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Ventral and incisional hernia: the cost of comorbidities and complications

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Abstract
Introduction Ventral and incisional hernia repair (VIHR) is among the most frequently performed abdominal operations with significant incidence of postoperative complications and readmissions. Payers are targeting increased "value" of care through improved outcomes and reduced costs. Cost data in clinically relevant terms is still rare. This study aims to identify hospital costs associated with clinically relevant factors in order to facilitate strategies by surgeons to enhance the value of VIHR.
Methods An IRB-approved retrospective review of VIHRs performed at the University of Kentucky from April 2009 through September 2013 was conducted. NSQIP clinical data and hospital cost data were matched. Operating room (ORC), total encounter (TEC), and 90-day postdischarge (90PDC) hospital costs were analyzed relative to clinical variables using non-parametric tests.
Results In total 385 patients that underwent VIHR during the time period were included in the analyses. Considering all VIHRs, median [interquartile range (IQR)] ORC was \$6900 (\$5600–\$10,000); TEC was \$10,700 (\$7500–\$18,600); and 90PDC was \$0 (\$0–\$800). Compared to all VIHRs, ASA Class ≥ 3 was associated with increased ORC and TEC ($p < .001$), and 90PDC ($p < .01$). Preoperative open wound was associated with increased ORC and TEC ($p < .001$). Numerous operative variables were associated with both increased ORC and TEC. Wound Class > 1 was associated with increased ORC and TEC ($p < .001$) and 90PDC ($p < .01$). Inpatient occurrence of any complication was associated with increased TEC and 90PDC ($p < .001$).
Conclusions ASA Class ≥ 3, Wound Class > 1, open abdominal wound, and postoperative complications significantly increase costs. Although the hospital encounter represents the majority of the cost associated with VIHR, additional costs are incurred during the 90-day postoperative period. An appreciation of global costs is essential in developing alternative payment models for hernia in order to provide the greatest value in hernia care.

Keywords Ventral hernia · Hospital costs · Comorbidities · Outcomes · Readmissions

Postoperative complications and hospital readmissions plague ventral and incisional hernia repair (VIHR) surgery. Patient comorbidities, wound class, and operative factors are thought to contribute to the increased risk associated with this commonly performed procedure. Depending on type of procedure and type of complication, the readmission rate following ventral hernia repair is significant with estimates ranging from 5 to 11 % [1–5]. Surgical site infection (SSI) is thought to be the most common complication and the most common reason for unplanned 30-day hospital readmission following VIHR [1, 2, 6]. The incidence of SSI following VIHR is reported to be as high

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as 19–25 % for open repairs [7, 8]. Other reasons for unplanned 30-day readmission following VIHR are ileus or obstruction, bleeding, pulmonary issues, and venous thromboembolism (VTE) [1]. Further complicating the postoperative outcomes of VIHR, SSI has been demonstrated to increase a recurrence [7], which in the long-term also contributes to increased health care costs.

Evidence of the impact of patient preoperative clinical characteristics on hernia repair outcomes has increased over the last decade. The externally-validated Ventral Hernia Risk Score (VIHRS), which allows a prediction of risk for SSI after VIHR, utilizes wound class, body mass index (BMI), raising of skins flaps, American Society of Anesthesiologists (ASA) Class, and performance of a concomitant procedure with VIHR to calculate the degree of risk [8]. While improved prediction of outcomes based on patient characteristics is valuable, the economic implications must still be inferred. The relationship of cost data with patient comorbidities, operative details, and postoperative complications that allows the cost data to be presented in clinically relevant terms is scarce.

Costs associated with VIHR were more than $3 billion in 2006 in the USA alone with escalating costs over time [9]. Federal and private insurers are targeting increased "value" of care through both improved outcomes and reduced costs. In an effort to coordinate care and improve quality and cost-efficiency, the Medicare Payment Advisory Commission (MedPAC) has recommended broader bundling of payments for surgical episodes, lumping reimbursements to hospitals, physicians and other providers involved in care around a surgical episode into a single payment [10]. The Merit-based Incentive Payment System (MIPS) and the Alternative Payment Models (APMs) are the two methods of payment mandated by the United States Congress in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The purpose of the MACRA was to modernize Medicare provider payment by promoting better care over more care [11]. With the rapid shift toward bundled and value-based payment strategies, the need to understand the economic impact of ventral hernia repair surgery has taken on a greater sense of urgency. In order to enhance the value of VIHR, it is important that health care providers understand how patient clinical characteristics, operative details, and postoperative complications influence the financial burden of VIHR. Furthermore, an appreciation of the drivers of increased costs will assist providers in making informed decisions to provide more cost-efficient care while ensuring quality outcomes. The purpose of this study was to identify hospital costs associated with clinically relevant factors in order to facilitate strategies by surgeons to enhance the value of VIHR.

Methods

This retrospective review of clinical and cost data was approved by the University of Kentucky Institutional Review Board. The local American College of Surgeons National Surgery Quality Improvement Program (ACS NSQIP) database was queried for cases of ventral hernia repair performed during the four and a half year time period of April 1, 2009, to September 30, 2013. Prior to 2011, approximately one-third of all ventral hernia repair cases performed at the University of Kentucky were captured by the ACS NSQIP review; after January 1, 2011, all cases of VIHR were included. Suture only VIHR were excluded. Preoperative patient characteristics included in analyses were demographics and over thirty clinical variables including comorbid conditions and laboratory values. Perioperative detail included the primary procedure Current Procedure Terminology (CPT©) code, the Centers for Disease Control and Prevention (CDC) Wound Class, mesh type and size, admission status, operative approach, concomitant procedure(s), emergent or elective status, transfusion status, and the duration of the procedure. Postoperative clinical outcomes data included wound occurrences, respiratory occurrences, sepsis, urinary tract infection, VTE, cardiac and cerebrovascular occurrences, and discharge destination.

At our institution, VIHR is performed by a variety of surgeons among different surgical specialties in both the inpatient and outpatient setting. Patient selection for laparoscopic versus open procedures are generally based upon both patient preference and hernia characteristics. Typically, large hernias with significant complexity or recurrent hernias are performed using an open approach, while patients with modest hernias will undergo laparoscopic repair. The choice of mesh materials is based on a combination of preoperative risk factors and CDC wound class. Intraoperative variables, such as enterotomy, may alter the decision to proceed with a different mesh type, for example a biologic or bioresorbable may be used in this circumstance when the preoperative plan had been to place a synthetic mesh.

Hospital cost data was obtained from the hospital cost accounting system (Allscripts EPSi Version 7.5 FP2, Chicago, IL) and matched to the cases identified via the NSQIP query. Total hospital costs were analyzed in three groups: (1) operating room services and supplies (includes the holding room, operating room and postanesthesia care), (2) total encounter (total admission for inpatient cases, outpatient surgery center for outpatient surgery), and (3) postdischarge hospital encounters within 90 days (including emergency room, readmission, or outpatient labs or imaging) of the surgical encounter. Total hospital costs

included both direct (supplies, nursing, OR and ICU equipment) and indirect costs (administration, facility and other overhead) but did not include professional fees.

Non-parametric tests were used for the bivariate analyses of costs: the Mann–Whitney *U* test for binary variables, the Kruskal–Wallis test for non-ordered categorical variables, and the Jonckheere–Terpstra test for ordinal variables. Significance was set at $p < .01$ due to the number of comparisons. Backward stepwise multivariable regression with a removal probability of .05 was used to assess the independent contribution to cost of the preoperative, perioperative, and postoperative factors. Statistical analysis was performed using SPSS™ version 22 (IBM™ Corp., Armonk, NY).

Results

Three-hundred and eighty-five cases of ventral hernia repair were included in the analyses. Of the total cases, the majority were female (59 %), and the mean age was 51.3 years (SD = 13.3 years). More than half of the patients (57 %) were categorized as American Society of Anesthesiologists physical status Class 3 (ASA class). The body mass index (BMI) of approximately one-fifth of the patients (18 %) was >40 kg/m^2. Of all VIHRs included in the analyses, 133 cases involved recurrent ventral hernia (laparoscopic or open) with open repair of initial, reducible incisional hernia being the most frequently performed procedure ($n = 69$). Across all ventral hernia repair types, the median costs [interquartile range (IQR)] were as follows: Operating room (ORC): $6900 ($5600–$10,000); total encounter (TEC): $10,700 ($7500–$18,600); and 90-day postdischarge (90PDC): $0 ($0–$800).

Patient preoperative factors associated with increased costs

ASA class was predictive of increased costs across all three cost groups (ORC, TEC, 90PDC). Female gender, increasing age, treated hypertension, and the presence of a preoperative open wound were associated with increased ORC and TEC. COPD and diabetes were predictive of increased TEC. Steroid use for a chronic condition was predictive of increased 90PDC (Table 1). Several comorbidities, including renal failure and dialysis were rare in this cohort so were not analyzable. The following preoperative factors were not significantly associated with any of the three cost groups: BMI group, smoking status, transfer status, and none of the routine lab values including elevated white blood cell count, elevated creatinine or reduced hematocrit.

Perioperative factors associated with increased costs

Open repair of initial reducible incisional hernia was the most commonly performed procedure; however, open repair of recurrent incarcerated incisional hernia was associated with highest median (IQR) costs (Fig. 1). Perioperative variables and the associated hospital costs are presented in Table 2. Nearly nine in 10 VIHR were performed for CDC Class 1 wounds, and the ratio of laparoscopic to open cases was nearly equal (4.8:5.2). Approximately one-third of cases were for recurrent ventral hernia and two-thirds required inpatient admission. The median duration of operative procedure was between 2.5 and 3.5 h. Most cases used synthetic mesh (79 %) and one-fifth of cases utilized two or more pieces of mesh. More than 90 % of the cases were for ventral hernia repair alone.

All perioperative factors were associated with increased ORC and TEC except for incarcerated versus reducible hernia (all $p < .01$, Table 2). Wound Class 3 patients incurred increased ORC, TEC, and 90PDC compared to wound Class < 3. The Diagnosis Related Grouping (DRG) of the VIHR admission reflected concomitant surgery and was predictive of increased ORC and TEC costs ($p < .001$, Table 3). Female gender was associated with both increased ORC and TEC. Specifically, it was noted that females were more likely than males to have inpatient admissions associated with their VIHR (75 vs. 59 %, $p = .001$). Women overall had longer operative duration than males, for example, the operative duration was less than 90 min for 14 %of females but 30 % of males; whereas, the operative duration was between 151 and 270 min for 30 % of males and 46 % of females [Chi-square for variation across operative duration quintiles ($p = .001$)]. While females more frequently had open versus laparoscopic repairs than males (55 vs. 48 %), the difference was not statistically significant.

Postoperative predictors of costs

A total of 2.1 % of patients developed an inpatient postoperative wound complication which was associated with more than a tripling of TEC. Other inpatient ACS NSQIP complications such as sepsis resulted in even larger increases in TEC (Table 4). After discharge, 6.2 % of patients experienced a wound complication which was associated with a $6700 increase in PDC on average ($p < .001$, Table 4). Postdischarge sepsis was diagnosed in 1 % of patients resulting in even larger PDC increases, while other ACS NSQIP complications were rarely diagnosed postdischarge in this cohort.

A total of 62 patients (16.1 %) were readmitted to the hospital during the 90-day postoperative time period with

Table 1 Median hospital costs (interquartile range) for ventral and incisional hernia (VIHR) repair by preoperative risk factor

Characteristic	Incidence, *n* (%) of patients	Operating room service and supply costs	Total encounter costs	90-day postVIHR discharge costs
All VIHR patients	385 (100 %)	6.9 (5.6–10.0)	10.7 (7.5–18.6)	0 (0–0.8)
Gender		**	***	NS
Female	228 (59.2 %)	7.2 (5.8–12.4)	11.5 (8.3–20.5)	
Male	157 (40.8 %)	6.6 (5.4–8.8)	9.5 (6.8–14.6)	
Age (years)		**[a]	***[a]	NS
≤40	86 (22.3 %)	6.6 (5.5–8.8)	9.5 (7.1–14.0)	
41–48	76 (19.7 %)	6.6 (5.5–9.0)	9.4 (6.8–15.4)	
49–56	88 (22.9 %)	7.0 (5.4–10.3)	10.9 (7.8–18.0)	
57–64	65 (16.9 %)	7.6 (5.7–14.3)	13.8 (9.8–21.7)	
65+	70 (18.2 %)	7.5 (6.3–14.5)	13.2 (8.2–27.6)	
ASA class[b]		***[a]	***[a]	**[a]
I–II	153 (39.7 %)	6.3 (5.3–8.5)	8.8 (6.8–12.2)	0 (0–0.2)
III	219 (56.9 %)	7.5 (6.0–15.1)	12.6 (8.9–24.4)	0.1 (0–2.1)
IV–V	7 (1.8 %)	6.5 (5.8–8.7)	8.1 (6.2–29.7)	0.1 (0–2.3)
Treated hypertension	217 (56.4 %)	7.2** (5.8–14.0)	11.7*** (8.0–22.5)	NS
Preoperative open wound	15 (3.9 %)	20.1*** (10.4–30.0)	29.1*** (23.4–83.0)	NS
BMI > 40 kg/m^2	69 (17.9 %)	NS	NS	NS
Smoker	126 (32.7 %)	NS	NS	NS
Diabetes	87 (22.6 %)	NS	13.4** (8.3–21.9)	NS
COPD	26 (6.8 %)	NS	17.6** (10.1–30.0)	NS
Steroid treatment for chronic condition	12 (3.1 %)	NS	NS	2.7** (0.5–6.7)

Costs are in thousands of US Dollars. $N = 385$. NS = No significant difference

IQR interquartile range, *VIHR* ventral and incisional hernia repair, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease

* $p < .05$; ** $p < .01$; *** $p < .001$ from Mann–Whitney *U* or Kruskal–Wallis tests of group differences in costs

[a] Jonckheere–Terpstra test for ordered alternatives which detects increasing or decreasing differences in medians

[b] Patients without ASA classification were excluded from the table, they comprised 1.6 % of the total

associated median 90PDC of $7700 (IQR: $4700, $19,200) compared to $0 ($0, $800) for all patients. 90PDC hospital costs were increased due to readmission, emergency room visits, and diagnostic testing (Table 5).

Multivariable analysis

The preoperative variables independently associated with increased ORC and TEC based on the regression analysis were identified to be: female gender, increased age, and presence of an open wound preoperatively. All the perioperative variables that were associated with increased costs from the univariate analysis remained independent predictors in the multivariable analysis of log-transformed ORC and TEC. Because of lack of new information, we do not show the results here.

Discussion

This study aimed to identify the specific clinical factors associated with increased hospital costs as related to VIHR. This study is unique in that hospital costs were captured as opposed to charges. Charges are frequently artificially elevated and do not reflect the cost of providing care. The hospital cost data presented in this study highlights the increased costs associated with the complex care of multiply comorbid, older patients with large ventral hernias requiring lengthy, complex repairs. Also, the data calls

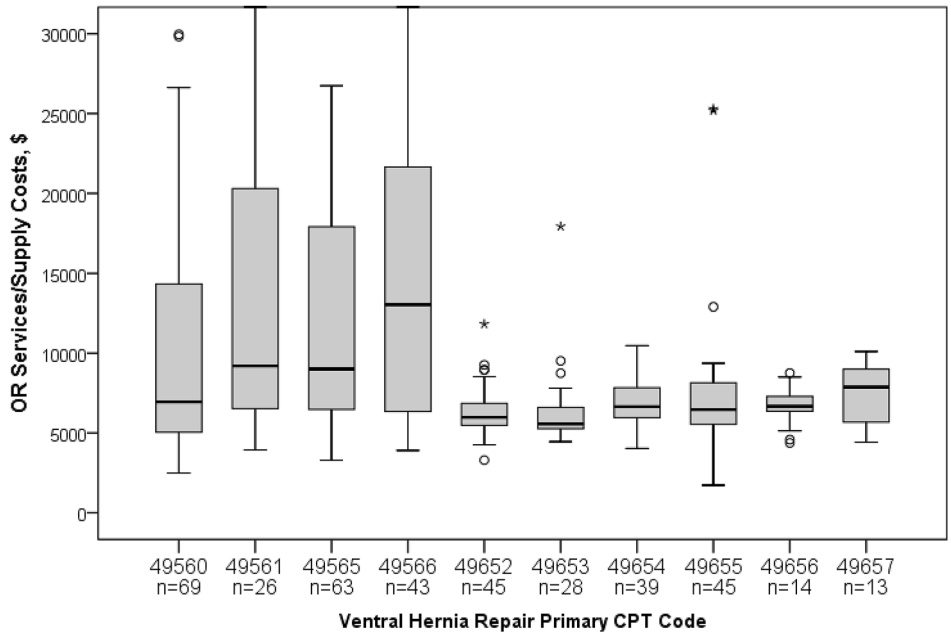

Fig. 1 Operating room service and supply costs by type of ventral hernia repair based on the primary Current Procedural Terminology (CPT) Code*, reported in US Dollars, $N = 385$

* CPT Code Descriptions
49560: Repair initial incisional or ventral hernia; reducible
49561: Repair initial incisional or ventral hernia, incarcerated or strangulated
49565: Repair recurrent incisional or ventral hernia, reducible
49566: Repair recurrent incisional or ventral hernia, incarcerated or strangulated
49652: Laparoscopy, surgical, repair, ventral umbilical Spigelian or epigastric hernia (includes mesh insertion, when performed); reducible
49653: Laparoscopy, surgical, repair, ventral umbilical Spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated
49654: Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible
49655: Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated
49656: Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible
49657: Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated

2016 Professional Edition Current Procedural Terminology. American Medical Association, 2015, Chicago, Il.

attention to the significantly increased costs associated with any postoperative complication. A previous hospital cost analysis from our institution that focused on 415 consecutive open VIHRs showed that the majority of cases were performed at a financial loss [12]. This challenging patient population requiring complex care demands a cost-efficient strategy. While achieving cost-efficient care has been an elusive goal, the data generated by the current study identifies areas for specific focus for cost containment with VIHR.

The negative financial impact of increased ASA Class was clearly exposed by our cost data. Risk reduction has been recommended as a means to enhance outcomes and reduce costs [13], but cost associated with risk reduction is not understood. Several VIHR risk score models have been developed to help surgeons predict readmission [4], surgical site infection [8], and wound morbidity and hernia recurrence [14]. Factors shown to be associated with increased risk with VIHR are numerous and include diabetes [4, 15], increased ASA Class [4, 8, 15], and increased wound class [8, 14], all of which mirror our cost data. While this study did not show evidence of a negative financial impact of morbid obesity or cigarette smoking, weight reduction and smoking cessation have been shown to enhance clinical outcomes postoperatively [16, 17]. We find this interesting and although not an independent predictor, patients that are obese or smoke cigarettes may be more likely to have other conditions which increase risk

Table 2 Median hospital costs (interquartile range) for ventral and incisional hernia (VIHR) repair by perioperative factors

Characteristic	Incidence, *n* (%) of patients	Operating room service and supply costs	Total encounter costs	90-day postVIHR discharge costs
All VIHR patients	385 (100 %)	6.9 (5.6–10.0)	10.7 (7.5–18.6)	0 (0–0.8)
Wound class		***[a]	***[a]	**[a]
1 Clean	335 (87.0 %)	6.6 (5.5–8.5)	10.1 (7.2–14.4)	0 (0–0.5)
2 Clean/contaminated	22 (5.7 %)	20.3 (8.8–22.9)	29.8 (17.8–35.8)	0 (0–3.6)
3 Contaminated	19 (4.9 %)	20.9 (14.3–31.6)	28.6 (21.9–58.2)	1.0 (0–6.0)
4 Dirty/infected	9 (2.3 %)	20.1 (15.0–26.6)	30.6 (24.2–34.9)	0 (0–8.4)
Mesh size (cm^2 tercile)		***[a]	***[a]	NS
≤310	143 (37.1 %)	5.7 (4.8–6.8)	7.4 (5.9–10.7)	
311–619	133 (34.5 %)	7.0 (6.0–17.3)	11.1 (8.2–22.1)	
620+	109 (28.3 %)	8.5 (7.2–14.0)	14.8 (11.1–25.2)	
Approach		***	***	NS
Laparoscopic	184 (47.8 %)	6.4 (5.5–7.5)	8.2 (6.7–10.7)	
Open	201 (52.2 %)	8.4 (5.9–18.1)	15.8 (10.5–27.0)	
Recurrent hernia versus initial	133 (34.5 %)	8.5*** (6.4–17.4)	15.3*** (10.8–25.2)	NS
Patient type		***	***	NS
Inpatient	264 (68.6 %)	7.9 (5.9–15.7)	13.7 (10.1–24.2)	
Outpatient	121 (31.4 %)	6.1 (5.2–7.0)	6.9 (5.6–8.2)	
Operation duration (min)		***[a]	***[a]	NS
≤90	96 (24.9 %)	5.5 (4.5, 6.5)	6.8 (5.4, 9.1)	
91–150	141 (36.6 %)	6.6 (5.5, 7.9)	9.9 (7.7, 12.9)	
151–210	77 (20.0 %)	8.4 (6.7, 17.1)	15.1 (11.0, 22.2)	
211–270	41 (10.6 %)	10.7 (8.0, 20.6)	19.6 (13.4, 28.0)	
271+	30 (7.8 %)	17.7 (12.6, 21.2)	28.5 (19.1, 32.0)	
Mesh type		***	***	NS
Synthetic only	303 (78.7 %)	6.3 (5.4–7.6)	9.4 (7.0–12.2)	
Biologic only	72 (18.7 %)	19.3 (16.4–25.6)	27.3 (21.1–35.2)	
Both	10 (2.6 %)	21.1 (15.5–26.2)	31.1 (23.7–34.3)	
No. of mesh pieces		***[a]	***[a]	NS
1	312 (81.0 %)	6.5 (5.4–8.5)	10.1 (7.1–15.4)	
2+	73 (19.0 %)	11.3 (8.0–19.9)	17.8 (10.8–29.7)	
Transfusion of PRBCs during or w/in 72 h of operation	6 (1.6 %)	21.9** (14.1–32.5)	40.7*** (25.2–93.4)	NS

Costs are in thousands of US Dollars. $N = 385$

* $p < .05$; ** $p < .01$; *** $p < .001$ from Mann–Whitney *U* or Kruskal–Wallis tests of group differences in costs

IQR interquartile range, *VIHR* ventral and incisional hernia repair, *PRBCs* packed red blood cells

[a] Jonckheere–Terpstra test for ordered alternatives which detects increasing/decreasing differences in medians

Table 3 Costs associated with the diagnostic related grouping (DRG) of the ventral and incisional hernia repair (VIHR) admission

Characteristic	Incidence, *n* (%) of patients	Operating room service and supply costs	Total encounter costs	90-day postVIHR discharge costs
All VIHR patients	100 %	6.9 (5.6–10.0)	10.7 (7.5–18.6)	0 (0–0.8)
DRG group		***	***	NS
Ventral hernia repair	205 (53.2 %)	7.1 (5.7–9.4)	11.6 (9.7–18.6)	
Outpatient VIHR (no DRG assigned)	121 (31.4 %)	6.1 (5.2–7.0)	6.9 (5.6–8.2)	
Peritoneal adhesiolysis	24 (6.2 %)	12.8 (7.7–17.8)	19.7 (16.1–27.7)	
Major gastrointestinal resection	21 (5.5 %)	19.9 (11.1–22.1)	28.5 (20.9–36.0)	
Major soft tissue procedure	9 (2.3 %)	17.3 (9.2–23.3)	24.9 (21.5–36.0)	
Gynecologic procedure	2 (0.5 %)	17.9	22.6	
Tracheotomy w/Mech. Vent. 96+ h	3 (0.8 %)	36.6	101.3	

DRG reflects more complex secondary or other operations during the admission. Median hospital costs in thousands of US Dollars (interquartile range), $N = 385$

* $p < .05$; ** $p < .01$; *** $p < .001$ from Kruskal–Wallis tests of group differences in costs

and cost Although this study did not demonstrate added costs to be independently associated with smoking and obesity, the benefits of patient optimization in enhancing recovery are well reported and should be discussed with patients preoperatively. Suggested actions to reduce risk prior to VIHR include weight reduction to BMI no greater than 35 kg/m^2, [16] smoking cessation [17], and diabetes control [18]. Pulmonary and cardiac optimization and physical pre-habilitation are also optimization considerations. Additionally, poignant and repeated patient counseling concerning risk reduction is critical to success in risk optimization.

In addition to optimization of modifiable risks, quality improvement provides an opportunity to enhance outcomes and reduce costs. Standardized quality improvement efforts such as Enhanced Recovery (ER) protocols with colorectal surgery have been reported to be associated with improved patient satisfaction, decreased length of hospital stay, reduced complication rate, and reduced costs [19, 20]. These evidence-based pathways provide the opportunity to standardize any number of aspects of patient care. Recently, a pilot study of an evidence-based approach to care of patients undergoing abdominal wall reconstruction which addresses optimal pain control and acceleration of intestinal recovery has been reported [21].

Another quality improvement effort, the 19-item World Health Organization (WHO) Surgical Safety Checklist, has been shown to be associated with significantly decreased complication rates (11.0–7.0 %, $p < .001$) and decreased mortality in the 30-day postoperative period [22]. While some form of this perioperative checklist may be in place in many facilities, the concept could be expanded to the other portions of surgical care via the Electronic Health Record (EHR). Confirming information about risk optimization, such as BMI, smoking cessation, A1c level, and discharge planning, including timely follow-up with the surgeon, postdischarge care, PCP follow-up for high-risk patients, and contact information, would allow the many participants across the continuum of care to be informed of the status of quality efforts. While this type of quality checklist currently is not in place at our facility, it could be helpful for communication and care coordination.

In an effort to determine the financial impact of quality improvement, Scally et al. [23], reviewed inpatient Medicare claims data for all Medicare beneficiaries that underwent 11 general and vascular procedures for two time periods several years apart. These authors found that hospitals that improved quality of care (evidenced by a significant decrease in complication rates between the two time periods) also significantly reduced their Medicare payments. Quality care is disincentivized in the current model in which care is paid based upon volume rather than outcomes. These findings demonstrate the potential financial benefits for patients and payers of quality improvement efforts. Hospitals and providers must balance the cost of quality improvement initiatives with cost reductions associated with improved outcomes. Because of the benefit to patients and payers, payer incentives to hospitals and providers for quality improvement measures would be a plausible solution for covering costs associated with quality improvement. While some quality improvement measures can be expensive to implement and maintain [24], other measures may be less costly.

Table 4 Hospital costs associated with inpatient and postdischarge occurrence of ACS NSQIP morbidities

Characteristic	Inpatient incidence, *n* (%) of patients	Total encounter costs	Postdischarge incidence, *n* (%) of patients	90-day postVIHR discharge costs
All VIHR patients	385 (100 %)	10.7	$N = 385$	0
		(7.5–18.6)		(0–0.8)
Any of the following wound occurrences	8 (2.1 %)	35.9***	6.2 %	6.7***
		(25.5–68.2)		(3.0–21.8)
Superficial SSI	4 (1.0 %)	30.9**	3.6 %	5.6***
		(25.5–36.1)		(0.1–9.7)
Deep SSI	1 (0.3 %)	58.2*	1.3 %	24.8***
		No IQR		(3.4–78.0)
Organ/space SSI	1 (0.3 %)	159.3*	1.0 %	20.7**
		No IQR		(9.2–27.8)
Dehiscence	3 (0.8 %)	71.6*	1.8 %	12.3***
		No IQR		(3.4–42.1)
Sepsis	6 (1.6 %)	36.0**	1.0 %	23.8***
		(23.1–61.5)		(22.0–28.3)
Septic shock	4 (1.0 %)	124.8**	0 %s	NC
		(84.7–165.0)		
UTI	7 (1.8 %)	36.5**	0.5 %	13.3*
		(11.5–90.2)		No IQR
Mechanical ventilation >48 h or unplanned intubation	7 (1.8 %)	82.9***	0 %	NC
		(50.0–159.3)		
VTE (DVT or pulmonary embolism)	5 (1.3 %)	30.9**	0.3 %	NS
		(20.0–108.4)		
Cardiac arrest/acute myocardial infarction/stroke/coma	5 (1.3 %)	50.0***	0.3 %	NS
		(32.3–119.2)		
Transfusion <72 h postoperatively	6 (1.6 %)	40.7***	0 %	NC
		(25.5–93.4)		
Pneumonia	3 (0.8 %)	47.0**	0 %	NC
		No IQR		

Median hospital costs (interquartile range) in thousands of U.S. Dollars, $N = 385$

VIHR ventral and incisional hernia repair, *SSI* surgical site infection, *UTI* urinary tract infection, *VTE* venous thromboembolism, *DVT* deep vein thrombosis

* $p < .05$; ** $p < .01$; *** $p < .001$ from Mann–Whitney *U* or Kruskal–Wallis tests of group differences in costs

Closer surveillance with standardized postdischarge care, especially for high-risk patients, is one method of potential cost reduction that should be considered for VIHR. A recent review of a large cohort of Medicare patients found that follow-up with the primary care provider (PCP) after open VIHR did not benefit the patient in terms of decreased risk of hospital readmission as did follow-up with PCP following thoracic aortic aneurysm repair [5]. While it has been shown that postoperative complications drive readmissions after VIHR, early and standardized surveillance by the surgical team for complications for high-risk patients likely would be beneficial in decreasing readmission rates, which in turn would drive cost reduction. Further study is recommended to understand if there would be a benefit of early follow-up with PCP after complex hernia repair in multiple comorbid patients.

This study showed that any complication postoperatively was associated with dramatically increased hospital encounter costs. Wound complications affected the postoperative recovery of 8.3 % of our patient cohort. Any wound occurrence was associated with a median of $35,900 ($25, 500, $68, 200) in total admission costs compared to all VIHR patient median (IQR) costs of

Table 5 90-day encounter for patients post ventral and incisional hernia repair (VIHR) discharge, Median (IQR) hospital costs, reported in thousands of U.S. Dollars, $N = 385$

Characteristic	Incidence, *n* (%) of patients	Total hospital costs 90-day postVIHR discharge
90-day postoperative encounters		
All patients	385 (100 %)	0
		(0–0.8)
Emergency department visits without readmission	46 (11.9 %)	2.6***
		(0.6–9.6)
Readmission	62 (16.1 %)	7.7***
		(4.7–19.2)
Outpatient surgery	7 (1.8 %)	4.2***
		(2.4–6.1)
Outpatient encounter	120 (31.2 %)	0.6***
		(0.2, 3.4)

* $p < .05$; ** $p < .01$; *** $p < .001$ from Mann–Whitney *U* or Kruskal–Wallis tests of group differences in costs

VIHR ventral and incisional hernia repair

$10,700 ($7500, $18,600) ($p < .001$) and a median $6700 ($3000, $21,800) in 90PDC hospital costs compared to all VIHR patients $0 ($0, $800) ($p < .001$). Wound dehiscence was associated with median (IQR) hospital costs of $12,300 ($3400, $42,100) compared to all VIHR patients $0 ($0, $800) ($p < .001$). SSI and wound dehiscence are not only associated with increased hospital costs but also increased financial implications for patients in terms of potential lost wages and transportation costs associated with increased number of office visits and/or emergency room visit or hospital readmission and the additional health care costs associated with home health care. While the full extent of the financial burden of wound complications following VIHR is not in the scope of this study, quantifying the complete costs of wound complications is needed to define the comprehensive financial impact of VIHR to patients, hospitals, and society.

Because of the high incidence, morbidity, and excess utilization of resources associated with central line-associated bloodstream infections (CLABSI), care bundles aimed at reducing the infection rate to near-zero have been introduced in health care systems [25, 26]. CLABSI rate prior to introduction of care bundle at one hospital was reported to be 12.8/1000 catheter days. Over time, following implementation of the intervention and with judicious process evaluation and monitoring, the infection rate was reported as 0 for a 3-year time period [25]. The authors of the study mentioned that a "culture of safety" was related to their success with this program. With implementation and judicious evaluation and monitoring of enhanced recovery protocols, it is within reason that that incidence of complications, including SSI, after VIHR can be reduced, but due to the many confounding factors it is not clear if SSI or other complications after VIHR can be reduced to near-zero. Further study would be necessary to answer that question; however, earlier recognition of postoperative complications is an attainable goal, which would likely lead to decreased morbidity and decreased cost.

While risk optimization and quality improvement efforts are critical to cost reduction and enhanced outcomes, and despite significant efforts aimed at prevention, surgical complications continue to occur, likely are not entirely preventable, and are associated with striking cost increases. An investigation of hospital costs, revenues, and contribution margins associated with surgical complications from 2013 reported that 5.3 % of the 34,256 surgical patients included in the analysis experienced at least one postoperative complication, finding that the per-patient variable hospital costs, total costs, and contribution margin were significantly higher and per-patient total margin was significantly lower for the patients that experienced a complication compared to those that did not have a postoperative complication [27]. Also, postoperative complications following hepato-pancreatico-biliary surgery have been shown to be associated with higher hospital costs, higher payments, higher contribution margins and net profits [28]. Revised payment strategies will eliminate increased net profits associated with surgical complications. Payment models that consider both the costs associated with preoperative risk and postoperative complications would be helpful in the shift away from fee-for-service payment strategies. Bundled care models for reimbursement need to adequately risk stratify patients to account for increased costs associated with non-modifiable risk factors.

The current study included open and laparoscopic VIHR, and the cost data clearly highlights the variation in costs associated with this type repair. In 2012, Colavita et al. utilized the Nationwide Inpatient Sample to compare outcomes and costs between open and laparoscopic VIHR. The findings of their review included that short-term outcomes of laparoscopic VIHR were more favorable than open repair in terms of length of stay, costs, complication rates, and mortality [29]. A subsequent study by the same authors demonstrated similar recurrence rates between laparoscopic and open repairs [30]. While many factors must be considered in determining the ideal approach to hernia repair, from a value perspective, it is plausible to postulate that laparoscopic ventral hernia repair when feasible should result in reduced costs and similar outcomes.

Hernia recurrence is an additional driver of cost and cannot be underestimated. However, in our study, the cost of wound complications far exceeded the cost associated with the repair of recurrent hernias. While it is often said that the most expensive hernia is the one that recurs, the current study demonstrates the significant cost of postoperative complications. Undoubtedly, those patients developing postoperative infections are even further likely to develop subsequent hernia recurrences.

Our data did not support smoking as a predictor of increased costs for VIHR patients; however, it did identify increased hospital costs associated with COPD. Findings of a recent study that assessed the relationship of smoking duration with respiratory symptoms and COPD concluded that while prevalence of COPD was decreased for smokers who quit $\geq$10 years previously, smoking duration had a linear relationship with COPD [31]. The NSQIP data bases smoking status on one item: "current smoker within 1 year: yes/no." Therefore, it is not known with certainty if our patients were smoking at the time of VIHR, which may be reflected in the lack of association between smoking and costs. This limitation of the NSQIP dataset makes it difficult to make assumptions regarding the impact of smoking upon hernia outcomes. It is the practice of the authors to avoid hernia repair in patients who have not abstained from smoking for at least 4 weeks preoperatively based upon studies demonstrating a reduction in perioperative complications with abstinence for this short duration [17].

The NSQIP ventral hernia data collection extends to the 30-day postoperative time point, while our accounting database is able to capture costs beyond this timeline. As a result, some outpatient costs within the 90 day interval may be unrelated to the hernia repair. A further limitation is that postdischarge costs that were incurred at a facility other than our two hospitals were not known and therefore not included in our analyses. For example, if a patient reported to an emergency room other than at our facility, the costs associated with that care were not retrievable. Additionally, any costs associated with home health care or repeated office visits, both of which were likely to have occurred for some of the patients that incurred complications were not part of our cost data, which leads to the assumption that in reality the 90PDC are even greater than our cost data reflect. We are currently conducting a VIHR cost analysis that will incorporate all estimated postdischarge costs involved for a large cohort of patients having undergone open VIHR.

The reality of the financial impact of hernia repair surgery is that patients with multiple comorbidities and large hernias command more expensive care. As payment strategies evolve into a value over volume foundation for all surgical care, and with increasing shift of risk to providers, such as penalties for readmission, surgeons must learn to provide high quality care at a reduced cost. This study provides a unique insight into the clinically relevant drivers of cost of VIHR allowing an opportunity for pinpointing areas in need of attention. Development of a hernia care bundle payment model that incorporates risk adjustment, complexity of repair, and postoperative outcomes is needed to allow hospitals to care for these patients without incurring a financial loss.

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Compliance with ethical standards

Disclosures Dr. Margaret A. Plymale, Ranjan Ragulojan, and Dr. Dan Davenport have no conflicts of interest or financial ties to disclose. Dr. Roth is a speaker for Bard, has grants with Bard, Life Cell, Gore, and MTF, and is a consultant for LifeCell.

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ORIGINAL ARTICLE

Epidemiology and cost of ventral hernia repair: making the case for hernia research

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Abstract
Purpose Ventral hernia repair (VHR) lacks standardization of care and exhibits variation in delivery. Complications of VHR, notably recurrence and infection, increase costs. Efforts at obtaining federal funding for VHR research are frequently unsuccessful, in part due to misperceptions that VHR is not a clinical challenge and has minimal impact on healthcare resources. We analyzed national trends for VHR performance and associated costs to demonstrate potential savings resulting from an improvement in outcomes.
Methods Inpatient non-federal discharges for VHR were identified from the 2001–2006 Healthcare Cost and Utilization Project, supplemented by the Center for Disease Control 2006 National Survey of Ambulatory Surgery for outpatient estimates. The total number of VHRs performed in the US was estimated along with associated costs. Costs were standardized to 2010 US dollars using the Consumer Price Index and reported as mean with 95% confidence intervals (95% CI).
Results The number of inpatient VHRs increased from 126,548 in 2001 to 154,278 in 2006. Including 193,543 outpatient operations, an estimated 348,000 VHRs were performed for 2006. Inpatient costs consistently rose with 2006 costs estimated at US $15,899 (95% CI $15,394–$16,404) per operation. Estimated cost for outpatient VHR was US $3,873 (95% CI $2,788–$4,958). The total cost of VHR for 2006 was US $3.2 billion.
Conclusions VHRs continue to rise in incidence and cost. By reducing recurrence rate alone, a cost saving of US $32 million dollars for each 1% reduction in operations would result. Further research is necessary for improved understanding of ventral hernia etiology and treatment and is critical to cost effective healthcare.

Keywords Ventral · Hernia · Recurrence · Incidence · Cost

Introduction

The management of ventral hernia (VH) remains a challenging problem for primary care physicians, surgeons, and patients. Wide variation exists in the management of similar VHs in comparable patients. Over 2 million laparotomies are performed each year in the United States for benign conditions alone [1]. Even under optimal conditions, VHs occur in up to 28% of patients undergoing abdominal operations [2, 3]. Recurrence rates ranging from 24% to 43% are reported, even with the use of mesh [4]. Recurrence of previously repaired VHs increases costs and morbidity to patients and can sometimes require multiple repairs. Despite developing literature describing new techniques and outcomes, reliable basic information regarding ventral hernia repair (VHR) is lacking. Most importantly,

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scant federal dollars have been allocated to VH research. The reasons for this are multifactorial, but are due in part to misperceptions that VH is not a clinical challenge with little impact on resource utilization and healthcare costs. The purpose of this study is to define the scope of VHR as performed in the United States more precisely by calculating the cumulative incidence of VHR and estimating the costs associated with these operations. It is hoped that this information will help convince policy makers to support research funding for VH—a common problem faced by most practicing general surgeons.

Materials and methods

Design overview

An observational study design was used. Adult patient discharges for VHR were identified from two data sources: the 2001–2006 Healthcare Cost and Utilization Project Nationwide Inpatient Sample (NIS), and the 2006 Center for Disease Control National Survey of Ambulatory Surgery (NSAS) [5, 6]. The cumulative incidence and estimated costs of VHR were calculated for both inpatient (2001–2006) and outpatient (2006) repairs. The analysis was performed using a 95% confidence interval approach, accounting for the complex sample survey scheme of the NIS and NSAS. Performance of this study was approved by the Vanderbilt University Institutional Review Board.

Identification of patients undergoing ventral hernia repair

The two data sources used for this study (NIS for inpatient data and NSAS for outpatient data) were chosen based on their potential to calculate the number of VHRs being performed in the United States along with an estimation of costs. The NIS is the largest all-payer inpatient dataset available, representing 20% of non-federal discharges within the United States. In 2006, data were included from 1,045 hospitals representing 38 states. The sampling design is structured so that over 8 million raw discharges within the database represent national estimates when appropriate analyses are performed. The NSAS represents the only publicly available dataset that allows evaluation of outpatient procedures on a national level. It includes procedures performed at hospital-based and freestanding ambulatory surgery centers. In this dataset, 52,000 ambulatory surgery cases from the first revision of the 2006 NSAS were used to calculate national estimates. Inpatient trend analysis utilized years 2001–2006 of the NIS. Both the NIS and NSAS do not include federal discharges, notably excluding patients undergoing procedures at military facilities or in the Department of Veterans Affairs (VA). The main analysis focused on the year 2006, when data were available for both inpatient and outpatient VHRs.

Adult patients undergoing VHRs were identified based on the *International Classification of Diseases, Ninth revision, Clinical Modification* (ICD-9-CM) codes. An individual discharge was identified as a VHR-associated discharge if any associated procedure code for VHR was identified (53.41, 53.49, 53.51, 53.61, 53.59, 53.69, 46.42). This included the spectrum of VHRs commonly performed: umbilical, epigastric, incisional, parastomal, and other hernias of the anterior abdominal wall. VHRs performed both primarily and using mesh were included; inguinofemoral repairs were not included in this analysis.

Cost estimation

Procedural costs were derived from total charges using cost to charge ratios, with a third party payor perspective. For the NIS, the year-specific cost-to-charge ratio file was utilized to estimate costs for a particular VHR discharge. Because a similar file did not exist for the NSAS, costs were estimated using the NIS year-specific cost-to-charge ratios stratified by payor status. The NSAS payor categories were mapped into the NIS payor categories and cost-to-charge ratios applied to the NSAS data. All costs were adjusted to 2010 US dollars using the Consumer Price Index for Healthcare.

Statistical analysis

Using complex-sample estimation, the number of inpatient VHRs was determined by year using the 2001–2006 NIS. In similar fashion, the number of outpatient repairs was estimated using the 2006 NSAS. The total number of inpatient and outpatient VHRs in 2006 was calculated by adding the number of inpatient VHRs identified in the 2006 NIS to the number of outpatient repairs identified in the 2006 NSAS. The estimated cost per hernia repair was determined by taking the total costs for VHR in a particular year divided by the number of procedures performed. A 95% confidence interval was calculated for each point estimate. Point estimates without overlapping confidence intervals were determined to be significantly different. Data processing and statistical analyses were performed using SAS 9.2 (SAS Institute, Cary, NC).

Results

In 2006, an estimated 154,278 inpatient (95% CI 145,495–163,060) and 193,543 outpatient (95% CI 70,364–316,722) operations were performed for VH, totaling an estimated 348,000 repairs. Characteristics of the two populations are

Table 1 Comparison of characteristics for patients undergoing ventral hernia repair in 2006

	Inpatient	Outpatient
Total estimated number of procedures	154,278	193,543
Mean age (years)	58.2	50.7
Percent women (%)	62.8	37.4
Payor status (%)		
Private insurance	40.7	69.1
Medicare	42.7	16.6
Medicaid	9.0	7.8
Self pay	3.2	2.3
Other	4.3	4.2

Based on 2006 Nationwide Inpatient Sample (NIS) and 2006 National Survey of Ambulatory Surgery (NSAS)

Table 2 Inpatient ventral hernia population—2006

Parameter	
Mean length of stay (days, mean ± SEM)	6.0 ± 0.7
Hypertension (%)	47.2
Chronic lung disease (%)	18.6
Diabetes (%)	18.3
Obesity (%)	16.5
Congestive heart failure (%)	6.3
Renal failure (%)	5.0

SEM Standard error of the mean

[a] Based on 2006 NIS

compared in Table 1. In general, patients undergoing inpatient repair were older and had a higher proportion of women. Outpatient VHRs tended to be paid by private insurers while inpatient VHRs had more patients funded my Medicare and Medicaid. Mean length of stay for patients undergoing inpatient VHR was 6 days; patients had a notable incidence of hypertension, chronic lung disease, diabetes, and obesity (Table 2). For the years spanning 2001–2006, inpatient VHRs increased steadily from 126,548 in 2001 to 154,278 in 2006 based on NIS data (Fig. 1). A significantly higher number of repairs were performed each year from 2003 to 2006 compared to 2001.

The estimated cost of inpatient repair in 2006 was US $15,899 (95% CI $15,394–$16,403) in 2010 dollars. For outpatients, the estimated cost per operation for VHR was US $3,873 (95% CI $2,788–$4,958). Taking into account the number of procedures performed in 2006, the total estimated procedural costs for VHR was US $3.2 billion. Costs for inpatient repairs increased steadily from 2001 to 2006 (Fig. 2).

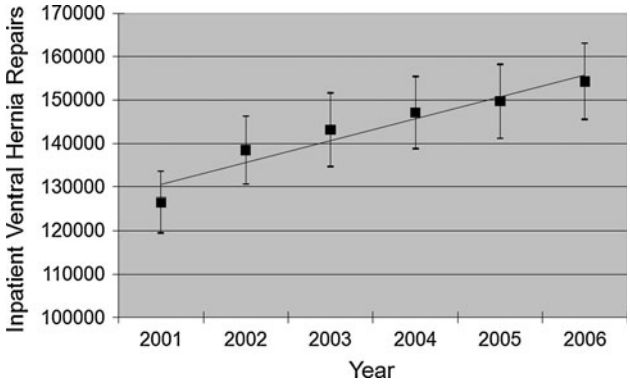

Fig. 1 Cumulative incidence of inpatient ventral hernia repairs performed between 2001 and 2006 (nonfederal US hospitals); point estimates for each year are shown with 95% confidence intervals (95% CI). Source: Nationwide Inpatient Sample (NIS)

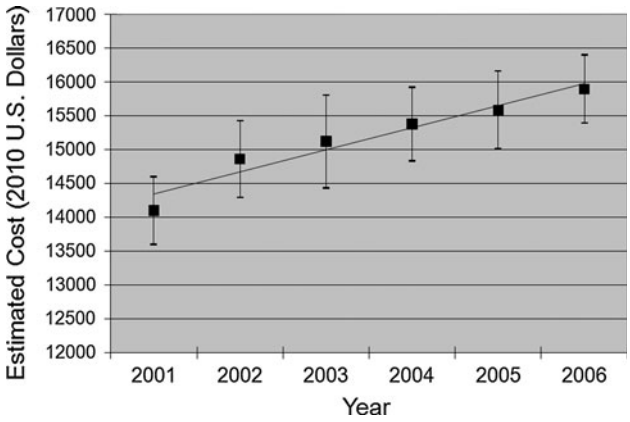

Fig. 2 Estimated periprocedural costs for inpatient ventral hernia repairs performed between 2001 and 2006 (non-federal US hospitals); point estimates for each year are shown with 95% confidence intervals (95% CI). Source: NIS

Discussion

The results of this study establish a modern estimation of the scope of VHRs performed in the United States on both an inpatient and outpatient basis. Based on these data, approximately 348,000 non-federal VHRs are performed yearly. In addition, estimated procedural costs range from US $3,873 to $15,899 for outpatient and inpatient repairs, respectively. For the inpatient VHRs analyzed, both the cumulative incidence and estimated costs are rising over time. Given the rather dismal recurrence rates for VHR, it is further estimated that every 1% reduction in hernia recurrence would result in a US $32 million yearly savings in procedural costs alone. For this reason, earnest efforts should be undertaken to identify patient populations who would be best served by VHR and to identify

measures that would reduce recurrence rates. It is hoped that these results will help foster support for VHR research and quality initiatives to improve patient care and reduce health care costs for such a common problem in general surgery.

Few studies have evaluated systematically the number of VHRs performed annually. Estimates from the Cochrane collaboration place the number of VHRs performed in Europe at about 400,000/year and in the US at 300,000/year [7]. Flum et al. [8] noted that approximately 153,000 hernias are created from the performance of prior laparotomies. These numbers, however, have all been 'ball park' estimates based on estimated numbers of laparotomies and expected incisional hernia formation rates. To date, the single best analysis prior to this work has been that of Rutkow [9], using inpatient data from the 1996 National Hospital Discharge Survey (NHDS) and the 1996 version of the National Survey of Ambulatory Surgery (NSAS). In this study, an estimated 339,000 VHR were performed in 1996. These estimates were updated in 2003 based on a 1% annual projected increase in the number of VHR performed, resulting in a 2003 estimate of 360,000 [10]. Also included in this estimate was a 5% increase due to the number of hernia repairs performed in the federal setting (VA, military). Our study builds on these results by providing more accurate figures for 2006 based on data and not purely on 'estimation.' The numbers found in our study are in general agreement with Rutkow's work, considering a modest (1%) increase in the number of repairs performed over time. Our estimate of 348,000 VHRs in 2006 does not take into account those performed in a federal setting. Using the 5% increase based on Rutkow's estimation, we estimate that 365,400 were performed in 2006 in the US when considering those performed in the federal and non-federal settings.

Given the increasing cumulative incidence of inpatient VHRs performed yearly between 2001 and 2006, we were able to calculate the percent increase in these procedures on an annual basis. Assuming a linear increase over time, an annual increase of about 5,000 inpatient VHRs was calculated (conservatively, 3%/year); this was somewhat higher than that estimated by Rutkow (1%). Using the earlier combined federal and non-federal estimate of 365,400 VHRs (both inpatient and outpatient), we project an increase of 11,000 VHRs each year in the near future. Considerable debate exists on the role of prophylactic measures to reduce the rate of hernia formation in selected populations. Identifying a group of patients in whom prophylactic mesh placement would be beneficial would have profound implications. Much investigation is needed to establish benefit, to identify the proper mesh type, and to ascertain the proper technique in hopes of reducing hernia formation in high risk populations.

Accurate cost estimates for surgical procedures remain elusive and depend critically on the perspective of analysis. In this study, we determined that the third party payor cost for an inpatient VHR was US $15,899 and for an outpatient repair US $3,873 (2010 US dollars). Adjusted for 2010, Earle et al. [11]. estimated costs for laparoscopic repair at US $7,389 and open repair at US $8,314. The estimated cost for VHR in Europe (2003) was €5,458–€6,122 [12]. Converting this to 2010 US dollars, results in cost estimates of US $8,351–$9,366. These studies did not differentiate between inpatient and outpatient repairs. Combining inpatient and outpatient results, our weighted mean cost (per case) for VHR was US $9,207, which is in general agreement with these published costs. The total costs were estimated to be US $3.2 billion in 2006. This is notably higher than previous studies estimating about US $2.5 billion in yearly health care costs associated with hernia repair [10]. It is interesting to note that the increasing costs observed for inpatient repairs (Fig. 2) occurred as the popularity of biologic meshes increased concomitantly during this period. We also note that our estimate of US $3.2 billion per year in VH associated costs was a very conservative underestimation of the true costs involved in caring for this challenging patient population. We did not take into account repairs performed in federal settings, nor did we account for physician fees involved with repair. Most importantly, we did not account for societal economic costs including time lost from work and chronic disability associated with hernias. Thus, by conservative estimates, we conclude that every 1% reduction in VHR achieved through reduced recurrence rates and improved patient selection would result in annual savings of *at least* US $32 million.

Placed in the context of federal funding for research, we can think of few clinical problems commonly faced by surgeons that are as ripe for improvement in outcomes and standardization of technique as VHR. However, scant federal clinical research dollars have been awarded to VH-associated investigation. The reasons for this are no doubt multifactorial. As hernia surgeons, we must 'prove our case' that the clinical challenges we face are worthy of federal research dollars. It is hoped that the results of this study will help achieve these goals for many investigators.

Several limitations need to be considered when interpreting the data from this study. The inpatient estimates were determined from an administrative dataset (NIS). The underlying information in this dataset was designed for billing and thus some ascertainment bias and coding errors may exist. At most institutions, however, billing for procedures is of paramount importance and coding accuracy is usually maintained at a high standard. The NSAS (used for outpatient estimates) contains far fewer raw discharges compared to the NIS. As such, confidence intervals for

outpatient estimates are much larger, with increased chance of estimation error. Nonetheless, we feel that the NSAS gives us the best (and only) approximation of outpatient procedures performed in the US. This survey was completed only in years 1996 and 2006 and we were unable to calculate trends incorporating intervening years. Neither of these datasets (NIS or NSAS) takes into account federal hospitals. Our results are presented with this exclusion. To compensate for this, a 5% increase in procedures was also calculated as described by Rutkow [9]. Cost estimates for outpatients were calculated using 2006 cost to charge ratios derived from the 2006 NIS data. To accomplish this, payor groups from the NIS were mapped to the analogous groups in the NSAS and cost to charge ratios applied. This is likely a simplification of outpatient costs, but was deemed a reasonable solution in lieu of other publicly available outpatient costing data. Estimation of costs from charge data can result in biased cost estimates, but we felt the datasets used provide the best available information for cost estimation in lieu of a more formal cost dataset. Additionally, we did not account for regional variation in costs which can vary significantly. The datasets used (NIS, NSAS) were designed to produce national estimates, which do provide a glimpse into the resources needed to perform these procedures.

This study provides an updated evaluation of the epidemiology of VH as performed in the US with an estimation of periprocedural costs. The results emphasize the need for additional research to identify patient populations who would be best served by VHR, and to identify measures that would reduce recurrence rates. A potentially large savings in healthcare costs could be realized by improving outcomes for such a common problem in General Surgery.

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EFFICIENCY OF MESH REINFORCEMENT FOR PATIENTS WITH RISK FACTORS FOR SSI IN FRANCE

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OBJECTIVE:

The abdominal wall reinforcement market has diversified considerably in the last 10 years with the arrival of biologic and biosynthetic prostheses. They are increasingly used to repair abdominal walls at risk of infection but they are costly and the clinical efficacy data are sparse[1, 2]. It is not easy to look at both the clinical and economic aspects at a national level. We have built an economic model that allows us to combine scientific and economic data to choose the most efficient strategy for patients at risk of infection within the French Health Insurance system. More than calculating the precise cost for a concrete patient, the goal was to establish the simplest possible reflection model to study the impact of the choice of the mesh reinforcement on a national level.

METHODS:

In line with the Budget Impact Analysis (BIA) good practice recommendations[3] we developed an Excel decision analysis model combining current efficacy and morbidity data for synthetic, biologic, slowly-absorbable biosynthetic (P4HB) prostheses, and two-step repairs for complex abdominal wall repair (grades 2 and 3 of the VHWG classification) at 18 months. The cost of each complication was estimated according to the Health Insurance data as has been done recently in other European countries[4–5].

For each of the four strategies, we considered the cost of purchasing the reinforcement, the range of incidence of each complication at 18 months according to the literature (infection, explantation, and recurrence) and the cost of its management according to Health Insurance[6–13]. Once the spreadsheet incorporating all these data is ready, the model will make it possible to study the various cost-effectiveness scenarios at the national level depending on the frequency of use of each of the four strategies (Table 1).

We considered a baseline scenario that reproduces the current distribution of these four strategies today in France (Table 2). Then three scenarios that reflect, respectively, the increase in use of P4HB prostheses instead of the two-step strategy (column 1), the increase in the use of P4HB instead of the biologic repairs (column 2) and the simultaneous decrease in biologic and two-step repairs in favour of P4HB (column 3).

TABLE 1: MODEL DIAGRAM

SET-UP		CONSEQUENCES (Complications/Costs)	RESULTS
PERSPECTIVE:	NHS	Hernia Recurrence	· Mesh acquisition costs
POPULATION:	CAWR-Mesh	Infected Mesh Removal	· Costs of clinical consequences potentially avoided
# CASES/YEAR:	6000	Deep Infection	
COMPARATORS:	Permanent P.- Biologic P.- P4HB P. - 2-step- -		
TIME HORIZON:	18 months		

TABLE 2: DESCRIPTION OF SCENARIOS USING VARIOUS STRATEGIES IN FRANCE

Mesh Technologies	Average Costs	Current Scenario (annual use)	Alternative Scenarios		
			Proposal 1	Proposal 2	Proposal 3
Permanent P.	350 €	3000 Units	3000 Units	3000 Units	3000 Units
Biologic P.	3.500 €	800 Units	800 Units	200 Units	200 Units
P4HB P.	2.000 €	500 Units	2000 Units	1100 Units	2600 Units
2-step	50 €	1700 Units	200 Units	1700 Units	200 Units

TABLE 3: INCIDENCE AND COST OF COMPLICATIONS

COMPLICATIONS	Incidence by Technology				Costs
	Permanent P.	Biologic P.	P4HB P.	2-step	
Hernia Recurrence	12%	18%	13%	70%	4.652 €
Infected Mesh Removal	9%	4%	0%	0%	10.000 €
Deep Infection	9%	8%	4%	10%	3.000 €

RESULTS:

According to the model, the increase in the use of P4HB prostheses shows the most favourable profile from an economic point of view.

TABLE 4: FINDINGS OF THE BUDGET ANALYSIS

	Current Scenario	Alternative Proposal 1	Alternative Proposal 2	Alternative Proposal 3
Cost of Meshes	4.935.000 €	7.860.000 €	4.035.000 €	6.960.000 €
Cost of Complications	12.894.868 €	8.647.408 €	12.443.308 €	8.195.848 €
TOTAL COSTS	17.829.868 €	16.507.408 €	16.478.308 €	15.155.848 €
Budget Impact for:	**NHS**	**-1.322.460 €**	**-1.351.560 €**	**-2.674.020 €**

Worst-case scenario analysis

These results might be caused by the fact that the model is based on very limited data in terms of the number and variety of these prostheses. This is why a more pessimistic scenario concerning P4HB prostheses was simulated by imagining a much higher incidence of complications than that indicated in the literature (Table 5). Despite these negative assumptions, the P4HB prosthesis is still the option with the most favourable cost-effectiveness profile.

The model is a dynamic spreadsheet that simulates all the desired situations by changing inputs at the user's discretion.

TABLE 5: WORST-CASE SCENARIO ANALYSIS RESULTS

Data for the budget impact analysis

Potential Incidence with P4HB p. for:	Base Case	Worst-case scenario
Hernia Recurrence	13%	17%
Infected Mesh Removal	0%	1%
Deep infection	4%	18%

Results of the Sensitivity Analysis:

	Current Scenario	Alternative Proposition 1	Alternative Proposition 2	Alternative Proposition 3
Cost of Meshes	4.935.000 €	7.860.000 €	4.035.000 €	6.960.000 €
Costs of Complications	13.247.908 €	10.059.568 €	13.219.996 €	10.031.656 €
TOTAL COSTS	18.182.908 €	17.919.568 €	17.254.996 €	16.991.656 €
Budget Impact for:	**NHS**	**-263.340 €**	**-927.912 €**	**-1.191.252 €**

CONCLUSIONS:

In Complex Abdominal Wall Repair, if we take into account the cost of the various types of abdominal wall reinforcements, the results and complications associated with each and the cost of overall management, the more frequent use of P4HB prostheses would imply a significant saving for Health Insurance (NHS). This model will need to be refined when new data become available on the long-term results of the most recent prostheses (biologic and biosynthetic).

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Original Research

Budget Impact Analysis of a Biosynthetic Mesh for Incisional Hernia Repair

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ABSTRACT

Purpose: With the development of newer prostheses for hernia repair, it is nowadays difficult to understand the total cost of managing patients treated with these advanced medical devices, especially in the complex abdomen, in which various complications may occur. The aim of this study was to determine the economic implications of these prostheses in order to inform decision making in the management of incisional hernia repair.

Methods: A budget impact analysis model was developed to evaluate the economic consequences related to the management of patients undergoing complex (Centers for Disease Control and Prevention wound class II–III or Ventral Hernia Working Group grade 2/3) incisional hernia repair through biosynthetic, synthetic, or biological meshes, from the hospital perspective in Italy. The model was populated with complication rates mainly retrieved from the literature to compare the current scenario with 60%, 10%, and 30% rates of synthetic, biosynthetic, and biological mesh utilization, respectively, with future hypothetical scenarios that consider increasing rates of biosynthetic mesh utilization with respect to the other types of mesh in the next 5 years. Hospital costs of the different events were estimated based on health care resource consumption derived from an electronic survey addressed to key opinion leaders in the field.

Findings: The analysis compared the current scenario with future hypothetical scenarios that consider increasing utilization rates of biosynthetic meshes of 25%, 38%, and 44% in the next 1, 3, and 5 years, as estimated by clinicians. Considering 40,000 incisional hernia repairs per year, an increasing use of the biosynthetic meshes may result in a decrease in the total hospital budget of about €153 million in the next 5 years, with a savings per patient of about €770.

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Implications: The findings of this study support the use of biosynthetic meshes for complex abdominal wall repairs in Italy, showing a potential decrease in the hospital budget in Italy after the diffusion of the new biosynthetic prostheses. Further studies and data from clinical practice would provide additional information to increase the understanding of the economic sustainability of these advanced devices. (*Clin Ther*. 2018;40:1830–1844)

Key words: budget impact, economic evaluation, incisional hernia, mesh, prosthesis.

INTRODUCTION

In the past 20 years, there have been changes in the treatment of hernias via abdominal wall surgery. Numerous improvements have been reported with innovations including the introduction of laparoscopy and tension-free, sutureless repair techniques with the use of prostheses, or so-called *meshes*. Today the use of prosthetic materials (in open and laparoscopic surgery) has almost completely replaced direct suture procedures, thus contributing to a decrease in the rate of recurrence.[1]

On the market, there are different types of prosthesis and fixation methods used in the repair of hernias in the abdominal wall. The most suitable type of prosthetic material can be chosen from among the following groups:

- *Synthetic nonabsorbable or partially absorbable material*: will remain in the body indefinitely and is considered a permanent implantation; it is used to provide permanent reinforcement to the repaired hernia.
- *Biosynthetic material*: constitutes a new class of materials that are completely absorbed by the surrounding tissue over time, also replacing the tissue as a scaffold.
- *Biological material*: "transforms" itself into the tissue with which it comes in contact. This concept is supported by findings from studies in animal tissues, which, after implantation, gradually replaced and "colonized" the material, so that the material disappeared completely after having exercised its containment effect for the necessary time.

When implanted into tissue, synthetic nonabsorbable or partially absorbable materials, being extremely compatible with tissue, act as foreign bodies, creating a scar reaction around the prosthesis itself. The use of these materials has become a proven success in the treatment of abdominal wall hernias, especially due to the low risk for recurrence.[2]

Biological and biosynthetic tissues are the result of the most recent studies in the field of abdominal wall repair. They are considered reshapeable because, after implantation, they are replaced, through a process of incorporation, by a new tissue formed at the site where the prosthesis is positioned and which has the anatomic and functional characteristics of the original one. In the patient, no trace of the prosthesis remains, but a "new" tissue is regenerated. These materials are now widely employed in cases of abdominal wall hernias at risk for infection, but their routine use is still limited because there are no robust scientific studies proving their effectiveness, especially concerning the risk for hernia recurrence, even many years after the intervention.[3] On the other hand, the literature in this setting reports a number of prospective or retrospective studies investigating the effectiveness profile of specific types of meshes, and further analyses or meta-analyses based on all of the available evidence, including data from registries, may be advisable in order to identify whether a particular mesh may perform better than others.

The considerable variety of materials and surgical techniques gives the surgeon the opportunity to choose the most appropriate technology in each individual patient, according to a "tailored surgery" approach.

The surgical technique and the materials used to close abdominal wall incisions are also of the utmost importance to avoid a high frequency of incisional hernias.[4] Incisional hernias are those formed on a surgical scar. It is a common postoperative complication following abdominal surgery, with a prevalence varying generally between 2% and 50%, but extreme values ranging from 0 to 91% have also been reported in the literature.[5] This wide variability may have resulted from a lack of accuracy in reporting, each surgeon's ability, the different periods of follow-up, and/or the heterogeneity (risk stratification) of the cohort of patients included in the studies.

With the development of newer meshes and approaches to hernia repair, it can be difficult to understand the total cost of use of these advanced medical devices. A recent systematic literature review[6]

highlighted that there is a paucity of studies evaluating the cost of incisional hernia repair. That review showed that significant heterogeneity in time periods, surgical approaches, and cost items considered in few published studies make it difficult to combine the data needed for a quantitative evaluation.

The aim of the present article was to develop knowledge about the clinical and economic implications of the prostheses available for abdominal incisional hernia repair, for the purpose of supporting decision making by "stakeholders" in the hospital setting in Italy. The evaluation took into account the various aspects of the management of patients undergoing incisional hernia repair, including the approaches to the management of complications.

Although few studies have assessed the cost-effectiveness of different surgical approaches, to our knowledge, no studies have presented a budget impact analysis (BIA), which is an essential component of a complete economic assessment of any health care technology. The main objective of this research was to perform a BIA, updating a model presented previously,[7] in order to estimate the current economic impact of the management of patients with complex incisional abdominal hernia through biosynthetic mesh implants, synthetic or biological meshes, from the perspective of the hospital in Italy. The BIA was also performed to evaluate changes in the hospital budget, considering a future scenario with increased utilization of biosynthetic meshes in the next 5 years.

In the preliminary phase of the study, a systematic literature review was performed in order to derive clinical evidence on the 3 types of prostheses considered, as better specified in the Materials and Methods section.

MATERIALS AND METHODS

Data on the clinical efficacy of the 3 types of devices were derived from the published literature and integrated with data from clinical practice regarding the use of biosynthetic meshes. Cost data were estimated based on the use of specific health care resources for primary repair and for the management of main complications. Data on health care resource consumption associated with each item were derived from questionnaires addressed to opinion leaders in the field. The analysis of the complications was focused on recurrence, infected mesh removal, infection (superficial, deep, or involving organ space), and seroma, as these are the clinical outcomes generally considered by surgeons for measuring the success of the procedure.[8]

Literature Review and Clinical Data Synthesis

Clinical studies may classify the wounds of patients according to 1 of 2 classification systems: (1) the Ventral Hernia Working Group (VHWG) 2010 classification[9] or (2) the newer VHWG 2012 modification.[10] The first one assigns a growing risk, from grades 1 to 4, for developing a surgical site occurrence based on patient and wound characteristics (grade 1 = low risk; grade 2 = comorbid; grade 3 = potentially contaminated; and grade 4 = infected), while the second one stratifies patients on the basis of wound contamination according to Centers for Disease Control and Prevention (CDC) classification[11] (class I = clean; class II = clean-contaminated; class III = contaminated; and class IV = dirty-infected). Wounds classified as CDC class I (clean) may be classified as VHWG 2012 grade 1 (clean cases; no comorbidity) or 2 (clean cases + comorbidity, history of infection), while CDC clean-contaminated, contaminated, and infected wounds would be VHWG 2012 grade 3.[12]

The VHWG 2010 classification suggests the use of synthetic mesh for low-risk defects (grade 1) and biological mesh for higher-risk defects (grade 2) and contaminated or infected wounds (grades 3 and 4). However, given the significantly higher acquisition cost of biological meshes compared to synthetic ones, often there is a shift toward choosing synthetic mesh even in case of wound contamination.[13] On the other hand, biosynthetic meshes have shown promising results in CDC class II/III (high-risk) wounds.[14,15]

A systematic literature review was performed in February 2018 to retrieve clinical studies reporting on complications related to the use of biological, biosynthetic,* and synthetic meshes in complex abdominal wall repair.

The search focused on studies presenting data collected after the year 2000 and that considered grades 1 to 3 of both the VHWG 2010 and CDC classifications, since clinicians generally choose among the 3 types of prostheses in this setting. Only studies with at least 15 patients and 18 months of follow-up (mean or median) were considered. The search strategy

* With regard to biosynthetic meshes, we refer to Phasix® (Davol Inc, Warwick, RI, a subsidiary of CR Bard).

is presented in the Appendix in the online version at https://doi.org/10.1016/j.clinthera.2018.09.003.

Data from Clinical Practice

As more importance is given to the collection and analysis of data from clinical practice for the evaluation of costs and outcomes associated with medical devices,[16] the multicenter registry "Italian Hernia Club" collects data on the biosynthetic mesh from 10 clinical centers in Italy (AO Universitaria Pisana, Pisa; Azienda Ospedaliero Universitaria, Ferrara; Città della salute, Ospedale Molinette, Torino; CTO, Azienda Ospedaliera dei Colli, Napoli; Ospedale Monaldi, Azienda Ospedaliera dei Colli, Napoli; Ospedale NOCSAE, Baggiovara, Modena; Ospedale S. Maria degli Ungheresi, Polistena; Ospedale San Paolo, Milano; Ospedale Santa Maria della Misericordia, Udine; Policlinico S. Orsola-Malpighi, Bologna, Week Surgery, Sede di Budrio). This registry was used, in addition to the literature search, to retrieve the frequencies of the main complications associated with incisional hernia repair (recurrence, removal of infected mesh, superficial infection, deep infection, organ infection, and seroma).

Health Care Resource Consumption and Costs

The analysis was performed from the perspective of the hospital, and the production and cost function for the provision of the health care services was considered (year-2017 euros; €1 = US $1.17). In particular, the cost function refers to the following direct-cost components: cost of drugs/treatments, cost of surgical materials, and cost of health care personnel. Indirect and general costs were not considered as they are not different among the alternatives compared.

Clinical pathways and health care resource consumption in the management of complications were estimated using data from a study-specific questionnaire administered to key opinion leaders in the field, affiliated with 12 hospitals in Italy, with great experience on mesh implants. On the basis of their clinical experience, clinicians were asked to estimate health care utilization. All of the clinicians received an electronic version of the questionnaire between January 24, 2017, and February 10, 2017. The questionnaire included the following sections:

- Introduction describing the patients' characteristics;
- Relevant examinations, laboratory tests, visits, drugs, and surgical materials related to hernia repair intervention, with personnel time for the different figures involved in the health care services and in the surgical activity; costs of drugs and surgical materials, including meshes;
- Management of main complications: recurrence, infected mesh removal, infection (superficial, deep, organ space), and seroma; data collection relates to examinations, laboratory tests, visits, drugs, negative-pressure wound therapy, hospitalizations, and related mean durations; and the costs of drugs and surgical materials, including meshes;
- Future scenarios of mesh use, including a forecast of possible future (1, 3, and 5 years) scenarios of the utilization of the 3 types of mesh in Italy.

Hospital costs were assigned to each health care resource reported (health care personnel time for surgery/visits/examinations, surgical materials, drugs, negative-pressure wound therapy, hospitalizations for complications). Health care professionals' time was monetized based on their wages. During hospital stays for the management of complications, the DRG (Diagnosis Related Group) reimbursement was considered a proxy for hospital cost. In this case we referred to DRG 453 (Complications of Treatment) for seroma, DRG 418 (Postoperative and Posttraumatic Infections) for superficial infection, and DRG 572 (Gastrointestinal and Peritoneal Infections) for deep/organ space infection. In cases of hospitalization for infection leading to treatment in a critical care unit, we referred to DRG 575 (Septicemia with Mechanical Ventilation 96 + hours, age >17 years).

Missing data were replaced with mean values calculated from the available reported data on material costs and health care personnel time. When data on hospital costs of drugs were missing, a search of the Pharmaceutical Database (http://www.federfarma.it), which reports cost data from the National Healthcare Service of Italy, was performed.

Finally, in each cost category, a weighted mean was calculated on the basis of the number of survey responders.

Budget Impact Analysis

A BIA model was developed to compare the current scenario with 60%, 10%, and 30% rates of synthetic, biosynthetic, and biological mesh utilization, respectively, with future hypothetical scenarios considering increasing rates of biosynthetic mesh

utilization, with respect to the other types of mesh, in the next 5 years. The estimation of current and new scenarios, including an increased proportion of biosynthetic meshes in the next years, was based on key opinion leaders' replies to the questionnaire. In this regard, recent (2015–2016) data on expenditure for medical devices in public hospitals, provided by Italy's Ministry of Health (MoH), were analyzed in order to evaluate the reliability of the assumptions about the current scenario.

We assumed that the costs of infected mesh removal, infection, and seroma were sustained in the first year after hernia repair, while costs for recurrences were related to the second year.

In order to perform the BIA, a review of epidemiologic data focused on patients undergoing incisional hernia repair in Italy was carried out.

The costs of the current and new scenarios were determined by multiplying the cost of each strategy by the proportion of the eligible population using it, taking into account subsequent yearly incident cohorts. Financial streams are presented as undiscounted costs, since the focus of the analysis was the expected budget at each point.[17]

A few scenario analyses were performed to test the robustness of the model results according to variations of the main model parameters.

RESULTS

Literature Review and Clinical Data Synthesis

Table I reports the studies retrieved by the literature search, with the characteristics and frequencies of complications. Since different studies considered a population mix, with wound classification ranging from classes I to III (CDC) or grades 1 to 3 (VHWG), we considered 2 scenarios in the analyses: (1) an *extended scenario*, with patients with wound classification ranging from classes I to III (CDC) or from grades 1 to 3 (VHWG); and (2) a *restricted scenario*, with patients with wound classification limited to classes II and III (CDC) and to grades 2 and 3 (VHWG). The extended scenario considers the extended setting of the use of meshes in clinical practice, while the restricted scenario represents the recommended setting for the use of the biosynthetic mesh (recommended for use in complex patients).

As the retrieved evidence was not from randomized, controlled trials but from retrospective or prospective studies, the meta-analyses of the 3 types of mesh (Stata software, metaprop command) were performed considering single-arm frequencies of the different complications and distinguishing the extended and restricted scenarios (Table II).

The same 2 scenarios were considered in the clinical-practice data on the biosynthetic mesh: scenario A presented 47 patients with 21.3% superficial infections, 14.9% seromas, 4.3% infected mesh removals, and 0 recurrences, deep infections, and organ space infections, while scenario B reported 43 patients with 23.3% superficial infections, 16.3% seromas, 4.7% infected mesh removals, and 0 recurrences, deep infections, and organ space infections.

Health Care Resource Consumption and Costs

Eight of 12 centers, involving a total of 13 opinion leaders, completed the questionnaire, representing institutions with the highest volumes of treated patients in Italy. The estimated health care resource utilization is reported in Supplemental Table I in the online version at https://doi.org/10.1016/j.clinthera.2018.09.003.

Costs related to health care resource consumption are summarized in Table III. Table IV reports the mean cost per patient, calculated including the cost of hernia repair, the mesh cost, and the cost of the management of the complications, weighted according to the complication frequencies reported in Table II. The mean cost of mesh in cases of recurrence was €2401 per patient, estimated by taking into account the mean cost of the mesh used (synthetic, €1322; biosynthetic, €3053; and biological, €6552), weighted for the percentage of use (synthetic, 67%; biosynthetic, 19%; biological, 14%). These costs are higher than the ones used for the primary intervention since larger meshes are used in cases of recurrence.

Budget Impact Findings

The BIA model was quantified with health care resource consumption and costs estimated from the earlier-cited electronic surveys. The analysis compared the current scenario with future hypothetical scenarios and considered increasing rates of biosynthetic mesh utilization of 25%, 38%, and 44% in the next 1, 3, and 5 years, as estimated by clinicians.

The expenditures, provided by Italy's MoH, of the different types of mesh were analyzed in order to obtain comparative data on the current market share. The expense distribution from 2015–2016 was 85%, 2% to 3%, and 12% to 13% with synthetic, biosynthetic, and biological mesh, respectively. It

Table I. Study characteristics and complication rates.

Type of Mesh/ Study	Follow-up Duration, mo	Study Type	Period	Population	No. of Patients	Recurr., %	Infected Mesh Removal %	Superf. Infect., %	Deep Infect., %	Organ Space Infect., %	Seroma, %
Biosynthetic*											
Buell 2017[18,†]	18 (mean)	Retrospective, comparative, single center	2010–2015	VHWG grade 2	31	6.5	–	–	–	–	–
Novitsky 2016[19]	18 (mean)	Prospective, single arm, multicenter	2014	CDC class I, 68%; class II, 20%; class III, 12%	25	4.0	–	12.0	8.0	–	4.0
Plymale 2017[20,†]	24 (mean)	Prospective, comparative, single center	NA	Matched population[‡]	31	0	–	–	–	–	–
Roth 2017[15,†]	18 (mean)	Prospective, single arm, single center	NA	VHWG grade 2	121	9.1	–	–	–	–	6.6
Synthetic											
Köhler 2015[22,†]	28 (mean)	Retrospective, single arm, single center	2009–2013	VHWG grade 2/ 3	108	8.3	3.7	–	–	3.7	–
De Noto 2013[21,†]	18 (mean)	Retrospective, comparative, multicenter	2008	VHWG grade 3	268	23.1	22.8	–	–	–	5.6
Koscielny 2018[23]	27.3 (mean)	Retrospective, comparative, single center	2009–2013	CDC class I, 8%; class II, 50%; class III, 42%	24	12.5	–	8.3	12.5	–	20.8
Krpata 2013[13,†]	18 (mean)	Retrospective, single arm, single center	2006–2011	VHWG grade 2	88	4.5	2.3	–	–	–	2.3
Liang 2014[24]	61 (median)	Retrospective, comparative, single center	2000–2011	VHWG grade 1–3 (12.5% grade 1)	40	22.5	–	25.0	12.5	5.0	7.5

(*continued on next page*)

Table I. (*Continued*)

Type of Mesh/ Study	Follow-up Duration, mo	Study Type	Period	Population	No. of Patients	Recurr., %	Infected Mesh Removal %	Superf. Infect., %	Deep Infect., %	Organ Space Infect., %	Seroma, %
Majumder 2016[25,†]	20 (mean)	Retrospective, comparative, multicenter	2009–2015	CDC class II, 65%; class III, 35%	57	7.0	1.8	5.3	5.3	1.8	3.5
Novitsky 2016[26]	31.5 (mean)	Retrospective, single arm, single center	2006–2014	CDC class I, 66%; class II, 26%; class III, 8%	428	—	—	6.5	2.6	—	2.6
Plymale 2017[20,†]	24 (mean)	Prospective, comparative, single center	NA	Matched population[‡]	51	7.8	—	—	—	—	—
Souza 2013[27]	23 (median)	Retrospective, single arm, single center	2005–2010	VHWG grades 1–3 (22% grade 1)	87	5.7	—	—	—	—	1.1
Abdelfatah 2015[28,†]	60 (mean)	Retrospective, single arm, single center	2004–2008	Subpopulation CDC class II/III	26	65.4	23.1	—	—	—	—
Biological											
Buell 2017[18,†]	18 (mean)	Retrospective, single center	2010–2015	VHWG grade 2	42	23.8	—	—	—	—	—
De Noto 2013[21,†]	18 (mean)	Retrospective, comparative, multicenter	2008	VHWG grade 3	56	16.1	3.6	—	—	—	1.8
Hood 2013[29,†]	20 (mean)	Retrospective, single arm, single center	2008–2011	CDC class II	68	1.5	—	30.9	0	—	8.8
Koscielny 2018[23]	23.5 (mean)	Retrospective, comparative, single center	2009–2013	CDC class I, 8%; class II, 50%; class III, 42%	24	25.0	—	12.5	12.5	—	29.2
Majumder 2016[25,†]	20 (mean)	Retrospective, comparative, multicenter	2009–2015	CDC class II, 65%; class III, 35%	69	21.7	2.9	5.8	21.7	4.3	4.3

Plymale 2017[20,†]	24 (mean)	Prospective, comparative, single center	NA	Matched population[‡]	44	18.2	—	—	—	—	—

Centers for Disease Control and Prevention (CDC) classification of wound characteristics: class I = clean; class II = clean-contaminated; class III = contaminated; and class IV = dirty-infected. Ventral Hernia Working Group (VHWG) classification: grade 1 = low risk; grade 2 = comorbid; grade 3 = potentially contaminated; and grade 4 = infected.

* Phasix® (Davol Inc, Warwick, RI, a subsidiary of CR Bard).

† Studies considered in the restricted scenario.

‡ Plymale 2017[20] presented results from matched populations that underwent ventral incisional hernia repair with the 3 types of meshes. The populations were matched according to age, body mass index, sex, wound class, and comorbidities.

Table II. Meta-analysis of different complication rates for the three kinds of meshes. Data are given as mean (95% CI) percentages.

Complication	Extended Scenario: CDC Wound Class I–III or VHWG Grade 1–3			Restricted Scenario: CDC Wound Class II/III or VHWG Grade 2/3		
	Synthetic Mesh	Biologic Mesh	Biosynthetic*	Synthetic Mesh	Biologic Mesh	Biosynthetic*
Recurrence	10.6 (5.4–17.2)	21.6 (9.5–36.6)	3 (0.1–8.5)	9.8 (3.6–18.5)	21.2 (8.1–38)	2.8 (0–9.5)
Infected mesh removal	6.2 (0.1–19)	7.2 (0.5–19.1)	4.3 (0.5–14.5)	6.2 (0.1–19)	7.2 (0.5–19.1)	4.7 (0.6–15.8)
Superficial infection	9.6 (3.5–17.9)	15.2 (2.4–35.1)	17.8 (9.5–27.8)	5.3 (1.1–14.6)	16.4 (10.5–23.1)	23.3 (11.8–38.6)
Deep infection	6.3 (1.5–13.5)	8.3 (0–31.5)	1.2 (0–6)	5.3 (1.1–14.6)	6.9 (3–11.9)	0 (0–8.2)
Organ space infection	3.2 (1–6.3)	4.3 (0.9–12.2)	0 (0–0.75)	2.9 (0.7–6.3)	4.3 (0.9–12.2)	0 (0–8.2)
Seroma	3.8 (1.7–6.6)	8.0 (1.6–17.9)	8.0 (3.3–14.2)	4.4 (2.5–6.6)	4.8 (1.6–9.3)	8.6 (4.6–13.6)

Centers for Disease Control and Prevention (CDC) classification of wound characteristics: class I = clean; class II = clean-contaminated; class III = contaminated; and class IV = dirty-infected. Ventral Hernia Working Group (VHWG) classification: grade 1 = low risk; grade 2 = comorbid; grade 3 = potentially contaminated; and grade 4 = infected.

* Phasix® (Davol Inc, Warwick, RI, a subsidiary of CR Bard).

Table III. Summary of the main cost items. Data are given as mean cost per patient (year-2017 euros).

Cost Type	Incisional Hernia Intervention	Recurrence Intervention	Infected Mesh Removal	Superficial Infection	Deep Infection	Organ Space Infection	Seroma
Health care personnel—visits/examinations	161	161	187	180	255	160	70
Hospital drugs	132	132	132	8	—	—	—
Consumables, mesh excluded	423	423	259	—	—	—	—
Health care personnel—surgery	332	367	400	—	—	—	—
Negative-pressure wound therapy	—	—	—	45	56	217	—
Hospitalizations	—	—	—	62	1593	5400	23
Total	1048	1083	978	296	1904	5777	93

should be noted that from these data it was not possible to distinguish the use of prostheses, and in particular whether a mesh was used for a hernia intervention or for an incisional hernia repair, which is the specific setting of the present analysis. The high percentage of use of synthetic mesh derived from the MoH data was likely due to the use of these types of mesh in the majority of hernia surgeries, while for incisional hernia repairs more advanced devices (biological and biosynthetic meshes) are used, due to the particular complexity of this kind of intervention.[3] Moreover, in 2017 the use of biosynthetic mesh more than doubled in comparison to 2016 according to involved clinicians, highlighting the need for more updated data. Due to the limitation of this analysis, we preferred to rely on data estimated by clinicians and to present a sensitivity analysis that adopted the expense distribution derived from the MoH data.

Considering 40,000 incisional hernia repairs per year,[30] an increasing use of the biosynthetic mesh may result in decreases in the total hospital budget in the next 5 years of €161.1 million in the extended scenario and €153.5 million in the restricted scenario (Table V), showing a savings per patient of about €770 in the next 5 years.

In the setting of diminished future rates of biosynthetic mesh utilization (year 1, 15%; year 3, 20%; and year 5, 25%, with redistributed values of the other meshes proportionally to the values of the current scenario), savings would be €11.0 and €13.1 million in the restricted and extended scenarios, respectively, with a savings per patient of about €55 to €65 in the next 5 years. Assuming double the prevalence rate of complications for biosynthetic meshes, the savings would become €129.4 and €138.1 million in the restricted and extended scenarios, respectively, showing a savings per patient of about €650 to 690€ in the next 5 years.

Assuming the current scenario based on the distribution of expenses from MoH data in 2016 (synthetic, 85%; biosynthetic, 3%; and biological, 12%), the model showed incremental expenses in the next 5 years of about €39 and €33 million in the restricted and extended scenarios, respectively, showing an additional cost per patient of about €165 to €195 in the next 5 years.

A set of univariate sensitivity analyses was performed by varying input costs. In particular, minimal and maximal values reported by clinicians of the main cost categories were used to inform the model. The results are summarized in Table VI. Greater variations in the model results are reported for variations of costs of the management of recurrences and deep infections.

The findings from these analyses suggest that variations in the market share in the current and future scenarios can greatly influence the model results.

DISCUSSION

Surgical repair with mesh implantation is considered the method of choice for the management of patients with incisional hernia.[31] Patients undergoing incisional hernia repair entail a substantial economic burden on

Table IV. Summary of mean costs for patient management for the different meshes for the different scenarios (extended and restricted). Data are given as euros.

Cost Type/Scenario	Synthetic Mesh	Biologic Mesh	Biosynthetic Mesh
Mesh	1007	5542	2523
Hernia intervention	1048	1048	1048
Recurrence, meshes: 67% synthetic, 19% biosynthetic, 14% biologic			
Extended	369	752	105
Restricted	341	665	98
Infected mesh removal + re-intervention (biologic mesh)			
Extended	469	469	322
Restricted	469	469	356
Superficial infection			
Extended	28	45	53
Restricted	16	50	69
Deep infection			
Extended	120	158	23
Restricted	101	154	—
Organ space infection			
Extended	185	251	—
Restricted	168	248	—
Seroma			
Extended	4	7	7
Restricted	4	4	8
Mean cost per patient			
Extended	3230	8348	4080
Restricted	3154	8180	4100

Extended scenario, patients with wound classification ranging from Centers for Disease Control and Prevention (CDC) classes I to III or from Ventral Hernia Working Group (VHWG) grades 1 to 3. Restricted scenario, patients with wound classification limited to CDC class II/III and to VHWG grade 2/3. CDC classification of wound characteristics: class I = clean; class II = clean-contaminated; class III = contaminated; and class IV = dirty-infected. VHWG classification: grade 1 = low risk; grade 2 = comorbid; grade 3 = potentially contaminated; and grade 4 = infected.

the health care system, as complications such as recurrence or infections may develop and result in additional hospitalizations and morbidity. Although different prostheses are available with various characteristics in terms of medical tolerability, functionality, and performance, there is currently no robust consensus as to which mesh type is the best.[3,32] The VHWG tried to develop a grading scale for use in selecting the appropriate surgical technique, repair material, and overall clinical approach to the patient. Although it is commonly used among surgeons, it is a nonvalidated instrument.

A recent study performed a comparison of synthetic mesh versus acellular dermal matrix in clean-contaminated ventral hernia repair through a decision model with a lifetime perspective.[33] Synthetic mesh reinforcement had an expected cost of $15,776 (21.03 quality-adjusted life-years), while biological mesh had an expected cost of $23,844 (20.94 quality-adjusted life-years). Sensitivity analysis demonstrated that synthetic mesh was the preferred and most cost-effective strategy in 94% of simulations, supporting its overall greater cost utility. Regardless, this conclusion seems in contrast with the

Table V. Budget impact analysis in the restricted scenario.

Year	Synthetic Mesh			Biosynthetic Mesh			Biologic Mesh			Total Budget Impact	Incremental Savings in Comparison to Current Scenario
	Market Share,%	Users Cohort	Cost,€	Market Share,%	Users Cohort	Cost,€	Market Share,%	Users Cohort	Cost,€		
Current scenario											
0	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	—
1	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	—
2	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	—
3	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	—
4	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	—
5	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	—
Future scenario											
0	60	24,000	75,684,743	10	4000	16,400,990	30	12,000	98,159,730	190,245,464	0
1	62	24,857	78,095,170	25	10,000	40,417,275	13	5143	46,630,632	165,143,077	25,102,387
2	62	24,857	78,387,770	25	10,000	41,002,476	13	5143	42,068,456	161,458,701	28,786,762
3	54	21,714	69,549,540	38	15,143	61,587,863	8	3143	27,039,135	158,176,538	32,068,925
4	54	21,714	68,476,673	38	15,143	62,089,463	8	3143	25,708,501	156,274,636	33,970,827
5	49	19,714	62,852,345	44	17,714	72,382,157	6	2571	21,414,409	156,648,911	33,596,553
Total incremental savings											153,525,455

Restricted scenario, patients with wound classification limited to Centers for Disease Control and Prevention (CDC) class II/III and to Ventral Hernia Working Group (VHWG) grade 2/3. CDC classification of wound characteristics: class I = clean; class II = clean-contaminated; class III = contaminated; and class IV = dirty-infected. VHWG classification: grade 1 = low risk; grade 2 = comorbid; grade 3 = potentially contaminated; and grade 4 = infected.

Table VI. Univariate sensitivity analyses in the extended (A) and restricted (B) scenarios according to cost-input variations.

Cost Type	Value			Savings in the next 5 y		
	Low	Base−Case	High	Low	Base−Case	High
Intervention	302	1048	2325	A: 160,082,447 B: 152,988,655	A: 161,083,376 B: 153,525,455	A: 162,797,144 B: 154,445,215
Recurrence	1815	3483	5428	A: 150,971,507 B: 144,645,135	A: 161,083,376 B: 153,525,455	A: 172,870,776 B: 163,876,618
Infected mesh removal management (mesh removal + re-intervention with biologic mesh)	6817	7567	8989	A: 160,076,056 B: 152,985,127	A: 161,083,376 B: 153,525,455	A: 162,991,409 B: 154,548,967
Superficial infection management	6	296	1202	A: 161,560,366 B: 154,666,836	A: 161,083,376 B: 153,525,455	A: 159,589,413 B: 149,952,887
Deep infection management	17	1904	4265	A: 154,922,550 B: 146,565,487	A: 161,083,376 B: 153,525,455	A: 168,791,748 B: 162,232,111
Organ space infection management	1359	5777	9001	A: 152,226,082 B: 144,848,274	A: 161,083,376 B: 153,525,455	A: 167,547,631 B: 159,857,162
Seroma management	26	93	274	A: 161,103,662 B: 153,663,714	A: 161,083,376 B: 153,525,455	A: 161,029,047 B: 153,153,613

Extended scenario, patients with wound classification ranging from Centers for Disease Control and Prevention (CDC) classes I to III or from Ventral Hernia Working Group (VHWG) grades 1 to 3. Restricted scenario, patients with wound classification limited to CDC class II/III and to VHWG grade 2/3. CDC classification of wound characteristics: class I = clean; class II = clean-contaminated; class III = contaminated; and class IV = dirty-infected. VHWG classification: grade 1 = low risk; grade 2 = comorbid; grade 3 = potentially contaminated; and grade 4 = infected.

VHWG's clinical recommendations, which endorse biological meshes for use in clean-contaminated fields.[9]

A recent study suggested that mesh reinforcement can be effectively and safely used to decrease the prevalence of incisional hernia in patients undergoing laparotomy.[34] In addition, together with patients after open surgery, this advantage also remained evident in patients undergoing laparoscopic surgery. Ideally, a perfect preoperative risk model can accurately estimate the possibility of incisional hernia formation and provide evidence-based recommendations on prophylactic mesh placement. In high-risk patients, mesh reinforcement may be effective and well-tolerated in preventing the formation of incisional hernia after abdominal surgery, and, consequently, it is likely to avoid future costs.

We show that in incisional hernia repair, an increasing use of the biosynthetic mesh may result in a savings per patient of about €770 in the next 5 years, considering the hospital's perspective. This result should be considered cautiously since the study presents a few limitations. First, the scenario analysis performed on data from the BIA model showed that savings are mainly based on the assumptions on current market share and high future utilization rates of biosynthetic meshes over the other types of prostheses, as estimated by clinicians; lower future utilization frequencies may lead to more contained savings, while a limited use in the current scenario of biological and biosynthetic meshes may lead to incremental hospital costs in the future. A continuous monitoring and analysis of the use of these prostheses could give insight into better estimation of present and future utilization trends.

The data on complication rates were retrieved from a limited number of studies with different durations of follow-up (18–61 months), numbers of patients (24–428), and a combination of wound-classification grades. Moreover, the rates of events varied across the studies, and the calculated weighted means may not have been fully representative of the scenario in Italy. In addition, the best option for synthesizing the available evidence would have been a formal meta-analysis that considered the relative risks for each complication. Regardless, all considered studies were not randomized, controlled trials but were retrospective or prospective studies, and next-best option of performing meta-analyses based on single-arm data was applied. In the future, powerful techniques, such as network meta-analyses, could be applied in order to obtain more robust results.

With regard to the estimation of health care resources, it must be noted that data derived from physician-reported questionnaires may be limited by varying recollection and poor generalizability. Variables derived from prospective, multicenter, observational studies would increase the validity of the current model. Using data from observational studies in addition to randomized controlled trials would also serve to support the clinical evidence of the comparative effectiveness of the meshes.

The present analysis focused only on clinical outcomes, which gives an indication of the success of the procedure. Regardless, the literature reports a prevalence of chronic pain of 7%–41% following ventral hernia repair.[8] A broader analysis taking into account also chronic pain and patients' functional status would be desirable to give a complete view of the costs of managing these conditions.

The study took into consideration only the hospital perspective. A study from France (Gillion et al [2016]),[6] which considered both direct and indirect costs, estimated a mean total cost of an incisional hernia repair of €6451, ranging from €4731 in unemployed patients to €10,107 in employed patients whose indirect costs were slightly higher than the direct costs. Considering that indirect costs represent >50% of the total cost in some patient categories, a broader analysis considering the societal perspective would give additional information on the sustainability of the use of the advanced prostheses.

CONCLUSIONS

In light of the paucity of cost (and cost-effectiveness) data from Italy, the present study adds evidence about the clinical and economic advantages of the use of biosynthetic meshes in complex incisional hernia repairs, but highlights the need for further studies or registries involving different types of meshes. In the future, prospective, randomized trials, or registries, of different mesh materials may facilitate a stronger level of recommendation. Ongoing and future analyses of the cost-effectiveness relationship, accounting for the expense of materials, surgical procedures potential complications, and indirect costs, would be greatly beneficial to practitioners and administrators.

CREDIT AUTHOR STATEMENT

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CONFLICTS OF INTEREST

The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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APPENDIX A. SUPPLEMENTARY DATA

SEARCH QUERIES

Synthetic meshes:

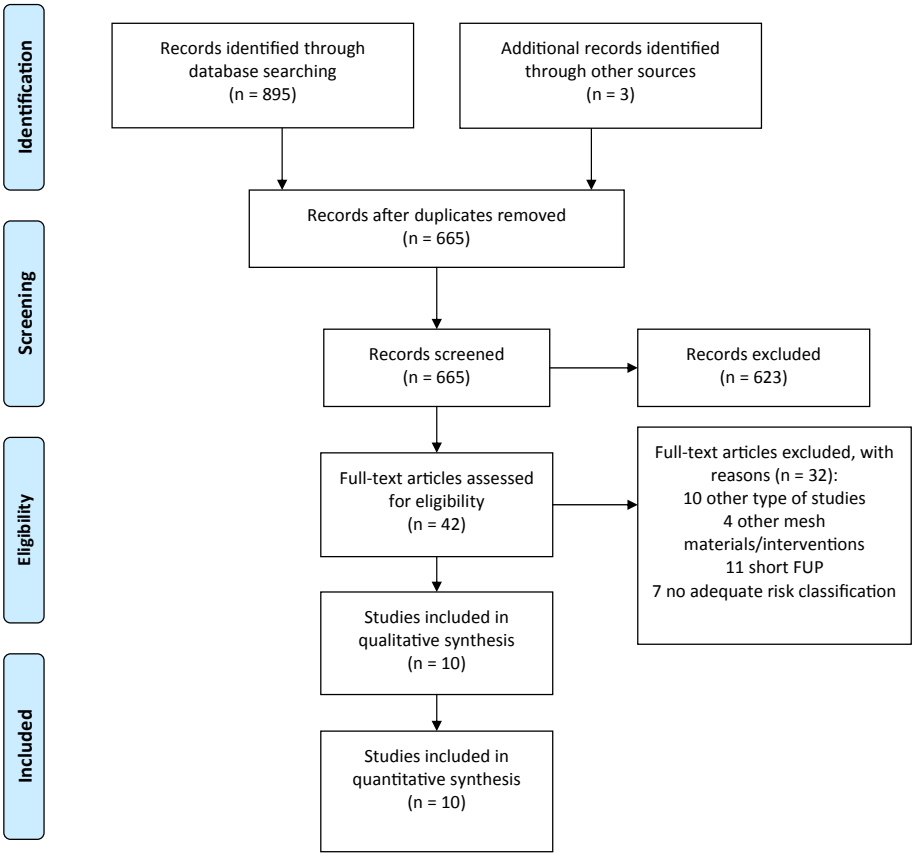
"synthetic mesh*" AND ("incisional hernia" OR "ventral hernia" OR ("major" AND "hernia") OR ("complicated" AND "hernia")) AND (complication* OR infection OR "surgical site occurrence" OR SSO)

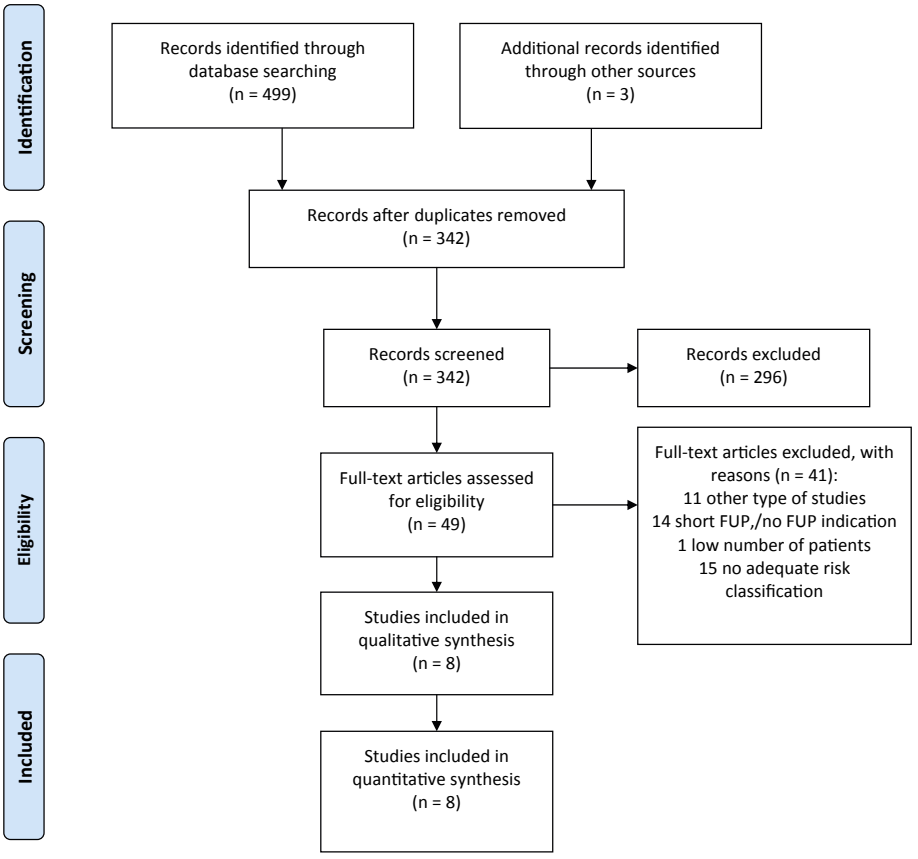
Biologic meshes:

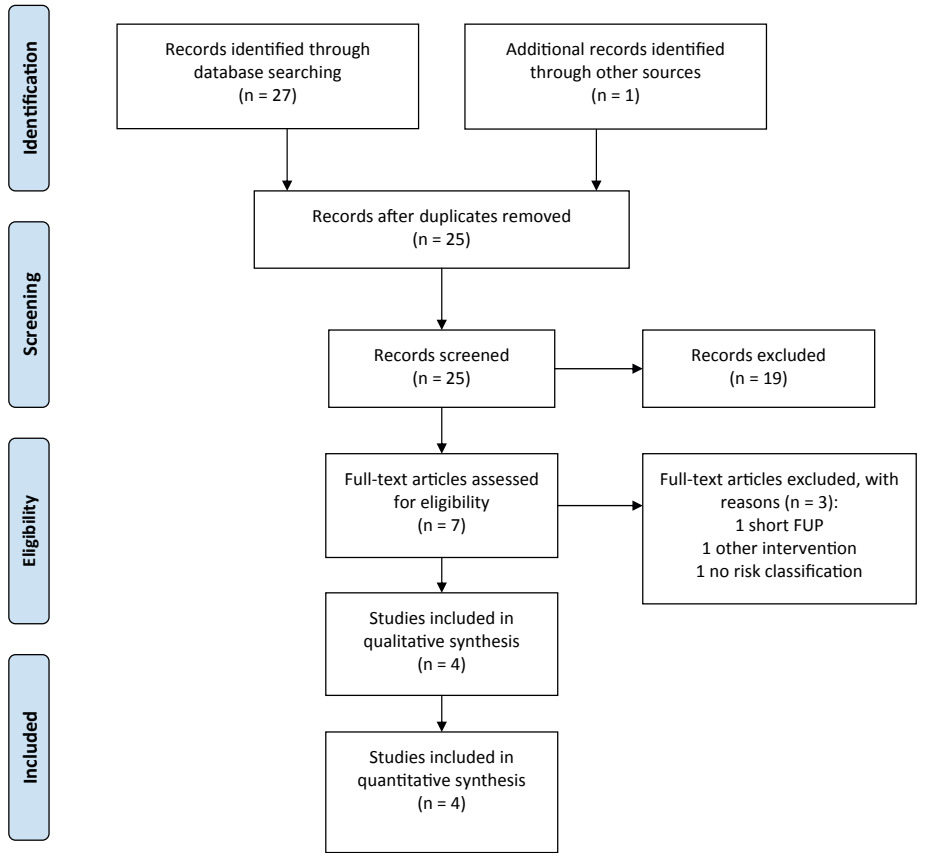
"biologic mesh*" AND ("incisional hernia" OR "ventral hernia" OR ("major" AND "hernia") OR ("complicated" AND "hernia")) AND (complication* OR infection* OR "surgical site occurrence" OR SSO)

Biosynthetic meshes:

("phasix" OR "poly-4-hydroxybutyrate" OR P4HB) AND ("incisional hernia" OR "ventral hernia" OR ("major" AND "hernia") OR ("complicated" AND "hernia")) AND (complication* OR infection* OR "surgical site occurrence" OR SSO).




Identification
Screening
Eligibility
Included
Records identified through database searching (n = 499)
Additional records identified through other sources (n = 3)
Records after duplicates removed (n = 342)
Records screened (n = 342)
Records excluded (n = 296)
Full-text articles assessed for eligibility (n = 49)
Full-text articles excluded, with reasons (n = 41):
11 other type of studies
14 short FUP,/no FUP indication
1 low number of patients
15 no adequate risk classification
Studies included in qualitative synthesis (n = 8)
Studies included in quantitative synthesis (n = 8)


Identification
Screening
Eligibility
Included
Records identified through database searching (n = 27)
Additional records identified through other sources (n = 1)
Records after duplicates removed (n = 25)
Records screened (n = 25)
Records excluded (n = 19)
Full-text articles assessed for eligibility (n = 7)
Full-text articles excluded, with reasons (n = 3):
1 short FUP
1 other intervention
1 no risk classification
Studies included in qualitative synthesis (n = 4)
Studies included in quantitative synthesis (n = 4)

Supplementary Table 1. Healthcare resource utilization.

Healthcare personnel (P=physician, N=nurse, T=technician) mean time per patient (minutes)

	Hernia repair/ recurrence			Mesh removal			Superficial infection			Deep infection			Organ space infection			Seroma		
	P	N	T	P	N	T	P	N	T	P	N	T	P	N	T	P	N	T
Visits																		
Anesthesiological	21	6		21	8													
Surgical	74	53		94	69		31	28		28	18		56	36		35	28	
Cardiologic	3	1																
Infectivologist				1														
Exams																		
Blood		17			18		6	12		16	10			20			2	
Culture																1	1	
ECG	8	11		5	10													
TC abdomen	21	16	3	25	20	4	7	6	1	18	14	4	41	36	5	1	1	
MRI abdomen	1	1		2	1		1	1										
Rx torax	10	11	2	9	10	3							2	2				
Echocardiogram	2																	
Abdominal ultrasound				1			2									10		
Treatments																		
Medications							67	92		149	149		35	35		7	7	
Negative-pressure wound therapy							8	19		38	38		4	4		4	4	

Surgery mean time per patient (minutes)

	Hernia repair	Recurrence	Infected mesh removal
Surgeon	128	143	161
Anesthetist	125	139	144
Scrub nurse	129	143	155
Operating room nurse	161	173	185

Negative-pressure wound therapy

	Superficial infection	Deep infection	Organ space infection
Mean number of disposables per patient	0.82	0.74	3.62

Hospital admissions — mean number of days per patient

	Superficial infection	Deep infection	Organ space infection	Seroma
Ordinary	0.28	6.52	13.95	0.08
Intensive care	—	0.02	1.26	—

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ORIGINAL ARTICLE

Cost-effectiveness analysis of resorbable biosynthetic mesh in contaminated ventral hernia repair☆

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HIGHLIGHTS

- Surgical management of contaminated ventral hernia repair is a challenge with mesh use.
- Few studies have compared biosynthetic mesh and biological mesh in contaminated ventral hernia repair (modified) VHWG grade 3.
- Cost-effectiveness studies may help to homogenize surgical practices: biosynthetic mesh appears to be the most effective and the least costly option.

KEYWORDS
Ventral hernia repair;
Biosynthetic resorbable mesh;
Cost-effectiveness.

Summary
Background: The aim of this study was to compare, in terms of cost and serious complications, the use of biosynthetic resorbable parietal mesh with biologic mesh in patients undergoing contaminated ventral hernia repair (modified Ventral Hernia Working Group grade 3). Poly-4-hydroxy-butyrate (P4HB) biosynthetic mesh has rarely been the subject of comparative studies in the context of contamination. Data are required to confirm the effects of a transition from biological mesh to biosynthetic resorbable mesh.
Patients and methods: A cost-effectiveness analysis was conducted. It was based on a decision analysis model built with clinical and economic data issued from a before-after study that included 94 patients hospitalized for ventral hernia repair at the University Hospital of Strasbourg (France) from June 2011 to February 2018. The effectiveness endpoint was the number of patients presenting with a serious specific complication or a general complication at 6 months. Data for surgical hospitalization stays, home hospitalizations and ambulatory care costs were included.

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Results: We found fewer serious complications with biosynthetic mesh: 21% versus 33% with biologic mesh. A cost savings of US $5146 was determined. Deterministic sensitivity analyses and a probabilistic analysis confirmed our findings and the robustness of the model.
Conclusion: P4HB biosynthetic resorbable mesh appeared to be the most effective and the least costly option. Additional data will be needed to confirm the superiority of biosynthetic mesh in terms of the recurrence risk reduction over a longer period.

Introduction

Ventral hernia is the result of intra-abdominal visceral bulging through an opening in the abdominal wall. Ventral hernia repair (VHR) is one of the most common operations in general surgery, with more than 386,000 repairs performed annually in the United States [1] and nearly 34,000 repairs performed annually in France [2]. Surgical techniques for VHR are standardized and based on mesh placement.

In clean surgery (grade 1 of the modified Ventral Hernia Working Group (mVHWG)) [3] or during surgery on patients with comorbidities (grade 2 of the mVHWG), the use of non-resorbable synthetic mesh has become an international standard [4]. However, its use is debated in contaminated surgery (mVHWG grade 3) because the risk of postoperative infections is high, between 10% and 50% [5], making biologic mesh an attractive alternative [6]. Biologic mesh is internationally recognized as an option that provides good healing support for poor-quality tissue, especially in cases of contaminated surgery. Based on animal studies and preliminary human series, biologic mesh supports neovascularization, which increases resistance to infection [7,8], introduces early cellular infiltration, and increases the local immune response [9]. However, in the largest series of human biologic explants, the authors detected no evidence of xenograft remodelling [10]. However, postoperative complications in these comorbid patients are frequent (approximately 50%) [6], and the recurrence rate is more than 50% at 5 years; the surgical situation remains complex regardless of the biologic mesh used [9,11]. Another issue that weighs in the balance is the high price of biological mesh, varying from $2000 up to $13,000 [12,13] depending on its size.

Recently, the Phasix® biosynthetic resorbable mesh has been developed as an alternative for contamination surgery. It is a biosynthetic resorbable mesh composed of a synthetic polymer called poly-4-hydroxybutyrate (P4HB) [14] that is absorbed completely between 12 and 18 months after placement [15].

To our knowledge, only one study has compared P4HB mesh to biologic mesh in a clinical setting [16]. The lack of comparative studies and the differences among published studies in terms of meshes, time periods and surgical contexts justify the need for further clinical investigation. Moreover, postoperative complications after VHR are a major source of health expenditures [17,18]. In one American study, Poulose et al. estimated that reducing the recurrence rate by 1% would be a cost saving of US $32 million [1].

In this context, additional data regarding the cost and efficiency of biosynthetic meshes could be used to homogenize surgical practices. Therefore, the aim of this study was to compare P4HB biosynthetic resorbable mesh (Phasix®) with biologic mesh for parietal repair in contaminated VHR (mVHWG grade 3) in terms of cost and effectiveness using a decision analysis model.

Materials and methods

Study population

We conducted a cost-effectiveness analysis based on a before-after study including patients hospitalized for VHR at the general and digestive surgery department of the University Hospital of Hautepierre in Strasbourg, France, from June 2011 to February 2018. Patients receiving a biological mesh were included between June 2011 and February 2018. From April 2016 onwards, the hospital decided to reduce its use of biologic mesh and switched to P4HB mesh; the ''after'' phase was thus the period between April 2016 and February 2018. We included patients aged ≥18 years who underwent surgery for a ventral hernia classified as clean-contaminated, contaminated or dirty, as per the mVHWG classification. Patients who underwent laparoscopic repair were excluded. Subcutaneous meshes were elective cases and were excluded. Cases with prophylactic mesh placed in a clean environment were excluded. This study is registered on www.clinicaltrials.gov # NCT03590184. Informed consent to participate in this study was provided by all patients enrolled.

General description of the model

A decision analysis model was built using TreeAge Pro 2018, Inc. (Williamstown, MA). Decision analysis models are particularly appropriate for prioritizing strategies with uncertain variables by considering each of their consequences. Two strategies were compared: VHR with biologic mesh and VHR with biosynthetic resorbable P4HB mesh. At the end of each alternative strategy of the decision tree, two payoffs were assigned corresponding to the total cost of care and its effectiveness.

Patients entered the model presenting with a ventral hernia in a contaminated context (classified mVHWG grade 3). For each strategy, the probability of post-operative complications at 6 months was modelled with a distinction between ''specific'' and ''general''. Specific complications were the occurrence of a seroma, superficial or deep surgical site infection, a haematoma, cellulitis, wound dehiscence, fistula, mesh removal, or recurrence. General complications were also taken into account even if we considered they were not directly related to the mesh. Both types of complications were categorized either as serious (grade ≥3 according to the Dindo-Clavien (DC) classification) or minor complications (grade ≤2) [19].

Characteristics of the study population

To ensure the comparability of the groups, we collected data for the factors that were likely to influence the clinical events and their associated costs. We therefore collected demographic data and potential risk factors for infection and recurrence. We also collected the reason for abdominal

Table 1 Patient characteristics.

	Biosynthetic mesh ($n = 52$)	Biologic mesh ($n = 42$)	P
Demographic characteristics			
Mean age (years), (± SD)	62.9 (± 12.7)	60.5 (± 14.0)	0.374
Gender (male), *n* (%)	34 (65.4)	25 (59.5)	0.559
Risk factors of infection and recurrence			
Median body mass index (BMI), kg/m^2 (+IQR)	27.9 (24.3—36.1)	26.0 (21.8—30.7)	0.201
BMI > 30 kg/m^2, *n* (%)	19 (37.3)	12 (28.6)	0.377
History of cancer, *n* (%)	20 (38.5)	15 (35.7)	0.784
Diabetes, *n* (%)	7 (13.5)	7 (16.7)	0.664
Smoking, *n* (%)	8 (15.4)	7 (16.7)	0.866
Chronic obstructive pulmonary disease, *n* (%)	6 (11.5)	4 (9.5)	1.000
Sleep apnea syndrome, *n* (%)	9 (17.3)	2 (4.8)	0.104
Immunosuppression, *n* (%)	1 (1.9)	2 (4.8)	0.585
History of hernia treatment, *n* (%)	19 (36.5)	14 (33.3)	0.746
Number of hernia treatments, mean (± SD)	0.5 (± 1.0)	0.4 (± 0.7)	0.636
Reasons for abdominal contamination, *n* (%)			
History of entero-fistula	6 (11.5)	2 (4.9)	0.459
History of infected mesh	12 (23.1)	6 (14.6)	0.306
Stoma	17 (32.7)	15 (36.6)	0.695
Intestinal resection	35 (67.3)	32 (78)	0.252
Mesh localisation, *n* (%)			
Retrorectus	15 (28.8)	1 (2.4)	< 0.001
Intraperitoneal	37 (71.2)	41 (97.6)	

Table 2 Values of clinical parameters used in the decision analysis model.

Variables	Biosynthetic mesh ($n = 52$) (%)	Biologic mesh ($n = 42$) (%)
Surgery without complications at 6 months	42	31
Postoperative complications at 6 months:	58	69
Specific complications	40	59
Dindo-Clavien ≤ 2	42	41
Dindo-Clavien ≥ 3	58	59
General complications	60	41
Dindo-Clavien ≤ 2	78	67
Dindo-Clavien ≥ 3	22	33

contamination (a history of entero-fistula, chronic mesh infection, stoma, and intestinal resection). We also identified the location of the mesh. All data were collected from the patients' medical files. If a patient presented with several complications, the most serious complication was used in the decision analysis model. Patient characteristics are presented in Table 1 and clinical parameters are shown in Table 2. SAS Software (Cary, NC), version 9.2 was used to describe the variables: means and standard deviations (SD) or medians and interquartile ranges (IQR) for continuous variables and frequencies and percentages for categorical variables. Fisher's, χ^2 and Mann-Whitney tests were used for comparisons, with significance set at $P < 0.05$. χ^2 and Fisher's tests were used for qualitative variables. Fisher's test was used for small datasets ($n < 5$), and the Mann-Whitney test was used for continuous variables.

Decision analysis model parameters

The medico-economic analysis took a collective perspective, broad enough to consider all of the stakeholders concerned by the interventions studied in the context of the French health system. The economic evaluation was carried out under real conditions of implementation of the interventions. The production costs of the interventions studied were identified, measured and valued, regardless of their source of funding.

Effectiveness

The effectiveness endpoint chosen was the proportion of patients presenting with a serious specific or general complication 6 months after VHR [20]. The 6-month period was chosen because serious short-term complications are the most expensive and are likely to lead to increased long-term complications and recurrence [21—23].

Cost

The cost analysis was performed from the point of view of collectivity as recommended by the French National Authority for Health (HAS) [20]. Only direct medical costs were considered. Costs were expressed in 2017 purchasing power parity (PPP) international dollars [24]. Direct medical costs included all expenditures from the time of surgical repair

Table 3 Mean costs of clinical events.

	Biosynthetic mesh (US $)	Biologic mesh (US $)
Specific postoperative complications		
Dindo-Clavien ≤ 2[a]	24,918	21,094
Dindo-Clavien ≥ 3[b]	22,876	32,391
General postoperative complications		
Dindo-Clavien ≤ 2[a]	18,129	17,945
Dindo-Clavien ≥ 3[b]	24,157	31,744
Surgery without complications	11,797	15,198

[a] Cost of ventral hernia repair surgery included cost of surgery and additional non-intrusive care (wound care, antibiotherapy, nursing care, consumables, surveillance).
[b] Cost of ventral hernia repair surgery included cost of surgery and additional intrusive care (endoscopic, radiological, surgical treatment) and/or Intensive Care management.

to six months later. They included the costs of hospitalization at the University Hospital of Strasbourg for the surgery and potential postoperative complications, hospitalization occurring after discharge (home hospitalization, rehospitalization at the University Hospital of Strasbourg for complications), and ambulatory care. The diagnosis-related group (DRG) was identified for each hospital stay induced by surgery or potential immediate postoperative complications. The cost of each DRG was then estimated using the ''*Échelle Nationale des Coûts*'' (ENC), which is a national cost survey sample [25]. Costs were categorized as medical costs (consumables, human resources, drugs, devices), logistical costs (laundry, restauration, global logistics, maintenance), and facility costs. To account for differences in the use of the type of mesh in the before and after phases, the DRG costs allotted by the ENC were adjusted as follows: for each DRG, medical staff, devices and consumables were dropped out and replaced by the mean quantity of resources required for mVHWG grade 3 surgeries (mean time for nurses, surgeons and anaesthetists, mean quantity of consumables and type of mesh used). The costs for each modelled clinical event are presented in Table 3.

Baseline cost-effectiveness analysis

Treatment with biologic mesh was used as the reference strategy. The cost-effectiveness analysis was based on the estimation of an incremental cost-effectiveness ratio (ICER). ICER was expressed in terms of cost per additional patient presenting with a serious complication. ICER was calculated by dividing the incremental expected cost by the incremental expected effectiveness of the two alternative strategies according to the following formula: ICER=(cost biosynthetic strategy - cost biologic strategy)/(effectiveness biosynthetic strategy - effectiveness biologic strategy). Because the period was less than one year, costs and effectiveness were not discounted.

Sensitivity analyses

Three deterministic sensitivity analyses were performed to test the robustness of the model. The first analysis concerned the incidence of specific DC$\leq$2 complications after placement of a biosynthetic mesh. A pessimistic scenario based on 60%, 70% and 80% rates was first modelled to take into account the variable rates found in the literature [26]. We then analysed the proportion of patients presenting with specific DC$\leq$2 complications after placement of a biologic mesh. It was also increased to reach 60%, 70% and 80% to be adequate for the published data [6,27,28]. The third analysis focused on the cost of specific DC$\geq$3 complications following a biosynthetic implant. The baseline cost was $22,876. It was increased by 40% ($32,391) to align the cost of specific complications costs with the biologic mesh.

Probabilistic analysis

A probabilistic analysis using Monte Carlo simulation was also performed; distributions of transition probabilities and costs were sampled with 10,000 consecutive iterations (TreeAge Pro 2018, Inc. (Williamstown, MA)). The choice was made to use a gamma distribution for costs and a beta distribution for clinical parameters [29]. Parameters of both distributions were estimated using the method of moments [30]. The Monte Carlo analysis allowed us to draw a cost-effectiveness plane divided into four quadrants.

Results

Comparability of the study population

A total of 94 patients were included. Between June 2011 and February 2018, 42 patients received biological mesh: Cellis® (Meccellis BioTech, France) in 4 patients, XenMatrix® (Bard Davol Inc, Warwick, RI) in 27 patients, and Strattice® (Lifecell Corp., Branchburg, NJ) in 11 patients. Between April 2016 and February 2018, 52 patients received a P4HB biosynthetic resorbable mesh (CR Bard Inc., Murray Hill, NJ). The patients were comparable in terms of all preoperative parameters that could influence the occurrence of serious adverse events (Table 1). A significant difference was found for localization because biological mesh was more often implanted in the intraperitoneal space ($P < 0.05$).

Baseline cost-effectiveness analysis

The results showed that at 6 months, the P4HB mesh was the most effective strategy, with a lower proportion of patients presenting with a serious complication: 21% for the biosynthetic mesh strategy versus 33% for the biologic mesh strategy. The biosynthetic mesh strategy was also the least costly, with a 23% reduction cost compared to that of the biologic mesh, leading to a cost savings of $42,883 to avoid an additional patient presenting with a serious complication (Table 4).

Table 4 Cost-effectiveness results.

Strategy	Cost (US $)	Incremental cost (US $)	Effectiveness[a]	Incremental Effectiveness	ICER[b] (US $)
Biosynthetic mesh	17,231	−5146	0.21	−0.12	Dominates (42,883)
Biologic mesh	22,376		0.33		–

[a] Effectiveness should be interpreted as following: 21% of the biosynthetic mesh patients presented a serious complication *versus* 33% of biologic mesh patients.
[b] Incremental cost-effectiveness ratio is expressed in terms of cost per additional patient presenting a serious complication.

Deterministic sensitivity analyses

The results of the three deterministic analyses confirmed the efficiency of the biosynthetic mesh (Table 5). The only situation where biosynthetic mesh was not better than the biologic mesh was when the rate of the biologic-specific DC≤2 complications was 80% rather than 41%. In this situation, the use of a biologic mesh would be associated with a significant overcost ($3353), but 4% fewer patients would present with a serious complication.

Probabilistic analysis

These results confirm the efficiency of the biosynthetic mesh strategy: 74% of the pairs of incremental costs and effectiveness presented superior effectiveness and cost savings, and only 17% were associated with superior effectiveness but also additional costs compared to biologic mesh.

Discussion

From a clinical and financial point of view, contaminated VHR remains a challenge for surgeons because they are tasked with choosing the safest meshes at the best price. Our study demonstrated that in contaminated VHR, the use of P4HB mesh reduced medical costs at 6 months and decreased the occurrence of serious complications per patient.

The importance of this study was enhanced by the fact that, to our knowledge, there are few published clinical data regarding the use of P4HB mesh in contaminated surgery [31]. Our study is therefore the first to compare biological mesh and P4HB mesh in such an environment. Most studies in this domain did not specify the mVHWG surgical grade, nor did they use a comparative design (19–22).

The main strength of this study was the use of patient-related data. Although our sample was small as a result of the ongoing transition to biosynthetic meshes at the Strasburg Hospital, we ensured the comparability of our populations. There were no significant differences in demographic data or in the variables likely to influence the occurrence of infection and recurrence, except mesh localization. A bias could be introduced due to a long comparison period (seven years). We consider that the surgical team was trained in this type of surgery. We therefore considered this bias to be minor.

Biologic mesh was more often implanted intraperitoneally, which was demonstrated to be a risk factor for recurrence in the long term [32]. This can be explained by the fact that biologic mesh may be more likely to be used

Table 5 Deterministic sensitivity analyses.

		Cost (US $)	Incremental cost (US $)	Effectiveness[a]	Incremental effectiveness	ICER[b] (US $)
Rate of biosynthetic specific DC≤2 complications (baseline value: 42%)						
60%	Biosynthetic mesh	17,316	−5060	0.17	−0.16	Dominates
	Biologic mesh	22,378	–	0.33	–	–
70%	Biosynthetic mesh	17,364	−5013	0.15	−0.19	Dominates
	Biologic mesh	22,376	–	0.33	–	–
80%	Biosynthetic mesh	17,410	−4968	0.12	−0.21	Dominates
	Biologic mesh	22,378	–	0.33	–	–
Rate of biologic-specific DC≤2 complications (baseline value: 41%)						
60%	Biosynthetic mesh	17,231	−4272	0.21	−0.04	Dominates
	Biologic mesh	21,503	–	0.26	–	–
70%	Biosynthetic mesh	17,231	−3812	0.21	−0.01	Dominates
	Biologic mesh	21,044	–	0.22	–	–
80%	Biosynthetic mesh	17,231	−3353	0.21	0.04	−83,814
	Biologic mesh	20,583	–	0.17	–	–
40% increase in the cost of biosynthetic specific DC≥3 complications ($32,391 instead of the baseline cost: $22,876)						
	Biosynthetic mesh	17,847	−4531	0.21	−0.12	Dominates
	Biologic mesh	22,378	–	0.33	–	–

[a] Effectiveness should be interpreted as the proportion of patients presenting a serious complication.
[b] Incremental cost-effectiveness ratio is expressed in terms of cost per additional patient presenting a serious complication.

in a staged approach compared to a single stage with P4HB mesh. Therefore, it could represent an inherent bias for the use of biologics.

The biologic mesh group was implanted with non-reticulated mesh, which is known to be more resistant to infection [33,34] and to have an increased mechanical strength [35]. Three different biologic meshes (XenMatrix®, Cellis® and Strattice®) were used in our study. Some of these meshes have been assessed by Huntington et al., who found differences in the long-term recurrence rates (59.1% for XenMatrix® and 14.7% for Strattice®; $P < 0.0013$), but the rates of infection for the incision and the mesh were comparable in the short term, with 33.3% vs. 29.9% and 0% vs. 1.5%, respectively ($P > 0.05$) [13]. Their respective costs were also similar. It is important to highlight the lack of a difference between XenMatrix® and Strattice® given the effectiveness criterion chosen for the study.

The effectiveness endpoint was expressed as the proportion of patients presenting with either a serious specific or general complication at 6 months and not in terms of the number of complications, which is typical in surgical publications. This choice was justified because the costs were calculated per patient. Therefore, it seems important, methodologically speaking, to express the effectiveness endpoint similarly. This choice explains why the rate of specific complications seems higher than in the general literature [13,26—28]. This finding also led us to consider only the most serious complication in each of the groups in the decision analysis model.

The micro-costing method was applied to only two patients because the surgery was highly standardized. The recommended method of ventral hernia reconstruction was primary fascial closure and mesh overlay, and if this was not possible, the mesh was placed intraperitoneally. The surgical technique was not modified during the study period.

Comparisons with other published medico-economic evaluations remain tricky because of the nature of the compared strategies, the patient profiles and the time horizon differed from one study to another. The only prior comparison of biologic and biosynthetic mesh was a cost-utility study published by Scheenerger et al. in 2018 [36]. In this study, a decision analysis model was used to simulate the medical costs and the number of QALYs for a baseline clinical profile of the patients. The main differences between this study and ours are the time horizon (6 months vs. 5 years), which is a major topic of debate, the nature of the data (individual data vs. data from published studies), and the choice of the effectiveness endpoint (complications vs. QALYs). At 5 years, the authors demonstrated that biologic and biosynthetic mesh were dominated by synthetic mesh, which became the better choice even as synthetic mesh complication rates increased over the long term. The hierarchy of costs for meshes was similar in their study and in ours. However, the different time periods make inter-comparisons very difficult. Our horizon may seem short considering the total resorption time of the mesh (12 to 18 months) but was justified by the fact that infection was demonstrated to be a risk factor for recurrence in the long term [21—23]. We also preferred to produce robust, even if local, estimations of the medico-economic consequences associated with the use of biosynthetic mesh than to use literature data and make assumptions that would have to be checked with population data. Moreover, since QALYs are now commonly used in medico-economic evaluations, we considered that, in the short term, complications would be more appropriate for informing the surgical decision-making process.

Conclusion

P4HB biosynthetic resorbable mesh appeared to be the most efficient strategy at 6 months. Further data are needed to confirm the superiority of biosynthetic mesh versus biologic mesh over a longer time period, taking into account the risk of recurrence. In the meantime, this study may help to harmonize surgical practices for grade 3 mVHWG VHR.

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Disclosure of interest

The authors declare that they have no competing interest.

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