Material

Analysis of Variance in Large Bowel Cancer Patients within a Clinical Pathway Using POSSUM

Naokuni YASUDA¹⁾, Makoto WATANABE²⁾, Osamu NAKASHIMA¹⁾
Toru OHNAKA¹⁾, Akira TSUNODA²⁾ and Mitsuo KUSANO²⁾

Abstract : The aim of this study was to assess analysis of variance of clinical pathways for large bowel cancer patients using the scoring system physiological and operative severity score for the enumeration of mortality and morbidity (POSSUM), which predicts postoperative morbidity and mortality. Large bowel cancer cases performed in our department between January 2002 and March 2004 were studied. These were divided into three groups: group one consisted of 48 patients without variance; group two consisted of 13 patients without variance and with complications; and group three consisted of 13 patients with variance. The average postoperative complication risk predicted by POSSUM was 34.4%. Observed complications were recorded in 26 out of 74 patients (35.1%), and variance developed in 13 of these 26 patients. There were no differences in the PS and OSS scores between patients with and without variance. Predicting the occurrence of variance using POSSUM is difficult as many factors can influence the development of variance. Therefore, POSSUM is unlikely to be a suitable scoring system for predicting which patients will develop variance.

Key words : POSSUM, clinical pathway, variance, colorectal cancer

Introduction

A clinical pathway is essential for efficient outcome management within the medical service¹⁾. The length of hospital stay and criteria for patient discharge are the two crucial outcomes. Variances are patient outcomes or staff actions that do not meet the expectations of a clinical pathway²⁾. Reasons for variances are generally categorized as being patient-related, staff-related, hospital-related and social factors. Most patient-related factors of variances are due to postoperative complications or a poor understanding of discharge guidelines.

Many scoring systems predict the risk of mortality and morbidity with varying degrees of accuracy³⁾. The physiological and operative severity score for the enumeration of mortality and morbidity (POSSUM) system was first described by Copeland *et al*⁴⁾ in 1991. Twelve physiological and six operative factors were developed for scoring, and these scores were applied to an equation to obtain a predicted postoperative morbidity rate for each patient. POSSUM was found to be the most accurate predictive system compared to the other available scoring systems⁵⁾.

¹⁾ Department of Surgery, Isesaki Municipal Hospital, 12-1 Tsunatorihonmachi, Isesaki 372-0817, Japan.

²⁾ Second Department of Surgery, Showa University, School of Medicine.

The aim of this study was to apply POSSUM analysis to assess the variance of clinical pathways for large bowel cancer patients.

Materials and Methods

Patients who underwent elective colorectal resection (excluding planned abdominoperineal examination of the rectum) between January 2002 and March 2004 as part of a clinical pathway were selected for this study. Patients whose performance status was rated at less than 2 on the POSSUM system were excluded, because palliative operations were sometimes undertaken instead of resection surgery. The remaining patients were divided into three groups: patients without variance or complications; patients without variance and with complications; and patients with variance.

Implementation of a clinical pathway in our department is characterized by patient education and clear discharge criteria. At the induction of a clinical pathway and prior to surgery, we outlined six goals that should be achieved before discharge to the patients and their families^{6,7)}. These goals included progression through the following phases: pain, effort, temperature, meals, shower and examination. These goals were achieved when the patient was comfortable with or without oral painkiller, could walk independently, ate solid meals more than 50% of the time, maintained a normal temperature for 48 hours, was able to take a shower, and had examination results that fell within the normal range before discharge.

The clinical pathway applied to the patients is described below and is based on the ability of patients to achieve the six goals before discharge by postoperative day 14. On the morning of postoperative day 1, the nasogastric tube was removed. On postoperative day 3, the epidural and Foley catheters were removed, and the patient was started on sips of clear liquid. On postoperative day 5, the patient was allowed a liquid diet. For the purpose of this study, variance was defined as when a patient was not able to achieve the six goals by postoperative day 16 and therefore not discharged.

The POSSUM system is based on scores from a four-grade, 12-factor physiological score (PS) and a six-factor operative severity score (OSS), which estimates the risk of adverse postoperative outcome (Table 1). The risk was calculated from logistic regression equations^{4,5)}. The equation used for postoperative morbidity (R: Outcome Risk) was: $\ln[R/(1-R)] = -5.9 + (0.16 \times PS) + (0.19 \times OSS)$

Statistical analysis

Differences between observed and predicted outcomes were assessed using chi-squared test and the Hosmer-Lemeshow goodness-of-fit test. The statistical significance of differences between patients with variance and patients without variance and complications was tested by student's t-test; a P value of less than 0.05 was considered significant.

Results

A total of 74 patients were involved in this study. These included 57 colic resections (31 right-sided hemicolectomies and 26 sigmoid resections or left-sided hemicolectomies) and 17 anterior resections or ultra-low anterior resections. Postoperative complications were observed in 26 patients (35.1%), 13 of whom developed variance. Table 2 shows characteristics of patients without variance and complications, patients without variance and

Table 1. Variables of PS and OSS in POSSUM

Physiological Score				
	1	2	4	8
Age	≤60	61-70	≥71	
Cardiac signs	No failure	Diuretic, digoxin, antianginal or hypertensive therapy	Peripheral oedema, warfarin therapy Borderline cardiomegaly	Raised jugular venous pressure Cardiomegaly
Respiratory history	No dyspnoea	Dyspnoea on exertion Mild COAD*	Limiting dyspnoea Moderate COAD	Dyspnoea at rest (≥30/min) Fibrosis or consolidation
Blood pressure (mmHg)	110~130	131~170, 100~109	≥171, 90~99	≤89
Pulse (/min)	50~80	81~100, 40~49	101~120	≥121, ≤39
Glasgow coma score	15	12~14	9~11	≤8
Haemoglobin (g/100ml)	13~16	11.5~12.9, 16.1~17.0	10.0~11.4, 17.1~18.0	≥18.1
White cell count ($\times 10^{12}/l$)	4~10	10.1~20.0, 3.1~4.0	≥20.1, ≤3.0	
Urea (mmol/l)	≤7.5	7.6~10.0	10.1~15.0	≥15.1
Sodium (mmol/l)	≥136	131~135	126~130	≤125
Potassium (mmol/l)	3.5~5.0	3.2~3.4, 5.1~5.3	2.9~3.1, 5.4~5.9	≤2.8, ≥6.0
Electrocardiogram	Nomal		Atrial fibrillation (rate 60~90)	Any other abnormal rhythm

* COAD, chronic obstructive airways disease

Operative Severity Score

	1	2	4	8
Operative Severity	Minor	Moderate	Major	Major +
Multiple procedure	1		2	>2
Total blood loss (ml)	≤100	101~500	501~999	≥1000
Presence of malignancy	None	Minor (serous fluid)	Local pus	Free bowel content, pus or blood
Mode of surgery	Elective		Emergency resuscitation of >2h possible Operation <24h after admission	Emergency (immediate surgery <2h needed)

Table 2. Clinical characteristics of patients without valiance and complications, patients without valiance and with complications, patients with valiance

		without variance		with variance
		without complications	with complications	
No. of cases		48	13	13
Age		63±9.9	68.9±11.3	64.2±13.3
Sex		28 : 20	10 : 3	6 : 7
Location				
	Right sided	18	5	8
	Left sided	20	3	3
	Rectum	10	5	2
Stage				
	0	0	1	1
	I	7	2	0
	II	21	7	6
	III A	11	1	5
	III B	3	0	0
	IV	6	2	1

Table 3. Comparison of complication rate between POSSM and observed

Hosmer-Lemeshow goodness-of-fit test for the POSSUM morbidity equation					
		Complication (-)		Complication (+)	
Predicted rete (%)	No. of patients	Observed	Predicted	Observed	Predicted
9.0 ~ 12.7	8	6	8.1	2	0.9
14.9 ~ 17.9	7	7	5.8	0	1.2
18.5 ~ 19.9	9	6	7.3	3	1.7
20.4 ~ 24.4	7	5	5.4	2	1.6
25.0 ~ 30.6	7	4	5.1	3	1.9
30.8 ~ 38.0	8	4	5.2	4	2.8
38.5 ~ 44.8	7	2	4.1	5	2.9
45.5 ~ 47.3	7	5	3.8	2	3.2
47.8 ~ 58.4	7	4	3.3	3	3.7
61.8 ~ 97.3	7	6	1.5	1	5.5

$$\chi^2 = 27.1, \text{ 8 d.f., } p = 0.00066$$

with complications, and patients with variance.

The mean complication rate predicted by POSSUM was 34.4%, which was comparable with the observed morbidity rate of 35.1%. In patients with observed morbidity, surgical site infection (SSI) was seen in 73.1%, ileus in 11.5%, delirium in 11.5%, and leakage in 7.7%. There was, however, no relationship between the rate predicted by POSSUM and

Table 4. Comparison of POSSUM results between patients without variance and complications and patients with variance

	without variance and complications	with variance	p-value
No. of cases	48	13	
PS	17.1 ± 4.4	17.1 ± 4.3	0.9963
OSS	12.9 ± 4.3	12.9 ± 2.8	0.9828
POSSUM	34.2%	35.4%	0.8593

observations using the Hosmer-Lemeshow goodness-of-fit test (Table 3). The group with the highest predicted rete consisted of two patients who had undergone ultra-low anterior resection and four patients who had undergone colectomy (mean PS=23, range 14–31; mean OSS=20, range 13–29). In the patients with variance, SSI was seen in 69.2%, ileus in 23.1%, and leakage in 15.4%. There were no differences in PS, OSS and the rate predicted by POSSUM between patients with variance and patients without variance and complications (Table 4).

Discussion

Clinical pathways have varying formats and are known by many names, including critical pathways and care paths⁸⁾. Clinical pathways were originally adopted from engineering fields. First developed in the 1950 s, the Critical Path Method and Program Evaluation and Review technique were used in the industrial setting to manage the efficiency and cost effectiveness of projects^{9,10)}. Clinical pathways were first developed and applied to health care in the 1980 s, when economic pressure and cost-effective medical practices developed in the United States^{8,11,12)}. Therefore, the goal of clinical pathways was to provide high quality care in a cost-effective manner^{8,13,14)}. In recent years, clinical pathways have become common in all areas of Japanese medicine. Clinical pathways encompass preoperative and intraoperative patient care in addition to postoperative care. Rather than simply reducing the length of hospital stay and health-care costs, clinical pathways are also useful for improving staff coordination, patient satisfaction, and patient care^{7,15)}.

Clinical pathways are advantageous to the safe management of medicine as they inform patients of the standard treatment schedule. The quality of surgical care influences morbidity, mortality and length of hospital stay. Previous studies^{16–18)} have found that clinical pathways can lead to a decrease in the cost and length of hospital stay without increasing morbidity and mortality in bowel resection procedures. However, these studies were not prospective randomized controlled studies. Such studies are difficult because a single institute needs a large number of patients and it is possible that increased surgical experience will contribute to a decrease in complications over time.

Recently, Haga *et al*^{19,20)} suggested that a scoring system used to predict postoperative risk might be useful for surgical decision making, medical expense estimations, and comparisons of surgical quality. Theoretically, if the number of variables is smaller, then the scoring system will be more user-friendly⁷⁾. POSSUM is a widely used scoring system that predicts postoperative risk of mortality and morbidity. The 12 PS factors are assessed at admission as part of the routine clinical history and examination, which includes biochemical,

radiological and cardiological investigations. The six features of OSS are assessed postoperatively. As POSSUM is based on both pre-and post-surgical criteria, we chose POSSUM to predict variance in patients within a clinical pathway.

In the present study, there was no relationship between the observed incidence of variance and risk predicted by POSSUM, although patient-related postoperative complications developed in all patients with variance. Our results suggested that the most significant difference was observed in the group with the highest predicted rate, between patients without complications and patients with complications. A possible explanation is that our medical care combined with a clinical pathway is effective for patients, especially those at high-risk. Therefore, a clinical pathway including patient education, in combination with good medical care, may help prevent variance in patients that have operable large bowel cancers.

Our results showed that there were no correlations between the complication rate predicted by POSSUM and the observed complication rate. Although some studies^{21, 22)} have suggested that POSSUM should be modified according to ethnicity or disease, we used the original POSSUM in this study. Due to the small number of patients in this study, we are unable to comment on the validity of these modifications. Further studies are required to determine whether these modifications should be incorporated. However, such predictive scores might be useful to inform and educate patients and their families about postoperative complications.

Clinical pathways for the treatment of cancer might prove difficult because of individual differences in both patients and surgeons¹⁵⁾. A balance between autonomy and standardization must be obtained⁸⁾. In the clinical setting, such a balance can lead to good management and hence enable medical staff to detect variations at an early stage, and therefore treat the individual appropriately. Thus, implementation of tailor-made clinical pathways may enable early detection and treatment for these variations.

In a strategy to reduce patient-related variance, we must adhere to guidelines for the prevention of SSI presented by the Centers for Disease Control²³⁾. Early feeding²⁴⁾ and sham feeding²⁵⁾ also might decrease the rate of ileus. To decrease the rate of variance, we have devised four recommendations: implementing a clinical pathway for patients; informing patients and their relatives about potential complications; detecting variations at an early stage; and ensuring complications are managed efficiently according to individual clinical situations.

In summary, our results demonstrate that the postoperative risk predicted by POSSUM does not correlate with the observed morbidity rate. It is possible that it can predict a subset of patients with variance caused by complications, but due to its poor specificity we would not permit its clinical use. However, POSSUM may be a useful educational tool for informing patients and their relatives about potential postoperative complications during the clinical pathway process.

References

- 1) Nomura K: General rule of critical path for outcome management. *J Jpn Soc Health Care Manage* 4 : 360-364 (2003) (in Japanese)
- 2) Zander K: Use of variance from clinical paths: coming of age. *Clin Perform Uual Health Care* 5 : 20-30 (1997)
- 3) Jones HJS and de Cossart L: Risk scoring in surgical patients. *Br J Surg* 86 : 149-157 (1999)

- 4) Copeland GP, Jones D and Walters M : POSSUM : a scoring system for surgical audit. *Br J Surg* **78** : 355-360 (1991)
- 5) Jones D, Copeland GP and de Cossart L : Comparison of POSSUM with APACHE II for prediction of outcome from a surgical high-dependency unit. *Br J Surg* **79** : 1293-1296 (1992)
- 6) Yasuda N, Watanabe M, Kusano T, Kamisaka K, Tsunoda A and Kusano M : The study on 6 goals by self-check in a clinical path for gastrointestinal cancers. *Surgery* **65** : 461-463 (2003) (in Japanese)
- 7) Yasuda N, Watanabe M, Kusano T, Tsunoda A and Kusano M : The study on clinical pathway with Six goals by self-check. *J Jpn Coll Surg* **28** : 698-701 (2003) (in Japanese)
- 8) Pearson SD, Goulart-Fisher D and Lee TH : Critical pathways as a strategy for improving care: problems and potential. *Ann Intern Med* **123** : 941-948 (1995)
- 9) Luttman RJ, Laffel GL and Pearson SD : Using PERT/CPM (Program Evaluation and Review technique/ Critical Path Method) to design and improve clinical processes. *Qual Manage Health Care* **3** : 1-13 (1995)
- 10) D'Aquila NW : Facilitating inservice programs through PERT/CPM. Project Evaluation and Review Technique/Critical Path Method. *Nurs Manage* **24** : 92-94 (1993)
- 11) Coffey RJ, Richards JS, Remmert CS, LeRoy SS, Schoville RR and Baldwin PJ : An introduction to critical paths. *Qual Manage Health Care* **1** : 45-54 (1992)
- 12) Hofmann PA : Critical path method: an important tool for coordinating clinical care. *Jt Comm J Qual Improv* **19** : 235-246 (1993)
- 13) Spath PL : Critical paths: maximizing patients care coordination. *Today's OR Nurse* **17** : 13-20 (1995)
- 14) Gadacz TR, Adkins RB Jr and O'Leary JP : General surgical clinical pathways: an introduction. *Am Surg* **63** : 107-110 (1997)
- 15) Konishi T and Agawa S : Clinical pathways in Oncology. *Jpn J Cancer Chemother* **27** : 655-670 (2000) (in Japanese)
- 16) Pritts TA, Nussbaum MS, Flesch LV, Fegelman EJ, Parikh AA and Fischer JE : Implementation of a clinical pathway decreases length of stay and cost for bowel resection. *Ann Surg* **230** : 728-733 (1999)
- 17) Stephen AE and Berger DL : Shortened length of stay and hospital cost reduction with implementation of an accelerated clinical care pathway after elective colon resection. *Surgery* **133** : 277-282 (2003)
- 18) Basse L, Jakobsen DH, Per Billesbolle RN, Werner M and Kehlet H : A clinical pathway to accelerate recovery after colonic resection. *Ann Surg* **232** : 51-57 (2000)
- 19) Haga Y, Ikei S and Ogawa M : Estimation of physiologic ability and surgical stress (E-PASS) as a new prediction scoring system for postoperative morbidity and mortality following elective gastrointestinal surgery. *Surg Today* **29** : 219-225 (1999).
- 20) Haga Y, Ikei S, Wada Y, Takeuchi H, Sameshima H, Kimura O and Furuya T : Evaluation of an estimation of physiologic ability and surgical stress (E-PASS) scoring system to predict postoperative risk: A multicenter prospective study. *Surg Today* **31** : 569-574 (2001)
- 21) Tekkis PP, Kessaris N, Kocher HM, Poloniecki JD, Lyttle J and Windsor CJ : Evaluation of POSSUM and P-POSSUM scoring system in patients undergoing colorectal surgery. *Br J Surg* **90** : 340-345 (2003)
- 22) Yui MK and Ng KJ : Risk-adjusted surgical audit with the POSSUM scoring system in a developing country. *Br J Surg* **89** : 110-113 (2002)
- 23) Mangram AJ, Horan TC, Peatson ML, Silver LC and Jarvis WR : Guideline for prevention of surgical site infection, 1999. *Am J Infect Control* **27** : 97-132 (1999)
- 24) DiFronzo LA, Cymerman J and O'Connell TX. Factors affecting early postoperative feeding following elective open colon resection. *Arch Surg* **134** : 941-946 (1999)
- 25) Asao T, Kuwano H, Nakamura J, Morinaga N, Hirayama I and Ide M : Gum chewing enhances early recovery from postoperative ileus after laparoscopic colectomy. *J Am Coll Surg* **195** : 30-32 (2002)

[Received August 20, 2004 : Accepted December 17, 2004]