shows a prolonged increase, and BV a transient decrease. It was also noted that K-ICG remains significantly higher than the preoperative value until POD 14, despite the return of CO, CI and BV to baseline levels.

Generally, in humans a crisis of depletion of BV is resolved by centralization of BV. The increase in K-ICG observed in the present study may be induced by centralization of BV in response to surgical stress. It has been reported that portal vein blood flow decreases after major abdominal surgeries (19). However, Kennedy et al. reported that estimated hepatic blood flow decreases significantly, as much as 23%, after high spinal anesthesia and that this decrease is associated with a reduction in mean arterial pressure. Additionally, no significant alteration in cardiac output or splanchnic vascular resistance was observed, and the fraction of cardiac output delivered to the splanchnic circulation was significantly reduced by 21% (20).

Circulating blood volume is a constantly changing parameter because of blood pooling in the spleen, liver and other organs. Further, it has been suggested that during strenuous conditions the spleen might release pooled erythrocytes to the general circulation (21). Correction of the volume depletion is the main therapy of resuscitation in hemorrhagic shock. In general, BV can be controlled by infusion of fluids such as a hydroxyethylstarch solution (22). In the present study, we observed no correlation between water balance and the [POD 1: preoperative value] BV ratio, indicating that fluid therapy may be insufficient for controlling circulating blood volume during the perioperative period. We also found that it is important to reduce intraoperative bleeding and surgical stress to maintain postsurgical hemodynamic stability; patients significant intraoperative blood loss tend to have decrease of BV at the early postoperative stage. Volume-deficit hypovolemia seems to be a crucial factor for determination of prognosis in various clinical settings. Shoemaker et al. reported that more than half of critically ill patients had a volume deficit of 0.5-2.0 L (23). BV monitoring using a DDG analyzer may help to identify such a volume deficit and act as a guide for fluid therapy. Most studies regarding BV have been performed in healthy individuals, while the present study was performed on patients undergoing abdominal surgery. To our knowledge, the present study is one of the first reports regarding BV monitoring in patients with abdominal surgery using the PDD method. It has been reported that hypovolemia can be predicted from a postoperative decrease in serum sodium. Hyponatremic hypovolemia may be induced by shift of fluid and sodium to the interstitial space due to surgical stress (24). Rothe et al. reported that BV decreased by nearly 30% in an endotoxin infusion model, suggesting a shift of intravascular blood to the extracellular space (25). Our study confirms that intraoperative blood loss effects hemodynamic changes (CO, CI, BV or K-ICG) on POD 1. Henry et al. reported that the hemorrhage of an amount representing 15 to 20% of the estimated blood volume produced significant reductions in splanchnic blood volume. Half of the blood lost was contributed by
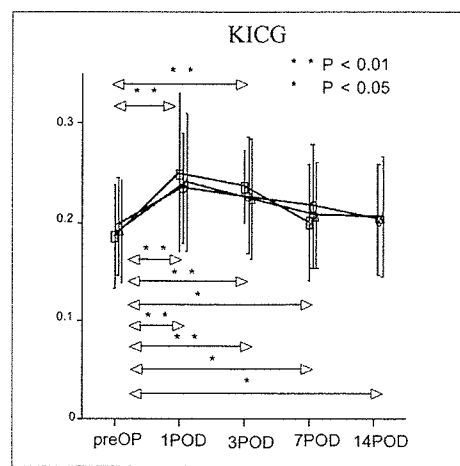

FIGURE 4
Changes in ICG elimination rate (K-ICG) (● - ●; gastrectomy, □ - □; colectomy, O - O; Laparoscopic cholecystectomy). The value of K-ICG increased significantly in the laparoscopic cholecystectomy, gastrectomy, and colectomy groups until POD 3, 7, and 14, respectively.
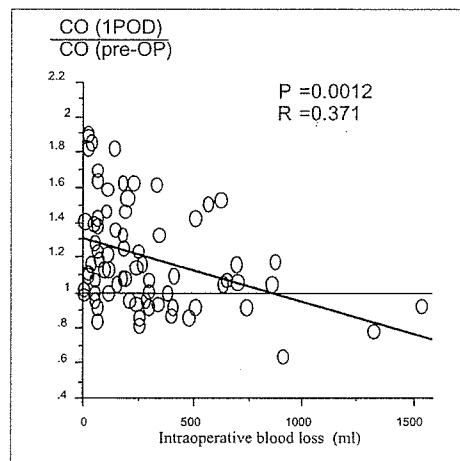

FIGURE 5
Correlation between the [POD 1/preoperative value] CO ratio and intraoperative blood loss in patients undergoing gastrectomy and colectomy. There was a correlation between CO ratio and intraoperative blood loss (R=0.38, p=0.001).

the splanchnic viscera, which lost roughly 40% of initial volume. In contrast, central blood volume was depleted by only 10% and cardiac output was unaltered (26).

In relationships between surgical procedures and hemodynamic changes, there are hardly any differences between gastrectomy and colectomy. Although it is generally recognized that laparoscopic cholecystectomy is less invasive than the open procedures (27), no studies regarding measuring hemodynamics through POD 14 have been performed. Our findings that CO, CI and BV values do not change following laparoscopic cholecystectomy supports the belief that laparoscopic cholecystectomy results in less surgical stress and fewer hemodynamic changes. Nevertheless K-ICG remains high until POD 3 in laparoscopic cholecystectomy patients, suggesting that centralization of BV occurs even under conditions of less surgical stress such as laparoscopic cholecystectomy. In only the gastrectomy group, postoperative BV decreased significantly on POD 1 compared with preoperative value, thus particular attention should be paid to decreased BV following gastrectomy. Adequate circulatory management should be provided to patients according to surgical method. We suggest that accumulation of more data using the PDD monitoring system will

reveal the utility of BV in estimating the amount of surgical stress resulting from various major abdominal surgeries.

A large multidisciplinary research effort has so far focused on the pathophysiologic response to diverse processes ranging from SIRS to severe sepsis. Postoperative SIRS, which was examined in the present study, was developed to indicate a clinical response arising from a surgical procedure rather than infection. The current study showed that the cardiac index increased until 3 days after surgery with a significant increase in patients with postoperative SIRS compared with patients without postoperative SIRS. However, postoperative changes in BV and K-ICG values showed no significant differences between the SIRS group and non-SIRS group.

Furthermore, most subjects with postoperative SIRS possessed an increased heart rate. Judging from the present findings, it is suspected that postoperative

SIRS results in a hyperdynamic state consisting of increased heart rate and stroke volume, but exhibiting little differences in changes of blood volume and hepatic blood flow volume between the two groups. Further work is needed to characterize the clinical and hemodynamic importance of SIRS.

CONCLUSIONS

With the ICG PDD method, we have more accurately characterized the hemodynamic changes that occur after major abdominal surgery. It is important to reduce intraoperative bleeding because blood loss negatively affects hemodynamic stability in the early postoperative stage. As well, more attention should be paid to perioperative hemodynamic changes in patients undergoing gastrectomy and colectomy so proper treatments can be administered. Further studies are needed to evaluate strategy to properly manage patients with complications resulting from major surgeries.

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Original Articles

Creating a Manual for Proper Hand Hygiene and Its Clinical Effects

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Abstract

Purpose. To prevent cross-infections, we created a manual for the treatment of infectious wounds that clarifies when to wash one's hands and when to wear gloves.
Methods. Six patients with widespread infectious wounds caused by methicillin-resistant *Staphylococcus aureus* (MRSA) were treated. The bacterial count on the hands of the staff was calculated. We then compared the number of patients with MRSA isolated, and typed the MRSA isolates using pulsed-field gel electrophoresis (PFGE).
Results. The pathogenic bacterial count among hospital staff before treatment/before hand hygiene was 8.2×10 colony-forming units (cfu)/hand, which were not detected before treatment/after hand hygiene. The pathogenic bacterial count on the hands before hand hygiene/after treatment climbed to 9.1×10^5 cfu/hand, and after treatment/after hand hygiene decreased to 0.38 cfu/hand. The number of patients with MRSA isolates before this protocol was 15/402 (3.7%), but that level significantly decreased to 5/411 (1.2%) after implementation of the manual. There were 13 strains of type F by PFGE before the manual was adopted, but five strains of MRSA isolated after the present manual was enforced were all observed to have different migration patterns.
Conclusion. A hand hygiene manual is effective for decreasing the rate of cross-infection.

Key words Surgical site infection · Infected wound · Cross infection · Methicillin-resistant *Staphylococcus aureus* · Hospital infection · Hand hygiene

Introduction

It is clear that hand hygiene is the most fundamental technique for preventing hospital infection. The Centers for Disease Control (CDC) recently published a manual on hand hygiene that recognizes the efficacy of and broadly recommends washing the hands with a disinfectant containing alcohol, in addition to a detergent and water as conventionally recommended.[1-3] However, when treating patients with infectious wounds, infection transmission via hand/wound contact by medical personnel is still likely to occur. The CDC recommends wearing gloves when coming into contact with all patient blood, feces, and secreta except for perspiration, and it also recommends thorough hand hygiene.[4,5] However, cross-infection cannot be prevented simply by hand hygiene after treatment. There is still the risk of contamination while physically moving to the next patient who requires treatment, and from contact with other medical utensils during treatment.

The decision on when to wash one's hands during the treatment of infectious sores is made by each individual medical member of staff. As a result of this inconsistent approach, cross-infection can occur due to inadequate hand hygiene, while too much washing of hands can cause contact dermatitis in the attending personnel.[6,7] To prevent hospital staff members from transferring pathogenic bacteria from previously treated patients to patients waiting for treatment, we created a manual for the treatment of infectious wounds that clarifies when to wash the hands and when to wear gloves. By following this manual it was possible to prevent a cross-infection in surgical wards during the study period. We herein report on the hand bacterial count of the treating staff during wound treatment and the number of patients with methicillin-resistant *Staphylococcus aureus* (MRSA) isolates, and also on the analysis of these MRSA isolates as demonstrated by pulsed-field gel electrophoresis (PFGE).

Table 1. Hand hygiene manual for the treatment of surgical wounds: timing of hand scrubbing and treatment handling

- Scrubbing of the hands is not necessary when entering the patient's room, pulling in the dressing trolley, and approaching the patient's bedside
- Once the dressing treatment preparation has been complete, the treating staff and caring staff should scrub their hands
- Caring staff or treating staff remove the patient's sleep wear and undo any abdominal bandage
- Treating staff put on gloves and remove dressings, and treat, the wound
- All nonhygienic tasks are performed by the treating staff
- The treating staff cover the wound with dressing, then the nurse applies taping, etc.
- The treating staff place nonhygienic material in an infectious waste container, remove their gloves, and finally scrub their hands
- The caregiver scrubs his/her hands
- The next patient is visited

The manual advises when treating and caring staff should wash their hands, and when they should wear gloves when treating infectious wounds. This schedule assumes the use of a trolley when the dressing is changed

Table 2. Changes in the incidence of patients with isolated methicillin-resistant *Staphylococcus aureus* (MRSA)

	Incidence of MRSA infection
Before the manual	3.7% (15/402)
After the manual	1.2% (5/411)*

*$P < 0.005$

Subjects and Methods

The procedure used for treating the infected wounds was developed in accordance with the manual shown in Table 1. All staff members washed their hands with a 70% alcohol-based antiseptic called "waterless antiseptic."

Bacteriological Investigation

Twenty-one surgeons and seven nurses treated six patients 21 times over 3 days. The patients were hospitalized in the gastroenterology/general surgery wards of the Toho University School of Medicine Ohashi Hospital (now Toho University Medical Center Ohashi Hospital) and they presented with a broad range of MRSA-infected wounds. The physicians treated the wounds and the nurses were responsible for all aftercare. The changes in hand the bacterial count during these treatments were measured using a palm stamp (Eiken Chemical, Tokyo, Japan). The hand bacterial count was measured four times, namely before treatment, after hand hygiene before treatment, before hand hygiene after treatment, and after hand hygiene after treatment. Before hand hygiene after treatment, the hand bacterial count was measured while gloves were being worn. In the calculation of the bacterial count, MRSA, *Pseudomonas aeruginosa*, *Escherichia coli*, *Enterococcus* spp., *Klebsiella* spp., and *Enterobacter* spp. on the hands were counted as pathogenic bacteria,

while *Staphylococcus aureus*, *Streptococcus epidermidis*, and hemolytic *Streptococcus* were regarded as indigenous skin bacteria.

Investigation by PFGE

The MRSA obtained from all MRSA-infected patients for a period of 6 months before and 6 months after the start of implementation of the present method was typed by PFGE, and the presence or absence of cross-infection was investigated.

Clinical Investigation

For the clinical investigation, the rate of postoperative MRSA infections (per number of operations) in the same ward from May 1997 to April 1998 (before the implementation of the manual) and from May 1998 to April 1999 (after the implementation of the manual), and the MRSA infection rate for 6 months after implementation, were all compared. Furthermore, the MRSA obtained from all MRSA infected patients in the 6 months before the implementation of the technique and in the 6 months after the implementation of the technique was typed by PFGE and the presence or absence of cross-infection investigated. The chi-square test was performed for a statistical analysis, and significance was defined as $P < 0.05$.

Results

Bacteriological Investigation

The hand bacterial count was compared between the treating staff and the caring staff (Fig. 1). The total bacterial count on the hands — before hand washing before treatment — for the treating staff was 3.4 × 10 (5 colony-forming units [cfu]/hand), of which 8.2 × 10
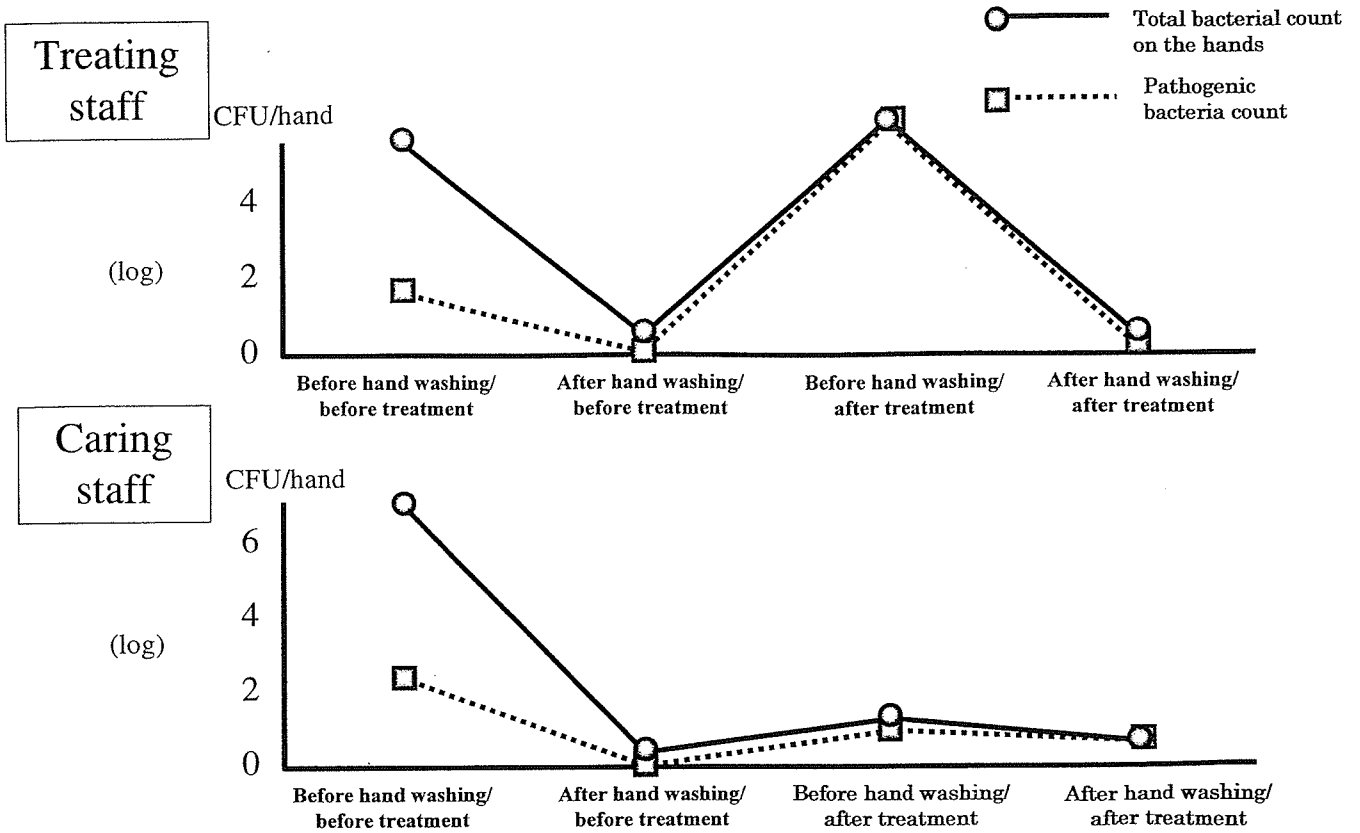
Treating staff

CFU/hand

(log)

Before hand washing/ before treatment   After hand washing/ before treatment   Before hand washing/ after treatment   After hand washing/ after treatment

Caring staff

CFU/hand

(log)

Before hand washing/ before treatment   After hand washing/ before treatment   Before hand washing/ after treatment   After hand washing/ after treatment

○——— Total bacterial count on the hands

□········ Pathogenic bacteria count

Fig. 1. Changes in hand bacterial count. By disinfecting the hands before and after treatment, the transfer of pathogenic bacteria from patient to patient was prevented. By washing the hands after treatment, pathogenic bacterial transmission to the next patient to be treated was thus prevented

(1 cfu/hand) were pathogenic bacteria. The total bacterial count on the hands of the treating staff after hand washing before treatment decreased to 2.9 cfu/hand, and no pathogenic bacteria were detected. Before hand washing after treatment the bacterial count on the hands of the treating staff increased to 9.1×10 (5 cfu/hand) and all were pathogenic bacteria. After hand washing after treatment, the total bacterial count was 1.5 cfu/hand, of which 0.38 cfu/hand were pathogenic. Both before and after treatment, the bacterial count decreased significantly after hand washing. The total hand bacterial count — before treatment and before hand disinfection — of the caring staff was 9.5×10 (6 cfu/hand), of which 1.8×10 (2 cfu/hand) were pathogenic bacteria. The total hand bacterial count of the caring staff after hand washing before treatment decreased to 1.6 cfu/hand, and no pathogenic bacteria were detected. In any event, the bacterial count significantly decreased compared to before treatment/ before hand washing. Before hand washing after treatment, the bacterial count of the caring staff increased to 5.1×10 cfu/hand, of which 3.4×10 cfu/hand were patho-

genic, but not significant compared to before treatment/ before hand washing. After hand washing after treatment, the total hand bacterial count was 3.4 cfu/hand, and all bacteria were pathogenic. There were no significant differences in the hand bacterial count of the treating staff between after treatment/before hand disinfection and after treatment/after hand disinfection. A comparison of the treating staff and caring staff revealed a significantly high pathogenic bacterial count among the treating staff after treatment/before hand washing.

Investigation by PFGE

During this period, when the MRSA obtained from the MRSA-infected patients was typed by PFGE, there was one strain each of type D and type E MRSA before this program was conducted, and all the remaining 13 strains were type F (Fig. 2). Five strains of MRSA isolated after the present manual was adopted were all seen to have different migration patterns, which thus ruled out cross-infection.
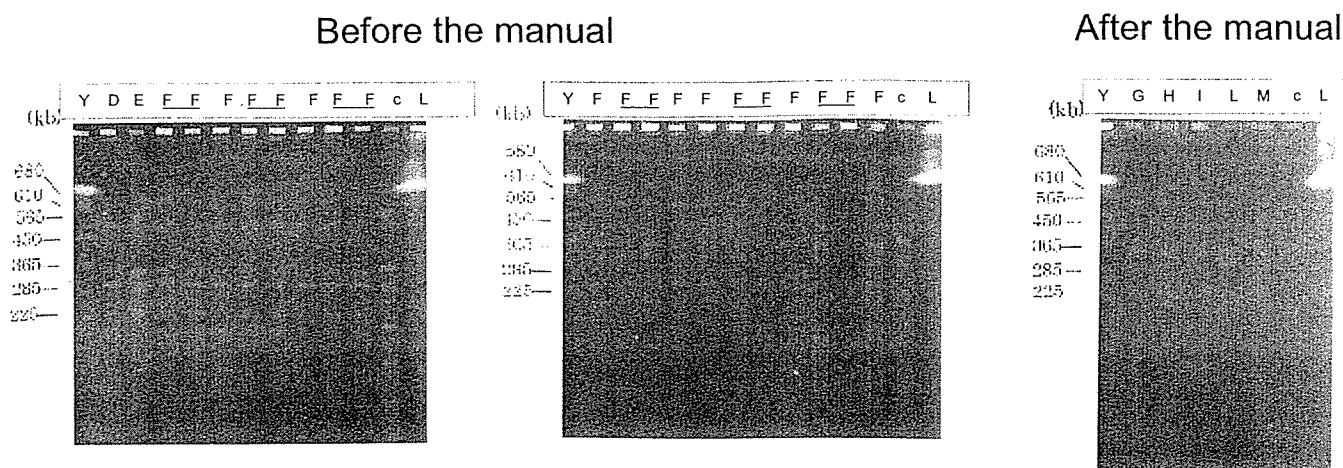
Before the manual

After the manual

Fig. 2. Classification of MRSA type by pulsed-field gel electrophoresis (PFGE). Before the introduction of the hand hygiene manual the same strain was conspicuous, but after the manual's introduction, different types of MRSA were isolated

Clinical Investigation

The number of patients with MRSA isolates in the year before this program was implemented was 15/402 (3.7%), but the number of patients with MRSA isolates in the year after implementation significantly decreased to 5/411 (1.2%).

Discussion

It is clear that the prevention of infection via medical personnel hand contact is the most important factor for dealing with hospital infection. As a guideline for hand hygiene, the CDC approved washing the hands with detergent and running water as per convention and then washing the hands by rubbing them with hand antiseptic as a new step in hand hygiene.[1-3] Since the rapid rise of MRSA infections in the late 1980s, measures against hospital infection, and particularly measures to combat contact infection via the hands of medical personnel, have been conducted throughout Japan.[8] Manuals on combating hospital infections in the West have been introduced, and it has become clear that there is little point in changing shoes in the operating room and intensive care unit and in disinfecting absorbent floor mats and the patient environment, as have conventionally been practiced in Japan. With regard to wound treatment also, such methods such as abolishing the dressing trolley and using pack-style dressing have also been adopted in some hospitals. However, although the risk of the dressing trolley becoming contaminated has been pointed out, many types of dressings are now required for patients with broad-ranging infectious wounds that secrete a considerable

amount of secreta. As a result, some type of trolley is necessary for transporting disinfectant or cleaning equipment to the bedside. Treatment products that were unanticipated can also at times become required and the use of a dressing trolley is extremely convenient considering the time it takes to visit the materials room each time. A dressing trolley is also a very convenient, clever way of collecting infectious waste or dressing materials containing such infectious waste so as to prevent contamination of the surrounding environment. From this point of view, it would be difficult to treat all wounds just by making packs available for wound treatment.

Our manual for treating wounds was designed to enable the staff to deal flexible with various situations, such as the use of a dressing trolley, the size of the infected wound, and the wound cleaning itself. In addition, the purpose was to design a manual to reduce medical costs and the chances of hospital staff contracting antiseptic-induced contact dermatitis or latex allergies, which could be implemented simply and effectively by all staff members. Educational courses concerning proper hand hygiene are still being debated,[9,10] but manuals supporting this technique are not being questioned.

Hand hygiene is recommended when treating each infected wound,[4,9,10] and cross-infection cannot be prevented simply by washing the hands after treatment. This is because even if hand hygiene is performed once an infected wound has been treated, the hands again come into contact with the patient's immediate surroundings and the bandaging utensils before the treating physician moves on to the next patient. As a consequence, the hands become contaminated and the infection may be carried to the next patient to be

treated. In addition, even if proper hand hygiene is performed before treatment, the doctor or nurse's hands will come into contact with the patient's surroundings after they have been disinfected, thus resulting in hand contamination and cross-infection. That is why consideration must be given to the timing of hand hygiene. In addition, when the staff members' hands come into contact with the dressing trolley and so forth after disinfecting the hands, there is a risk that the hands will again become contaminated, and this contaminant from the dressing trolley will be carried to other patients being treated. It is therefore essential that the roles of the persons treating the wounds and other caregivers be separated into nonsterile and sterile tasks. This issue is also perceived differently among individual medical personnel. Some people stress strict hand hygiene, while others believe that brief hand washing is acceptable. Because there are different opinions within the medical setting, the effects of measures to combat cross-infection are not realized and educational efforts do not improve the overall environment, and hence the need has arisen for the present type of manual. The use of such a manual has not been looked into previously.

In the manual that we created, washing the hands was deemed unnecessary before entering a patient's room. Even if the hands are washed before entering the room of a patient, it is completely meaningless to do so because the dressing trolley still needs to be wheeled in, the curtains drawn, and the patient's environment entered into in order to reach the patient's bedside.

Next, it is effective for the medical staff to check all of the necessary equipment, move alongside the patient, and then wash their hands so that no pathogenic bacteria are transferred from other patients. In reality, our investigation also revealed that the hand bacterial count before hand hygiene before treatment reached 10^{3-7}. Most of the contaminated bacteria on the hands before treatment were passing bacteria and only mildly pathogenic. However, MRSA was isolated from two cases so the hands do indeed need to be washed before treatment.

Gloves should not be worn until after removing the gown of the patient awaiting treatment and exposing the dressing, but this is done primarily to prevent tape sticking to the gloves. By peeling off the tape directly with the fingers, damage to the surface of the patient's skin and contact dermatitis are prevented. However, since the old dressing contains infectious effusion, the wearing of gloves is required. Consequently, it is necessary to wear gloves from that point on, immediately after peeling the tape back, until the patient has been treated and the wound has been covered with a new dressing. It is important that all procedures involving the risk of the hands becoming contaminated from the dirty dressing or wound cleaning be done after treat-

ment. When caregiving personnel perform such unhygienic procedures there is a risk that clean equipment on the dressing trolley will also become contaminated. The caregiving staff should therefore not perform any unhygienic procedures. Once the procedure on the wound has been completed and a treating staff member has covered the wound with a new dressing, then the caregiving staff member should apply tape to the new dressing. During this time, the treating staff should place any infectious waste in a plastic bag, which in turn should be placed in an infectious waste disposal container. The treating staff should then remove their gloves and disinfect their hands before moving on to the next patient. Before disinfecting their hands after treatment, 10^{3-5} cfu/hand bacteria were detected on the hands of the treating staff members. The fact that most were isolated bacteria such as MRSA from patient wounds highlights the extreme importance of washing the hands after treatment.

However, a comparison of the incidence rates of MRSA isolated from patients before and after this technique was adopted during the target period revealed a significant reduction in patients with isolated MRSA after the technique was applied, which reascertained the importance of hand hygiene as a measure against MRSA infections. In addition, based on the clinical PFGE typing of the MRSA isolates during the target period, the same type of MRSA was isolated before the introduction of the manual, whereas after the manual was enforced each isolate represented a different type of MRSA. This therefore shows that it is quite possible to prevent cross-infection via the hands of medical staff members when treating wounds.

In conclusion, while it is common knowledge that it is vitally important for the medical staff to wash their hands to prevent hospital infection, implementing this fully has been an extremely difficult problem. One of the reasons has been the difficulty of medical personnel agreeing on the timing of hand disinfection, the decision of which has been left to each individual. A manual such as ours detailing the present protocol can be shown to all medical personnel, who can then point out the faults of each other's technique. This would thus likely contribute to the education and awareness of the medical staff involved in infectious wound treatment. The bacteriological and clinical validity of the present manual has also been demonstrated.

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Review Article

Questionnaire on Perioperative Antibiotic Therapy in 2003: Postoperative Prophylaxis

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Abstract

We distributed a questionnaire to institutions accredited by the Japan Surgical Society asking about the use of antibiotics in digestive tract surgery in Japan in 2003, and compared the results with those of a similar questionnaire distributed in 1993. The period of antibiotic administration for esophageal resection was at least 6 days in 64.9% of the 1993 questionnaire responses, but less than 4 days in 60.4% of the present questionnaire responses. For distal gastrectomy, antibiotics were given for 5 days postoperatively at 53.0% of the responding institutions in the 1993 survey, but for only 3 days, at 72.4%, in the present survey. An oral antibiotic was given as part of antibacterial colon preparation before colon resection at 70% or more of the institutions in the 1993 survey, while no antibiotic colon preparation was given at 80% of the institutions in the present survey. The period of antibiotic administration for laparoscopic cholecystectomy was at least 4 days in 72% of the institutions in the 1993 survey, but this decreased remarkably to fewer than 2 days at 80.8% of the institutions in the current survey. There were no differences in the selection of antibiotics between the two surveys. The period of antibiotic administration has decreased remarkably in the last decade.

Key words Postoperative infection · Prophylaxis · Surgical site infection · Antibiotics

Introduction

Both drug selection and the periods of administration of perioperative antibiotic therapy in Japan differ considerably from those in Western countries.[1-3] However,

the protocols for postoperative antibiotic therapy in Japan were revised after the outbreak of Methicillin-resistant *Staphylococcus aureus* (MRSA) infections in the late 1980s.[4] At the 43rd Conference of the Japanese Society of Gastroenterological Surgery in 1994, a panel discussion called "On the usage methods of antibiotic agents in gastroenterological surgery" published the results of a questionnaire on the use of antibiotics in gastroenterological surgery in 1993.[5] The Japanese Association for Infectious Disease and the Japanese Society for Chemotherapy published an Antibiotic Guide 10 years later. An observation of related societies' titles clearly confirms that the trends of perioperative antibiotic usage are changing.

Thus, we recently sent out a questionnaire survey targeting institutions accredited by the Japan Surgical Society, to establish the present status of perioperative antibiotic therapy. We also evaluated the changes in the last 10 years.

Methods

We asked the Chief Medical Officers of 771 institutions accredited by the Japan Surgical Society to respond to the issues listed below. The response format was sent by fax, clearly stating the name of the person in charge.

Results

We received responses from 550 of the 771 institutions targeted, resulting in a response rate of 71.3%.

Decision-Making About Perioperative Antibiotic Therapy

The answers about perioperative antibiotic therapy decision-making are given in Table 1. In the 1993 ques-

tionnaire, 80.0% of the responding institutions left the decision to the physician in charge, but in he present questionnaire, 41.7% stated that the decision was incorporated into the group or clinical pathway, and only 55.8% of institutions left the decision to the physician. This suggests that control over the usage of antibiotics is being dispersed to different medical care teams or medical care units.

Start of Antibiotic Administration

The protocols for starting antibiotic administration on the day of surgery are given in Table 2. Of the institutions that administered antibiotics in the ward, the time antibiotics were started before surgery was "1 hour prior" in 51.7%, and "30 minutes prior" in 20.3%; thus, at least 70% started the administration of antibiotics 30 min to 1 h before surgery. In the 1993 questionnaire, only 19.3% of the responding institutions administered antibiotics to all patients during surgery, including immediately before and during surgery, but in the present questionnaire at least 70% did. This suggests that the

Western trend of administering antibiotics, which until recently was followed randomly in Japan, has now been adopted without resistance since the introduction of Evidence-Based Medicine (EBM).

Thoracoesophageal Resection

In response to "What drugs (drug names) do you use as postoperative prophylactics for thoracic esophageal resection involving reconstruction accompanying esophageal resection with right thoracolaparotomy and 3 field lymph node dissection?", all surgeons reported using first- and second-generation cephems (Fig. 1). There were no major differences in the 1993 questionnaire regarding the selection of postoperative prophylactic antibiotics given in thoracic esophageal resection by right thoracolaparotomy. However, it is notable that in the 1993 questionnaire, the administration period was less than 4 days in only 3.8% of the responding institutions, 5 days in 31.8% of the responding institutions, and at least 6 days in 64.9% of the responding institutions, whereas in the present questionnaire the administration period had decreased to less than 4 days in 60.4% of the responding institutions (Table 3).

Table 1. Who selected perioperative antibiotics?

(a) Medical care unit or group	27.1%
(b) Integrated into clinical pathway	14.6%
(c) Physician in charge	55.8%
(d) Other	1.8%
(b + c)	0.6%
No answer	0.2%

Table 2. Start of antibiotic administration

(a) In the ward	21.5%
(b) Immediately before surgery	53.6%
(c) After the commencement of surgery	16.0%
(d) After the completion of surgery	8.4%
Other	0.4%
No answer	0.2%

Table 3. Duration of antibiotic administration in esophageal resection

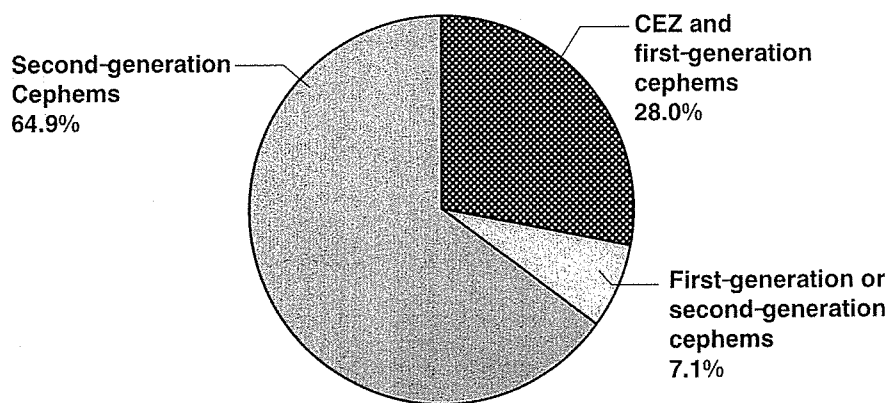|	
(a) Day of surgery only	0.9%
(b) Until POD 1	1.8%
(c) Until POD 2	10.9%
(d) Until POD 3	31.5%
(e) Until POD 4	15.3%
(f) Until POD 5	22.2%
(g) Until POD 6	8.2%
(h) Until POD 7 or later	6.0%
Other	0.9%
No answer	2.4%

POD, postoperative day

Fig. 1. Types of antibiotics given for thoracic esophageal resection via right thoracolaparotomy. Among the second-generation cephems, CTM, CMZ, and FMOX were used almost equally. First- and second-generation cephems accounted for 100%

Gastric Cancer Surgery

The responses to questions on the length and type of postoperative antibiotic prophylaxis for patients undergoing distal gastrectomy with lymph node dissection for gastric cancer are given in Table 4. The results of the 1993 questionnaire survey revealed that 53.0% of the responding institutions gave antibiotics until postoperative day (POD) 4 or 5, and 3.9% gave antibiotics for fewer than 3 days postoperatively. The current questionnaire revealed that 72.4% of the responding institutions administered antibiotics for a shorter period; until hospital day 3 (Table 5). Regarding the types of antibiotics, 21.3% of the responding institutions administered first-generation cephems and penicillin in the 1993 questionnaire, whereas in the current survey, 46.5% of the institutions gave CEZ (Fig. 2).

Colon Resection

In response to questions on preoperative colon preparation for colon resection, 80.7% of the responding institutions in he current survey answered: "a.) Mechanical

colon preparation (administration of PEG: polyethylene glycol electrolyte solution) only" (Fig. 3). The periods·of postoperative antibiotic prophylaxis after colon resection are shown in Table 6. In selecting the antibiotics for patients undergoing colon resection, 62.5% of the responding institutions answered that they selected drugs with an antibacterial activity against anaerobic organisms (Fig. 4).

Concerning the perioperative use of antibiotics in colon resection, in the 1993 questionnaire 75.4% of the responding institutions gave the same type of oral antibiotics preoperatively, but in the current questionnaire, 80.7% answered that they provided "mechanical treatment only" without administering oral antibiotics preoperatively. In the 1993 questionnaire, 65.9% of the responding institutions administered postoperative prophylactic antibiotics for at least 6 days, but in the present questionnaire this period was reduced, with 63.3% of the responding institutions administering postoperative prophylactic for fewer than 3 days, and only 4.2% administering them for at least 6 days. No major differences were seen in the drugs selected.

Table 4. Duration of antibiotic administration in esophageal resection

(a) Day surgery only	3.6%
(b) Until POD 1	5.1%
(c) Until POD 2	19.1%
(d) Until POD 3	44.6%
(e) Until POD 4	12.7%
(f) Until POD 5	10.4%
(g) Until POD 6 or later	3.3%
Other	0.2%
No answer	1.1%

Table 5. Administration period in colonic resection

(a) Day of surgery only	3.1%
(b) Until POD 1	4.0%
(c) Until POD 2	15.3%
(d) Until POD 3	40.9%
(e) Until POD 4	16.6%
(f) Until POD 5	15.1%
(g) Until POD 6 or later	4.2%
Other	0.2%
No answer	0.7%

SBT/ABPC 3.1%
Penicillins 1.3%
FMOX 4.4%
CTM 9.6%
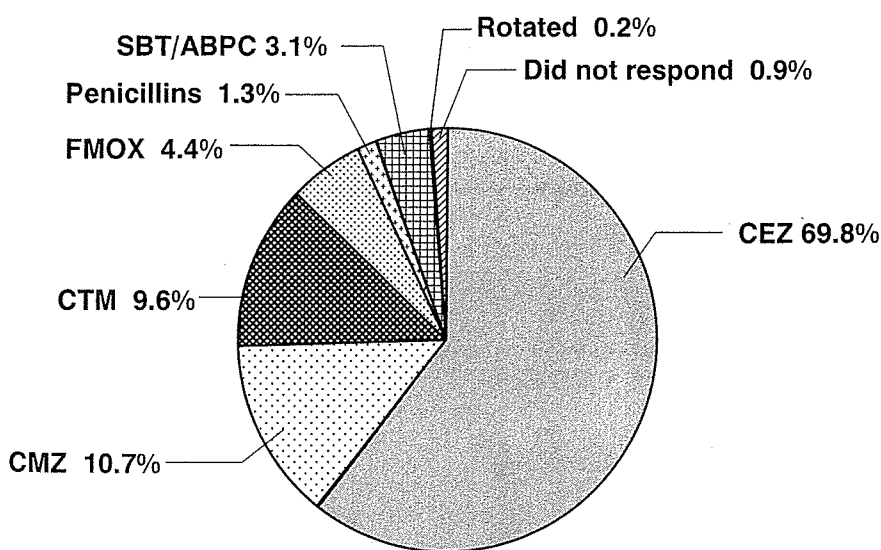CMZ 10.7%
Rotated 0.2%
Did not respond 0.9%
CEZ 69.8%

Fig. 2. Antibiotics given for distal gastrectomy with lymph node dissection, based on the responses-stating that only one drug was used

Table 6. Preoperatve treatment for Miles' operation

(a) Mechanical treatment (such as PEG) only	80.6%
(b) Mechanical treatment + enema preparation for 2 days preoperatively	0.2%
(c) Mechanical treatment + N.Ab. for more than 2 days preoperatively	7.1%
(d) Mechanical treatment + N.Ab. for 1 day preoperatively	10.6%
(e) Other	1.1%
No answer	0.4%

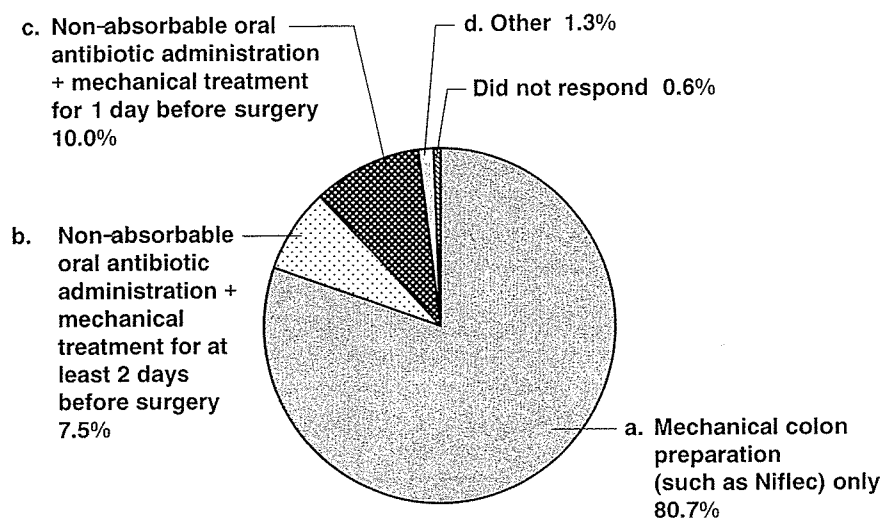N.Ab., nonabsorbable oral antibiotic administration; PEG, polyethylene glycol electrolyte solution

Fig. 3. Colon preparation for colon resection
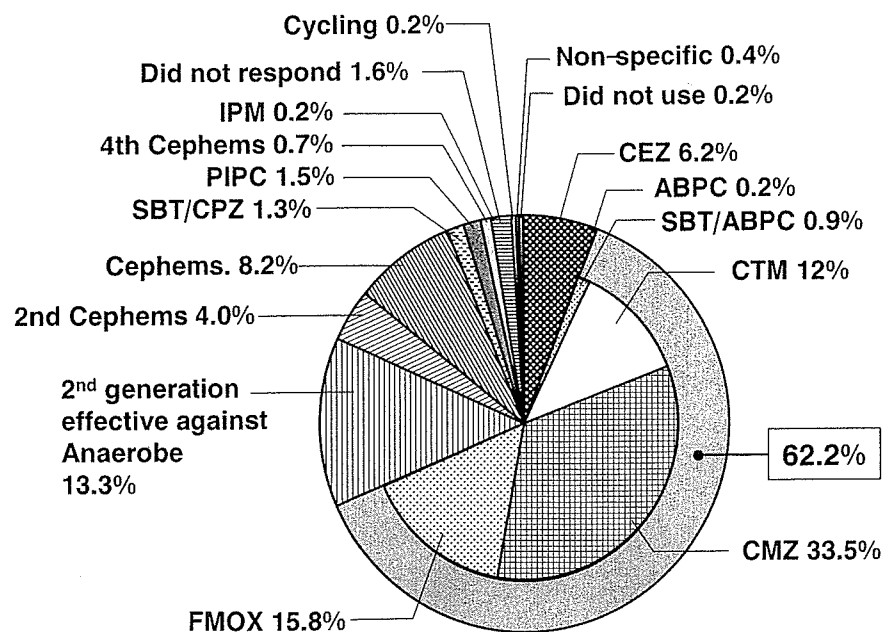
Fig. 4. Selection of drugs for colon resection

Miles' Operation

The answers regarding preoperative colon preparation and a period of administration of prophylactic antibiotics are shown in Tables 6 and 7. In selecting the antibiotics for use in Miles' operation, 84.4% of the responding institutions used second-generation cephems, and 53.3% of these institutions selected antibiotics that recognize anaerobic bacteria. These antibiotics included CMZ, FMOX, SBT/CPZ, SBT/ABPC, and PIPC (Fig. 5). Regarding the method of administering antibiotics for Miles' operation, 70.5% of the responding institutions in 1993 administered oral antibiotics preoperatively, whereas 80.6% of the responding institutions in the present questionnaire performed surgery with only mechanical treatment. Regarding the period of postoperative administered, in the 1993 questionnaire 23.1% of the responding institutions administered postoperative prophylactic antibiotics for fewer than 4 days, and 76.9% administered them for at least 5 days. In contrast, 72.4% of the responding institutions

in the current questionnaire administered postoperative prophylactic antibiotics for fewer than 4 days. There were no major differences seen in the selection of antibiotics administered systemically.

Laparoscopic Cholecystectomy

In response to the question, "Which drugs [drug name(s)] do you use and for how many days do you administer them for laparoscopic cholecystectomy in which the inflammation is very mild and no particular problems are encountered?", 79.8% of the responding institutions specified one drug. In selecting the antibiotics, 46.9% of these institutions specified CEZ, and 20.0% specified second-generation cephems such as CTM, CMZ, and FMOX (Fig. 6). Regarding the administration period, 22.7% administered antibiotics on the day of surgery only, 34.2% administered them until postoperative day (POD) 1, and 23.9% administered them until POD 2. Thus, 80.8% administered them until POD 2. In the 1993 questionnaire, 72% administered them until POD 4 or later, so the administration period was remarkably reduced.

Pancreaticoduodenectomy

The periods of antibiotic administration for pancreaticoduodenectomy are shown in Table 8. CEZ was used at 14.9% and second-generation cephems were used at 76.9% of the responding institutions (Fig. 7). In the 1993 questionnaire, the period of administration was less than 4 days in 10.8% of the responding institutions and at least 6 days in 80.9%, whereas in the current questionnaire, the period of administration was
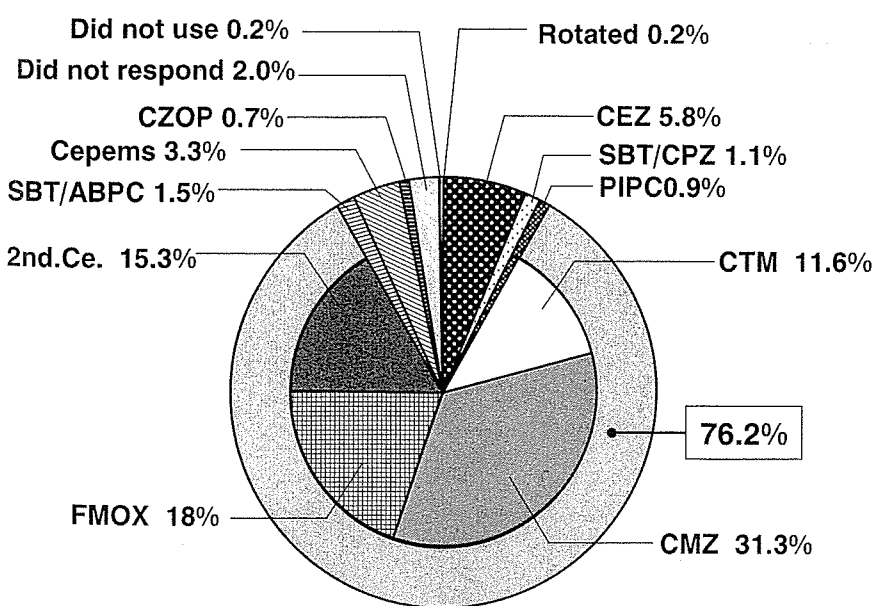
Table 7. Period of prophylactic antibiotic administration for Miles' operation

(a) Day of surgery only	2.6%
(b) Until POD 1	3.3%
(c) Until POD 2	14.4%
(d) Until POD 3	39.8%
(e) Until POD 4	14.9%
(f) Until POD 5	18.4%
(g) Until POD 6 or later	5.4%
Other	0.2%
No answer	1.1%

Fig. 5. Antibiotics given for Miles' operation

Not decided 1.8%
Others 0.9%
ABPC 0.2%
FOM 1.5%
CTRX 2.9%
SBT/CPZ 5.8%
PIPC 2.0%
2nd/4th gen. Cephams 6.4%
FMOX 3.1%
20.0%
CMZ 6.6%
CTM 10.3%
CEZ or SBT/ABPC 5.6%
No cases 0.4%
Rotated 0.2%
Did not respond 2.5%
Did not use 0.9%
CEZ 46.9%
SBT/ABPC 1.8%
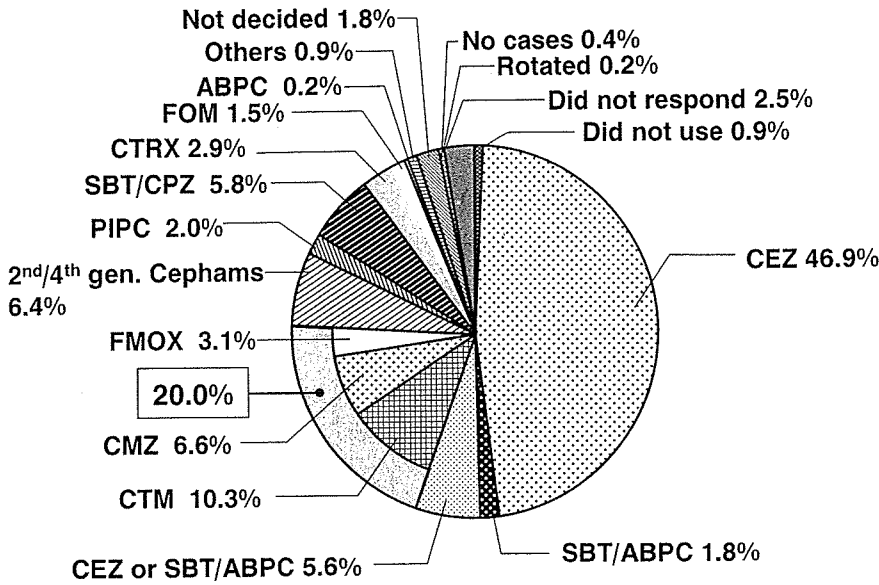
Fig. 6. Selection of antibiotics for laparoscopic cholecystectomy

Sensitive to Isolutes from bile 0.2%
PIPC 1.6%
CTRX 0.7%
Carbapenem 0.4%
2nd gen. Ce and others 28.2%
SBT/CPZ 11.7%
FMOX 9.5%
Do not use 0.2%
Not decided 0.7%
Rotated 0.2%
Did not respond 1.5%
CEZ 14.9%
SBT/ABPC 2.7%
CTM 21.2%
85.9%
CMZ 15.3%
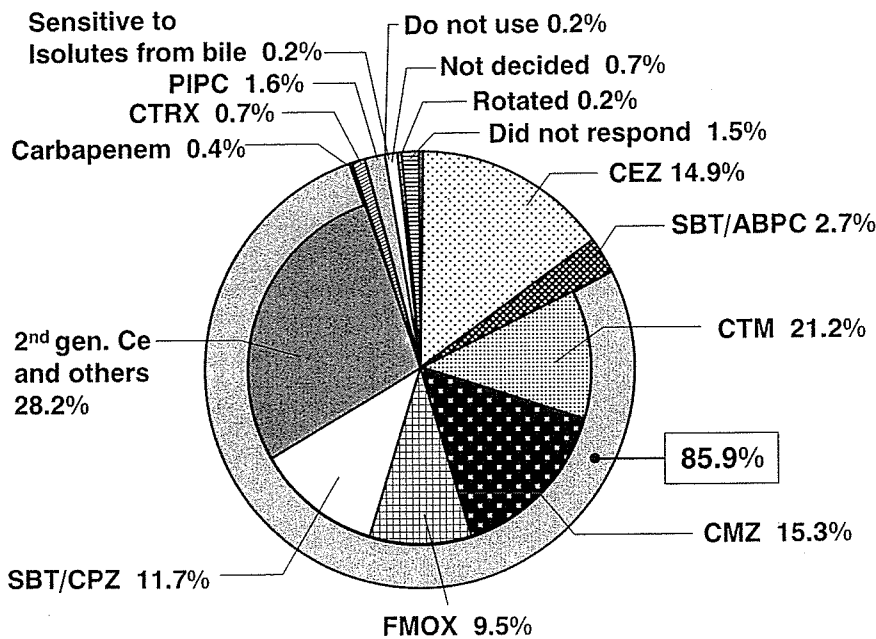
Fig. 7. Antibiotics given for pancreatico-duodenectomy

Table 8. Period of antibiotic administration for pancreaticoduodenectomy

(a) Day of surgery only	1.6%
(b) Until POD 1	2.0%
(c) Until POD 2	9.8%
(d) Until POD 3	32.0%
(e) Until POD 4	16.4%
(f) Until POD 5	21.8%
(g) Until POD 6 or later	14.7%
Other	0.2%
No answer	1.5%

less than 3 days in 45.4% and fewer than 5 days in 83.6%.

Discussion

In Japan, large quantities of antibiotics were conventionally administered perioperatively, which contributed largely to the emergence of multiple drug-resistant bacteria.[4] From the late 1980s, MRSA enteritis became a major problem in field of digestive tract surgery in

Japan, prompting the principal surgery-related societies to discuss postoperative infection, hospital infection, antibiotic administration regimens, and MRSA countermeasures at numerous symposiums, panel discussions, and workshops. Antibiotic regimens have been extensively reviewed and guidelines prepared, as outlined in the Antibiotic Guide published by the Japanese Society for Chemotherapy and the Japanese Association for Infectious Disease.

In 1993, we conducted a questionnaire targeting institutions accredited by the Japan Surgical Society on the usage of antibiotics perioperatively in the field of digestive tract surgery. The results were published in a panel discussion called "On the usage methods of antibiotic agents in gastroenterologic surgery" at the 43rd Conference of the Japanese Society of Gastroenterological Surgery in 1994.[5] By that time, many institutions had already begun revising their antibiotic use, so there were no major differences in the selection of antibiotic drugs in the current questionnaire. We considered this a good opportunity to introduce a clinical pathway to prevent the emergence of multiple drug-resistant strains such as MRSA. On the other hand, the period of postoperative prophylactic antibiotic administration decreased remarkably in 1993, and only about 20% of the responding institutions gave antibiotics for less than 4 days, except for cholecystectomy, and most gave them for 5 days or more. Conversely, in the current questionnaire, at least 80% of the responding institutions staked that they gave antibiotics for less than 4 days, signaling a marked reduction in the administration period. Regarding preoperative treatment for colonic surgery, in the 1993 questionnaire 76% of the responding institutions included oral antimicrobial agents for several days in colon preparation, but in the current questionnaire 80% stated that they perform survey after only preparation, without preoperative chemical enteric canal treatment. The 1999 CDC surgical site infection prevention guidelines have been widely adopted in Japan.[6] These recommend that oral antibiotics be administered for 1 day before colonic surgery, although we suspect that

many surgeons do not follow this recommendation. It is likely that because surgery is highly invasive in Japan and postoperative MRSA infection is prevalent, antibiotic administration is more prudently considered than in the Western countries. Because a review of antibiotics was already underway in 1993, no major differences were seen in the selection of antibiotics between the two surveys. However, it is clear that the start times and administration periods have improved greatly. The suitability and timing of readministration during long operations remains an issue to be resolved.

The Japan Society for Surgical Infection is now conducting a randomized control trial with the aim of establishing evidence unique to Japan. We expect that these issues will be improved dramatically by the introduction of clinical pathways and more widespread comprehensive medical care.

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II　医療環境とクリニカルパス

医療の質管理とクリティカルパス

Quality control of care and critical path

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◆key words：クリティカルパス，医療の質の評価，診療プロセス，診療アウトカム

はじめに

　1980年代に包括支払い制度 DRG/PPS が米国で導入された当時，ニューイングランド・メディカル・センターに勤務していた看護師であるカレン・ザンダー女史は，製造業で工期の短縮法として開発されていた critical pathway method に着目し，これを医療界に取り入れた[1]。Critical pathway method は，本来米国海軍がミサイルを生産するために開発された PERT（Program Evaluation and Review Technique）にその起源を置く。これは1950年代に，複雑な製造過程をフローチャート式に表し，工期の短縮を図るプログラムとして開発されたものである。ザンダー女史は，産業界の critical pathway method を患者管理ツールとして利用できないかと考え，横軸に時間，縦軸に達成目標，作業内容を書き写した表を作成し，治療や管理の内容が一目でわかるようにした。これにより，作業の効率化が図れ，在院日数の短縮，医療コストの削減という時代のニーズに沿う結果が得られた。この手法は，全米にまたたく間に広がり，患者管理ツールとしての地位を確立した[2]~[6]。わが国でも1990年代後半から，クリティカルパスを取り入れる病院が増えてきている。

　本稿では，最近米国で起こっている医療の質の評価に関する動向を紹介し，医療の質の管理におけるクリティカルパスの重要性について解説する。

米国における医療の質の評価に関する動向

　米国では，医療の質の評価が急速に進められている。医療の質の評価には，診療過程（プロセス）の評価と診療結果（アウトカム）の評価がある。米国の公的保険であるメディケア，メディケイドでは，手術合併症改善プログラム（Surgical Complication Improvement Program；SCIP）の中で，次の4つのプロセスの報告を病院に求めるよう計画している[7]。

　①手術前の抗菌薬の予防的投与
　②麻酔導入時のβブロッカーの投与
　③術後深部静脈血栓症予防のための抗凝固薬の投与
　④院内肺炎予防のための院内マニュアル整備

　これらは無作為比較試験で術後合併症を減らすことが証明されている介入であるが，病院が公的保険を受ける条件としてこれらを行うことを義務づけようというものである。

　アウトカムの評価としては，退役軍人病院協会（Department of Veterans Affairs）および米国外科医学会（American College of Surgeons）は共同で「国家的外科の質向上プログラム（The National Surgical Quality Improvement Program；NSQIP）」を策定し，施設間の外科の技術評価を行う準備を進めている[7]。これは，各病院の術後死亡率を予測死亡率で割った比（Observed-to Expected-mortality ratio；OE ratio）で外科の技術評価を行うもので，OE ratio が小さい病院ほど技術水準が高く，逆にOE ratio が大きい病院ほど技術が悪いことを意味している。つまり，OE ratio により病院の順位をつけようというものである。この OE ratio を一般

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表 1　E-PASS scoring system

1. 「術前リスクスコア(PRS) = － 0.0686 ＋ 0.00345X$_1$ ＋ 0.323X$_2$ ＋ 0.205X$_3$ ＋ 0.153X$_4$ ＋ 0.148X$_5$ ＋ 0.0666X$_6$」
   X$_1$：年齢，X$_2$：重症心疾患有り (1)，無し (0)，X$_3$：重症肺疾患有り (1)，無し (0)，X$_4$：糖尿病有り (1)，無し (0)，X$_5$：Performance status (0-4)，X$_6$：麻酔リスク (1-5)
   重症心疾患の定義：NYHA 3 以上の心不全，または mechanical supports を要する重篤な不整脈
   重症肺疾患の定義：% VC ＜ 60%あるいは FEV 1.0%＜50%のいかなる状態
   糖尿病の定義：WHO の診断基準に基づく
   Performance status：日本癌治療学会固形がん化学療法直接効果判定基準に基づく
   麻酔リスク：アメリカ麻酔学会重症度分類 (ASA class) に基づく
2. 「手術侵襲スコア(SSS) = － 0.342 ＋ 0.0139X$_1$ ＋ 0.0392X$_2$ ＋ 0.352X$_3$」
   X$_1$：体重当たりの出血量 (g/Kg)，X$_2$：手術時間 (hr)，X$_3$：手術切開創の範囲
   0：胸腔鏡創または腹腔鏡創のみ（いわゆる補助下手術や 10cm 以下の小手術創も含む）
   1：開胸あるいは開腹のいずれか一方のみ
   2：開胸および開腹
3. 「総合リスクスコア(CRS) = － 0.328 ＋ 0.936 (PRS) ＋ 0.976 (SSS)」

(Haga Y, Ikei S, Ogawa M：Estimation of Physiologic Ability and Surgical Stress (E-PASS) as a new prediction scoring system for postoperative morbidity and mortality following gastrointestinal surgery. Surg Today 29：219-25, 1999. より引用)

表 2　外科入院治療費と術後死亡率の予測式

1. 予測入院治療費(万円) = 126 ＋ 167 (CRS)
2. 予測在院死亡率 (%) Y
   CRS ＜ 0.159 のとき，Y≒0
   0.159 ≦ CRS ＜ 2.98 のとき，Y = 0.356 ＋ 2.729 (CRS) ＋ 10.555 (CRS)^2
   CRS ≧ 2.98 のとき，Y = 100

CRS：E-PASS scoring system の総合リスクスコア
1. 予定消化器外科手術全般に適用。手術日から術後管理が終了する日までの医療費を予測 (Haga Y, Wada Y, Takeuchi H, et al.：Estimation of surgical costs using a prediction scoring system of E-PASS. Arch Surg 137：481-5, 2002. より引用)
2. 予定消化器外科手術全般に適用 (Haga Y, Wada Y, Takeuchi H, et al.：'Estimation of Physiological Ability and Surgical Stress' (E-PASS) for a surgical audit in elective digestive surgery. Surgery 135：586-594, 2004. より引用)

表 3　予定消化器外科手術における臨床指標

1. 経済効率の指標 Economic Index (EI) = 実治療費の総額/予測治療費の総額
2. 外科技術水準の指標 OE ratio = 実死亡率/予測死亡率

予測治療費および予測死亡率は，E-PASS scoring system から算出
(芳賀克夫：消化器外科におけるクリティカルパスの評価. 外科治療 91：498-503, 2004. より引用)

に公開することにより，技術の高い病院に患者を集中させ，術後合併症による患者の死亡を減らそうという考えである。また，医療保険会社の間では，技術の高い病院に保険料を高く支払う "pay for performance" の支払い制度も検討されている[8]。もし，これが実施されるようになれば，医療の質が低いと評価された病院は倒産に追い込まれるであろう。

クリティカルパスによる診療プロセスの管理

　医療の質の評価の動きはわが国でもいずれ導入されてくるだろう。そのとき，病院は自らの医療の質をいかに上げるかがもっとも大きな課題となる。それでは，医療の質の管理はどのように行えば良いのであろう。プロセスの管理を行う一番良い方法は，病院内のすべての診療科でクリティカルパスを作成することである。クリティカルパスは各科の診療内容を一目瞭然にみることができる。予防的抗菌薬の

術前投与を行っていない診療科があれば，ただちに変更を求めることができる。また，感染症の起炎菌を考慮していない不適切な抗菌薬を使用していれば，これも是正することができる。弾性ストッキングの術中術後の着用やヘパリンの投与など，深部静脈血栓症の予防策をクリティカルパスに繰り込むことにより，ガイドラインを遵守することができる。このように，クリティカルパスを作成し，その診療内容の妥当性を検討することにより，診療プロセスを evidence に基づくものに近づけることができる。
　国立病院機構熊本医療センターでは，25診療科で433種類のクリティカルパスを作成している (2006年 8 月現在)。毎週水曜日の早朝に，多職種からなるクリティカルパス検討会を開催し，クリティカルパスの内容を一つ一つチェックしている。もし，ある診療科のクリティカルパスで抗菌薬が執刀前に投与されていないときは，当該診療科の医長にその理由を求めることができる。医長が合理的な説明ができないときは，文献を参考に evidence に基づくも
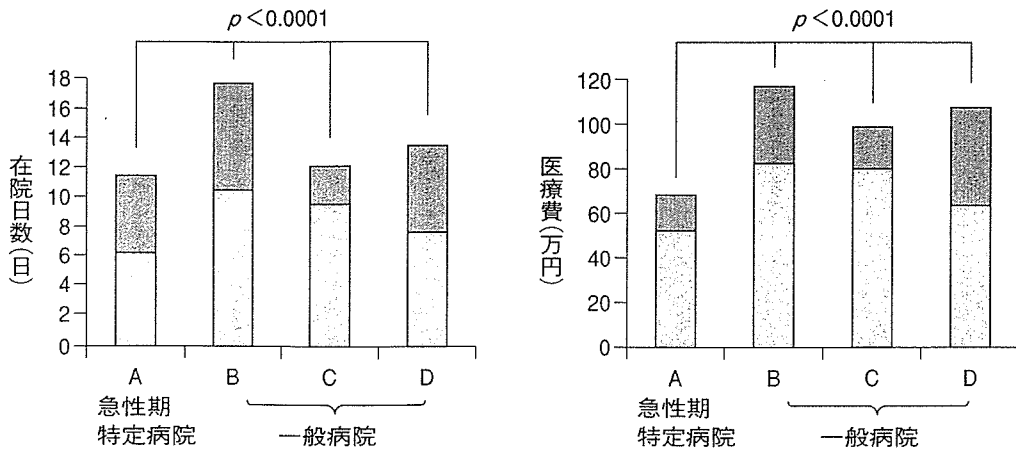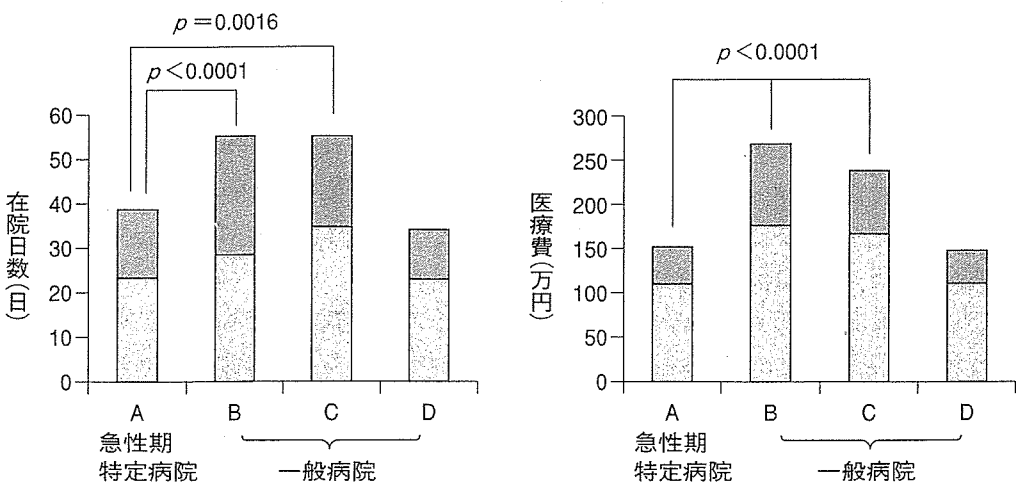
(芳賀克夫：消化器外科におけるクリティカルパスの評価．外科治療 91：498-503，2004．より引用)

Data：Mean ± SD。1998-2001 年度の手術症例で，術後合併症例も含む。急性期特定病院加算は 2002 年 4 月より急性期特定入院加算と名称を変え，2006 年 3 月には廃止された（図 1 〜 5 同様）
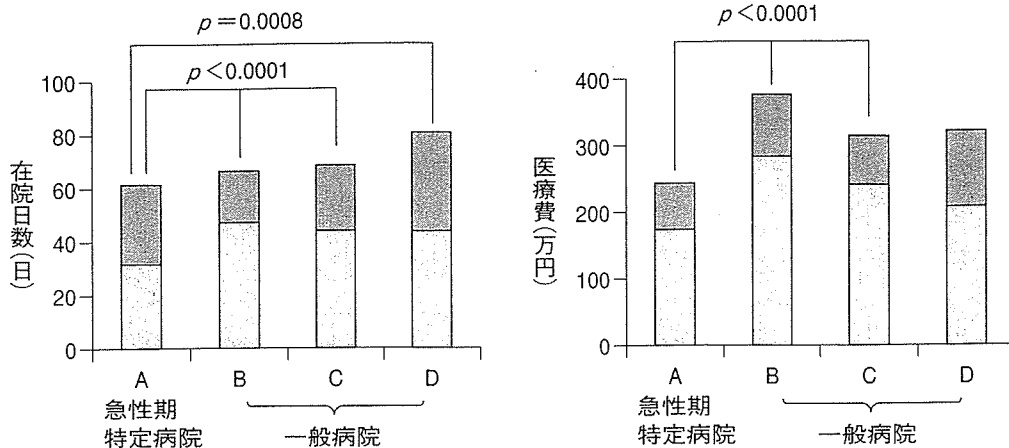
図1　急性期特定病院と一般病院における腹腔鏡下胆摘の在院日数・医療費
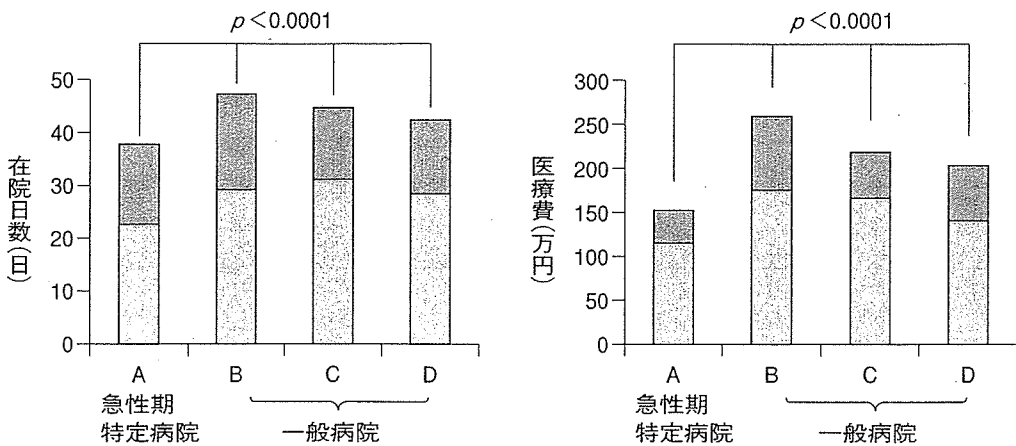
(芳賀克夫：消化器外科におけるクリティカルパスの評価．外科治療 91：498-503，2004．より引用)
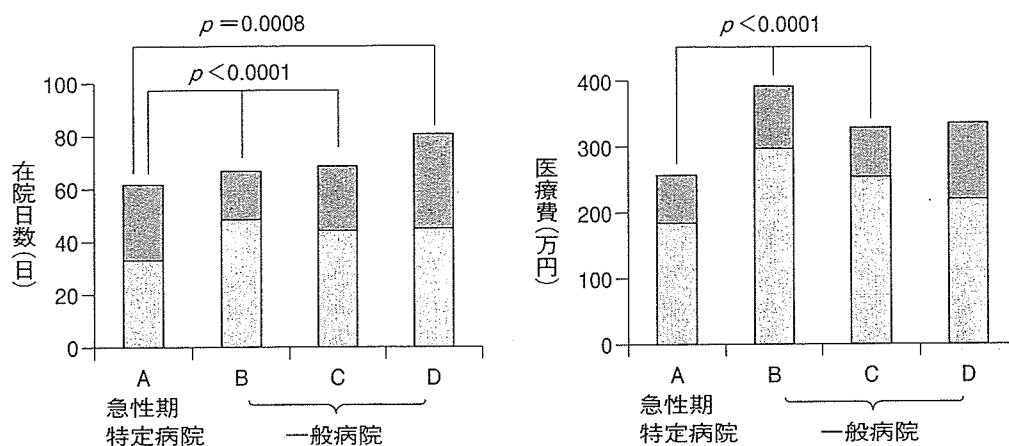
図2　急性期特定病院と一般病院における幽門側胃切除の在院日数・医療費

(芳賀克夫：消化器外科におけるクリティカルパスの評価．外科治療 91：498-503，2004．より引用)

図3　急性期特定病院と一般病院における結腸切除の在院日数・医療費

$p = 0.0008$
$p < 0.0001$

在院日数（日）

A 急性期特定病院　B　C　D 一般病院

$p < 0.0001$

医療費（万円）

A 急性期特定病院　B　C　D 一般病院

（芳賀克夫：消化器外科におけるクリティカルパスの評価．外科治療 91：498-503，2004．より引用）

図4　急性期特定病院と一般病院における胃全摘の在院日数・医療費

$p = 0.0008$
$p < 0.0001$

在院日数（日）

A 急性期特定病院　B　C　D 一般病院

$p < 0.0001$

医療費（万円）

A 急性期特定病院　B　C　D 一般病院

（芳賀克夫：消化器外科におけるクリティカルパスの評価．外科治療 91：498-503，2004．より引用）

図5　急性期特定病院と一般病院における膵頭十二指腸切除の在院日数・医療費

のに改訂させることができる．これにより，診療科間の診療プロセスの差異を是正している．その結果，病院全体の医療の質の向上も期待できる．

クリティカルパスの医療の質に及ぼす効果

前述したように，クリティカルパスを普及させ，診療プロセスを改定することにより，果たして診療アウトカムも向上することができるのであろうか．われわれは，1999年に消化器外科手術後の患者のリスクを評価する E-PASS scoring system を開発した[9]が（表1），この E-PASS を用いてクリティカルパスが医療の質に及ぼす影響を検討した．ある病院で行った手術症例の医療費の総額を予測医療費の総額で割ったものを Economic Index（EI）と定め，

経済効率の指標とした[10]．また，実在院死亡率を予測在院死亡率で割った比を OE ratio と定め，外科技術水準の指標とした[11]（表2，3）．EI が1より小さいということは，実際の治療費が予測治療費より少ないことを意味し，経済効率が良いことを意味している．逆に，EI が1より大きいことは，経済効率が悪いことを意味している．OE ratio についても同様であり，OE ratio が1より小さいことは技術水準が高いことを意味し，1より大きいことは技術水準が低いことを意味する．

筆者は厚生労働省科学研究費医療技術評価総合研究事業の主任研究者を務めていたが，同研究に参加した全国地方国立病院4施設で，1998～2001年度に行った予定消化器手術症例で，術式別に在院日数および医療費を比較した（図1～5）[12]．A病院は1998年からほとんどの予定手術にクリティカルパスを適

用している急性期特定病院で，その他の病院は同時期にはほとんどクリティカルパスを適用していなかった地域中核病院である。術後合併症を発症した例も含めて検討したが，いずれの術式においても，A病院は在院日数が有意に短く，医療費も安いことが判明した。同様に，E-PASSを用いて，経済効率と外科技術水準を調べてみた。表4に示すように，急性期特定病院であるA病院が経済効率および技術水準ともにもっとも良いことが明らかにされた。このことは，クリティカルパスを用いることにより，医療の経済効率を上げるのみならず，医療の質も向上できる可能性を示している。

おわりに

われわれの検討で，クリティカルパスを用いてevidenceに基づく診療プロセスの改定を行えば，診療アウトカムも改善されることが示唆された。これは，単に周術期管理にevidenceを取り入れたことによるものだけではなく，手術手技自体にもevidenceを取り入れた結果であろう。いかに，出血量を減らすべきか，いかに手術時間を短縮すべきか，壊死物質を体内に残さないようにするにはどうすべきか，予防的ドレーンは必要か，などを外科チームで検討した結果，診療アウトカムが改善されたものと考えられる。つまり，クリティカルパスを通じて診療全般にevidenceを議論する土壌を養成し，病院全体にEBMの考えを普及させることが重要と考えられる[13]。

今後わが国でも，医療の質の評価を求める動きは起こってくるであろう。クリティカルパスを用いてプロセスおよびアウトカムを改善することが新時代における病院の生き残り策であろう。

表4　施設間の外科技術水準と経済効率

施設	外科技術水準（OE ratio）	経済効率（EI）
A	0.62 (0.26-1.48)	0.78 (0.76-0.81)
B	0.67 (0.36-1.24)	1.09 (1.04-1.14)
C	1.00 (0.42-2.38)	1.06 (1.03-1.10)
D	1.18 (0.62-2.23)	0.87 (0.84-0.90)

（芳賀克夫：消化器外科におけるクリティカルパスの評価．外科治療 91：498-503, 2004. より引用）
A：急性期特定病院。（　）内は，95%信頼区間を示す

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