

The use of porcine mesh implants in the repair of abdominal wall hernia: An Islamic perspective for an informed consent.

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Keywords: *Islamic bioethics, Informed consent, Porcine mesh, Hernia repair, biologic mesh, Muslims*

Abstract

The use of porcine derived mesh for the repair of abdominal wall hernia is increasing in surgical practice in recent years. Dietary consumption of porcine containing products is prohibited in Islam and Muslim patients would not accept it in usual circumstances. However, the majority of Muslims would only use forbidden material in life saving conditions. The Islamic jurists allow it in dire need and in the absence of any other suitable alternative. This study employs a review of the literature about the use of porcine derived mesh for the repair of incisional hernia and also comprising historical evidences from Qur'an, traditions of Islamic Prophet Muhammad and views according to Islamic Jurisprudence. The findings explicate the religious and legal basis of using porcine mesh for the use of repair of abdominal wall hernia in Muslim patients. This study will provide a guidance on the understanding of its use to obtain a formal informed consent.

Introduction

Incisional hernia represents a significant problem representing up to 20% of patient at some stage postoperatively. It results in causing pain, strangulation of bowel, skin erosions, poor cosmesis, social embarrassment and impaired quality of life. New techniques like component separation and laparoscopic approaches have provided significant benefits to the patients effected with these problems. Introduction of new techniques and surgical products like meshes for reinforcement has revolutionized the results of abdominal wall reconstructive surgery. Patients, even with former hopeless abdominal wall conditions, can be offered a new life gained from these developments. There is a huge variety of mesh available which are made of absorbable synthetic, non-absorbable synthetic material, pure biological and the composite mesh which is a combination of both the synthetic and biological components.

Method

This study addresses three key areas. Firstly, current evidence and practice of use of biologic mesh for the repair

of abdominal wall hernia. Secondly, the Islamic medico-ethical deliberations are examined in light of modern knowledge and finally the concept and components of an informed consent which are reviewed in the light of a recent judgment by the Supreme Court of United Kingdom and its impact on the use of porcine derived mesh for the Muslim patients.

Biological tissue grafts

The ultimate goal of biological meshes (tissue graft) is to support the abdominal wall until new healthy collagen tissue, produced by the patient, has replaced the mesh and resulted in a stable abdominal wall [1]. The biological mesh may be harvested from human, porcine, bovine, or equine hosts and from skin, pericardium, small intestine submucosa and urinary bladder mucosa. This is a relatively recent advancement in the world of surgery and has a beneficial role in abdominal wall reconstruction especially in contaminated fields [2]. Human cadaveric grafts and other non-cross-linked grafts show initial success due to rapid tissue remodelling. The porcine dermal collagen implant has been developed and recently its use has increased widely. During manufacture into biologic scaffolds, these

matrices undergo a variety of chemical and mechanical processes including de-cellularization, sterilization, and preservation for storage to render the scaffold free of immunogenic agents and safe for therapeutic application. Many of these processes remain proprietary, deterring further scientific investigation of their potential impact on clinical outcomes [3].

The studies of incisional hernia repair with various types of biological mesh have shown that the failure rate of mesh containing small bowel mucosa is 8% at 19 months and 15% at 12 months with acellular human dermis graft. Whereas its 8% at 15 months with cross-linked porcine dermis graft [4]. Because of many variables involved, it is very difficult to perform a randomized control trial on this subject [5].

There is a variety of biological mesh available to surgeons and many of these contain porcine derived material. Some of the examples are given in Table 1 [3, 6]. A study in 2014 has shown that porcine dermal meshes have come to dominate the market of biological mesh. There is an increasing evidence to support their safety. However, the long term follow-up studies to support their efficacy are lacking. Several factors must have to be considered in deciding which mesh to use for a ventral/ incisional hernia repair. The United States Food and Drug Administrating agency (FDA) reported that complications of these materials warrant caution and sound surgical judgment. At present clinical trials evaluating the comparative effectiveness of available biologic implants in ventral hernia repair are limited and on-going trials may help to elucidate their precise role in future [1, 7-10].

Islamic Bioethics deliberations (Shari'ah and Fiqh)

When Muslims are faced with an ethical dilemma of permissible (Halal) and forbidden (Haram) they will look for the rulings in Islamic law (Shari'ah) and deliberation in jurisprudential understanding (Fiqh). It is important to understand the basis of the Shari'ah and the, "Fiqh" before understanding this subject.

The Qur'an and the traditions of the Prophet (known as the Hadith and Sunnah) are the principal sources of Shari'ah. In Islam, the Qur'an occupies a unique and singular status as the literal word of God. The Sunnah is the orally transmitted record of what the Prophet said or did during his lifetime, as well as various reports about the Prophets' companions. Traditional purporting to quote the Prophet verbatim on any matter are known as Hadith. Hadith are second only to the Quran in developing Islamic jurisprudence and regarded as important tools for understanding the Quran and commentaries written on it. The "Fiqh" is an Arabic word. It literally means knowledge or understanding especially of that which is

not self-evident and requires a certain degree of intellectual exertion to comprehend. It is defined as knowledge of the practical rules of shari'ah which are deduced from their particular evidence in the sources. The revealed sources of Shari'ah, are the Quran and Sunnah, which provide the basic evidence from which the rules of fiqh are deduced. It not only legislates but also assign moral values. In Islamic teaching, Shari'ah is the source of Muslim existence as it represents 'the correct path of action as determined by God'. The Shari'ah, not only separates actions into required and forbidden, but also the intermediate categories of recommended, discouraged and permitted [11]. The science that identifies the sources of Fiqh and also lays down rules for weighing these sources against each other in case of conflict is usul-ul- fiqh, literally the roots of law. It expounds the indications and method by which the rule of fiqh are deduced from their sources.

Human consumption of porcine derived material and its permissibility in Islam

Evidence from the Quran:

There are four verses in the Quran where it has been clearly mentioned that eating flesh of swine is forbidden [12-15]. "Forbidden to you (to eat) : dead meat, blood, the flesh of swine, and that on which hath been invoked the name of other than Allah;...[15] (Al-Maeda).

According to three of these verses of Qur'an, a concession has been granted in case of "dire" needs. In the Quran as it says in the following verses. "He hath only forbidden you dead meat, and blood, and the flesh of swine, and that on which any other name hath been invoked besides that of Allah. But if one is forced by necessity, without wilful disobedience, nor transgressing due limits, - then he is guiltless. For Allah is Oft-forgiving Most Merciful." [13] (Al-Baqara). "He has only forbidden you dead meat and blood and the flesh of swine and any (food) over which the name of other than Allah has been invoked. But if one is forced by necessity, without wilful disobedience, nor transgressing due limits,- then Allah is Oft-forgiving Most Merciful." [14]. (An-Nahl). Say "I find not in the message received by me by inspiration any (meat) forbidden to be eaten by one who wishes to eat it, unless it be dead meat, or blood poured forth, or the flesh of swine, - for it is an abomination - or, what is impious, (meat) on which a name has been invoked, other than Allah's. But (even so), if a person is forced by necessity, without wilful disobedience, nor transgressing due limits, - thy Lord id Oft-forgiving. Most Merciful" [12] (Al-Anaam).

As a general agreement, "necessity overrule prohibition", a concession has been granted in case of "dire" needs, which has been recognized by the Sharia. Permissibility is granted for impermissible for life saving and health care need. Muslim faith allows the dietary consumption

of pig flesh and use of porcine surgical products in dire situation known as “darrurah”, where all other options are exhausted, “dire necessity renders the impermissible to be permissible”.

Evidence from the Hadith:

According to one verse in Quran, the flesh of swine has been described “rijs” means “filthy”, “abomination” [12]. However, there is evidence from the Hadith which indicates that impure skins are rendered pure through tanning. [16-18]. In a narration once Prophet Muhammad passed by a dead sheep and said (to the people), “why don’t you use its hide? They said, “But it is dead, “He said, “Only eating it, is prohibited.”[19].

Concept of Tanning (Dibagh) in Islam

Tanning means a process of removing fat and dirt from animal skin. It can be done by any material reachable to the meaning and purpose of tanning. It preserves the skin from being damage and demolished. According to Hadith mentioned above, skins whether obtained from carcass will become purified after they have undergone tanning process [19]. In general, skin from halal animals which has been slaughtered based on Islamic way with or without tanning, is purified. However, there is a dispute among Muslim scholars in this issue is on whether the skin from non- slaughtered animal is purified even after undergoing tanning process. Some scholars are of the opinion that tanning purifies all types of animal skins. Some scholars made exemption of two types of skin i.e. the skin of dog and pig. Whereas, other scholars only exclude the skins of pig [20].

According to many jurists’ pig skin cannot be purified, this is due to the fact that a pig is considered essentially filthy (“rijs”, or “najas al-ayn”), in that the essence of a pig with all its body-components is filthy, whether dead or alive. Hence, the filthiness is not because of the blood that is contained in its body like other non-pure animals.

Use of other forbidden material

Maintaining good health is an important aspect of Islam. Muslims are expected to keep their bodies healthy in order to perform their duties towards God (Allah). According to one Hadith “The Prophet said: Allah has sent down both the disease and the cure, and He has appointed a cure for every disease, so treat yourselves medically, but use nothing unlawful”[21].

There are few examples from the life of Prophet Muhammad, where forbidden materials were allowed for better healthcare of individuals [22]. There is a tradition narrated where Prophet used to permit the use of camel’s milk and urine to cure the sickness in stomach [23], and in

another narration wearing silk which is generally Haram for men was allowed for skin itch treatment [24, 25]. At present there is no blanket rule of prohibition or permission despite their adherence to the religious and legal aspects of the Islamic law as promulgated by the jurists [22].

The religious and legal basis of forbidden material can be used to make a case for their use for healthcare. In cases where there are alternatives to the forbidden materials, the permission is only given to the use of the Halal alternatives.

Use of Porcine derivatives and controversy among Muslims

Some Muslim Jurists allow the dietary and non-dietary consumption and use of porcine derived material like gelatine and skin for health and non-healthcare reasons if it has gone through a process of “complete transformation” called in Arabic “Istihala”.

Istihala:

Literally, Istihala means transformation and conversion of one material to other material [26]. Istihala has been defined as the “changing the nature of the defiled or forbidden substance to produce a different substance in name, properties and characteristics. Istihala can be divided in three types. First, Istihala includes the transformation of physical appearances, secondly transformation of chemical substances and thirdly the transformation occurred both in physical and chemical. Physical transformation includes odour, taste and colour. While chemical transformation is the changes of chemical substances in materials. At the same time, transformation of physical and chemical of one substance involve complete changes hence produce new materials [27].

The process of Istihala has three elements namely the raw material, conversion agents and finish products. The mixing process occurred as a result of interaction between raw material and conversion agent, naturally or artificially. Then the finish product will undergo conversion process which is different physically and chemically from the original material. [27]

Some scholars believe that changes have to be in the material nature into a new nature, not only the characteristics. Some people believe that not only the nature and characteristics but the properties must change as well and it must have a new independent nature, another characteristics and a new name.

A meeting of 112 jurisprudents and eminent scholars held in Kuwait in 1995 under the auspicious of the Islamic Organization for Medical Sciences (IOMS) recommended that “Transformation which means the conversion of a substance into another substance, differ in characteristics,

changes substances that are judicially impure or are found in an impure environment, into pure substances, and changes substances that are prohibited into lawful and permissible substances". Accordingly the Gelatine formed as a result of the transformation of the bones, skin and tendons of a judicially impure animal are pure, and it is judicially permissible to eat it" [28].

However, according to another group of Muslim jurist's opinion pig has been declared as "rijs" or "najas al-ayn, that means essential filthy. Therefore, every part of it be it meat, hair, bones or skin is considered impure and strictly do not allow its use for any purpose except lifesaving situation where there is no alternative available [29].

Istihala and Porcine Dermal implant

The process by which the porcine skin goes through to make it suitable for the implantation involves removal of cells, cell debris, DNA and RNA in a gentle process that is not damaging to the 3D collagen matrix. The resulting acellular collagen matrix may then be cross-linked for enhanced durability in complex repairs. This acellular porcine dermis is used as a dermal scaffold, which eventually becomes vascularized and remodelled to reconstruct the abdominal wall in complex patients [30].

Collagen molecules are composed of three alpha chains intertwined in the so-called collagen triple helix. This particular structure, which mainly stabilized by intra and inter chain hydrogen bonding, is the product of an almost continuous repeating of the Gly-X-Y – sequence, where X is mostly proline and Y is mostly hydroxyproline [31].

Gelatine is an irreversibly hydrolysed form of collagen obtained from various animal by-products. The amino acid composition and sequence in gelatine are different from one source to another source but always consists of large amount of glycine, proline and hydroxyproline. The molecular composition of collagen and gelatine are almost identical [32]. The composition of collagen encompasses all 20 amino acids [33]. Glycine, proline and hydroxyproline are the largest numbers of amino acid that exist in gelatin. The chemical properties of gelatine are affected by amino acid composition, which is similar to that of the parent collagen, thus influence by animal species and type of tissues. [34-36]

If the gelatine of porcine origin cannot be accepted as permissible product, then the pure porcine mesh which physically looks like porcine skin cannot be permissible. The question remains that the process by which the porcine skin is made suitable for its use as mesh results in a complete transformation of the original product, and the ruling of "Istihala" applies? Whether it is a istihala sahahah (acceptable change) or istihala fasidah (unacceptable change).

If we apply the true concept of Istihala then as it has been described that gelatine obtained from any animal sources is transformed physically but not chemically. Therefore, the Istihala method cannot be fully applied [27]. The collagen is a less processed product than gelatine, therefore the process which has been described for a porcine skin to make it suitable for the human use as a non-dietary health care product i.e. mesh or an implant, is not transformed in a state where it can be declared Halal, i.e. permissible per se in ordinary circumstances, unless there are other justifications under the rule of Fiqh which allow its use. If the argument is made that it would provide better result hence quality of life after implanting such a mesh which is derived from porcine skin compares to acellular human dermis or bovine tissues, then at present there is no significant data which can support this argument.

The informed consent

Surgeons, in general, like to follow recommendations by their respective specialised recognised associations and/or authorities in their surgical practice. However, There is an insufficient level of high-quality evidence in the literature on the value of biologic mesh for the incisional hernia repair [10]. It is fair to state that in the light of current literature for the effectiveness of use of porcine mesh for the repair of abdominal wall hernia, the option of the use of a biological mesh given to a patient by a surgeon largely depends on the surgeon's interpretation of the available data and personal experience.

The information on the details of the contents of the products used are either not always easily available to health care practitioners or they seem to have very little knowledge about the correct composition of the biological surgical products or they do not fully understand the properties of the available prosthetics which can result in unintentional harm to patient [37-40]. Moreover, the vast majority of people, even Muslims, in general, have very poor knowledge about Istihala [41-43]. The knowledge of religious and cultural preferences regarding biologic mesh assists the surgeon in obtaining a culturally sensitive informed consent for procedures involving acellular allogeneic or xenogeneic grafts [44]. Also the patients do prefer their doctors to ask them about their spiritual and religious belief if are seriously ill and they would like their spiritual needs to be taken care. There is an anecdotal report that a Muslim women has refused the porcine skin collagen implant for pelvic surgery [45]. If the information from the manufacturers about any animal content in surgical meshes is very clearly provided and meshes are labelled appropriately then it would help doctors to choose the treatment according to patient's wishes and priorities [46].

Providing the options of alternative treatment is the part of informed consent [47]. The age of "medical Paternalism"

is over and healthcare is now a partnership between patients and professionals. [48]. According to a historic judgment by the UK Supreme Court, doctors should no longer decide what information a patient should be given before agreeing to treatment [49]. If the options of treatment are not presented, and the patients are not given their right to refuse the offered treatment then this act can create serious medico-legal issues, though it may well be all in good faith and unintentional [50]. In light of a judgment in *Montgomery v Lanarkshire Health board* by the Supreme Court of the United Kingdom, given in March 2015 [49], the popular “Bolam” test for the clinical negligence, whether a doctor’s actions would have been acceptable to a responsible body of medical opinion, applies to the information given as well as the treatment chosen and the method of it carrying out, can be challenged by an offended patient.

The knowledge of the cultural and religious belief of patients is an important factor in doctor-patient interaction to obtain an informed consent. The understanding or misunderstanding of a belief, wrong assumption about a patient’s belief and or difference in the religious belief of the doctor and patient may result in conflicts of opinions regarding the choice of available and alternative treatment and an offer provided to an individual patient. Muslims in the West come from various cultural backgrounds. There are varying degrees of observance of traditional Muslim beliefs and practices. It is important to recognize this sensitivity and avoid a stereotype approach towards all the patients. Each individual should be treated according to his or her belief [51]. The General Medical Council of the United Kingdom advises doctors to tailor their approach to discussions with patients according to their needs, wishes and priorities. Doctors should not make assumptions about the information a patient might want or need and a patient’s level of knowledge or understanding of what is proposed. Doctors should listen to patients concerns, ask for and respect their views, and encourage them to ask questions [52, 53] and cannot cherry pick what information to give to patients [48].

Conclusion

There are 1.57 billion Muslims in the world, representing 23% of an estimated 2009 world population of 6.8 billion [54]. It is important to consider religious belief of all the patients and their choice for treatment should be respected. At present there is no high quality scientific research evidence justifying the use of abdominal wall implant containing porcine derivatives for the better quality of life for the abdominal wall reconstruction. Muslim patients and various Jurists might have various views for the use of porcine derived products for their use in the quality of life issue.

It is very important for healthcare providers to keep

themselves aware with up to date knowledge of the subject in order to provide appropriate information and choice of implant to their patients to fulfil all the criterion of a valid informed consent. It will help to provide a satisfactory care to individual patient according to their belief and failure to do so can result in medico- legal implications. Medical Councils should consider introducing a practice of a separate consent form for the biological implant. This will not only protect doctors and patients but also will also bring the informed consent in line with the Good Medical Practice as described by the General Medical Council of United Kingdom. [55].

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Table 1: Biologic/bioresorbable graft comparison [6]

Brand Name	Company	Type		Additionally Crosslinked?	Sterilized?
Alloderm®	LifeCell	Dermis	Human	No	No
Allomax™	CR Bard	Dermis	Human	No	Yes
Collamend™	CR Bard	Dermis	Porcine	Yes	Yes
FlexHD™	MTF	Dermis	Human	No	No
Periguard®	Synovis	Pericardium	Bovine	Yes	Yes
Permacol™	Covidien	Dermis	Porcine	Yes	Yes
Strattice®	LifeCell	Dermis	Porcine	No	Yes
Surgimend®	TEI	Dermis	Bovine fetal	No	Yes
Surgisis®	Cook	Intestinal submucosa	Porcine	No	Yes
Tutopatch®	Tutogen	Pericardium	Bovine	No	Yes
Veritas®	Synovis	Pericardium	Bovine	No	Yes
XenMatrix™	CR Bard	Dermis	Porcine	No	Yes
BioA®	WL Gore	Synthetic bioabsorbable		N/A	Yes
TIGR®	Novus Scientific	Synthetic bioabsorbable		N/A	Yes