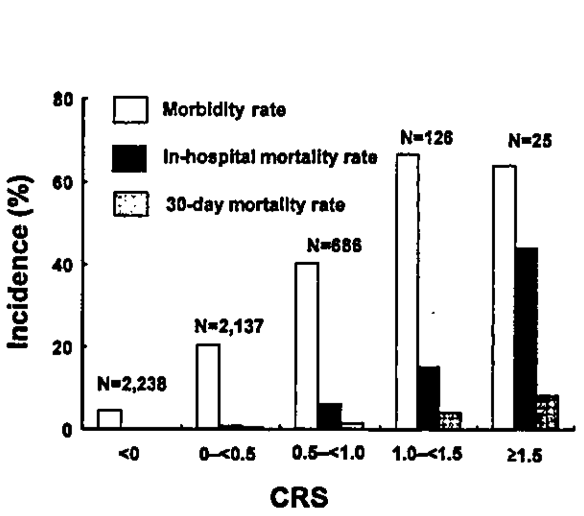

Fig 1. Relationship between CRS and morbidity in all patients of group A. The rates of morbidity, in-hospital mortality, and 30-day mortality after elective GI surgery were analyzed according to the CRS ranges in 5212 patients of group A.

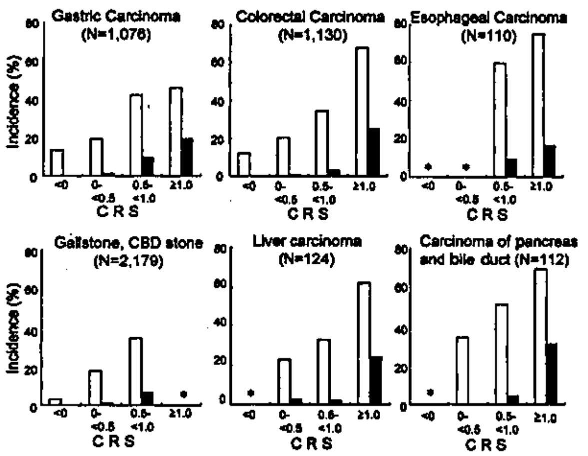

Fig 2. Relationship between CRS and morbidity in individual diseases. The morbidity and in-hospital mortality rates after surgery were analyzed in individual diseases. Morbidity rate, *white bar*, mortality rate, *black bar*. *CRS rates are not indicated because the number of patients is <20.

coordinates of the mortality rates and the CRS. The significance of the regression model was determined by analysis of variance.

RESULTS

Figure 1 shows the relation between the morbidity and the CRS of the E-PASS in 5212 patients who underwent elective digestive surgery (group A). Morbidity rates increased at a CRS <1.0 and plateaued thereafter (<0, 4.5%; 0 to <0.5, 20.4%; 0.5 to <1.0, 40.2%; 1.0 to <1.5, 66.7%; and ≥1.5, 64.0%). However, for the in-hospital mortality rates, there was a steep increase at a CRS greater than 0 (<0, 0%; 0 to <0.5, 0.75%; 0.5 to <1.0, 6.0%; 1.0 to <1.5, 15.1%; and ≥1.5, 44.0%). The 30-day mortality rates increased as the CRS increased (<0, 0%; 0 to <0.5, 0.42%; 0.5 to <1.0, 1.5%; 1.0 to <1.5, 4.0%; and ≥1.5, 8.0%). Subsequently, we evaluated these rates in individual diseases (Fig 2). In each situation, the in-hospital mortality and morbidity rates increased as the CRS increased.

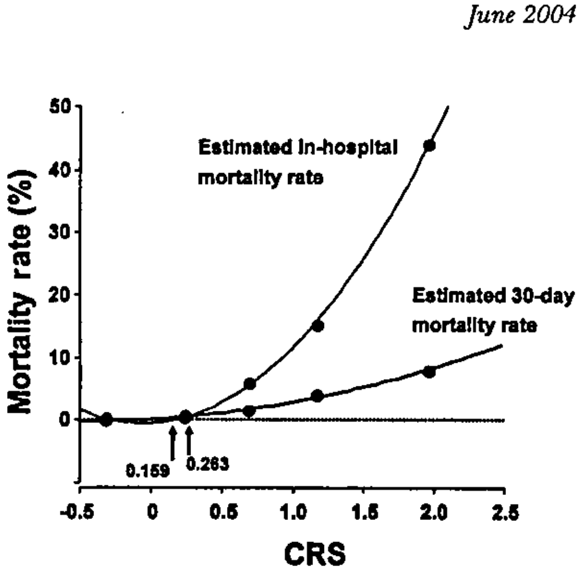

Fig 3. Postoperative mortality curves as defined by CRS. The relationship between the CRS and mortality rates was analyzed by polynomial regression analysis. Each coordinate indicates the average CRS and mortality rate at each range of the CRS. Equations for estimated mortality rates were obtained as $Y = -0.465 + 1.192(CRS) + 10.91(CRS)^2$ for in-hospital mortality ($R = 0.9996$, N = 5, $P = .0008$), and $Y = 0.161 + 1.303(CRS) + 1.404(CRS)^2$ for 30-day mortality ($R = 0.997$, N = 5, $P = .0060$)

When we analyzed the relationship between the mortality rates and the CRS in all patients of group A by various regression models. A polynomial model best fit this relationship for both in-hospital and 30-day mortality rates (Fig 3), providing an equation of $Y = -0.465 + 1.192X + 10.91X^2$ for in-hospital mortality rates, and $Y = 0.161 + 1.303X + 1.404X^2$ for 30-day mortality rates, where Y is the estimated mortality rate and X is the CRS. However, some problems occurred when we simply applied these equations. Although the CRS varied from −0.56 to 3.14 in these patients, the equation for in-hospital mortality gave a minus value for the mortality rates in the range of CRS −0.268 to 0.159. Moreover, the in-hospital mortality rates increased when the CRS decreased below −0.268, even though no patients died when the CRS was below 0. In contrast, when the CRS exceeded 2.98, the equation produced rates greater than 100%.

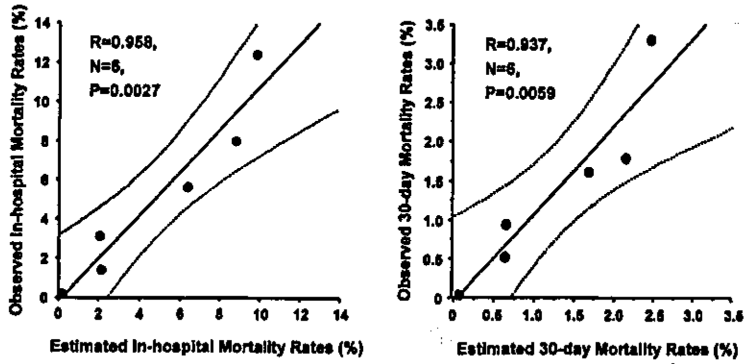

Fig 4. Relationship between the observed and estimated mortality rates in individual diseases. The estimated and observed rates for in-hospital mortality were 0.18% and 0.18% in patients with gallstones and common bile duct stones (N = 2179), 2.1% and 1.4% in patients with colorectal carcinoma (N = 1130), 2.0% and 3.1% in patients with gastric carcinoma (N = 1076), 6.3% and 5.6% in patients with liver carcinoma (N = 124), 8.7% and 8.0% in patients with carcinoma of pancreas and bile duct (N = 112), and 9.7% and 12.4% in patients with esophageal carcinoma (N = 121), respectively. The estimated and observed rates for 30-day mortality were 0.059% and 0.046% in patients with gallstones and common bile duct stone, 0.58% and 0.53% in patients with colorectal carcinoma, 0.60% and 0.94% in patients with gastric carcinoma, 1.7% and 1.6% in patients with liver carcinoma, 2.0% and 1.8% in patients with carcinoma of the pancreas and bile duct, and 2.5% and 3.3% in patients with esophageal carcinoma, respectively. Dotted lines indicate the 95% confidence limits.

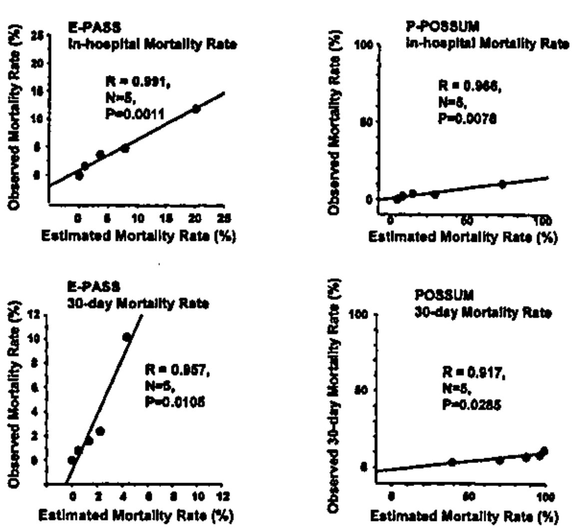

Fig 5. Accuracy of the estimated mortality rates in the E-PASS, POSSUM, and P-POSSUM systems. The observed and estimated mortality rates at 5 ranges of risk were computed in the 1934 patients of group B.

Therefore, this equation should be used only when $0.159 \leq \text{CRS} < 2.98$. Since the in-hospital mortality rate was 0.07% for CRS <0.159 (2 deceased patients in 2936 operations), the estimated mortality rate was determined as almost 0 for this range (Table IV). Similarly, the equation for 30-day mortality produced values that exceeded the estimated in-hospital rates at the CRS range of 0.263 or less. Since the 30-day mortality rates for CRS <0.263 was 0.03% (1 deceased patient in 3123 operations), the estimated mortality rate was determined as almost 0 for this range. When we applied these rules, the estimated mortality rates agreed well with the observed rates (Table V). Furthermore, the estimated mortality rates in individual diseases were significantly correlated with the observed rates (Fig 4).

Subsequently, we evaluated the usefulness of the E-PASS in defining quality of care in another series of 1934 patients (group B), compared with the POSSUM and P-POSSUM. As shown in Fig 5, all of the systems had significant correlations with the observed rates; however, the POSSUM and P-POSSUM overpredicted the mortality rates. The E-PASS estimated the 30-day mortality rates by 0.63-fold (linear analysis), whereas the POSSUM was 11.0-fold (exponential analysis). The E-PASS estimated the in-hospital mortality rates by 1.2-fold (linear analysis), whereas the P-POSSUM was 4.5-fold (linear analysis).

We then compared the OE ratios among 6 hospitals using 3 audit systems (Fig 6). In estimating 30-day mortality rates, the OE ratios defined by the E-PASS significantly correlated with those by the POSSUM. Similarly, the OE ratios defined by the E-PASS significantly correlated with those by the P-POSSUM when evaluating in-hospital mortality rates. The OE ratios defined by the E-PASS to estimate 30-day mortality also correlated

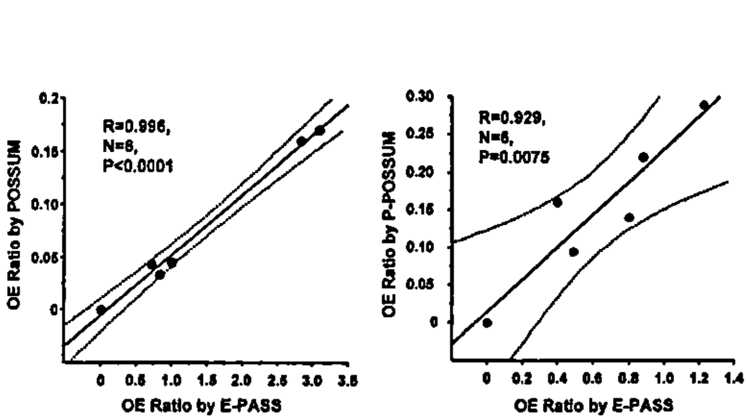

Fig 6. Results of quality care determined by the E-PASS, POSSUM, and P-POSSUM systems. The OE ratio among 6 hospitals of group B were determined by E-PASS for 30-day and in-hospital mortality rates, POSSUM for 30-day mortality rate, and P-POSSUM for in-hospital mortality rate. Each coordinate indicates the OE ratio of each hospital. Left: The OE ratios determined by E-PASS for 30-day mortality had a significant correlation with those determined by POSSUM for 30-day mortality. Right: The OE ratios determined by E-PASS for in-hospital mortality had a significant correlation with those determined by P-POSSUM for in-hospital mortality. Dotted lines indicate the 95% confidence limits.

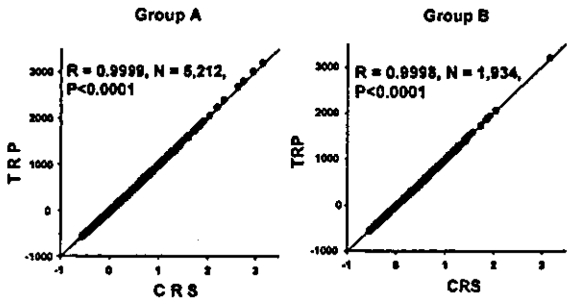

Fig 7. Relationship between CRS and TRP. In groups A and B. There were significant correlations between CRS and TRP.

Table IV. Equations for estimated mortality rates in gastrointestinal surgery

In-hospital mortality rate	
$X < 0.159$	$Y \fallingdotseq 0$
$0.159 \leq X < 2.98$	$Y = -0.465 + 1.192X + 10.91X^2$
$X \geq 2.98$	$Y = 100$

X is CRS; Y is in-hospital mortality rates.

30-day mortality rate	
$X < 0.263$	$Y \fallingdotseq 0$
$X \geq 0.263$	$Y = 0.161 + 1.303X + 1.404X^2$

X is CRS; Y is 30-day mortality rates.

with those by the E-PASS to estimate hospital mortality ($R = 0.881$, $N = 6$, $P = .0204$). The OE ratios defined by the POSSUM to estimate 30-day mortality correlated with those of the P-POSSUM to estimate in-hospital mortality ($R = 0.995$, $N = 6$, $P < .0001$).

To obtain a risk-stratification system that is more convenient for use in clinical practice, we generated a point-adding system that mimics the CRS (Table IV) as done in other prediction rules.[1,4] Total risk points (TRP) obtained in this system significantly correlated with the CRS in groups A and B (Fig 7).

DISCUSSION

Comparisons of surgical quality between individual hospitals must consider differences in patient populations and the complexity of surgery performed. We previously generated a scoring system, E-PASS, that predicts the postoperative risk by estimating the patients' physiologic ability and the effects of surgical stress. This study was undertaken to obtain a mortality equation with the use of the E-PASS scoring system and to evaluate the equation's usefulness in defining the surgical quality. This study produced equations for estimating in-hospital and 30-day mortality rates by polynomial regression analysis. We did not simply apply these equations as a prediction rule, since they sometimes have contradictory values at the extreme risk ranges.[18,25] We therefore checked the equations and applied them at ranges with no contradictory values. For example, the equation for in-hospital mortality gave minus values at the CRS range of <0.159; therefore, the equation was not applied at this range. After this manipulation, the rules correlated well with the observed mortality rates.

Using these rules, we conducted a prospective comparative study with POSSUM and P-POSSUM.

Table V. Comparison between estimated- and observed-mortality rates

			In-hospital death rates (%)		*30-day death rates (%)*	
Range of CRS	*N*	*Average of CRS*	*Observed*	*Estimated*	*Observed*	*Estimated*
<0	2238	−0.314	0	0	0	0
0-<0.5	2137	0.237	0.75	0.70	0.42	0.29
0.5-<1.0	686	0.689	6.0	5.7	1.5	1.7
1.0-<1.5	126	1.17	15.1	16.0	4.0	3.9
≥1.5	25	1.96	44.0	45.7	8.0	7.8

The estimated- and observed-mortality rates were compared in 5212 patients who underwent elective gastrointestinal surgery.

Table VI. Determination of TRP

	Factors	*Points*
1	Age	× 3
2	Presence of severe heart disease	+300
3	Presence of severe pulmonary disease	+190
4	Presence of diabetes mellitus	+140
5	Performance status (0–4)	× 140
6	ASA class (1–5)	× 60
7	Blood loss (g)/body weight (kg)	× 14
8	Operation time (h)	× 40
9	Extent of skin excision (0-2)	× 340
	TRP	Pts.

Total risk prints (TRP) is computed by the sum of points for factors 1-9. Factors 1-6 can be determined preoperatively and 7-9 immediately after the operation. Criteria for factors 2, 3, 4, 5 and 9 are shown in Patients and Methods. The in-hospital mortality rates were 0% for TRP < 500 (N = 1681), 0.26% for TRP of 500-1000 (N = 1943), 3.0% for TRP of 1000 to 1500 (N = 1253), 9.3% for TRP of 1500 to 2000 (N = 280), and 32.7% for TRP of 2000 or greater (N = 55) in group A.

Our data revealed that the POSSUM and the P-POSSUM overpredicted the mortality rates. The reason for the over-prediction is unclear. The POSSUM and P-POSSUM targeted both emergency and elective operations, but there may be substantive differences in mortality between these types of operations,[26] which would explain why the scoring systems overpredicted the mortality rates of the data that included only elective operations. Alternatively, it is possible that differences in quality of care exist among countries. Therefore, these rules may need some adjustment when applied in different countries. There was a significant correlation between the surgical quality of 6 hospitals defined by the E-PASS and the POSSUM or its modified version, P-POSSUM. The E-PASS and the POSSUM have only 2 factors, age and blood loss, in common. Therefore, these systems may be reliable and useful for the surgical audit. The E-PASS scoring system requires only 10 variables, whereas the POSSUM or P-POSSUM needs 18 variables. Therefore, the E-PASS may have advantages over the POSSUM or P-POSSUM in amount of data entry needed and the complexity of the analysis.

Both the E-PASS and POSSUM were devised to be applied to a wide variety of procedures. However, it is possible that procedures for individual diseases differ in their mortality rules,[27] although this study demonstrated significant correlations between the observed and estimated mortality rates defined by the E-PASS in the individual diseases. Therefore, it would be better to develop a curve for each procedure. This study had insufficient patients to generate mortality curves in individual diseases. The number of patients with gastric carcinoma and colorectal carcinoma, however, exceeded 1000 with a sufficient number of deaths, thus allowing a valid statistical analysis. In these patients, there were polynomial correlations between the CRS and in-hospital mortality rates (gastric carcinoma $R = 0.985$, N = 5, $P = .0053$; colorectal carcinoma $R = 0.991$, N = 5, $P = .0024$). Further studies will be performed to determine if there were significant differences in mortality rates between individual diseases.

For the comparison of surgical quality, 30-day or in-hospital mortality usually was used as an endpoint.[28] This study demonstrated that the outcome of 6 hospitals for 30-day mortality, as defined by the E-PASS, was significantly correlated with that for hospital mortality by the same scoring system. Although 30-day mortality represents only a small percentage of the operated patients, it is more objective and easier to investigate than the in-hospital mortality; therefore, 30-day mortality should be used as the endpoint for surgical audits. On the other hand, avoiding in-hospital mortality is the most important goal for clinicians. This rule for in-hospital mortality will be useful as a prediction guideline in clinical practice. It is difficult to remember and calculate the equations; therefore, we used a computer program in a surgical ward to calculate the estimated mortally rates within 10 seconds. Such programs are indispensable for the E-PASS scoring system and will be developed in the future.

The POSSUM or P-POSSUM scoring system cannot be used as a prediction guideline, since the estimated mortality rates can be determined only after the pathologic results are obtained.[14] Moreover, the POSSUM, devised for exponential analysis, does not provide accurate predicted mortality rates for individual patients. The E-PASS scoring system was originally generated as a prediction guideline, so the estimated mortality rates can be computed immediately after an operation. A quick chart of the TRP presented in this paper may predict the postoperative course and may be useful in promoting the outcome management. However, when surgeons analyze risk stratification using the CRS or TRP, they should be aware of a broad range of mortality for the various numerical ranges of the risk.

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E-PASS (The Estimation of Physiologic Ability and Surgical Stress) Scoring System Helps the Prediction of Postoperative Morbidity and Mortality in Thoracic Surgery

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Key Words
Comprehensive risk score · Thoracic surgery · Postoperative morbidity and mortality

Abstract
Objective: When a new scoring system, 'E-PASS', standing for the Estimation of Physiologic Ability and Surgical Stress that predicts the postoperative surgical risk by quantification of the patient's reserve and surgical stress applied to a population of general thoracic surgery patients, it should be investigated if this system could help us or not. ***Methods:*** The comprehensive risk score (CRS) of the E-PASS and the clinical course were evaluated retrospectively in 282 consecutive patients with primary lung cancer (group A), and in 458 patients who underwent elective thoracic operations (group B). ***Results:*** The morbidity and mortality rates in both group A and group B increased as the CRS increased. The CRS correlated significantly with the morbidity score, length of stay and cost of hospitalization. ***Conclusions:*** E-PASS scoring system may be useful in surgical decision-making and evaluating quality of care in patients who are tolerable for lung resection.

Introduction

A variety of tests have been evaluated to aid the identification of patients at high risk of developing complications after thoracic surgery. These tests include arterial blood gas analysis, spirometry, exercise testing, and radionuclide lung scanning. Most of these studies have utilized a combination of these modalities to define the risk [1–6]. However, the difficulty to find a test, data, and a multifactorial scoring system capable to predict with a high grade of certainty mortality or severe morbidity after pulmonary resection is well known.

It has recently been reported that homeostasis cannot be maintained and it leads to various postoperative complications if surgical stress greatly exceeds a patient's reserve capacity [7]. Therefore, the balance between the surgical stress and patient's physiologic reserve is important.

We hypothesized that the morbidity and mortality rates may be correlated with a patient's physiologic risk and the surgical stress applied, and that surgical stress may be estimated in general since tissue destruction, bleeding, and ischemia caused by basic surgical techniques produce inflammatory cytokines.

Previously, we generated a predictive scoring system designated as E-PASS (Estimation of Physiologic Ability

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and Surgical Stress) to estimate the postoperative risk in general gastrointestinal surgery [8]. Based on the results of multiple regression analysis using 11 preoperative factors and 6 surgical factors, 6 preoperative and 3 surgical factors were identified as risk factors in gastrointestinal surgery. Using these factors, multiple regression analysis was reperformed to obtain the preoperative risk score (PRS), surgical stress score (SSS), and comprehensive risk score (CRS) determined by the PRS and SSS. Our multicenter prospective study revealed that the postoperative morbidity and mortality rates increased as the CRS increased [9, 10]. The CRS was significantly correlated with the severity of postoperative complications and the cost of hospitalization. In this study, we demonstrated that the E-PASS is useful in estimating the morbidity and mortality rates in general thoracic surgery even if all the patients were tolerable for lung resection, similar to the results observed in gastrointestinal surgery.

Patients and Methods

This study was approved by the institutional ethics committee of each hospital and two different groups of patients. Group A, which was investigated retrospectively, consisted of 282 consecutive patients who underwent elective thoracic operations for lung cancer between January 1995 and November 2000 in three regional hospitals in Kumamoto (Kumamoto National Hospital, Kumamoto Chuo Hospital, Arao Municipal Hospital), Japan. This study excluded patients who underwent emergency operations and patients who met the criteria of systemic inflammatory response syndrome (SIRS) prior to surgery. The male to female ratio was 177:105. The median age was 65 years old with a range of 29–79 years. The subjects included patients who underwent extended operation (n = 9), bronchoplasty (n = 4), pneumonectomy (n = 17), bilobectomy (n = 20), lobectomy (n = 171), partial resection or segmentectomy (n = 6), video-assisted thoracoscopic surgery (VATS); VATS-lobectomy (n = 51), VATS-partial resection or segmentectomy (n = 7), and others. All findings were collected retrospectively for the E-PASS scores, surgical procedure and postoperative course.

On the basis of these analyses of group A, we extended the target to all kinds of thoracic disease which consisted of 458 consecutive patients who had undergone elective thoracic operations between April 2000 and March 2002 in four national hospitals (Kumamoto National Hospital, National Himeji Hospital, National Ryukyu Hospital, National Seiranso Hospital) in Japan (group B). The male to female ratio was 323:135. The median age was 65 years with a range of 14–85 years. A number of thoracic disease types are included in this study as follows: primary lung cancer (n = 253), metastatic lung cancer (n = 27), pneumothorax (n = 76), mediastinal tumor (n = 25), and others, i.e. infection or benign tumor.

The subjects included patients who underwent extended operation (n = 12), pneumonectomy (n = 6), bilobectomy (n = 7), lobectomy (n = 70), partial resection or segmentectomy (n = 82), mediastinal tumor resection (n = 11), video-assisted thoracoscopic surgery (VATS); VATS-pneumonectomy (n = 1), VATS-bilobectomy (n = 1), VATS-lobectomy (n = 90), VATS-partial resection or segmentectomy (n = 124), VATS-mediastinal tumor resection (n = 9), and others. Table 1 shows the characteristics of the patients. All findings were collected prospectively for the E-PASS scores, surgical procedure, postoperative course and the costs of hospitalization. The equations for the E-PASS scoring system are shown in table 2. The hospitalization costs were calculated only for the surgical period. These included the fees for the operation, hospital laboratory tests, diagnostic imaging, ward costs and costs for the treatment of postoperative complications. These excluded the costs unrelated to surgical operations, such as chemotherapy and radiotherapy. The Japanese government has maintained a health insurance policy for 40 years that compels all people to join one of the public insurance systems, where everybody can receive necessary medical care for a small fee. These systems are regulated by the same rules – securing free access to the providers and sustaining a traditional fee-for-service system.

Postoperative complications were only included when medical or interventional treatment had been carried out. The complications included wound infection, alveolar air leakage, wound dehiscence, anastomotic leakage of the bronchus, intra-thoracic abscess or empyema, intra-thoracic bleeding, severe atelectasis, anastomotic stenosis requiring dilation, pneumonia, interstitial pneumonitis, atrial fibrillation, bronchial asthma, mediastinitis, chirothorax, heart failure, disseminated intravascular coagulation, acute respiratory distress syndrome, acute renal failure and multiple organ failure. Complications developed in 37 of 282 patients (crude morbidity rates; 13.1%) in the retrospective study and 88 of 458 (19.2%) in the prospective study. The crude mortality rates were 0.35% (1 of 282 patients) and 0.65% (3 of 458 patients), respectively. The morbidity score (MS) was determined arbitrarily as [8]: grade 0, no complications; grade 1, mild complications that were not life-threatening; grade 2, moderate complications that were potentially life-threatening unless adequate treatment was initiated; grade 3, severe organ dysfunction that usually required mechanical support, being equivalent to stage III in our own classification of organ dysfunction [7], with precise definitions determined in seven organs, and grade 4, in-hospital death as a direct result of complications.

Statistical analyses were carried out as previously reported [11]. Significance between the values of three independent groups was determined by the Kruskal-Wallis test. The correlation between different variables was quantified by the Spearman rank correlation (r_s), the significance of which was determined using the Spearman rank-sum test. Linear regression analysis between two variables was done using a simple regression method, the significance of which was quantified by analysis of variance (ANOVA). Two-tailed $p < 0.05$ was considered significant.

Results

Retrospective E-PASS Analyses of Surgery for Lung Cancer Patients

As the E-PASS scoring system was designated to assess the postoperative morbidity and mortality rates in general gastrointestinal surgery, we retrospectively investigated if this scoring system is useful for thoracic surgery or not.

All patients were operated after the estimation which a predicted minimum forced expiratory volume in 1 s ($FEV_{1.0}$) was more than 1 liter for lobectomy and 0.8 liters for pneumonectomy, and determined as tolerable for pulmonary resection by each thoracic surgeons.

Figure 1 shows a range of SSSs for each operative thoracic surgery procedure. The SSS was higher for major operations, such as pneumonectomy. The SSS for VATS was extremely low, namely, that for VATS-lobectomy, a less-invasive alternative to standard lobectomy, was about a quarter of that for standard lobectomy, indicating that the SSS seems to represent surgical stress.

The relationship between the CRS and postoperative complications in group A is shown in figure 2. The incidence of postoperative complications gradually increased as CRS increased.

A marked step-up of morbidity rates was observed with a CRS of more than 0.5, reaching 44.3%. There were no patients whose CRS exceeded 1.0; therefore, the relationship between the mortality rates and CRS was unclear. The CRS correlated well with the severity of postoperative complications as determined by the Spearman's rank correlation test ($r = 0.427$, $p < 0.0001$, $n = 282$; fig. 3).

Multicenter Analyses of General Thoracic Surgery for E-PASS

On the basis of analyses of group A, we investigated the usefulness of the E-PASS scoring system in all kinds of thoracic surgery. Although this investigation was planned as a multicenter prospective study, the relationship between the CRS and the postoperative complications showed reproducible results similar to group A.

The incidence of postoperative morbidity linearly increased as the CRS increased. When the CRS was less than 0.5, the postoperative mortality rate was 0%; however, the mortality rate increased to 9.5% when the CRS ranged between 0.5 and <1.0. It reached 66.6% when the CRS exceeded 1.0 (fig. 4). The CRS significantly correlated with the morbidity score MS ($R_s = 0.728$, $p < 0.0001$, $n = 458$). It also correlated with the cost of hospitalization (fig. 5a) and the length of hospital stay (fig. 5b).

Discussion

Several methods analyzed by univariate analysis have been applied to generate an equation for risk estimation [12–18]. However, these methods cannot account for the influence of other factors on the selection of risk factors

Table 1. Demographic data of the subjects

	Retrospective study	Prospective study
Number of patients	282	458
Extended operation	9	12
Tracheoplasty or bronchoplasty	4	23
Pneumonectomy	17	6
Bilobectomy	20	7
Lobectomy	167	70
Partial or segmental Resection	6	82
VATS-pneumonectomy	–	1
VATS-bilobectomy	–	1
VATS-lobectomy	51	90
VATS-partial resection	7	124
Mediastinal tumor resection	–	11
VATS-resection	–	9
Others		1
Male to female	177:105	323:135
Age	65 [29–79]	65 [14–85]
Crude morbidity rate, %	13.1	19.2
Crude mortality rate, %	0.35	0.65

VATS = Video-assisted thoracoscopic surgery.

Table 2. Equations for E-PASS scores: preoperative risk score (PRS), surgical stress score (SSS), and comprehensive risk score (CRS)

1. $PRS = -0.0686 + 0.00345\,X1 + 0.323\,X2 + 0.205\,X3 + 0.153\,X4, + 0.148\,X5 + 0.0666\,X6$

   X1, age; X2, presence (1) or absence (0) of severe heart disease; X3, presence (1) or absence (0) of severe pulmonary disease; X4, presence (1) or absence (0) of diabetes mellitus; X5, performance status index (0–4); X6, American Society of Anesthesiologists physiological status classification (1–5)

   Severe heart disease was defined as heart failure of New York Heart Association Class III or IV, or severe arrhythmia requiring mechanical support; severe pulmonary disease was defined as any condition with a %VC of less than 60% and/or a $FEV_{1.0\%}$ of less than 50%; performance status index was based on the definition by the Japanese Society for Cancer Therapy

2. $SSS = -0.342 + 0.0139\,X1 + 0.0392\,X2 + 0.352\,X3$

   X1, blood loss/body weight (g/kg); X2, operation time (h); X3, extent of skin incision (0: minor incisions for laparoscopic or thoracoscopic surgery [including scope-assisted surgery]; 1: laparotomy or thoracotomy alone; 2: both laparotomy and thoracotomy)

3. $CRS = -0.328 + 0.936\,(PRS) + 0.976\,(SSS)$

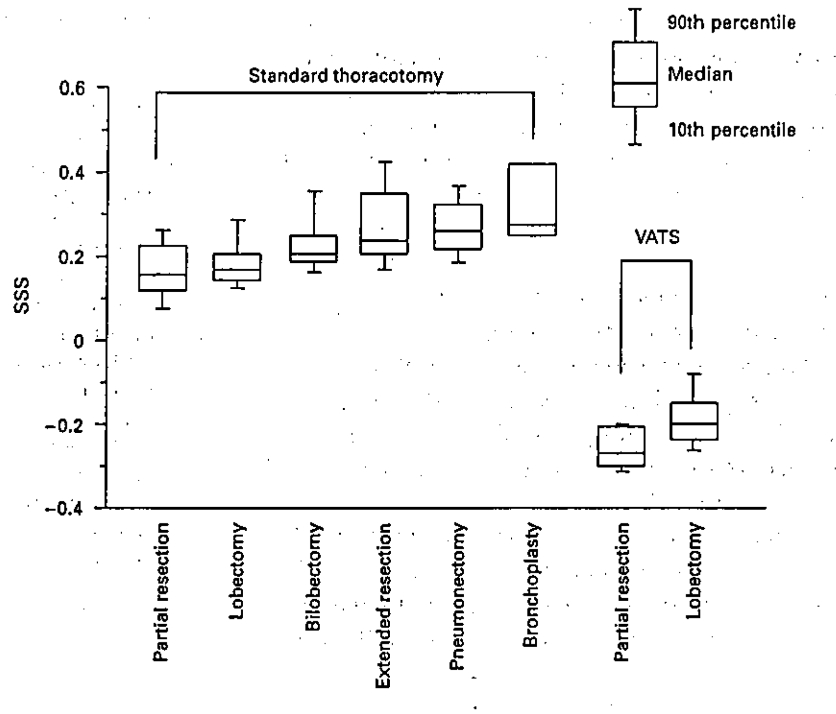


Fig. 1. SSS of each surgical procedure. The SSS for each individual surgical procedure is shown in the retrospective study. A horizontal bar within a box, a box, and outer bars represent the median, the 25th to 75th percentile range, and the 10th to 90th percentile range, respectively.

and did not produce a marked step-up of morbidity and mortality rates, except for the CRS.

The E-PASS scoring system was designated on the basis of our hypothesis that the balance between the patients' reserve capacity and surgical stress is important in the occurrence of postoperative complications. The E-PASS scores were calculated by multiple regression analysis and can express degree of the patients' reserve capacity and severity of surgical stress as continuous variables [8].

Although several estimation methods for postoperative lung function have been proposed, these methods have limited accuracy rates and still remain unclear for prediction of postoperative morbidity and mortality. The aim of this study is the prediction of postoperative morbidity and mortality of the patients who get through several kinds of lung function test. In this study, all patients were evaluated tolerable by predicted $FEV_{1.0}$ for pulmonary resection and resting oxygen saturation more than 90%.

The E-PASS scoring system (especially PRS) doses not include several factors for predicting residual lung function. In the present study, the E-PASS scoring system reflected the mortality and morbidity rates well, even if this system was generated by general gastrointestinal surgery.

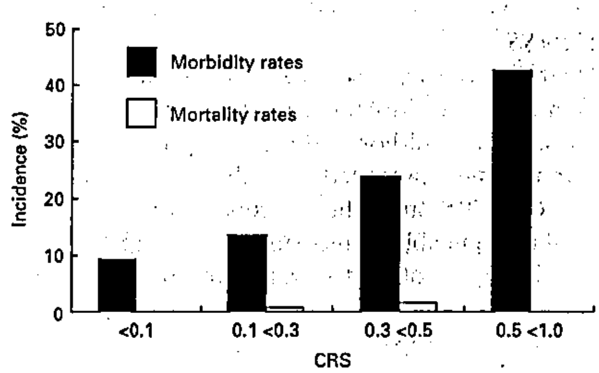


Fig. 2. Relationship between the CRS and postoperative complications. The morbidity and mortality rates were quantified according to the CRS in the retrospective study. ■ = Morbidity rate; □ = mortality rate.

Of course, it might be unusual to apply a model for gastrointestinal surgery to thoracic surgery; however, we could evaluate the risk in addition to the well-known pulmonary function test.

A physiologic and operative severity score for the enumeration of mortality and morbidity (POSSUM) was val-

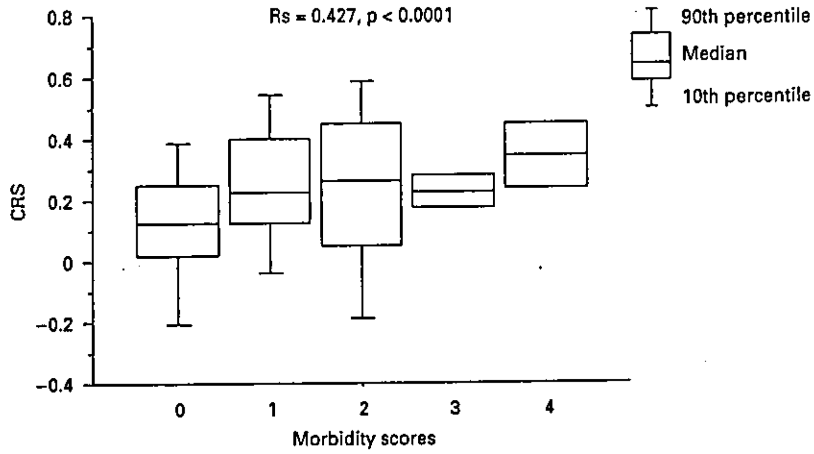
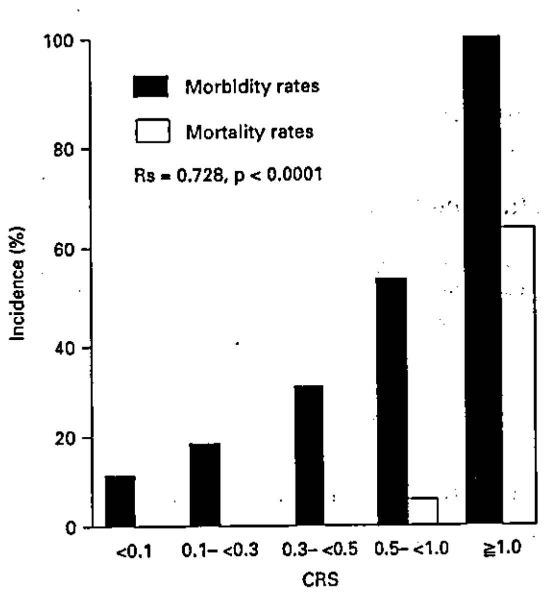


Fig. 3. Relationship between the CRS and morbidity scores. The CRS correlated well with the severity of postoperative complications as determined by Spearman's rank correlation test ($r_s = 0.427$, $p < 0.0001$, n = 282). Morbidity grade: 0 = no complications; 1 = mild; 2 = moderate; 3 = severe organ dysfunction; 4 = in-hospital death.



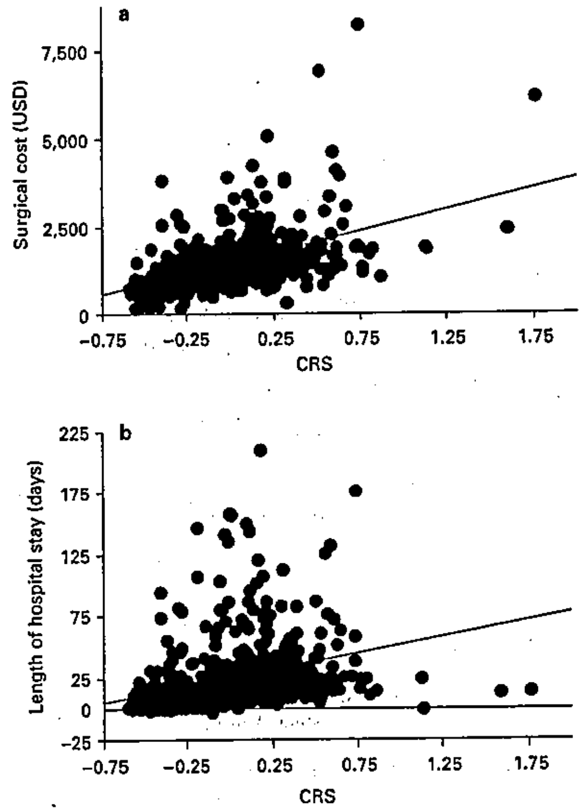


Fig. 4. Relationship between the CRS and postoperative complications. The morbidity and mortality rates were quantified according to the CRS in the prospective study. The CRS correlated significantly with the MS ($r_s = 0.728$, $p < 0.0001$, n = 458). ■ = Morbidity rate; □ = mortality rate.

Fig. 5. a Relationship between the CRS and surgical cost. The correlation between the CRS and the surgical cost was quantified by the Spearman rank correlation ($r_s = 0.530$, $p < 0.0001$, n = 282). **b** Relationship between the comprehensive risk score (CRS) and length of hospital stay. The correlation between the CRS and the surgical cost was quantified by the Spearman rank correlation ($r_s = 0.332$, $p < 0.0001$, n = 282).

idated for the same purpose and previously reported for thoracic surgery [19, 20]. However, the POSSUM scoring system calculated a greater number of variables and over-predicted the morbidity and mortality rates compared with E-PASS [unpubl. data].

The relationship between the CRS and morbidity and mortality rates obtained in the present study was quite similar to that of previous studies in gastrointestinal surgery [8, 9, 10].

The current PRS comes from the comprehensive categories of age, performance status index, ASA class, severe heart disease, severe pulmonary disease, and diabetes mellitus. In patients with severe diseases other than of the heart or lung, the risk will be reflected by the ASA class.

The SSS is quite simple, consisting of blood loss/body weight, operation time, and the extent of skin incision. Instead of the last factor, skin incision, resected lung volume (i.e. partial, one-lobe, two-lobe, etc.) might take its place in a modified system. Regardless, these scores do not require special examinations, and can be determined in any hospital.

Postoperative complications may depend on three major factors: namely, the quality of the surgical team, the patient's physiological status, and the degree of surgical stress. The quality of the surgical team includes surgeons' skill, quality of postoperative care, number of staff in attendance, equipment, and availability of an ICU. Where the quality of a surgical team in one hospital has remained stable for a certain period, the morbidity and mortality rates for individual patients can be estimated by quantification of the patient's physiological status and the surgical stress applied. Using the E-PASS scoring system, a surgeon can clarify the relationship between CRS and the morbidity and mortality rates for a certain period in his hospital, as shown in figure 2, and calculate a range of SSSs for each surgical procedure from the previous operation records, as shown in figure 1. The predictive risk for each surgical procedure on an individual patient can then be determined preoperatively. If the risk is too high for a patient, a less-invasive procedure can be selected. Thus, in our multicenter study, the E-PASS scoring system may be useful in the selection of surgical procedures. The purpose of this study is not the comparison between group A and group B, but the demonstration of morbidity and mortality rates were closely related to CRS in each group. In this manner, we could find similar results in group B as in group A even if group B consisted of variable thoracic disease.

It was previously reported that the E-PASS is useful in estimating surgical costs in gastrointestinal surgery [9], and that the CRS was more closely correlated with the cost and length of hospital stay than PRS. This was also found to be the case in the present study. E-PASS will be useful for the determination of the rates in a risk-based payment system.

In conclusion, the E-PASS scoring system which was designated based on the quantification of preoperative risks and surgical stress in general gastrointestinal surgery may be a powerful tool for decision-making in general thoracic surgery.

Acknowledgments

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第9章 EBMとクリティカルパス

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はじめに

Evidence-Based Medicine（以下，EBM）は，1990年代にGuyattらによって提唱された概念であり[1]，「個々の患者の医療判断の決定に，最新で最善の根拠を良心的かつ明確に，思慮深く利用する手法」と定義される[2]。Evidence（エビデンス）とは科学的に証明された事実を意味しており，EBMは目の前の患者にエビデンスに基づいた最良の診療を行おうという考えである。その後，EBMの考えは多くの支持を得て世界的に普及した。EBMとほぼ同じ時期に，米国で広く浸透してきたクリティカルパスは，医療行為の標準化と質の向上を目指して開発された患者管理ツールである。Spathは，クリティカルパスを「医療チームが共同で作り上げげた，患者の最良の管理だと信ずるところを示した仮説である」と称している[3]。すなわち，多くの試行錯誤を繰り返しながら，最良の患者管理ツールを探し求めていった結果がクリティカルパスである，というのである。こうして考えていくと，EBMとクリティカルパスでは，医療の質の向上を求めるという基本精神は同じであることがわかる。したがって，クリティカルパスはEBMを実践するには最良の場であるといえる。

本稿では，国立病院機構熊本医療センターでの経験を紹介しながら，クリティカルパスを通じてEBMを取り入れるプロセスとその効用について解説する。

I EBMとは

EBMを端的に言い表せば，実証主義に基づく医療ということができる。たとえば，手術後に起こる感染症を予防するにはどのくらい抗菌薬を投与すればよいのであろうか。この答えは外科医にとって大きな命題であった。多くの無

作為比較試験（Randomized Controlled Trial：RCT）で，清潔手術および準清潔手術では，術前に1回だけ抗菌薬を投与した場合と，術前術後に3回程度抗菌薬を投与した場合とで，手術部位感染症の発生率に差がないことが判明した。つまり，手術創が閉じられてから抗菌薬を投与しても，感染を予防できないことが証明されたのである。現在，欧米のガイドラインでは，清潔手術および準清潔手術では，抗菌薬の術前単回投与が推奨されている[4~6]。結果が同じであれば，抗菌薬の使用が少ない方が，MRSAなどの耐性菌の出現が少なくなる分よいという考えである。

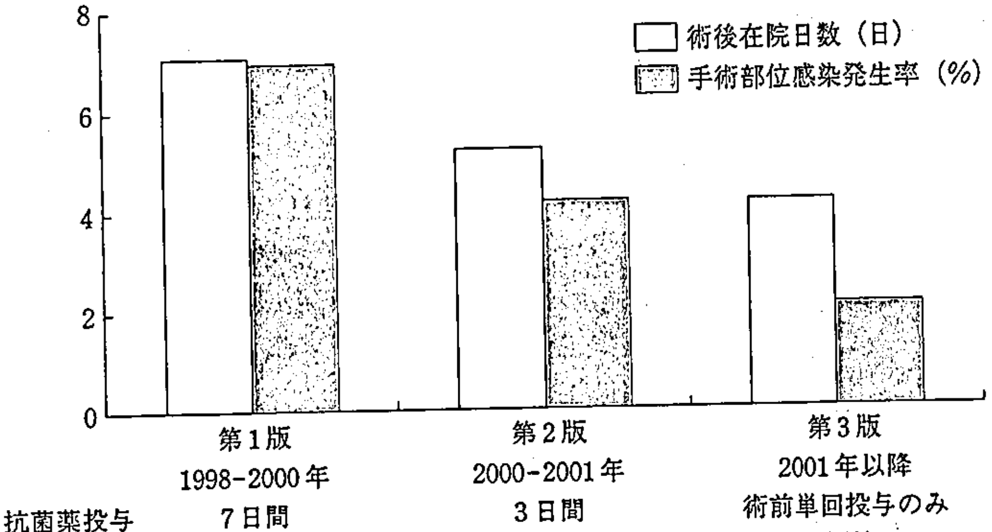
EBMを実践する手順は，①疑問の定式化，②情報の収集，③情報の批判的吟味，④患者への適用，⑤自己検証の5つのステップからなる[2]。最初のステップは，臨床上の疑問を一定の形にすることで，患者の対象は何か，何を介入させるのか，結果は何をもって評価するのか，などを明確にする作業である。2番目のステップは，①の疑問に関する英語論文をPubMedやコクランライブラリーなどを用いて，効果的に収集する作業である。3番目のステップは，収集した情報から得られる根拠が妥当であるか（真理に近いか）を判断する過程である。論文の具体的な吟味の方法（critical appraisal）は，論文の内容ごとにワークシートを用いて行う。最終ステップは，果たしてEBMを取り入れることによって，アウトカムが向上したかどうかを評価する段階である。こうしてみると，EBMの実践手順は，アウトカムの改善を目指してクリティカルパスを繰り返し改訂していく作業（アウトカム・マネジメント）によく似ていることがわかる。これは，EBMもクリティカルパスも臨床アウトカムを重視するという点が一致しているからである。

II EBMのクリティカルパスへの適用

われわれは院内に多職種からなるクリティカルパス・プロジェクトチームを結成し，その中にEBM班を設けた。EBM班は，院内のクリティカルパス研究会を通して，さまざまな提言を行ってきた。

まず，手術後の感染症を予防するために，院内で広く行われていた剃毛の廃止を1999年に提言した。これはカミソリを用いた剃毛を行った患者は，除毛剤で除毛したか，バリカンで除毛した患者に比べて，有意に手術部位の感染症が増加することがRCTで明らかにされているからである[7,8]。その結果，院内でカミソリを用いた剃毛は廃止され，必要なときはバリカンあるいは除毛剤を用いた除毛を行うことが決まった。

次に，包交車の鑷子（せっし）立ておよびキャストを廃止し，滅菌した単独の鑷子およびガーゼを使用するように提言を行った。これは種々の学会で，鑷子立てやキ



手術部位感染発生率(%)＝(手術部位感染症発症数÷手術件数)×100
腹腔鏡下胆嚢摘出術（国立病院機構熊本医療センター）

図1　クリティカルパス改訂による手術部位感染の推移

ャストを介して細菌の接触感染が起こることが報告されていたからである。

また，手術後の感染症予防のための抗菌薬投与に関しては，先ほども述べたとおりアメリカの疾病管理・予防センター（Centers for Disease Control and Prevention：CDC）[4] や医療保険制度薬剤師会（American Society of Health-System Pharmacists）のガイドライン[5]，カナダ医学会のガイドライン[6] を参考にした。腹腔鏡下胆嚢摘出術のクリティカルパスでは，1998年当初7日間投与されていた抗菌薬の投与期間は徐々に短縮され，2001年から術前の単回投与のみとなった。その結果，手術部位感染はむしろ減少していた（図1）。その他の手術でも抗菌薬の投与期間は徐々に短縮されている。

次に，CDCの血管内カテーテル関連感染症予防のためのガイドライン[9] や多くの施設から発表されているセラチア菌の院内感染予防策を参考にし，血管内カテーテルの管理法に関する提言を行った。輸液ラインに接続される三法活栓は死腔があり，しばしば細菌感染を起こすことが知られている。したがって，IVHラインでは三法活栓を使用せず，死腔のない閉鎖式の輸液セットを使用するよう提言した。また，IVHのフィルターは，感染予防の意義はないとCDCのガイドラインに明記してあったため，ルーチンに使用する必要がないことを提言した。また，過去のセラチア菌の血流感染の集団発生例では，作り置きのヘパリン加生食水の汚染が原因であることが示唆されているので，血管内カテーテルのヘパリンロックは原則として行わないように提言した。

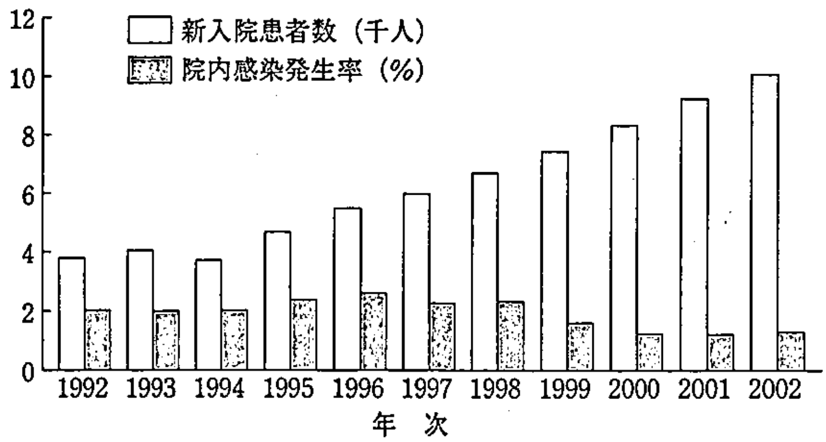
さらに，CDCの手指衛生ガイドライン[10] やCDCの耐性菌対策キャンペーン[11] を院内に周知させ，院内感染対策の強化を図ってきた。

Ⅲ EBMの臨床評価

EBMを実践することにより，医療の質は向上したのだろうか。われわれはEBMを実践する前と後で，感染症の発生率を比較した。外科の乳がん手術のクリティカルパスでは従来セファゾリンを4日間投与していたが，これを1日間の投与に短縮した。その結果，手術後に起こった感染症は，逆に4.2％から2.9％に減少した。また整形外科手術では，多くの手術のクリティカルパスにおいて抗菌薬をセフォチアムかセファゾリンのいずれかを主治医の判断で選択できるようにし，投与期間も3日間に設定してあった。EBM班の提言を受けてからは，抗菌薬の種類を第一世代セフェムであるセファゾリンに統一し，投与期間も2日間に短縮した。その結果，手術部位感染症は，有意差を認めなかったが0.93％から0.36％まで約1/3に減少した。

次に，血管内カテーテル管理に関する提言が実際に血流感染を減少できたかを，血液内科の血液幹細胞移植患者で検証した。IVHラインを開放式から閉鎖式に変えてから，38℃以上の有熱期間は平均3.0日であったものが，0.95日まで有意に減少した（P＝0.0045）。また，血液培養の陽性者は8.7％であったものが，まったくみられなくなった。

それでは，院内感染症全体の発生率はどうなったのであろうか。当院での入院患者数と院内感染の発生率を図2に示す。当院の入院患者数は年々増えていき，10年間で約2.5倍に増加した。一方，院内感染の発生率は1992年から2％



当院では，1998年から院内全体でクリティカルパスを導入し，EBMの普及に努めてきた。院内感染発生率は，1998年では2.3％であったが，1999年では1.6％（P＝0.0037），2000年および2001年では1.2％（ともにP＜0.0001），2002年では1.3％（P＜0.0001）と有意に減少した。院内感染発生率は，カイ二乗検定で検定した。

院内感染発生率(％)＝(院内感染症発症数÷新入院患者数)×100

（国立病院機構熊本医療センター）

図2　年次別にみた新入院患者数と院内感染発生率

前後で推移していたが，院内で本格的にクリティカルパスを導入した1998年からは徐々に減少していき，2001年では1.2％，2002年は1.3％であった。これはクリティカルパスを通じてEBMを取り入れた結果であると考えられる。

おわりに

クリティカルパスは本来医療を標準化することにより，医療の質の向上を図っていくツールである。したがって，積極的にEBMをクリティカルパスの中に取り入れるべきである。逆に，クリティカルパスを材料としてEBMを推進していくことも重要である。われわれは院内のクリティカルパス研究会をEBM提言の場とし，EBMを浸透させてきた。従来から行ってきた医療を捨て，EBMを実践するには，通常多くの抵抗を伴うものである。重要なことは，EBMを強制するのではなく，時間をかけてその効果と検証結果を繰り返し発表することである。そうすれば，地下水が湧き出るように徐々に力を発揮していくであろう。

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