Transthoracic versus transhiatal esophagectomy: A prospective study of 945 patients

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Objective: Debate continues as to whether transhiatal esophagectomy results in lower morbidity and mortality than transthoracic esophagectomy. Most data addressing this issue are derived from single-institution studies. To investigate this question from a nationwide multicenter perspective, we used the Veterans Administration National Surgical Quality Improvement Program to prospectively analyze risk factors for morbidity and mortality in patients undergoing transthoracic esophagectomy or transhiatal esophagectomy from 1991 to 2000.

Methods: Univariate and multivariate analyses were performed on 945 patients (mean age, 63 ± 10 years). There were 562 transthoracic esophagectomies and 383 transhiatal esophagectomies in 105 hospitals, with complete 30-day outcomes recorded.

Results: There were no differences in recorded preoperative variables between the groups that might bias any comparisons. Overall mortality was 10.0% (56/562) for transthoracic esophagectomy and 9.9% (38/383) for transhiatal esophagectomy ($P = .983$). Morbidity occurred in 47% (266/562) of patients after transthoracic esophagectomy and in 49% (188/383) of patients after transhiatal esophagectomy ($P = .596$). Risk factors for mortality common to both groups included a serum albumin value of less than 3.5 g/dL, age greater than 65 years, and blood transfusion of greater than 4 units ($P < .05$). When comparing transthoracic esophagectomy with transhiatal esophagectomy, there was no difference in the incidence of respiratory failure, renal failure, bleeding, infection, sepsis, anastomotic complications, or mediastinitis. Wound dehiscence occurred in 5% (18/383) of patients undergoing transhiatal esophagectomy and only 2% (12/562) of patients undergoing transthoracic esophagectomy ($P = .036$).

Conclusions: These data demonstrate no significant differences in preoperative variables and postoperative mortality or morbidity between transthoracic esophagectomy and transhiatal esophagectomy on the basis of a 10-year, prospective, multi-institutional, nationwide study.

There is ongoing debate as to whether transhiatal esophagectomy (THE) results in lower morbidity and mortality than transthoracic esophagectomy (TTE). Most data addressing this issue come from single-institution studies. To investigate this question from a nationwide multicenter perspective, we used the Department of Veteran Affairs (VA) National Surgical Quality Improvement Program. This article prospectively analyzes risk factors for morbidity and mortality and compares

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outcomes in patients undergoing TTE or THE from January 1991 to December 2000.

Patients and Methods

There were 109 VA centers contributing prospectively collected data from patients undergoing esophagectomy between January 1991 and December 2000. A total of 945 patients had an esophageal resection: 383 THEs (Current Procedural Terminology codes 43107-43108) and 562 TTEs (Current Procedural Terminology codes 43112, 43113, 43117, 43118, and 43121). Published reports describe the methods of the VA National Surgical Quality Improvement Program.¹⁻⁴

A trained nurse reviewed each patient's chart and recorded 122 individual variables for each operation. Reviewers were continually tested and monitored on a set of standard criteria and definitions for each variable. The recorded variables were selected by a panel of surgical experts, as well as from literature reviews. Laboratory values and demographics were automatically downloaded to the statistical center from computers at each participating VA medical center. Audits were frequently performed to ensure accurate and reliable data collection. Periodic internal and random external audits for data quality were performed at every center.

A multivariable logistic regression analysis was used to determine which preoperative and intraoperative patient-specific factors were good predictors of mortality and morbidity. Important predictive factors were first analyzed by means of bivariate analyses. Namely, the association of demographic and laboratory variables with 30-day morbidity and mortality was investigated. The unpaired *t* test was used for continuous variables, and the χ^2 test was used for categorical variables. A prevalence of greater than 0.5% and significance by means of bivariate analysis defined as a *P* value of less than .20 were used for selection of potential independent variables for the multivariable logistic regression analysis. Entry and exit criteria set at a level of 0.10 and 0.05, respectively, were used for the stepwise logistic regression, with mortality or morbidity as the dependent variable. In the morbidity analyses the dependent variable was the presence or absence of at least one serious complication.

The risk-stratification model was created for the entire data set (945 patients) by using the methods explained by Le Gall and colleagues.⁵ Briefly, our scoring system for each patient's mortality and morbidity was based on the multivariate logistic regression models that contained only preoperative factors. Each β coefficient taken from the logistic model was multiplied by 10 and rounded off to the nearest integer (except age coefficient). In this way we weighted the significance of risk factors. For each patient, we assigned a mortality and morbidity score equal to the sum of all risk factor points.

Results

From January 1991 through December 2000, 945 patients underwent esophagectomy. Among these patients, 562 (59.5%) underwent TTE, whereas 383 (40.5%) underwent THE. The mean age was 63.4 years for the TTE group and 63.2 years for the THE group (*P* = .83). Cancer was the indication for surgical intervention in 85.2% (479/562) of patients undergoing TTE and 86.4% (331/383) of patients undergoing THE (*P* = 1.0). Thirty-day mortality was 10.0%

(56/562) for the TTE group and 9.9% (38/383) for the THE group (*P* = .983). Any morbidity occurred in 47.3% (266/562) of patients undergoing TTE and 49.1% (188/383) of patients undergoing THE (*P* = .596). Serious morbidity was seen in 41.6% (234/562) of patients undergoing TTE and 41.8% (160/383) of patients undergoing THE (*P* = .969). Serious morbidity was defined as pneumonia, unplanned reintubation, failure to wean from the ventilator within 48 hours, pulmonary embolus, pulmonary edema, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, wound dehiscence, coma for longer than 24 hours, acute renal failure, systemic sepsis, perioperative bleeding of greater than 4 units, and graft or prosthesis failure (Table 1).

Pulmonary complications, including pneumonia, failure to wean within 48 hours, and reintubation for respiratory distress, were the most common morbidities in both groups. Pneumonia was seen statistically more often in patients undergoing TTE (26% for TTE vs 18% for THE, *P* = .007). However, there was no difference in the number of patients extubated after 48 hours or in unplanned intubations. Systemic sepsis was the next most common morbidity after both procedures. Other morbidities and their frequencies are shown in Table 1. Wound disruptions were seen in 5% (18/383) of patients undergoing THE and 2% (12/562) of patients undergoing TTE (*P* = .036). Postoperative myocardial infarction occurred in 1% (7/562) of patients undergoing TTE and no patients undergoing THE (*P* = .046).

The incidence of pre-existing pulmonary disease or risk factors, including smoking, dyspnea, severe chronic obstructive pulmonary disease (COPD; defined as dyspnea with minimal exertion or dyspnea at rest), and current pneumonia, did not differ between the 2 groups. Heavy alcohol use, dependent functional status, or immunosuppressed states, such as diabetes mellitus, disseminated cancer, steroid use, and chemotherapy within 30 days before surgical intervention, did not differ between the TTE and THE groups (Table 2). Likewise, serum creatinine levels, blood urea nitrogen levels, alkaline phosphatase values, platelet counts, and prothrombin times did not vary between the TTE and THE groups (Table 3). However, patients undergoing TTE had lower mean albumin values (*P* = .01), had lower mean hematocrit values (*P* < .001), underwent more emergency operations (*P* = .008), and had more American Society of Anesthesiologists classes of 3 or greater (*P* = .009).

Albumin values of 3.5 g/dL or less, dyspnea, and a preoperative red blood cell transfusion of greater than 4 units were risk factors for morbidity in the TTE group on the basis of the multivariable analysis. The following risk factors were predictive of mortality after TTE: current pneumonia, preoperative weight loss of greater than 10%, advanced age, and preoperative red blood cell transfusion of

TABLE 1. Observed 30-day mortality and morbidity by operative procedure

Variable	TTE, n = 562 (%)	THE, n = 383 (%)	P value
30-d mortality	56 (9.96%)	38 (9.92%)	.93
30-d morbidity (≥ 1 serious complication)	234 (41.64)	160 (41.78)	.99
Respiratory complications			
Pneumonia*	145 (26%)	70 (18%)	.007
Unplanned reintubation*	98 (17%)	61 (16%)	.595
Failure to wean >48 h*	101 (18%)	84 (22%)	.134
Pulmonary embolus*	6 (1%)	2 (1%)	.485
Cardiac complications			
Pulmonary edema*	1 (0%)	4 (1%)	1.000
Cardiac arrest with CPR*	25 (4%)	21 (5%)	.538
Myocardial infarction*	7 (1%)	0 (0%)	.046
Wound complications			
Superficial wound infection	26 (5%)	23 (6%)	.372
Deep wound infection	23 (4%)	20 (5%)	.430
Wound dehiscence*	12 (2%)	18 (5%)	.036
CNS complications			
Coma >24 h*	1 (0%)	2 (1%)	1.000
Cerebral vascular accident*	3 (1%)	0 (0%)	1.000
Urinary tract complications			
Urinary tract infection	25 (4%)	19 (5%)	.754
Progressive renal insufficiency	19 (3%)	8 (2%)	.320
Acute renal failure*	6 (1%)	7 (2%)	.320
Other complications			
Systemic sepsis*	52 (9%)	30 (8%)	.482
Bleeding requiring >4 units transfused*	11 (2%)	13 (3%)	.207
Graft-prosthesis failure*	4 (1%)	0 (0%)	1.000

CPR, Cardiopulmonary resuscitation; CNS, central nervous system.

*Serious complication.

TABLE 2. Frequency of dichotomous variable comorbidities in 562 patients undergoing TTE and 383 patients undergoing THE

Variable	TTE, n (%)	THE, n (%)	P value
Diabetes mellitus, oral control	38 (7)	35 (9)	
Insulin control	29 (5)	20 (5)	.434
Smoke <1 y	258 (47)	159 (52)	.139
Alcohol use ≥ 3 drinks/d	110 (20)	65 (17)	.267
Dyspnea			
Exertion	104 (19)	66 (17)	
At rest	15 (3)	4 (1)	.166
Functional health-dependent	41 (7)	26 (7)	.953
Severe COPD	134 (24)	88 (23)	.815
Current pneumonia	8 (1)	4 (1)	.770
Disseminated cancer	47 (8)	23 (6)	.206
Steroid use	11 (2)	12 (3)	.285
$>10\%$ weight loss	186 (33)	126 (30)	.394
Bleeding disorder	14 (3)	4 (1)	.146
Emergency	19 (3)	3 (1)	.008
ASA III or IV	106 (19)	39 (10)	.009
Chemotherapy within 30 d	63 (12)	42 (12)	.916
DNR	4 (1)	5 (1)	.497

ASA, American Society of Anesthesiologists; DNR, do not resuscitate.

greater than 4 units. The risk factors for morbidity after THE were as follows: diminished functional health, current smoking, dyspnea, prolonged operative time, advanced age, and a preoperative albumin value of 3.5 g/dL or less. Risk

factors for mortality after THE were as follows: creatinine level of greater than 1.2 mg/dL, albumin value of 3.5 g/dL or less, and a diminished functional health.

We also evaluated whether the number of esophagecto-

TABLE 3. Quantitative variables in 562 patients undergoing TTE and 383 patients undergoing THE

Variable	TTE, mean (SD)	THE, mean (SD)	P value
Creatinine (mg/dL)	1.02 (0.29)	1.02 (0.3)	.900
Albumin (g/dL)	3.62 (0.61)	3.72 (0.51)	.010
Alkaline phosphatase (U/L)	93.3 (44.5)	90.2 (43.7)	.340
Hematocrit (%)	37.8 (6.1)	39.0 (6.1)	<.001
Platelet count (1000s/ μ L)	259 (99)	254 (99)	.470
Prothrombin time (s)	12.2 (1.2)	12.3 (1.2)	.720
BUN (mg/dL)	15.0 (7.9)	14.8 (6.8)	.710

BUN, Blood urea nitrogen.

mies performed per center affected morbidity and mortality rates for both groups. We defined lower-volume centers as performing 10 or fewer esophagectomies over the time course of the study and higher-volume centers as performing greater than 10 esophagectomies over the time course of the study. TTE mortality in lower-volume centers was 10.0% (36/369), and TTE mortality in higher-volume centers was 10.4% (20/193, $P = .92$). Serious morbidity after TTE was seen in 42.5% (157/369) of patients in lower-volume centers and 31.7% (61/193) of patients in higher-volume centers ($P = .45$). Mortality rates after THE were 8.9% (11/128) in higher-volume centers and 9.5% (24/255) in lower-volume centers ($P = .86$). Serious morbidity after THE was seen in 52.9% (135/255) in higher-volume centers and 45.0% (58/128) in lower-volume centers ($P = .27$).

A risk-stratification model was applied to the entire cohort (Tables 4 and 5). Parameters for mortality included albumin values of 3.5 g/dL or less, age, dyspnea, and functional status. Patients with scores of 0 to 4 points had a mortality of 2.5%, patients with scores of 1 to 5 points had 10.7% mortality, and patients with scores of greater than 12 points had 17% mortality. Significant risk factors for morbidity included albumin values of 3.5 g/dL or less, creatinine levels of greater than 1.2 mg/dL, alkaline phosphatase values of greater than 125 U/L, prothrombin times of greater than 12 seconds, diminished functional status, and a history of severe COPD (Table 5). Patients without risk factors had a morbidity of 29.6%. Patients with scores of 1 to 6 points had a 32.7% incidence of morbidity, patients with scores of 7 to 12 points had 51.0% morbidity, and patients with scores of greater than 12 points had 59.4% morbidity.

Discussion

In this prospective multi-institutional study over 10 years, we found no significant difference in morbidity and mortality when comparing TTE with THE. The mortality rate for both procedures considered in our study was 10%, and overall morbidity approached 50%, whereas serious morbidity was seen in 41% of patients. The most common complications were pulmonary. Overall, the TTE group appeared to have a slightly higher preoperative severity. Specifically, this group was more likely to have a preoper-

ative albumin value of less than 3.5 g/dL, have abnormal serum sodium levels, undergo an emergency operation, and have an ASA class of 3 or greater. Multivariable risk factors that appeared more than once for morbidity or mortality in the TTE or THE groups included the following: age, intraoperative red blood cell units of transfusion, albumin values of less than 3.5 g/dL, diminished functional status, and dyspnea. A number of other factors were identified for risks of either morbidity or mortality for THE or TTE alone.

On the basis of our risk-stratification model, we have identified the most important risk factors for morbidity and mortality. These include the following: COPD, dyspnea, diminished functional health, advanced age, albumin value of 3.5 g/dL or less, alkaline phosphatase value of greater than 125 U/L, creatinine level of greater than 1.2 mg/dL, and prothrombin time of greater than 12 seconds. On the basis of our risk-stratification system, surgeons can predict outcomes on the basis of preoperative risk factors.

This study constitutes the largest prospective cohort comparing outcomes after TTE and THE. Two prospective randomized studies with much smaller numbers corroborate our findings. Goldminc and associates⁶ prospectively studied 35 patients undergoing TTE and 32 patients undergoing THE and found no difference in outcomes. Chu and colleagues⁷ prospectively randomized 39 patients to TTE or THE and also found no difference in outcomes.

All of the patients were operated on in the last decade. Many improvements in perioperative care occurred in the 1990s. Preoperative imaging studies, such as endoscopic ultrasonography, have improved patient selection. Epidural catheters have dramatically improved postthoracotomy care by allowing patients to participate more vigorously in pulmonary toilet.⁸ Comparative studies that took place before routine use of epidural catheters frequently show higher rates of pulmonary complications among patients undergoing TTE.^{9,10} Newer stapling devices have improved the quality of anastomoses. Antibiotic therapy and ventilator management also improved during the last 10 years.

Other smaller retrospective reviews have reported risk factors for morbidity and mortality after esophagectomy that we identified as well. Diminished functional status and advanced age have been found to be significant risk factors

TABLE 4. Risk stratification scores for mortality after esophagectomy on the basis of preoperative variables

Parameter	β coefficient	P value	Points
Albumin ≤ 3.5 g/dL	0.56	.0135	6
Moderate functional status	0.63	.0220	6
Poor functional status			12
Age 55-65 y	0.41	.0001	4
Age 66-70 y			8
Age >70 y			12
Dyspnea	0.41	.0477	4

Correlation of total points to mortality: 0 to 4, 2.47%; 5-12, 10.67%; and greater than 12, 16.99%.

TABLE 5. Risk stratification scores for morbidity after esophagectomy on the basis of preoperative variables

Parameter	β coefficient	P value	Points
Albumin ≤ 3.5 g/dL	0.37	.0102	4
Creatinine >1.2 mg/dL	0.38	.0383	4
Prothrombin time >12 s	0.35	.0109	4
Alkaline phosphatase >125 U/L	0.51	.0162	5
Moderate functional status	0.54	.0222	5
Poor functional status			10
History of COPD	0.56	.0005	6

Correlation of total points to risk of morbidity: 0, 29.59%; 1 to 6, 32.73%; 7 to 12, 51.04%; greater than 12, 59.43%.

by other groups.¹¹ Karl and coworkers¹² published a report finding diabetes to be a risk factor for complications after esophagectomy. Diabetes mellitus did not quite reach statistical significance in our study ($P = .056$). By using retrospective data, 2 recent and large meta-analyses were able to identify risk factors for complications after esophagectomy. These meta-analyses found no difference in overall morbidity or mortality when comparing TTE and THE.^{13,14}

Older reports had noted differences between the 2 procedures. Pac and colleagues¹⁵ retrospectively reviewed 118 patients undergoing TTE and 120 patients undergoing THE from 1983 to 1991 and determined that THEs were safer. This study is limited by the fact that it is a retrospective review and that TTEs were the predominant operations in the early years of the study. The transhiatal approach was more common later in the study.

Some groups report that the THE is a superior operation for patients with COPD, but our study demonstrated no difference in outcomes in this subset of patients.¹⁶ Some authors also suggest that groups of patients undergoing THE have fewer complications; however, we found no difference in the rate of complications.¹⁷ It has also been suggested that THE is better tolerated by debilitated patients.¹⁸ We found no difference in outcomes between the TTE and THE groups on the basis of ASA classification or functional health status.

In conclusion, our present study demonstrates no significant differences in postoperative mortality or morbidity between TTE and THE on the basis of a 10-year, prospec-

tive, multi-institutional nationwide study. Our work has identified modifiable risk factors that might reduce morbidity and mortality, as well as assisting in the selection of the procedure best suited for a particular patient.

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Discussion

Dr Walter Ehrman (*Loma Linda, Calif*). This group has undertaken a rather large multicenter trial to address the issue of the relative levels of morbidity and mortality in patients undergoing esophagectomy through the transhiatal and transthoracic approaches. As they have alluded to, the answer to this question has previously been provided in small single-institution studies, but this current study attempts to answer the same question by using a rather large multi-institutional approach. To their credit, the authors have undertaken a rather sophisticated statistical analysis to ensure appropriate matching of preoperative variables to ensure the validity of their data.

However, I would submit that bigger does not necessarily mean better. There are 109 participating centers in this study, and approximately 1000 cases were performed over a period of 10 years. That means that on average each center performed approximately 1 procedure per year. One should be skeptical about the value of the morbidity and mortality data produced by an institution or an individual performing a particular procedure once per year. Appropriately, the authors have attempted to discriminate between what they term high-volume and low-volume centers; however, the point of discrimination between low- and high-volume centers is the performance of greater than 10 procedures during the course of the study. I would argue that the difference between performing a procedure once and twice per year is essentially no difference at all. The influence of the data generated by these low-volume centers cannot be discounted because two thirds of the cases were performed in so-called low-volume centers. A more cynical interpretation of this study might be that if you perform a procedure infrequently, then the results will most likely be the same, regardless of the operative approach that you choose.

There are 3 specific questions regarding standardization and patient selection that are of some concern.

By your account, 70 patients in this study had what you called disseminated disease at the time of surgical intervention. What staging and screening procedures were used before inclusion in this study?

Second, were there any attempts to standardize surgical techniques, and what were the clinical or anatomic factors that guided the decision to use a specific approach, or did it merely amount to a dealer's choice?

Third, you had alluded to prolonged operative time as an independent predictor of morbidity. What is your definition of prolonged operative time, and was the same definition applied to all groups?

I hope to hear more on the basis of this information.

Dr Rentz. Thank you. No center had a particularly high volume of cases, with the maximum number of procedures in either group being 27 TTEs over the 10-year period. The largest number of esophagectomies of both types performed at one center was 44 in 10 years. This would hardly qualify as a high-volume center. Therefore, we have chosen to remove it from the article, and I decided not to include it in this presentation in favor of a risk-stratification model that became available at a later period.

We did not have information on disseminated disease and staging procedures, because this was collected from 109 centers with a view to understanding what the patients went through and how the decision was made.

The choice of surgical technique was left to the surgeon, and, although we cannot say this was randomized, we do believe there is some validity in allowing the surgeons to proceed with the technique that they believe they are most comfortable performing.

Prolonged operative time is another issue that we evaluated, and the operative time for the groups was similar overall, and we looked at this as a continuous variable, meaning that we do not have a specific cutoff for time. However, it would appear that as operations proceed for longer periods, they will certainly have a higher risk of morbidity.

Dr Douglas Wood (*Seattle, Wash*). I am sure you have been warned about me potentially standing up and having a comment after having discussed a similar article from the National Surgical Quality Improvement Program (*NSQIP*) at the Society for Thoracic Surgeons' meeting. There certainly is great value in the analysis, and as to the results, part of them are a quantification of what we already know. That is useful. We know that functional status and poor nutritional status are high risk factors for virtually any surgical intervention and certainly for larger operations, such as esophagectomies. Having some quantification from the volume of information that you have and a risk-stratification model is useful information.

However, there are some potential confounding variables that your database and your analysis of it avoid. Dr Ehrman talked about the volume issue and that cannot be avoided. I would urge you to look at the same issues, not by volume of greater than 10 over the course of the series but greater than 5 or 10 per institution in a year, and to look at those volumes compared with the volumes of the cohort overall.

The other potential confounding variable is selection bias on the basis of expertise of surgeons. It is quite likely that general surgeons doing esophagectomies in the VA system would preferentially do THEs but potentially less frequently and with less expertise than thoracic surgeons who might choose transhiatal or transthoracic operations. That might have obscured a potential benefit of THE in your series, it being masked by an unexamined selection bias of the type of surgeons that are approaching it. Is

there an ability with the NSQIP of looking at the volume issues and looking at the surgeons doing the procedure to try to get better details of comparison of morbidity and mortality between the procedures?

Dr Rentz. Dr Wood, thank you for bringing that up. It gives me the opportunity to speak about volume a bit more. Several, I believe it is 5, major centers of excellence throughout the country are joining the NSQIP, which will allow us to look at volume a bit better and to look at these centers, which are performing quite a few more than even 5 procedures a year. I think that will add quite a bit in the future, but it will take a number of years to get that online and to get good data from it.

As far as the selection bias, on the basis of your comments at the Society of Thoracic Surgeons' meeting, we have looked to see

whether it is possible to know who is operating on patients with esophagectomies. It is possible through records at the VA system, but it is not part of the NSQIP at this time.

Dr Thomas Rice (*Cleveland, Ohio*). It is a very nice article. You are trying to compare 2 very dissimilar groups undergoing 2 very dissimilar operations, and I do not think you will be able to dissect any difference with your present analysis. Have you considered doing a propensity analysis, developing matched pairs, and seeing whether you can dissect out the difference between THE and TTE by this approach?

Dr Rentz. Yes, I believe you are exactly right. One of our goals was to try to understand when one operation is safer or will have a better outcome than another one, and I think that it is a logical next step to match them.

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