilateral procedures throughout the world.

Dr Arshinoff acknowledged that there are contraindications for same-day bilateral cataract surgery, such as increased risk for infection or corneal decompensation. And while he allows that a serious complication in the first eye is reason to postpone the second surgery to another session, he also believes that there is a distinct advantage to operating immediately on the second eye in patients presenting iris control problems or other less serious intraoperative challenges. Because the nature of the problem is fresh in your mind, you know what to expect, he explained.

“You are more relaxed, the patient is more relaxed and you already have one successful outcome behind you.”

Bilateral surgery patients also are often more satisfied because they get it all over with in one encounter instead of two, Dr Arshinoff said. He also believes implanting two lenses at once can speed the process of neuroaccommodation to multifocal lenses. Based on his own impressions and informal data collection, bilateral surgery also has the potential to significantly cut costs, he noted. It may also reduce waiting times for surgery in resource-short countries.

Still, many eye surgeons remain sceptical if not outright opposed to operating both eyes for cataracts simultaneously. Despite a growing understanding of precautions that must be taken to ensure sterility in the second eye surgery, and a growing volume worldwide of bilateral surgery, many believe there are too many unknowns and it’s just not worth the risk.

Study suggests millions of euro could be saved without increasing risk

Exactly how much could be saved by increasing SBCS was the subject of a prospective study presented by Tiina Leivo MD, M.Sc (Econ.) Helsinki University Eye Hospital, Finland. By her calculations, as much as €1,600 could be saved each time a simultaneous bilateral procedure is performed in place of two separate operations.

To evaluate the cost-effectiveness of simultaneous bilateral surgery versus sequential surgeries, Dr Leivo and her colleagues enrolled 520 patients in a randomised trial, with half assigned to bilateral surgery on the same day and half to having the two eyes done one month apart. The main clinical outcome measures were postoperative refraction, complication rates and patient satisfaction. Cost outcomes were determined by reviewing direct and indirect costs to both the healthcare system and the patients.

With 94 per cent of enrolled patients completing the trial, clinical outcomes were comparable in the two groups, Dr Leivo said. The rates of adverse events, post surgery best corrected vision, refraction, functional vision measured by the VF-7 questionnaire and patient satisfaction scores all were similar.

“So if the clinical outcomes are similar it is no longer a cost effectiveness comparison, it is simply a cost comparison,” Dr Leivo said.

In terms of cost, there was no comparison. Considering only the direct medical costs of care, such as surgeons’ pay, other clinical staff, operating room time and office overhead, the savings per patient in the bilateral group came to €447. Add in direct non-medical costs incurred by the patient, such as transportation, and the savings rises to €739. With less time lost for work, the cost advantage of the bilateral procedure rises to €843. If you include the reduced cost of the time for the patient’s family to act as caregivers, the total savings of bilateral surgery came to €1,625.

Looking at this from a system perspective, Dr Leivo pointed out that if Finland (with a population of just five million) converted one third of its cataract procedures, although the company producing the device received an additional €235 million, the total savings of bilateral surgery came to €739m per case avoided.

Economic vs. patient health interests

Not everyone agrees, however, that enough research has been done to rule out the possibility that simultaneous bilateral surgery might increase the risk of serious bilateral complications.

“The published series to date have insufficient numbers to be definitive about the rate of such complications,” said Narman Puvanachandra MB, BChir, MA, FRCSocPh, who reported in the June 2008 Journal of Cataract and Refractive Surgery what he believes is the third published account of a patient who experienced bilateral endophthalmitis after undergoing separate sterile phacoemulsification cataract procedures in the same operative session.

In the case Dr Puvanachandra reported, the 81-year-old patient recovered after administration of intravitreal antibiotics and went on to achieve an excellent visual outcome. Other potential serious bilateral complications include corneal decompensation, increased intraocular pressure, cystoid macular oedema, uveitis and refractive surprise.

“There must always be a risk of bilateral complications,” he said.

James Salz MD, Los Angeles, US, agrees. “In the US [simultaneous bilateral cataract surgery] is considered beneath the standard of care. If a doctor gets in trouble and both eyes go bad, he will have a hard time medico-legally defending it,” said Dr Salz, who is a board member and risk management committee member for the Ophthalmic Mutual Insurance Company (OMIC), which insures about 3,600 ophthalmologists throughout the US.

In fact, OMIC will not insure surgeons who perform simultaneous bilateral cataract procedures, although the company will cover simultaneous bilateral LASIK because it is not a globe-penetrating procedure, Dr Salz added.

“You will never convince me that it is in the best interest medically to do both eyes.
It may be better from a convenience and economic standpoint, but I don’t think it is medically better. CME may be rare but you can get it even with perfect surgery. If you had it in both eyes you’d be in trouble.”

Other observers, such as Peter Barry, FRCS, Dublin, Ireland, lead investigator of the landmark ECRS endophthalmitis prophylaxis study, point out that while there may be no definitive published studies linking bilateral surgery to higher rates of bilateral complications, the fact that some complications appear to be anecdotal in origin may increase the risk of bilateral complications.

For example, about 10 years ago in Germany an outbreak of endophthalmitis affecting about 30 patients within a 30 mile radius near Dusseldorf resulted from a batch of contaminated infusion solutions bought “on the cheap” by a central purchasing officer without authorisation, Dr Barry said.

“In this scenario, no amount of proper precautions taken preoperatively could ensure sterility.”

Similarly, widespread outbreaks of TASS have been traced to contaminated solutions, and localised outbreaks to inadequate instrument sterilisation procedures, Dr Salz noted. Systemic problems such as these could expose both eyes to the same set of infectious or allergenic agents, leading to serious bilateral complications, he said.

“When we start making clinical decisions that carry an extra risk to a patient for economic reasons then I think we have neglected our basic duties as doctors, especially when the potential outcome of bilateral blindness would be devastating for that individual. Only one such complication would be necessary to make you question your own practice, and so to switch your entire practice to bilateral surgery would be a bold step,” Dr Puvanachandra said.

Surgical skill and sterile technique are paramount

That’s not to say that Dr Puvanachandra opposes SBCs. He believes it is appropriate in cases where the risk of a second surgery outweighs the potential for bilateral complications, such as when a patient needs general anaesthesia, but two anaesthetics are not desirable.

This is consistent with practice recommendations by major ophthalmological societies. For example, the American Academy of Ophthalmology’s (AAO’s) Preferred Practice Pattern states, “bilateral simultaneous surgery has advantages and disadvantages that must be carefully weighed.” It may be indicated in cases where the health of the patient allows only one surgery and in rare cases where travel and follow-up for additional surgeries create significant hardship or risk for the patient. “If bilateral surgery is considered as an option, the patient should be carefully informed of the potential disadvantages,” the AAO statement says.

Similarly, the UK Royal College of Ophthalmologists cataract guidelines call for informing patients of the risk of simultaneous surgery and avoiding it except in unusual circumstances, such as a need for general anaesthesia. “The ophthalmologist should be prepared to justify the decision to perform bilateral cataract surgery on grounds other than convenience,” the guidelines say.

Dr Arshinoff believes that patient risks not directly related to surgery also should be taken into consideration when making a risk-benefit analysis for simultaneous surgery. Patients with significant bilateral cataracts or who become asymmetrical as a result of unilateral cataract surgery may be at higher risk of injuries due to auto accidents, falls, and other mishaps related to lack of functional binocular vision.

Dr Puvanachandra suggested that reducing the risk of bilateral complications starts with patient selection. He recommends eliminating patients with glaucoma or uveitis; patients with guttata and corneal dystrophies because they are at risk of corneal decompensation; patients with blepharitis, diabetes, or who are immuno-compromised or allergic to iodine because they are at higher risk of infection; and those with high refractive errors or with unusually long or short axial lengths because they are at higher risk for refractive surprise. “This really excludes a lot of people,” he said.

Both Dr Arshinoff and Dr Leivo emphasised the need for rigorous operating room sterility procedures, including an entirely sterile set of instruments and drapes for operating the second eye, as well as experienced surgeons for effective implementation of bilateral procedures. To reduce the chances of infections or allergic reactions related to systemic causes, Dr Arshinoff recommended using BSS, viscoelastics and other injectables from different lots or even different manufacturers in the two eyes, and using instruments sterilised in separate batches for the two surgeries.

Dr Puvanachandra adds to that list complete rescrubbing for surgeon and assistants between surgeries, povideon foam in fornix pre-op and lashes, and stepped incision with postoperative hydration to retain incision integrity, and intracameral antibiotics.

Johann Kruger MD, of TygerValley Eye and Laser Center, Cape Town, South Africa, also emphasised the need for sterile procedures and recommended routine use of intracameral antibiotics in simultaneous bilateral procedures. He also stressed the need for accurate biometry to choose the correct lens the first time, which is more important if both are being implanted at the same session.

Dr Kruger, who presented his own survey showing that about 30 per cent of South African cataract surgeons do bilateral procedures, also pointed out other impediments to successful bilateral surgery. These include patient support after the operation, which is more difficult after a bilateral procedure. Other reasons his colleagues gave for not wanting to do bilateral procedures were fear of the “refractive surprise” and lawsuits. A few answered, “It’s not the right thing to do.” Among the 30 per cent who did do bilateral procedures, the most often cited reason for doing so was logistics and patient preference, particularly when the patient had to travel a long way for service.

However, both Dr Arshinoff and Dr Leivo believe that in the absence of clinical evidence that it poses any harm, the economic advantages of simultaneous bilateral procedures will greatly increase their popularity worldwide.

Still, Dr Puvanachandra urges caution. “The bottom line is that experienced surgeons who do immediately sequential cataract surgery are extremely careful to avoid bilateral complications.