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Needleless Closed System Does Not Reduce Central Venous Catheter-Related Bloodstream Infection: A Retrospective Study

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The needleless closed system (NCS) has been disseminated in several clinical fields to prevent central venous catheter–related bloodstream infection (CVC-RBSI), in place of the conventional Luer cap system (LCS). The purpose of this study is to examine whether NCS is really superior to conventional LCS for prevention of CVC-RBSI. Between May 2002 and December 2008, 1767 patients received CVC in our department. The time interval from insertion to development of CVC-RBSI was compared retrospectively between selected patients who were treated using the conventional LCS (group 1, n = 89, before June 2006) and the NCS (group 2, n = 406, June 2006 and after). Kaplan-Meier analysis revealed no significant difference in the time interval from insertion to development of CVC-RBSI between the two groups. NCS does not reduce CVC-RBSI in adult colorectal cancer patients who undergo CVC insertion.

Key words: *Centers for Disease Control and Prevention guideline – Central venous catheter – Central venous catheter-related bloodstream infection – Luer cap system – Needleless closed system – Retrospective study – CDC guideline – CRC – Colorectal cancer – CVC – CVC-RBSI – LCS – NCS – PN – Parenteral nutrition*

Although central venous catheters (CVCs) play crucial roles in patient management in a variety of clinical fields, central venous catheter–related bloodstream infection (CVC-RBSI) is still one of the major complications associated with their use.[1]

Among improvements in anti-infectious procedures,[2,3] such as the use of a needleless closed system (NCS),[4,5] special types of catheter[6] and dressing,[7,8] and effective disinfection, the NCS has rapidly disseminated, resulting in a lower incidence of not only CVC-RBSI but also needlestick injuries.

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However, there is still insufficient evidence that NCS is indeed superior to the conventional Luer cap system (LCS) for preventing CVC-RBSI. Because few reports have compared conventional LCS with NCS in terms of CVC-RBSI prevention, the efficacy of NCS is still debatable.[4,5,9–12] Moreover, it has been suggested that NCS is used mainly to reduce the risk of potential needlestick injuries rather than to prevent CVC-RBSI.

Here, we report for the first time a retrospective study based at a Japanese university teaching hospital to compare conventional LCS with NCS use regarding the time interval from catheter insertion to development of CVC-RBSI in adult patients with colorectal cancer who underwent CVC insertion.

In addition, it is well known that we have to be very careful about sterility, because the catheter tip can get contaminated when it is being withdrawn.

Patients and Methods

We collected data for 1767 patients who underwent CVC insertions for colorectal surgery or postoperative chemotherapy for advanced colorectal cancer at the Department of Gastroenterological Surgery, Dokkyo Medical University, between May 2002 and December 2008 under the care of the same trained surgical team. Informed consent was obtained from all patients before CVC insertions.

In June 2006, our department had begun to use NCS instead of conventional LCS to reduce the incidence of CVC-RBSI and needlestick injuries. To compare these two systems for the prevention of CVC-RBSI, we divided the patients into two groups: those who had undergone CVC insertion before June 2006 (n = 768) and those who had done so from June 2006 and thereafter (n = 999). Moreover, to unify the backgrounds of the patients, we selected those with the same background characteristics, such as having undergone right internal jugular venous catheterization, having the same type of CVC, having been treated with the same type of disinfectant at the time of CVC insertion, and lacking any incidents related to CVC insertion. On the basis of this definition, 89 patients who had been treated in the earlier period were selected as group 1, and 406 patients who had been treated in the later period were selected as group 2.

Although number of patients in groups 1 and 2 was different, this phenomenon should be recognized as the limit of retrospective study.

Intervention

In all instances, CVCs were inserted into the internal jugular vein by the single-puncture method in the patient room using maximal barrier precautions.[13,14] The insertion area was disinfected with 10% povidone-iodine[15–17] and draped. Topical anesthetic skin infiltration with 1% lidocaine was performed to reduce the pain.

Catheter insertion was performed by the conventional method described elsewhere (http://www.medstudents.com.br/proced/proced4/jugular.htm). We routinely performed ultrasound examination beforehand to clarify the relationship between the internal jugular vein and the common carotid artery or other organs. However, we did not perform ultrasound-guided catheter insertion routinely. For this study, we selected the Argyle central venous catheter (16-gauge single-lumen 30-cm catheter, Nippon Sherwood, Tokyo, Japan). Accurate catheter tip placement in the superior vena cava was confirmed by chest X-ray film.[18] No procedures were performed under intravenous sedation.

Maintenance

After CVC insertion, patients were followed with routine route exchange every 72 hours until CVC removal.[8,19,20] CVCs were removed whenever fever occurred or if symptoms of infection were present, such as skin redness and pus discharge at the insertion point, and we routinely performed CVC tip culture whenever the patient had an acute fever (>38.5°C) to diagnose CVC-RBSI by blood culture.[21] We did not perform routine CVC tip culture or blood culture for the other cases.

Malposition of the catheter tip, oozing or hematoma formation at the insertion point, arterial bleeding, and symptoms of nerve injury were considered to be "insertion incidents."

Definition of CVC-RBSI

In accordance with the Centers for Disease Control and Prevention (CDC) guideline,[22] CVC-RBSI was diagnosed on the basis of at least one of the following criteria. Criterion 1: The patient had a pathogen recognized from one or more blood cultures, and the pathogen cultured from the blood was not related to an infection at another site. Criterion 2: The patient had at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension.

Table 1 General background factors in groups 1 and 2[a]

Variable	Group 1 (n = 89)	Group 2 (n = 406)	*P*
Sex, female/male, No. (%)	42 (47)/47 (53)	141 (35)/265 (65)	0.027
Age, y	64.6 ± 1.2	64.3 ± 0.6	0.789[b]
Catheter length, cm	14.5 ± 0.2	13.3 ± 0.1	<0.001[b]
Duration of insertion, d	15.1 ± 1.1	9.8 ± 0.4	<0.001[b]
Surgery, −/+, No. (%)	53 (60)/36 (40)	307 (76)/99 (24)	0.002
Chemotherapy, −/+, No. (%)	38 (43)/51 (57)	114 (28)/292 (72)	0.007
PN, −/+, No. (%)	50 (56)/39 (44)	288 (71)/118 (29)	0.007
Fever, −/+, No. (%)	69 (78)/20 (22)	370 (91)/36 (9)	<0.001
Positive blood culture, −/+, No. (%)	86 (97)/3 (3)	394 (97)/12 (3)	0.836
Positive catheter tip culture, −/+, No. (%)	84 (94)/5 (6)	396 (98)/10 (2)	0.116
CVC-RBSI, −/+, No. (%)	83 (93)/6 (7)	389 (96)/17 (4)	0.300

[a]Group 1: patients who received conventional LCS. Group 2: patients who received NCS. *P* values are χ^2 test unless otherwise indicated.

[b]Mann-Whitney *U* test.

On the basis of the CDC guideline, we decided that the primary endpoint of the study was the development of any CVC-RBSI, which included either bacteremia or fungemia, or blood or catheter tip culture positivity. Therefore, either blood culture positivity or catheter culture positivity was considered to be indicative of CVC-RBSI.

In addition, we evaluated the frequencies of catheter-related complications per 1000 catheter days on the basis of fever, blood culture positivity, catheter tip culture positivity, and CVC-RBSI. Catheter days mean the period from catheter insertion to removal.

Statistical analysis

Differences in background characteristics between conventional LCS use (group 1) and NCS use (group 2) were analyzed by Mann-Whitney *U* test and χ^2 test. Kaplan-Meier analysis and log rank test were used to compare the time interval from insertion to development of CVC-RBSI between groups 1 and 2. Statistical analyses were performed using the SPSS software package version 16.0 (SPSS Inc, Chicago, Illinois) at a significance level of $P < 0.05$. The results are presented as means ± SE.

Results

Table 1 summarizes the baseline data for the patients and general background factors. The mean age of the patients was 64.6 ± 1.2 years in group 1 and 64.3 ± 0.6 years in group 2.

There were significant differences in factors such as sex (female/male, 42:47 versus 141:265; $P = 0.027$), length of inserted catheter (length, 14.5 ± 0.2 versus 13.3 ± 0.1 cm; $P < 0.001$), duration of catheter insertion (duration, 15.1 ± 1.1 versus 9.8 ± 0.4 days; $P < 0.001$), use of surgery (not performed/performed, 53:36 versus 307:99; $P = 0.002$), administration of postoperative chemotherapy (not administered/administered, 38:51 versus 114:291; $P = 0.007$), and administration of parenteral nutrition (PN; not administered/administered, 50:39 versus 288:118; $P = 0.007$), and occurrence of fever (absent/present, 69:20 versus 370:36; $P < 0.001$), for groups 1 and 2, respectively.

There were no significant intergroup differences in blood culture positivity (negative/positive, 86:3 versus 394:12; $P = 0.836$), catheter tip culture positivity (negative/positive, 84:5 versus 396:10; $P = 0.116$), and incidence of CVC-RBSI (negative/positive, 83:6 versus 389:17; $P = 0.300$).

Table 2 shows the details of CVC-RBSI. Fever occurred in 56 patients. There were no significant differences in the frequency per 1000 catheter days for complications such as fever, positive blood culture, positive tip culture, and CVC-RBSI between groups 1 and 2. From the results of culture, 23 patients received a diagnosis of CVC-RBSI. There were 15 positive blood cultures and 15 positive catheter tip cultures. Seven patients had both positive blood cultures and positive catheter tip cultures. The overall frequencies per 1000 catheter days of fever, blood culture positivity, catheter tip culture positivity, and CVC-RBSI were 10.5, 2.8, 2.8, and 4.3, respectively. No patients in this series had severe incidents such as pneumothorax.

Blood culture positivity involved *Staphylococcus* in 10 patients, *Pseudomonas* in 1 patient, *Bacteroides* in 1 patient, *Streptococcus* in 1 patient, and *Candida* in 2 patients. Catheter tip culture positivity involved

Table 2 Details of CVC-RBSIs

Complication	No. of Patients (%)	Per 1000 catheter days (group 1/group 2)	*P*
Fever	56 (11); group 1/group 2: 20 (2.2)/36 (8.9)	10.5 (14.8/9.1)	0.076
Positive blood culture	15 (3.0); group 1/group 2: 3 (3.4)/12 (3.0)	2.8 (2.2/3.0)	0.635
Positive tip culture	15 (3.0); group 1/group 2: 5 (5.6)/10 (2.5)	2.8 (3.7/2.5)	0.478
CVC-RBSI	23 (4.6); group 1/group 2: 6 (6.7)/17 (4.2)	4.3 (4.5/4.3)	0.935

Staphylococcus in 10 patients, *Pseudomonas* in 1 patient, *Corynebacterium* in 1 patient, *Enterococcus* in 1, and *Candida* in 2 patients (Table 3).

Kaplan-Meier analysis and log rank test revealed no significant intergroup difference in the time interval from insertion to development of CVC-RBSI ($P = 0.450$; Fig. 1).

Discussion

Most retrospective control studies have shown that treatment conducted in the later period tends to offer greater advantages than treatment conducted in the early period. In fact, in the present study, there were several significant intergroup differences in background factors such as sex ratio, length of inserted catheter, duration of catheter insertion, use of surgery, and administration of postoperative chemotherapy and PN between the group treated using conventional LCS (group 1) and the group treated using NCS (group 2).

Group 2 benefited from many improvements in the management of CVC, such as a shorter inserted catheter length and duration of catheter insertion, compared with group 1. Moreover, group 2 had lower frequencies of use of surgery and administration of PN, as well as a higher frequency of administration of postoperative chemotherapy, than group 1. In both groups, these differences were due to the change of treatment.

Although group 2 would have been expected to benefit in terms of CVC-RBSI prevention, Kaplan-Meier analysis and log rank test demonstrated no significant intergroup difference in the time interval from insertion to development of CVC-RBSI. Moreover, there was no significant intergroup difference in the frequency of catheter-related complications per 1000 catheter days. Therefore, NCS was considered not to have been responsible for the reduction in catheter-related complications, particularly the potential for minimization of CVC-RBSI.

It is well known that the main causes of CVC-RBSI lie in the environment external to blood vessels, such as contamination via route connectors,[23,24] dressing change at the insertion point,[19,25] administration of PN,[26] or use of surgery. It is considered that the frequency of postoperative chemotherapy does not affect the incidence of CVC-RBSI. *Staphylococcus*, which is commonly distributed on the surface of the body as part of the normal flora, is a major pathogen responsible for CVC-RBSI,[21,27,28] and only a few patients had pathogens associated with colorectal surgery (*Pseudomonas* and *Enterococcus*).

In fact, conventional LCS has an inherent dead space, which itself might be a cause of proliferation of contaminating pathogens. On the other hand, although NCS has no dead space, the surface of the connector is always exposed to the outside environment. Therefore, it is thought that if insufficient

Table 3 Pathogens detected in blood culture and catheter tip culture[a]

Pathogen	Blood culture	Catheter tip culture
Staphylococcus	10 (2.0)	10 (2.0)
Pseudomonas	1 (0.2)	1 (0.2)
Bacteroides	1 (0.2)	0 (0.0)
Streptococcus	1 (0.2)	0 (0.0)
Corynebacterium	0 (0.0)	1 (0.2)
Enterococcus	0 (0.0)	1 (0.2)
Candida	2 (0.4)	2 (0.4)

[a]Values in parentheses are percentages.

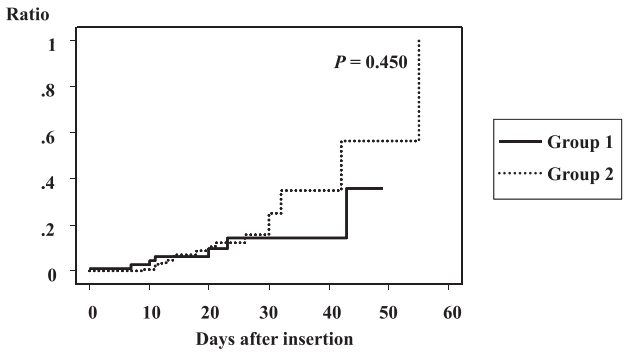

Fig. 1 Time interval from insertion to development of CVC-RBSI in the two groups. There was no significant intergroup difference.

disinfection is performed before injection, contamination via the connector might easily occur.[9,12] Although our retrospective data might have included sample bias due to the adoption of the new device, other factors such as the duration of CVC insertion and length of the inserted CVC showed an improvement in group 2.

In conclusion, this report is, to our knowledge, the first to compare conventional LCS use with NCS use for prevention of CVC-RBSI in adult patients in the field of colorectal cancer surgery. Our results clearly demonstrate that NCS use has no superiority over conventional LCS use for preventing the incidence of CVC-RBSI.

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