Ethical Issues Associated With the Introduction of New Surgical Devices, or Just Because We Can, Doesn't Mean We Should

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Abstract

Surgical devices are often marketed before there is good evidence of their safety and effectiveness. Our paper discusses the ethical issues associated with the early marketing and use of new surgical devices from the perspectives of the six groups most concerned.

Health Canada, which is responsible for licensing new surgical devices, should amend their requirements to include rigorous clinical trials that provide data on effectiveness and safety for each new product before it is marketed.

Industry should comply with all Health Canada requirements to obtain licenses for new products. Until Health Canada requires effectiveness and safety data, industry should cooperate with physicians in appropriate studies before releasing new products and should make balanced presentations of all the available evidence.

Surgeons should, before using a new surgical device, assess the evidence on its effectiveness and safety and ensure they are properly trained and competent in using the device. Surgeons should provide their patients with an evaluation of the available evidence and inform them about possible complications and the surgeon's level of experience with the new device,

Patients, who should be given an honest evaluation of the available evidence, possible complications, and the surgeon's experience, should be encouraged to evaluate the evidence and information to their own satisfaction to ensure that fully informed consent is given.

Health institutions, responsible for regulating practice within their walls, should review new devices for safety, effectiveness, and economic impacts, before allowing their use. They should also limit the use of new surgical devices to surgeons trained and competent in the new technology.

Professional societies should provide guidance on the early adoption of new surgical devices and technologies.

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We urge all those involved in the development, licensing, and use of new surgical devices to aim for higher ethical standards to protect the health and safety of patients requiring surgery. The lowest acceptable ethical standard would require device manufacturers to provide surgeons with accurate and timely information on the efficacy and safety of their products, allowing surgeons and patients to evaluate the evidence (and the significance of information not yet available) before surgery.

Résumé

Les instruments chirurgicaux sont souvent mis sur le marché avant l'obtention de données fiables quant à leur innocuité et à leur efficacité. Notre article traite des questions éthiques associées à la mise en marché précoce et à l'utilisation des nouveaux instruments chirurgicaux du point de vue des six groupes les plus touchés.

Santé Canada, qui est responsable de l'autorisation des nouveaux instruments chirurgicaux, devrait modifier ses exigences afin d'y inclure la tenue d'essais cliniques rigoureux permettant l'obtention de données sur l'efficacité et l'innocuité de chaque nouveau produit avant sa mise en marché.

L'industrie devrait se plier à toutes les exigences de Santé Canada en ce qui a trait à l'autorisation des nouveaux produits. Jusqu'à ce que Santé Canada en vienne à exiger des données sur l'efficacité et l'innocuité, l'industrie devrait collaborer avec les médecins, dans le cadre d'études appropriées avant de lancer de nouveaux produits, et présenter de façon équilibrée toutes les données disponibles.

Les chirurgiens devraient, avant d'utiliser un nouvel instrument chirurgical, évaluer les données disponibles sur son efficacité et son innocuité, et s'assurer de disposer de la formation et des compétences nécessaires. Les chirurgiens devraient offrir à leurs patientes une évaluation des données disponibles et les aviser des complications possibles et de leur expérience quant à l'utilisation du nouvel instrument en question.

Les patientes, qui devraient bénéficier d'une évaluation honnête des données disponibles, des complications possibles et de l'expérience du chirurgien, devraient être incitées à évaluer les données et les renseignements jusqu'à ce qu'elles soient satisfaites, et ce, afin d'assurer l'obtention d'un consentement pleinement éclairé.

Les établissements de santé, responsables de la réglementation de la pratique en leur sein, devraient analyser les nouveaux instruments afin d'en déterminer l'innocuité, l'efficacité et les répercussions économiques avant d'en permettre l'utilisation. Ils devraient également limiter l'utilisation des nouveaux instruments chirurgicaux aux chirurgiens formés et compétents quant à ceux-ci.

Les sociétés professionnelles devraient fournir des lignes directrices au moment de l'entrée en jeu des nouvelles technologies et des nouveaux instruments chirurgicaux.

Nous incitons toutes les parties intéressées au développement, à l'autorisation et à l'utilisation des nouveaux instruments chirurgicaux à viser l'atteinte de normes éthiques accrues, afin de protéger la santé et d'assurer la sécurité des patientes nécessitant une chirurgie. La norme éthique minimalement acceptable contraindrait les fabricants à fournir aux chirurgiens des renseignements précis et opportuns sur l'efficacité et l'innocuité de leurs produits, ce qui permettrait aux chirurgiens et à leurs patientes d'évaluer les données disponibles (et l'importance des données non encore disponibles) avant la chirurgie.

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As a group of individuals working together to develop clinical practice guidelines in urogynaecology, we are concerned that new surgical devices are being marketed without sufficient evidence of effectiveness and safety. Our primary area of interest is urogynaecology, and the examples we use in this paper relate to the surgical management of urinary incontinence; however, the ethical issues we discuss are common to the introduction of any new device into medical practice.

A recent editorial by Ostergard discussed the dangers of early adoption of new surgical products, highlighting as an example the release of a new tension-free vaginal tape device for the surgical treatment of stress urinary incontinence.[1] The device was initially released in Canada in September 2006 before it had ever been used in a patient.[1] In its device brochure, the manufacturer quoted evidence from other similar devices they make to treat urinary incontinence and "data on file" from animal and cadaver studies.[2] The manufacturer met all the requirements of the licensing authority before marketing this product, although it was unclear why there was so little information from human studies specific to this new device.

As of September 2007, in Canada 34 trained clinicians (urogynaecologists, urologists, and gynaecologists) had implanted 1021 of these devices. (Personal communication, Johnson & Johnson, 7 August 2007.) Evidence of cure rates is beginning to emerge, suggesting that use of the device is more difficult to learn than initially predicted[3–8] and that highly specialized training is required.

We are concerned that such activity heralds a trend towards earlier, and possibly premature, marketing of surgical devices. Six parties are involved in early marketing and adoption of surgical devices.

- **Health Canada** licenses products for use in Canada.
- **Industry** manufactures and markets new products.
- **Surgeons** adopt new devices.
- **Patients** receive new devices as part of surgical procedures.
- **Health institutions** are responsible for regulating practice within their walls.
- **Professional bodies** may provide guidance on the early adoption of new surgical devices.

Ethical Principles

Four medical ethics principles are relevant to a discussion about the introduction of new surgical devices.[9]

- **Beneficence** refers to the clinician's obligation to provide benefit (effective treatments) to their patients.
- **Non-maleficence** denotes the obligation to avoid harm by providing safe treatments.

- **Autonomy** in this context means the patient's right and ability to make an informed choice about whether to have a particular procedure.
- **Justice** may be interpreted as the equal and fair availability of safe treatments for patients in similar circumstances, and it is also relevant to responsible stewardship of resources and compensation for patient injury.

In the discussion that follows, we examine the roles of the six key parties in light of the ethical issues associated with the adoption of new surgical devices. We do not consider the development and testing of new devices or the role of the six parties in that context.

Health Canada

In Canada, licensing of medical devices is governed by the Health Canada Therapeutic Products Division Medical Device Regulatory Framework.[10] The framework classes medical devices according to level of risk (based on invasiveness) and describes the types of information required. For devices of moderate risk (including urogynaecology mesh devices), manufacturers must provide detailed information about the medical condition the device is intended to treat, the device itself, and the manufacturer, including design philosophy, marketing history, and manufacturing standards. A summary of safety and effectiveness studies is also needed,[10] although detailed investigation is not required.[11] Additional safety or effectiveness evidence is not required to license new "family members" (devices made by the same manufacturer for the same intended use[10]) over that provided for the first device in the family. It is notable that practising clinicians may assume that a device approved by Health Canada has met rigorous criteria,[12] but clinicians are not permitted to review confidential evidence provided to Health Canada.

Health Canada, the licensing agency, is responsible for ensuring that surgeons have timely access to approved devices for surgical procedures. It appears that Health Canada is failing in ethical roles of beneficence and non-maleficence by failing to ensure that new devices are effective and safe.

Industry

Industry should comply with all requirements to obtain product licenses. Unless directed to provide effectiveness, safety, and economic data, device manufacturers are unlikely to carry out expensive clinical trials, which delay the release and increase the cost of new products.[13] A first step towards higher standards would be to petition Health Canada to enforce more stringent regulations requiring complete clinical and economic evidence before the release of new devices. Similar suggestions have been proposed for changing FDA requirements.[1] Guidelines have suggested that regulatory bodies require minimum standards for data[14] instead of accepting manufacturers' statements of expected (versus actual) benefits.[15]

There is growing evidence that manufacturers can and do influence research findings and how they are published.[16,17] Thus there is also a need for independent research. It is encouraging to note that industry is beginning to support such research: for example, Boston Scientific and Johnson and Johnson have provided grant-in-aid funding for independent clinical trials. Unfortunately, designing and carrying out rigorous randomized trials is complex and costly.[12] Such trials may also prove difficult to undertake after devices have been widely marketed, because surgeons may consider it unethical to withhold accepted devices.[18]

Trials conducted after favourable initial reports sometimes show less benefit than predicted, or even show harm[15]; later trials may lead to denunciation of a device after its earlier widespread clinical use.[18,19]

The imperative of industry is to satisfy company owners and shareholders by seeking market share and financial success. While this may be the primary motivation, no company will consciously ignore patient safety and satisfaction, but will rely upon regulatory authorities to build sufficient safeguards into the regulations. In order to meet the ethical obligations of beneficence and non-maleficence industry should be prepared to cooperate with physicians in the appropriate study of their products before releasing them for general use, and to make balanced presentations of the available evidence.[15]

Surgeons

Physicians desire to introduce new technologies for many reasons. Of utmost importance is benefit for patients. Surgeons expect that new surgical procedures will be effective, and that they will be safer for patients and less costly than established procedures.[15,19] Surgeons may also be prompted by self-interested desires to learn new techniques, be leaders in their field, be reimbursed at an enhanced level,[15] or maintain "market share" of patients.[13] New procedures requiring medical devices are appealing because they tend to be less invasive and are claimed to have shorter operative times. The apparent ease of use may lead to adoption by less skilled surgeons.

As stressed in a recent AJOG editorial,[19] and the ACOG Committee on Ethics statement,[20] surgeons should insist on the best level of evidence to guide clinical choices, rather than allow themselves to be persuaded by the intensive promotion of new products and fears of being left behind their peers. Unfortunately, newer industry-driven procedures may not offer improvements over more established

procedures,[15,20] and premature adoption may compromise the ability to determine device effectiveness and safety.[17,20] The ACOG statement advised clinicians not to adopt new treatments until evidence is available from rigorous randomized clinical trials.[20]

According to the principles of beneficence and non-maleficence, surgeons should provide benefit to patients, while avoiding harm. Ultimately, individual surgeons are responsible for setting their own standards when introducing new technologies.[21] Surgeons should assess (independent of marketing claims or industry training[22]) the evidence on effectiveness and safety of the treatment and their own competence in its use. If surgeons have doubts about either aspect, they should not use the new treatment.[21]

Patients trust surgeons to possess all the information necessary for their best care, and they expect to be given all available facts in order to give informed consent.[1,20] Ethical principles mandate that surgeons should be scrupulously honest in providing full information on the effectiveness, safety, and rates of complications of the proposed treatment.[23] They should provide the same information about any other appropriate treatments, acknowledge any lack of evidence about the new device, and be open about their own level of experience with that device.[13,19] The ideal method for surgeons to discharge the duty of disclosure is currently undefined.[24]

The early adoption into clinical practice of new devices with no or limited evidence of safety or effectiveness may mean that patients do not receive a reasonably expected standard of care in particular circumstances.[25] As final arbiters of the introduction of new medical devices, physicians carry the greatest moral and ethical responsibility.

Patients

Patients are sometimes criticized for driving the demand for new surgical techniques.[15] They are particularly at risk because of their readiness to seek a cure for their condition[26] and their sometimes misplaced belief that new must be better.[13] Patients are the most vulnerable of the parties involved in the introduction of new medical devices; it is they who suffer the consequences of a new device used inappropriately or by an inadequately trained surgeon. Therefore it is clear that the surgeon should provide a balanced presentation of information to ensure that patients are truly informed before consenting to the use of a new device[13,15,20] The surgeon should bear in mind that patients may be unable to fully evaluate the quality of evidence.[26]

In order that the patient's autonomy is not compromised in this context

- industry should provide adequate and honest evidence of safety and effectiveness;
- surgeons should independently evaluate all available evidence;
- surgeons should ensure they are adequately trained to use the device;
- surgeons should provide the patient with an honest evaluation of the available evidence and address the suitability of the device for treating that patient;
- patients should evaluate the evidence to their own satisfaction before consenting to have the procedure carried out.

The medical system, which includes all of the parties discussed earlier, should ensure that each of these criteria is fulfilled to ensure that patients can truly give informed consent.

Health Institutions

There are clear ethical roles for institutions (such as health authorities and hospitals), in the introduction of new technologies[21] First, institutions should ensure that patients receive effective and safe treatments (beneficence and non-maleficence). Many hospitals and health authorities review the introduction of new technologies; however, the quality of the review process has been questioned in some institutions because of lack of standardization.[12] In addition, good evaluation of new technologies requires careful review of published literature.[27] If such evidence is not available, institutions should refuse to allow the use of the new technology. If institutions rely on physician request rather than careful evaluation of evidence, they will be open to criticism for failing to fulfil their responsibilities[12,21] As a further safeguard, institutions should consider limiting the use of new devices to named surgeons who are appropriately trained.

The ethical principle of justice means ensuring both the equitable availability of treatments and the responsible stewardship of resources. Health institutions should consider their full range of patients, not only urogynaecology patients. Inevitably, economic issues sometimes cause institutions to apply arbitrary quotas as a result of constrained budgets. Sometimes newer devices are marketed at higher prices than standard devices, without supporting evidence of health care savings. Thus the principle of justice, ensuring that the medical needs of all patient groups are given equal consideration, may prevent some patients from having a particular new device.

Professional Societies

Professional societies such as SOGC endeavour to take responsibility by providing guidance on a wide range of issues. Among the concerns of SOGC is the ethical introduction of new medical treatments and surgical devices. SOGC has developed training standards for laparoscopic

surgery and has endeavoured through CME programs to provide training in new technologies that does not rely on industry.[19] ACOG has developed specific guidelines on ethics and innovative practice.[20] Such initiatives will only affect the practice of surgeons affiliated with professional societies.

Professional societies have an important role in highlighting the ethical issues surrounding the introduction of new technologies and encouraging all members to undertake relevant ethics education.[21]

CONCLUSIONS

Most people assume that the standard of evidence required for new surgical devices is similar to that required for new pharmaceutical products and that any surgical device licensed in Canada must be safe for human use. As things currently stand, this assumption is not justified.

The early marketing and adoption of surgical devices brings potential hazards for patients and surgeons.[19] We urgently need new Canadian standards to ensure full disclosure to surgeons and patients of evidence on the effectiveness and safety of surgical devices. Furthermore, the standards of evidence required for licensing surgical devices should be as rigorous as those required for licensing medicines: safety and effectiveness should be paramount. Only if rigorous evidence is available will surgeons be able to give their patients the best counsel and patients enabled to give truly informed consent for surgery.

Until such time as the licensing requirements for surgical devices are changed, industry should take responsibility for marketing their products ethically by disclosing the absence of evidence in addition to providing the evidence that is available. Physicians should demand appropriately designed prospective studies from industry to support their decision making, resisting the adoption of new devices until appropriate evidence is available. Patients who need surgical treatment should always ask about the safety and effectiveness of a device, as well as about the experience of their surgeon with that specific device.

This paper is a call to all those involved in the development, licensing, and use of new surgical devices to aim for higher ethical standards to protect the health and safety of patients who require surgical interventions.

The lowest acceptable ethical standard requires device manufacturers to provide surgeons with accurate and timely information on the efficacy and safety of their products, allowing surgeons and patients to evaluate the evidence (and the significance of information not yet available) before surgery. It is up to surgeons and health institutions to investigate and evaluate available literature, ensure that surgeons are trained and competent in their use, and inform patients candidly about the available information, the experience of their surgeon, and other available treatments.

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