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REVIEW ARTICLE

Promises and Ethical Pitfalls of Surgical Innovation: the Case of Bariatric Surgery

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Abstract The last two decades have seen remarkable advances in and acceptance of bariatric surgery. These advances include quality assurance, certification of surgeons and their institutions and the development of national bariatric registries. Yet, in spite of these advances, an urgent need to improve ethical standards in bariatric surgery remains. In particular, surgical innovation must be subjected to adequate scrutiny and sufficient safeguards. New procedures and the processes by which they are assessed should be subject to review and approval by the ethics committees operating under clearly defined guidelines. The public must be able to have confidence that the surgery itself, and the innovative practices that are introduced within it, are not subject to distortions associated with personal, wider professional, industry or institutional interests.

Keywords Ethics · Bariatric surgery · Surgical innovation · Informed consent

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The public presentation of obesity as a major health crisis has created a sense of urgency about the need for effective treatments [1]. Together with the ever increasing number of obese people seeking help, this has in turn, generated pressure for innovation in bariatric surgical procedures. In response to this need, several procedures have been developed and refined with significant benefits to both individual patients and the community. As in other cases, however, the pressure has also raised concerns about the extent to which novel procedures are evaluated for both safety and efficacy and, in the absence of adequate validation, the possibility that patients could be subjected to harm. The fact that purely surgical procedures are largely exempt from the rigorous regulatory scrutiny applied to drugs and surgical devices potentially increases risks to the public. In this article, we draw attention to these risks, using as an example an old but recently popularised bariatric procedure, gastric plication [2]. We argue that this case highlights the need for caution, and possibly for a more clearly defined set of regulatory processes relating to surgical procedures.

Originally developed in a single centre in Iran [3], interest in and support for gastric plication has in recent years, developed rapidly in a number of countries. This has been in the face of, at best, limited clinical experience. Indeed, the first contemporary manuscript appeared in the literature only in 2010 [4] and the first systematic review in late 2012. The latter paper describes no more than 307 patients who have undergone the procedure [5] and draws attention to the fact that long-term data is available from only one centre and that standardisation of the surgical procedure and generalised safety and efficacy data are critically lacking.

The flurry of international interest in gastric plication—and the marketing hyperbole accompanying it—in the absence of reliable data have caused alarm in some circles. In response, the American Society for Metabolic and Bariatric Surgery has declared the procedure to be investigational and directed that it should be performed only under independent ethical oversight

and with appropriate provision for data monitoring and safety review. The Society has stressed that in the meantime, promotion of the procedure must draw attention to its investigational status [6].

In contrast to this cautious approach, many surgeons continue to actively promote the procedure, either on its own or in conjunction with other approaches, such as the laparoscopic adjustable gastric band [7]. Indeed, in a position statement on its publicly available website, the Obesity Surgery Society of Australia and New Zealand (OSSANZ) expresses support for gastric plication as a valid contemporary surgical option [8]. While acknowledging the as-yet-unproven nature of the procedure, the society refers to the currently available—anecdotal—evidence as 'promising' and highlights the operation's hypothetical advantages. Proposing limited practice of gastric sleeve plication in units with a relevant sub-speciality interest where outcomes and issues can be evaluated and subsequently presented in the peer-reviewed literature, the statement makes no reference to ethical oversight. Although the possibility of nausea and vomiting, exacerbation of reflux and anatomical distortions—which may prevent subsequent revisional surgery—are mentioned, concerns about nutritional deficiencies are summarily dismissed. Consistent with this approach, a number of surgeons in several centres have taken up and are actively practising the procedure. Regrettably, this expansion of practice has not been accompanied by an upsurge in research: in fact, as of June 22, 2013 not a single clinical trial for gastric plication has been registered on the Australian or New Zealand Clinical Trials Registers and the only published data from the entire region remains a single case report of an unusual complication [9].

Innovation Versus Research in Surgery

The broad enthusiasm for gastric plication in spite of the uncertainties about the surgical technique and its safety and efficacy strongly suggests the need for more rigorous regulation of surgical innovation, including increased independent ethics review and oversight. However, stricter regulation is strongly resisted by surgeons, institutions and some surgical associations and industry, supposedly on the basis that ethical requirements imposed on surgeons will limit innovation and will ultimately therefore undermine patient care. It is argued that the present arrangements, which consist of broad exhortations about the need for ethical behaviour [10], are adequate and that the complexity and time-consuming nature of the ethics committee processes will destroy the current flexible and unregulated approach, discourage innovation and thereby obstruct advances in health care [11]. The history of surgery, which has until now, avoided the rigorous oversight required of drugs, devices and other therapies, is called on to support this laissez faire approach.

A key question concerns the boundary between what is regarded as legitimate innovation in routine clinical practice and research. The concept of 'innovation' in surgery is itself hard to define, as the idea spans the continuum between minor variations in clinical practice and more fundamental changes in technique that require rigorous processes of documentation and oversight. Indeed, often the terms 'improvisation', 'innovation' and 'surgical research' are used interchangeably, even though they can, in reality, refer to very different things [12]. A clear definition is important because all the stakeholders—patients, surgeons, regulators, ethicists and institutions—need to be aware of when the line beyond which formal independent review, oversight and regulation are required has been crossed [13]. This need is all the greater given that many surgeons oppose regulation of innovative surgery altogether, and subsequently, that recognition of obligations with respect to research is not necessarily matched by action [14].

In the classical textbook, *Bailey and Love's Short Practice of Surgery*, in its chapter on surgical ethics, addresses the distinction between research and minor surgical innovation [15]. It points out that surgeons often face a dilemma between their duties to act in the best interests of individual patients, on the one hand, and to improve surgical standards in a manner that inevitably exposes these patients to risk, on the other. While the need for improvements in techniques and standards is uncontested, it is noted that the pressure to maintain a high research profile and to enhance status or reputation may increase patient exposure to risk.

The authors of *Bailey and Love's Short Practice of Surgery* propose a simple test to distinguish between routine innovation and research. They suggest that the crucial criterion relates to whether a proposed procedure falls within the scope of the standard techniques or procedures for which surgeons are trained and therefore represents no more than an incremental change in personal practice or whether it departs more radically from it. This approach, based on the concept of personal innovation, undoubtedly has some strength; however, it also suffers from major limitations. For example, the ideas of 'incremental' and 'radical' still have to be defined unambiguously, and no reference is made to the need for collection of data to inform the evolving practices of other surgeons; as a result, innovation in this sense cannot contribute to wider knowledge or to enhanced surgical training [15].

The call from OSSANZ for the rigorous collection and dissemination of data relating to the clinical experiences of bariatric surgeons clearly implies that the society views gastric plication surgery as research rather than 'merely' innovation. A consequence of this should be that all such clinical practice must be subject to ethics committee oversight. We would support this conclusion and consider that it is consistent with the state of knowledge about risks and benefits associated with gastric plication.

Ethical Issues Raised by Innovation in Surgery

Johnson and Rogers have identified four major areas of ethical concern in innovative surgery: harm to patients, informed consent, conflict of interest and distribution of health care resources [13]. Each of these is of relevance to bariatric surgery.

As has already been discussed, innovation in bariatric surgery has the potential to cause harm, including well beyond the immediate post-operative period. There are uncertainties regarding efficacy, the need for revisional surgery or irreversibility of surgery, nutritional deficiencies and long-term body composition, and functional and psychosocial outcomes. By its very nature, bariatric surgery aims to produce enduring changes, and as such, studies of sufficient duration with clinical outcomes are needed to provide the confidence needed for a new procedure to be adopted into common use. This is the accepted standard for new drugs and there is no reason why it should not also apply to new surgical procedures. The fact that previous misadventures have occurred—as with the example of jejuno-ileal bypass, which generated catastrophic nutritional and metabolic outcomes in many patients [16]—highlights this point further. There are positive examples too: the evolution of Roux-en-Y gastric bypass and laparoscopic adjustable gastric banding as standard procedures on the basis of extensive data collection, including in the long-term post-surgical period, can be regarded as setting the current bar for comparison [17–19].

Innovation in bariatric surgery presents challenges with respect to consent. Consent is a fundamental condition of ethical practice in both clinical interactions and research and signifies the respect held by practitioners and researchers for their patients and research participants. While the form and content of the consent process can vary, a key, common aspect is a clear statement of what is known about potential risks and benefits of any proposed procedures [13]. Such a statement must be disinterested and free from biases arising from underlying assumptions about the inherent benefits of novel approaches or distortions associated with potential benefits to third parties, such as hospitals, device manufacturers and the surgeons themselves [10]. Where the researcher is also the clinician—as is often the case in surgical innovation—the divergent interests associated with the two roles may make it impossible for consent to be obtained by the surgeon himself or herself, necessitating the introduction of a third party to conduct the discussion and to ensure that the patient's decision is free and fully informed.

The dual role of clinician and researcher is an example of a conflict of interest. In addition, cutting edge surgeons are usually direct beneficiaries of their new procedures, which may enhance their reputations and increase demand for their services. 'Pioneers' in surgery are often praised for their ingenuity and skills [20] and may gain in career opportunities, prestige and status [13]. These attractions, however, come with a price: they often erode the independence of the surgeons involved, influence their judgement, and may distort the consent process, as the innovative surgeon is unlikely to be seen as providing open and objective counselling regarding their own innovation. Clearly, independent oversight of this process is necessary.

Even without proof of safety and efficacy, novel surgical procedures compete for a share of scarce health care resources. Indeed, there have been many circumstances where surgical procedures have become established in the absence of evidence of effectiveness [13], especially including cost effectiveness. Surgical innovation is usually expensive, and enthusiasm from surgeons, institutions and industry may well generate excessively optimistic expectations [21]. An example of the adoption of an expensive new technology in the absence of a convincing case in support is that of bariatric surgery robotic assistance which—contrary to the expectations of the institutions that have invested in it—has proved to be more expensive than the alternatives, in both financial costs and procedure time, as well as lacking any clear clinical advantages [22]. In view of the large-scale nature of the obesity problem and extensive resource implications of practices in this area, the adoption of a novel procedure for the management of obesity should only be undertaken once a compelling case has been established regarding the costs and benefits to the affected communities.

Regulation of Research and Innovation

In almost every country in the world today, the assessment in humans of new therapeutic drugs and devices is subject to formal processes of regulation under the guidance of a clearly articulated set of principles. Despite important variations in the details, the principles are common and generally straightforward. It is expected that the methods and execution of scientific studies meet adequate standards, that researchers respect their participants, that an independent review process verifies that risks are justified by potential benefits, and that the conduct of the research does not support inequitable or discriminatory practices. In virtually all developed countries, the responsibility for such review is granted to ethics committees, which operate according to well-defined processes. These committees address the issues of the justification, design and conduct of the research, the balance between potential risks and likely benefits, consent processes, data management, the distribution of resources, and the management of dualities and conflicts of interests. This modern approach to the regulation and oversight of research has not limited innovation or experimentation; rather, it has supported creative endeavour, ensured the rigour and trustworthiness of data [23] and sustained the confidence of patients and the wider public.

There seems no compelling argument to distinguish surgical innovation from those forms of innovation in therapeutics that relate to drugs and devices. The fact that the boundaries of existing surgical practices may be difficult to define and that regulation and review of the practices of individual surgeons may not be straightforward do not exempt surgeons from their ethical responsibility to conform to the standards that guide other aspects of innovation in both national and international settings. While in some cases, the line between legitimate innovation and research may be blurred, this is not the case with respect to gastric plication, which appears to meet all relevant criteria for formal ethical review.

Conclusion

Innovation in bariatric surgery has delivered significant advances over recent decades. During this time, there have also been major forward steps in quality assurance, certification of surgeons and their institutions, and the development of national bariatric registries [24–27]. In spite of these advances an urgent need remains to improve ethical standards in this area of surgery [28]. In particular, innovative practices must be subjected to adequate scrutiny, and sufficient safeguards must be established to ensure proper training and surveillance of surgeons. New procedures, and the processes by which they are assessed, should be subject to review and approval by ethics committees operating under clearly defined guidelines. The public must be able to have confidence that the surgery itself, and the innovative practices that are introduced within it, are not subject to distortions associated with personal, wider professional, industry or institutional interests.

Practical Steps in Developing a Policy Framework

The main argument against increased ethical oversight of new bariatric surgery procedures is the time and effort required to gain such approvals and run a research study. Current guidance (NICE, OSSANZ) suggests the recording and reporting of data from novel bariatric surgical techniques does not specify what data should be collected and how, when and where it should be actually reported, therefore complicating the process further and impeding rapid meta-analysis of results. However, the existing mechanisms of surgical societies, registries and centre for excellence schemes, could be utilised to make this far simpler for participating centres.

First Reports of Novel Procedures

There is a responsibility of journal editors and conference chairs to ensure that all research published in their journal/presented at their conference has been done in accordance with the Declaration of Helsinki. This should include the presentation of results from novel bariatric surgical procedures. A commitment by journal editors and conference organising committees to only publish research on novel bariatric surgery techniques that had a favourable ethical opinion prior to recruitment would quickly change practice.

Subsequent Evaluation and Adoption of Novel Procedures

Bariatric surgical practice can change quickly, and after presentation or publication of the initial results of a novel technique, there will be strong interests in offering the new operation to patients as soon as possible. Therefore, there would be some urgency required on the part of bariatric surgery societies and governance bodies to ensure that novel techniques are only carried out within the ethical confines of a research study and yet help facilitate this as much as possible and ensure the timely reporting of results.

Possible actions include the creation of a working group for each novel technique who will define the following:

- The novel technique itself based on available evidence to ensure a standard surgical approach as much as possible.
- The minimum training requirements for a surgeon to perform the procedure within a study setting.
- The potential risks and benefits that would be required to explain to a patient to gain fully informed consent—this can then form part of the local ethical review application.
- The minimum data set including defined outcomes, length of follow-up, and subsequent planned (meta) analysis.
- A plan for long-term evaluation of durability, safety, complications, nutrition, patient reported outcomes, and health economics to monitor issues that may not emerge for many years.
- Criteria for acceptance as an evaluated bariatric surgical technique (numbers of patients, outcome criteria—e.g., pre-defined post-op complication rate of less than or equal to existing techniques).

Existing registries could be modified to allow the simple collection of data on these novel techniques within the confines of a research study, though work would be required to ensure the rules on data security and agreement on collaboration for meta-analysis were clearly defined.

Conflict of Interest Prof. John Dixon acts as a consultant for Allergan Inc., and Metagenics Inc.; is a member of the Optifast Medical Advisory Board for Nestle Australia; has received honoraria from iNova Pharmaceuticals and research grants from Allergan Inc. None of these entities had any input in the current review. Dr. Logue and Professor Komesaroff have no relevant disclosures.

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