CASE STUDY

Doctor, let us not tell her about the porcine implant

VISHAL G SHELAT

Abstract

With the proliferation of pharmaceuticals and advances in innovative medical technologies, use of animal-derived products is widespread in the healthcare industry. The use of these products sometimes conflicts with the religious beliefs of patients. I was involved in an ethical dilemma during reoperative abdominal hernia surgery. I engaged with the patient's next-of-kin via an intraoperative phone discussion regarding the possible use of a porcine-derived biological mesh implant. Here, I reflect on the experience to help clinicians who seek ethical competence alongside clinical competence.

Keywords: *explant, hernia, mesh implant, porcine, religious beliefs*

I have been a practising surgeon for about two decades. Only in exceptional circumstances do I speak over a telephone to the next-of-kin of a patient who is already anaesthetised for a surgical procedure. In my experience, the intraoperative possibilities and outcomes are generally foreseeable and included in discussions during the informed consent process with the patient, before the surgical procedure. I took an elderly Malay patient for reoperative surgery for failure to progress following an elective laparoscopic surgery. This was an intraperitoneal mesh repair performed ten days earlier, for a symptomatic incisional hernia. Based on symptoms and circumstantial evidence, I suspected postoperative small bowel obstruction. I offered a reoperative surgery and discussed various intraoperative options, adding how each possible scenario would impact perioperative recovery, associated morbidity, and long-term clinical outcomes, including quality of life. In particular, I discussed the options of mesh explant — removal of an implant — with the possibility of either component separation, ie muscle separation for reconstruction of the abdominal wall, or new synthetic mesh placement. I did not discuss the possibility of using a biological implant as it is generally reserved for use in patients with sepsis which my patient did not have. In keeping with the patient's wish, the next-of-kin was also involved in the informed consent process.

During laparoscopic exploration, I encountered dense and extensive adhesions that warranted an open conversion to facilitate safe surgery. After open conversion, I encountered dense fibrotic adhesions of the synthetic mesh onto the adjacent bowel. This fibrotic reaction was the source of a small bowel obstruction, and in my opinion, the mesh was the cause of this reaction and an explant was the most prudent option. I explanted the mesh and was left with three choices, namely, (i) repair with a new synthetic implant, (ii) use of a biological implant, or (iii) repair using muscle separation methods. As the patient had developed a dense fibrotic reaction to the initial synthetic mesh implant, the repeated use of a similar mesh was deemed likely to generate adhesions, and thus best avoided. Also, as evidence has shown, repair without a mesh is three times more likely to fail compared to mesh repair, hence mesh repair is more appropriate [1]. The component separation technique was technically challenging due to dense adhesions of bowel loops to the abdominal wall. Thus, using a biological mesh was deemed safer to mitigate intraoperative technical complexities and associated morbidity [2]. Biological hernia implants are usually derived from the animal dermis with various proprietary processing techniques that ensure durability and strength [3]. An estimated five porcine-derived and four bovine-derived biological grafts are available in the market [4]. The only available bovine-derived dermis is not widely used in my unit due to a lack of high-quality real-world data in patients with a ventral hernia [5]. Thus, I considered using a porcine dermis mesh for my patient.

As the institutional policy entails that a nursing colleague seeks a read-back of the order from the operating surgeon before opening consumable packages, I was asked by a nursing colleague if she can proceed to open the package. It struck me that my patient is Muslim and the mesh in question is derived from pork. I had to decide whether to reconsider using a biological implant instead of performing the component separation technique. However, knowing the technical difficulties associated with the component separation procedure, I had to consider using a biological

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implant. I discuss my immediate thoughts on the options below: (a) use first, tell later; (b) phone consult the patient's next-of-kin for a consensus; or (c) proceed with the component separation technique, accepting the risks.

Use first, tell later

A surgeon has a duty to always act in the patient's best interests and engage a patient in all decision-making. This patient had two unique features:

- postoperative bowel obstruction following synthetic mesh repair of abdominal hernia with the mesh as driver of adhesions, which is uncommon;
- the decision to explant the mesh during reoperative surgery without technical faults of mesh or sepsis is rare.

Following the mesh explant, my choices of repair included using a biological implant or performing a muscle (component) separation technique. Since muscle separation is more complex, the insertion of a biological implant was considered preferable. Due to the remote risk of a possible need for a biological implant, this was not included during the informed consent process. I could potentially exploit the vulnerability of my patient by using a porcine-derived implant and later rationalise the necessity on clinical grounds, supported by ethical principles based on consequentialism. The placement of a biological mesh would not entail physical harm, but it certainly was likely to inflict moral harm.

Phone consult with the patient's next-of-kin for a consensus

Due to involvement in the informed consent process, I elected to call the patient's next-of-kin. I explained to them about the intra-operative events and available options of component separation, and the best option of using a biological implant. I briefly described the pros and cons of both procedures. The next-of-kin was anxious on hearing that, in my view, a porcine implant was a simpler procedure and muscle separation may entail more complications. I sought their opinion about the patient's religious belief system. The next-of-kin confirmed that the patient was a devout follower of Islam and would not want to have a porcine-based implant placed in the body, and added that if the implant was the best choice, *"Please put it, but let's not tell her about it".* Upon clarifying if the family would agree for me to disclose this after the surgery, I was told that the patient would not accept it well.

Proceed with the component separation technique

After mutual discussions, we decided to proceed with the component separation procedure.

What if I had been ignorant that the proposed mesh was derived from pork? Ignorance is no excuse for a specialist. A healthcare practitioner should be judged not only based on his rank and profile, but also on his own academic pursuits and clinical experience. Thus, it is reasonable for society to expect awareness and knowledge of recent innovations from a surgeon with two decades of surgical experience and routine practice of hernia surgery. In a multinational survey including the six largest religions globally (Christianity, Islam, Hinduism, Buddhism, Sikhism, and Judaism), Eriksson et al reported that Muslims did not accept the use of porcine-derived drugs, dressings, or implants, except in emergent situations with no reasonable alternative [6]. All the religious leaders considered it permissible to use animal-based medicinal products in situations of emergency or lack of suitable alternatives [6]. My patient did not face a life-saving emergency; muscle separation was a possible alternative. However, as muscle separation is complex, with associated risks, I had elected to discuss the situation with the patient's next-of-kin.

Discussion

Religious beliefs may conflict with healthcare decisions. What if the next-of-kin insisted on a porcine implant to reduce operative risk, and I agreed and elected not to disclose the ingredients of the biological mesh and simply stated "I have removed the old mesh and placed a new mesh", where the patient is in no position to learn what is placed? The medical profession is a self-governing profession where society puts its trust in practitioners, and it is our responsibility to uphold the public trust. Thus, we have a self-imposed duty of integrity, honesty, trustworthiness, and a duty of candour. The Francis report, following the Mid Staffordshire Trust inquiry, recommended a statutory duty to be introduced for healthcare providers that enforces openness and transparency, timely disclosure to the harmed patient of any injury, with a necessary apology offered, regardless of whether a complaint has been made or a question asked about it [7]. Though the General Medical Council in the United Kingdom has included the duty of candour within the professional code of practice, the Singapore Medical Council Ethical Code and Guidelines do not explicitly include the phrase "duty of candour". However, in principle, the ethical code endorses the ethos of such duty [8: p 114]. Lack of explicit mention of such an ethical duty doesn't excuse a moral breach in hiding a fact that a patient cannot discover. The disclosure must be total, complete, and explicit to qualify as honest and transparent. In the present context, the issue is avoidance of moral wrongdoing.

To restore health and enhance healthy living, the pharmaceutical and medical device industry's reliance on animal-derived ingredients is increasingly common. For example, gelatine, derived from animals, is a common ingredient used in the coating of "capsule" formulations. In a study including 41 psychotropic medications, Sattar et al reported 14 medicines containing gelatine [9]. Similarly, 12 out of 14 formulations of common proton pump inhibitors (Omeprazole) in the Danish market have gelatine coating derived from pigs [10]. It is difficult for a healthcare

professional to keep abreast of every product. While scholars debate the use of human or animal-derived products during surgery or life-saving situations, there is a general consensus that, as far as possible, and if a reasonable alternative is available, the use of such products should be minimised, even when the alternative achieves the end result with some degree of compromise of time or quality [11,12]. However, one should not generalise from evidence, as each patient will have their own socio-cultural and religious values that a surgeon must seek to learn for therapy to be not only clinically effective but also in compliance with ethical norms. Rightly so, when I asked my patient about her perspective on using porcine implants at a follow-up clinic visit, the patient replied outright with an unconditional "No". What "if" I had placed the porcine implant? The answer is, "One should not make a clinical dilemma become an ethical dilemma." After all, I had an alternative option for my patient.

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