Patient safety must be a priority in all aspects of care

In December, 2013, the Society of Gynecologic Oncology (SGO) released a position statement regarding intracorporeal morcellation, a technique by which tissues excised during minimally invasive surgery are cut up to facilitate removal through small excisions, which might increase the risk of disseminating tumour cells. The statement follows the case of a Harvard anaesthetist who had a hysterectomy involving intracorporeal morcellation at Brigham and Women's Hospital, Boston, MA, USA, to treat presumed benign fibroids, and was subsequently found to have leiomyosarcoma; the patient is now being treated for stage IV disease. Subsequent to this case and another similar incident at the same hospital, the chair of obstetrics and gynaecology issued a note to medical staff warning that morcellation of an occult tumour may occur in between one in 400 and one in 1000 women who have this procedure—a risk at least ten times higher than previously assumed. The department head also cautioned staff that destruction of tissue could make it difficult for pathologists to determine the size of a tumour and extent of tissue invasion. The recommendation of the department head and the SGO is to ensure this risk is discussed with patients as part of the informed consent procedure before surgery. In view of the strong risk of developing high-grade cancer following the procedure, this advice is prudent, but does it go far enough?

Minimally invasive surgery does, of course, have major advantages and the advent of these techniques has heralded an era of shorter hospital stays, lower infection risk, quicker recovery times, reduced use of donor blood, and less scarring. Since the introduction of these techniques, an array of devices has poured onto the market, often carrying a hefty price tag. Robot-assisted laparoscopic devices and power morcellators are examples. In most areas of life, new technologies are received with an implied assumption that they are better than the device or procedure they are intended to replace, and so seems to be the case in medicine. However, contrary to the situation with new drugs, medical devices do not have to undergo such rigorous testing and safety profiling before they are propelled into everyday clinical practice by the manufacturers' extensive, unregulated marketing. The attitude prevails that new and expensive equipment must be an advance. New techniques and devices are widely adopted, and often only regulated when evidence of harm accumulates. This situation is unacceptable.

Patients have no choice but to trust the good judgement of their surgeons, and in return treating physicians should consider the best treatment for their patients based on available evidence. It is not practical to subject every new surgical procedure to the same trial processes as new drugs, but nevertheless structured follow-up and full reporting of adverse events should be the minimum standards. Guidelines should err on the side of caution where hazards are reported, as has been the case with intracorporeal morcellation—the risk of disseminating malignant cells by morcellation has been shown numerous times over the past couple of decades. Furthermore, power morcellation, which effectively minces the tissue, probably carries an inherently higher biological risk than manual morcellation. It is difficult to understand why the SGO has taken such a soft line.

Professional bodies and regulators should be proactive in ensuring that safety data is adequately reviewed before making recommendations for new devices and techniques. A black-box warning system could be implemented for devices to flag serious safety concerns. Regulators should monitor manufacturers to ensure they share responsibility for informing patients and clinical users of their equipment about any safety issues. For instance, the patient information website for one manufacturer's minimally invasive system extols the benefits of the system in hysterectomy for a range of conditions—including cancer—but fails to mention that morcellation could spread cancer cells. Companies should be obliged to make known risks clear, and not selectively report published literature in their marketing. This problem needs urgent attention, not only because hysterectomy is extremely common and a one in 400 risk of morcellating an occult tumour is unacceptable, but also because these techniques are used in a wide range of settings. The problem is amplified by the number of unregulated devices and procedures used across the whole sphere of clinical activity. Patients must be protected by stringent safety standards in every aspect of their clinical care. New techniques and devices should be proven safe before widespread acceptance, rather than being widely used until proven hazardous. ■ *The Lancet Oncology*

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For the **Society of Gynecological Oncology's position statement** see https://www.sgo.org/newsroom/position-statements-2/morcellation/