Cost-Utility Analysis of Biologic and Biosynthetic Mesh in Ventral Hernia Repair: When Are They Worth It?

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BACKGROUND: Biologic and biosynthetic meshes typically cost more than synthetic meshes for use in ventral hernia repair (VHR), with unknown comparative effectiveness.

STUDY DESIGN: Cost-utility analysis was performed from a limited societal perspective assessing direct medical costs and outcomes for open, elective, retromuscular VHR. Short-term and 5-year major complications and costs were modeled using best available evidence from published studies, Healthcare Cost and Utilization Project data, and Americas Hernia Society Quality Collaborative data. Costs were analyzed in 2017 US dollars, and utilities were assessed using quality adjusted life years (QALYs). Sensitivity analyses were performed to determine threshold probabilities of long-term complications favoring particular mesh types.

RESULTS: Synthetic mesh was the preferred strategy, with a cost of $15,620 and QALYs of 18.85, assuming a baseline 5.6% rate of long-term complications for all meshes. One-way sensitivity analysis demonstrated that biosynthetic and biologic mesh became the better choice as long-term complication rates for synthetic mesh increased to 15.5% and 26.2%, respectively. Two-way sensitivity analysis demonstrated that biologic and biosynthetic meshes became favorable as the cost of biologic mesh decreased and long-term synthetic mesh complication rates increased. Biologic and biosynthetic meshes also became more cost-effective when their relative long-term complication rates decreased and long-term synthetic mesh complication rates increased.

CONCLUSIONS: Using modeling techniques, synthetic mesh is the best option for retromuscular VHR given currently available evidence. We established long-term complication thresholds, possibly justifying the higher up-front costs for biologic or biosynthetic meshes. This emphasizes the critical need to obtain long-term complication surveillance data to help individualize mesh choice in VHR. (J Am Coll Surg 2019;228:66–71. © 2018 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Ventral hernia repair (VHR) accounts for more than $3 billion in health care costs in the United States annually.[1] One variable expense in the operation is the type of mesh used for the repair. A wide variety of meshes are currently available to surgeons,[2] with considerable difference in price point. Biologic and biosynthetic meshes typically have higher upfront costs than synthetic meshes; however, long-term comparative effectiveness is unknown compared with less expensive products. Increasing concern about the long-term effects of synthetic mesh

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use after VHR have raised awareness among patients and other stakeholders, especially in the backdrop of ineffective or nonexistent post-market surveillance. Kokotovic and colleagues[3] demonstrated a 5% rate of major mesh-related complications requiring reoperation within 5 years after VHR in a Danish population. The vast majority of these meshes were synthetic products including polypropylene, polyester, and expanded polytetrafluoroethylene. This rate in other populations is unknown, but provides a critical starting point to evaluate long-term cost-effectiveness of these products. A surgeon often uses the mesh type with which he or she is familiar, within an "acceptable" price range.[4] It is nearly impossible to incorporate variations in long-term outcomes with this decision, because no reliable data exist. Furthermore, surgeons, patients, and payers are typically removed from the wide variation in mesh price in the United States because hospitals usually cover the cost of these products.

As the cost of health care continues to rise,[5,6] it is increasingly important that the medical community find the most cost effective long-term patient solutions to improve value.[7,8] In this study, we sought to determine if thresholds for long-term complication rates and costs favoring one type of mesh over another could be identified using cost-utility modeling techniques.

METHODS

Design overview

A decision analysis model was created to compare the cost-effectiveness of biologic, biosynthetic, and synthetic meshes used in VHR over a 5-year period after repair. Using data from the Americas Hernia Society Quality Collaborative (AHSQC), the profile of a typical patient (base case) undergoing VHR was identified. Additional data were obtained from the Nationwide Inpatient Sample and best available evidence in the published literature. Cost-utility analysis was performed with one-way and two-way sensitivity analyses to identify factors important to the best decision under different circumstances. The willingness to pay (WTP), which represents the maximum cost that society is willing to pay for an additional year of perfect health, was set at $50,000.[9] Vanderbilt Institutional Review Board approval was obtained, and the study was performed according to the guidelines from the Panel on Cost-Effectiveness in Health and Medicine.[10]

Decision model

The decision model was built using TreeAge Pro 2018 to determine the cost-effectiveness of the 3 mesh options while taking into account associated short- and long-term complications. The optimal mesh strategy in VHR was determined within in a wide range of complication probabilities and mesh costs. The model assumptions included:

1. The patient underwent an open, elective, retromuscular VHR using mesh.
2. Short-term and long-term complications were independent from each other.
3. The long-term complication profile consisted of problems that required reoperation: bowel obstruction, bowel perforation, bleeding, surgical site infection, late intra-abdominal abscess, enterocutaneous fistula, seroma, hematoma, nonhealing wound, and/or diagnostic surgery due to pain.[3]
4. Recurrence of the hernia was considered a treatment failure and was not modeled as a long-term complication.
5. The short-term complication profile, which was defined in alignment with the paper used to determine cost, was composed of problems commonly encountered in the first 30 post-operative days: seromas, seromas requiring intervention, cellulitis, wound dehiscence, intra-abdominal abscess, and mesh infection.[11]
6. Short-term complication probabilities were based on surgical site infection rates in the Americas Hernia Society Quality Collaborative.
7. Short- and long-term complication rates were assumed to be the same for all meshes at baseline.
8. Short-term complications were experienced within 30 days after the initial procedure, with full recovery.
9. The patient spent 6 months in the initial hernia repair recovery state.
10. Long-term complications were assessed up to 5 years after the initial operation.
11. Long-term complication recovery was 1 year, with recovery resulting in recurrent hernia and repeat operation for recurrence in year 2 with full recovery.
12. Mesh size was determined using the base case scenario from Americas Hernia Society Quality Collaborative data. This, in turn, determined pricing based on the area of mesh.
13. Biosynthetic mesh was assumed to cost 50% less than biologic mesh based on expert opinion.

Patient population and base case

The base case was a healthy, white 57-year-old woman with a BMI of 32 kg/m^2, undergoing open, elective, retromuscular midline VHR of a defect 14 cm long and 9 cm wide, using mesh. The patient had no diabetes and was a nonsmoker with a life expectancy of 80 years. The mesh size used for repair was 25 cm (length) $\times$ 21 cm (width). Base case probabilities, costs, and effectiveness outcomes used in the model are summarized in Table 1.

Costs

Cost estimates were calculated from a limited societal perspective. The 2014 Nationwide Inpatient Sample from the Healthcare Cost and Utilization Project[12] was used to generate the procedure and long-term complication costs. Diagnostic and procedural International Classification of Diseases 9 codes were used to query the database. The raw charges were then converted to costs using the Medicare cost-charge ratios. Short-term complication costs were found in best available evidence from published studies.[11] Mesh costs were calculated using the average cm^2 prices determined by Fischer and associates.[13] All monetary values were adjusted to 2017 dollars using the consumer price index for medical care.[14]

Effectiveness

Quality-adjusted life years (QALYs) represent a patient's quality of life over a given amount of time. The QALYs for each health state period were calculated using the following formula[15]:

$$\text{QALY} = \text{Health Utility} \times \left(1 - e^{-\text{discount rate} \times \text{yrs in health state}}\right) \Big/ \text{discount rate}$$

The accepted 3% discount rate[10] was used, and health utilities were obtained through the Tufts Medical Center Cost-Effectiveness Analysis Registry.[16] In this study, we assumed the patient lived for 80 years and underwent the initial VHR at the age of 57; therefore QALYs attained represent the patient remaining alive for 23 years after initial repair.

RESULTS

Base case analysis

In the base case scenario, using synthetic mesh for the VHR was less costly and equally as effective as using biosynthetic and biologic mesh. The incremental costs for biosynthetic and biologic mesh were $7,410 and $15,436, respectively (Table 2).

One-way and two-way sensitivity analyses

One-way sensitivity analyses were performed evaluating the impact of long-term complication rates for the biologic, biosynthetic, and synthetic mesh. These rates varied from 0% to 30%. Biosynthetic and biologic mesh became more favorable as long-term complication rates for synthetic mesh increased to 15.5% and 26.2%, respectively.

Two-way sensitivity analyses were performed to evaluate the impact of cost and long-term complication rates for the biologic, biosynthetic, and synthetic mesh (Fig. 1). The long-term complication rates varied from 0% to 30%, and the mesh costs ranged from $0 to current prices. The analysis demonstrated that biologic and biosynthetic meshes became favorable as the cost of biologic mesh decreased and long-term synthetic mesh complication rates increased. Biologic and biosynthetic meshes also became more cost-effective when their relative long-term complication rates decreased and long-term synthetic mesh complication rates increased (Fig. 2).

DISCUSSION

Using modeling techniques, this study sought to better understand the cost-effectiveness of various mesh options in VHR. Our results supported the fact that synthetic

Table 1. Variables and Sources

Source	Variable	Probability/other	Cost, $*	Utility†	Note
Procedure					
Healthcare Cost and Utilization Project (HCUP-2014)[13]	VHR operation	–	11,658	0.495	
Fischer et al[13]	Synthetic mesh	–	615	–	
NA	Biosynthetic mesh	–	8,025	–	EO
Fischer et al[13]	Biologic mesh	–	16,051	–	
Complication					
American Hernia Society Quality Collaborative, Cox et al[11], Fischer et al[13]	Short-term	0.13	9,056	0.558	1-mo duration, EO
Healthcare Cost and Utilization Project (HCUP-2014)[12], Stevenson et al[25], Jansen et al[26], Fischer et al[13], Tarride et al[27], Kokotovic et al[3]	Long-term	0.056	37,942	0.503	1-y duration, EO

*Costs are reported in 2017 US dollars.
†Utility is a number representing the health state of an individual ranging from 0 (utility of death) to 1 (utility of perfect health).
EO, expert opinion; NA, not available; VHR, ventral hernia repair.

Table 2. Cost-Effectiveness Comparison of Synthetic, Biosynthetic, and Biologic Mesh in Ventral Hernia Repairs

Type of mesh used in VHR	Cost, $	Incremental cost, $	Effectiveness, QALY	Cost-effectiveness, $/QALY	Incremental cost-effectiveness, $/QALY
Synthetic	15,620	—	18.85	828	—
Biosynthetic	23,030	7,410	18.85	1,221	Dominated*
Biologic	31,056	15,436	18.85	1,647	Dominated*

Costs are reported in 2017 US dollars.
*Incremental cost-effectiveness was not calculated because the biosynthetic and biologic mesh were dominated by the synthetic mesh, which was less costly but equally as effective as the biosynthetic and biologic mesh.
QALY, quality-adjusted life-year; VHR, ventral hernia repair.

mesh is the most cost-effective strategy in clean open VHR. However, higher priced biosynthetic and biologic mesh can be justified as the 5-year synthetic mesh related complication rates rise above 15% and 26%, respectively.

Previous efforts have been taken to understand this important topic. Totten and coworkers[17] found that in low risk patients, VHR costs in a 180-day perioperative period were significantly higher in biologic mesh vs synthetic mesh. However, the sample size of the matched group was small (n = 35), because biologic mesh is usually used in higher wound classifications. Although a meta-analysis by Atema and colleagues[18] found no benefit of biologic mesh compared with synthetic mesh, "head-to-head comparisons were lacking" between the 2 groups. Fischer and associates[13] also investigated the cost-utility of mesh selection in VHR. Their model predicted that synthetic mesh was more cost-effective than biologic mesh in clean-contaminated hernia repairs. The main limitation of these current studies is the lack of dependable published data concerning long-term, mesh-related complications.

In 2017, Kokotovic and coauthors[3] published the first reliable long-term outcomes evaluation of mesh-related complications after VHR. A total of 3,242 patients were included from the Danish National Patient Registry, with a primary outcome of 5-year mesh-related complications requiring operation. Overall complications were 5%, with little variation based on surgical approach (open repair [5.6%] and laparoscopic repair [3.7%]). This publication was the cornerstone of the clinical question our study aimed to answer: are there thresholds for long-term complication rates that make biologic and/or biosynthetic mesh more cost-effective than their synthetic counterparts?

Limited by the minimal number of biologic and biosynthetic mesh cases, Kokotovic and colleague's study[3] was unable to compare the complication rates between the 3 major mesh categories. Our analysis, therefore, assumed that all meshes have the same baseline complication rates at 5 years. On this assumption, the base case scenario indicates that synthetic mesh is the more cost-effective option in clean VHRs. This result aligns with previously published short-term studies.[13,19] Regardless, long-term complications must be taken into account in these modeling scenarios and ultimately, in any evaluation of these products designed to last a lifetime for our patients. We performed this evaluation exploring the possibility that there may be differences in long-term complications based on mesh type. We used a modeling approach and sensitivity analyses to incorporate the uncertainty with respect to differences in long-term mesh-related complications. Our model did show that small changes in long-term complication rates could significantly affect the cost-effectiveness of mesh strategies.

Our study highlights 2 important findings. First, there are long-term complication rate thresholds that could justify the higher up-front costs for biologic or biosynthetic meshes. Second, these threshold rates were lowered as the cost of the biologic and biosynthetic meshes decreased. This potential benefit emphasizes the critical need to obtain accurate long-term follow-up data on patients undergoing VHRs, thereby allowing clinicians,

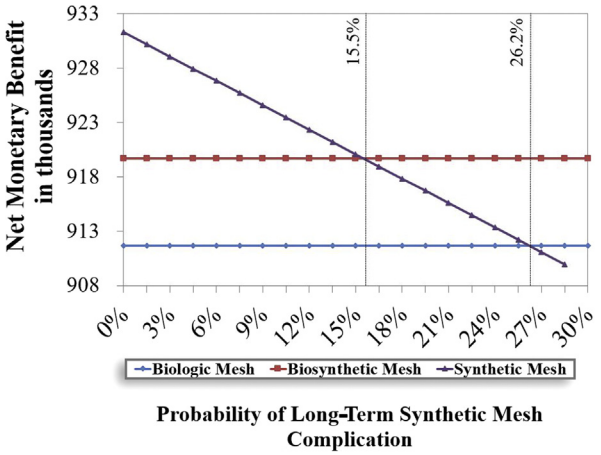

Figure 1. One-way sensitivity analysis of long-term synthetic mesh complication rates and net monetary benefit. As the rate of long-term synthetic mesh complications increases past 15.5% and 26.2%, biosynthetic and biologic mesh become favorable treatment options, respectively. Willingness to pay is set at $50,000.

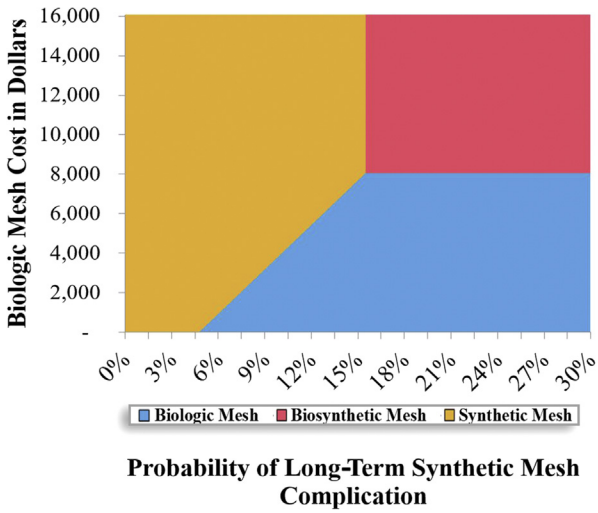

Figure 2. Two-way sensitivity analysis of long-term synthetic mesh complication rates and biologic mesh cost. Colors indicate areas of best mesh choice ([blue] biologic mesh, [red] biosynthetic mesh, [yellow] synthetic mesh). As the rate of long-term synthetic mesh complications increases and the biologic mesh cost decreases, biosynthetic, and biologic mesh become the more favorable treatment options. Willingness to pay is set at $50,000.

patients, hospitals, and payers to fully understand the impact of mesh choice to determine the most cost-effective option for individual patients. These follow-up data would also increase our ability to identify specific populations at risk for long-term complications and tailor mesh choice. Realistically, obtaining this type of long-term follow-up is extremely difficult on a clinical basis. Developing a patient-reported outcome measure sensitive to these low-rate, potentially catastrophic complications might be a powerful way to obtain this follow-up. This would "decouple" the need for a clinical visit or evaluation and obtain the information directly from the patient. This approach has been successfully used in the ascertainment of recurrence after VHR.[20,21]

When seeking FDA approval for a new type of hernia mesh, a manufacturer is only required to indicate that the product is equivocal to previous synthetic mesh.[22] This low barrier to entrance, combined with the high volume of VHRs performed in the US annually,[1] led to a rapidly saturated market. The surge of mesh variety also created a healthy skepticism as more expensive meshes—biologic and biosynthetic—were commercialized. In modern cost-conscious health care, the balance between higher-priced innovation[23] and incremental positive patient outcomes needs to be carefully evaluated. It is therefore critical to understand the cost-effectiveness of the current ventral hernia mesh options. For decisions concerning VHR, robust long-term outcomes have to be considered.

The findings of this study need to be interpreted in light of several limitations. Although decision analysis models are powerful tools that help answer clinical questions in the face of uncertainty, the conclusions are restricted by the limited available data. Currently, there are minimal long-term follow-up data on VHR patients, so our analysis is dependent on Kokotovic and associates'[3] report. However, information from the Danish population may not be generalizable to other populations with different comorbidities. Furthermore, our analysis is based on a single base case, and therefore has limited generalizability. The cost estimates were calculated from a limited societal perspective and did not consider indirect economic costs; therefore, costs are likely underestimated by a significant but unknown amount. In a recent study, Gillion and colleagues[24] found that the indirect costs of a VHR in France were roughly 80% of the clinical costs. The pricing scheme used to calculate mesh costs was based on each square centimeter used. This differs notably from mesh unit pricing at the product level. Nonetheless, we believed this approach accurately reflected that resources used as mesh products are often trimmed at the time of operation. Additionally, assumptions were made about the patient's life span and recovery time after the initial operations and subsequent complications. Our patient experience was developed based on expert opinion, but this will certainly vary in true clinical practice because not all patients will recover in the same manner. Finally, our model highlighted the importance of long-term complications as a key factor in cost-effectiveness. We may find, in future studies, that the long-term complications might not vary across mesh types, and pricing alone is the dominant factor to be considered. In spite of these limitations, we believe that this practical analytic model can inform clinical decision-making and facilitate future investigation of differences in hernia mesh materials.

CONCLUSIONS

Cost-effectiveness analyses are growing increasingly important in our modern, cost-conscious health care system. Using modeling techniques, we established long-term complication thresholds quantifying the balance of cost and effectiveness for the 3 major classes of mesh available for hernia repair in the current market. Our analysis emphasizes the critical need to obtain long-term complication surveillance data to help individualize mesh choice in VHR.

Author Contributions

Study conception and design: Schneeberger, Pierce, Poulose

Acquisition of data: Schneeberger, Phillips, Huang, Poulose
Analysis and interpretation of data: Schneeberger, Phillips, Huang, Poulose
Drafting of manuscript: Schneeberger, Etemad, Poulose
Critical revision: Schneeberger, Phillips, Huang, Pierce, Etemad, Poulose

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