Xenograft and Allograft Disclosure Practices Among Otolaryngologists

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Abstract

Educational Objective: At the end of the presentation, participants will be familiar with commonly used biologic graft materials as well as current disclosure practices as part of informed consent among otolaryngologists.
Objective: Allograft and xenograft materials are commonly used in otolaryngology. The use of these materials should be disclosed during the informed consent process as patient religious and ethical observances may preclude their use.
We sought to determine the knowledge base of otolaryngologists biologic graft materials as well as their disclosure practices when using these materials.
Study Design: Cross sectional study of attending otolaryngologists.
Methods: Internet-based anonymous survey
Results: A convenience sample of attending otolaryngologists yielded 22 respondents. Over half (54%) knowingly routinely use biologic graft materials. Religious and ethical/dietary practices that may impact graft material preferences are routinely collected in only 22% and 9% of practices,
respectively. Knowledge based questions regarding biologic grafts were correctly answered 56% of the time. For example, 42% correctly identified Gelfoam as a porcine derivative; 28.6% Floseal as a bovine derivative. Disclosure of xeno- or allograft use is most common with Alloderm (31%). Gelfoam, Floseal and the species of origin of these materials, is not routinely disclosed (0%). Physician demographics had no impact on disclosure practices.
Conclusion: Xenograft and allograft materials are commonly used. Assessment of factors impacting patient preference for use of these materials is not routine. Knowledge deficiencies and disclosure practices have implications for patient care. The informed consent process should include dialogue about biologic grafts to avoid potential religious and ethical issues, possible litigation, and respect patient autonomy.

Introduction

Graft materials and implants of human or animal origin are widely available. Today's patients increasingly desire access to information and relative autonomy regarding care decisions. The surgical informed consent process should include discussion not just about the procedure, but also biologic graft materials. This is important not just for patient empowerment, but also to avoid potential religious/ethical issues and possible litigation.

In otolaryngology, frequently used biologic implants include Gelfoam®, Floseal®, and Alloderm®. Practice patterns of disclosure during the informed consent process regarding procedures involving these, and other biologic, implants have not previously been investigated.

We sought to determine the knowledge base of attending otolaryngologists regarding biologic graft materials and disclosure practices regarding their use.

Methods and Materials

- Anonymous web-based survey of attending otolaryngologists

- 10 demographic questions
- 6 questions to ascertain knowledge regarding biologic implants
- 7 questions regarding disclosure and practice patterns

Results

22 attending otolaryngologists responded to a survey regarding use of biologic graft materials. Over half (54.5%) knowingly use biologic graft materials routinely. 22.7% collect religion as part of their history, while only 9.1% collect dietary practice information. 56% correctly identified biologic graft material derivatives. Alloderm® was identified as an allograft 90.9%, Gelfoam® as a porcine derivative 42.9%, and Floseal® as a bovine derivative 28.6% (Figure 1). Those who intend on using Gelfoam® in a case inform their patients of its porcine derivative 0% of the time. 26.3% who intend on using Alloderm® will disclose it's cadaveric skin derivative 100% of the time. 5.3% disclose this 50% of the time, and 68.4% never disclose (Figure 2). Physician demographics had no impact on disclosure practices.

Common Implants, Religious Considerations

Implant	Tissue of Origin
Alloderm	Human cadaveric skin
Duoderm	Synthetic
Floseal	Bovine gelatin matrix, human thrombin from pooled plasma
Gelfoam	Porcine
Nasopore/Otopore	Synthetic
Surgicel	Oxidized cellulose polymer
Surgiflo	Porcine gelatin, bovine thrombin

Religion	Considerations
Judaism	Generally accepted to use porcine products
Islam	Porcine products acceptable only after other options exhausted; non-animal alternative preferable even if it takes longer to heal or is more expensive
Hinduism	Bovine material is not acceptable
Jehovah's Witness	Human blood is not acceptable
Buddhism	Non-animal products preferred
Vegan/Vegetarian	Variable

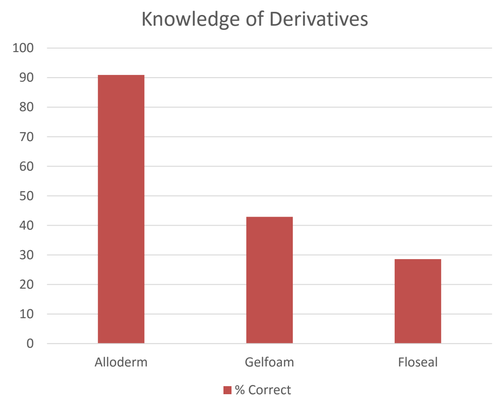

Figure 1: Percentage of participants who know the derivatives of biologic graft materials

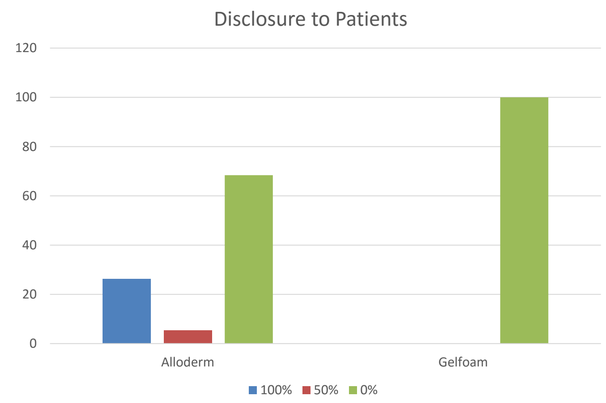

Figure 2: Percentage of time that participants disclose use of biologic graft materials prior to procedures

Discussion

Despite the ethical, religious, and potential consent issues arising from the use of xenograft and allograft use, there is a paucity of literature on this issue. There is also a lack of knowledge among otolaryngologists regarding the constituents of commonly used biologic products.

It has been previously established that to not obtain adequate informed consent is a breach of professional duty and violated patient autonomy. Some argue that failure to inform patients about the constituents of biologic implants – some of which may be religiously forbidden – is in violation of the Human Rights Act, Article, which states "Everyone has the right to manifest his religion or belief, in worship, teaching, practice, and observance. Furthermore, the most common cause of litigation is a failure in the informed consent process.

Where the use of biologic grafts, implants, and medications fits into the informed consent process is neither well established nor well studied. Our study shows that there is a clear lack of knowledge and disclosure in the attendings who completed the survey. It is important to note that while some religions have blanket rule-s about biologics (i.e. Jehovah's witnesses universally refuse blood transfusions), the decision is still up to the individual and consent should not be assumed based on religion alone.

Conclusions

Regardless of known faith, dietary, or ethical observances, adequate information should be given regarding the use of biologic products so that each individual can conscientiously make the choice that is best for them.

It is impossible to disclose something you are not aware of. There is a need to improve baseline biologic implant knowledge among otolaryngologists and to standardize the informed consent process when these products might be used.

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