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“A salvage technique using a fibrous sheath to avoid the loss of the central veins in cases of pediatric intestinal failure”

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ABSTRACT

Purpose

The number of accessible central veins (CVs) affects the prognosis of patients with intestinal failure (IF). The loss of residual CVs should be avoided. We therefore evaluated the efficacy of a new CV catheter-exchange technique using a subcutaneous fibrous sheath (FS) in pediatric IF patients.

Methods

We retrospectively collected the CV catheter (CVC) data of pediatric IF patients managed from January 2009 to December 2019. The data were divided into two groups; Groups 1 (CVCs placed with the FS method) and Group 2 (CVCs placed by the primary or another insertion). The main outcome was the CVC indwelling time.

Results

Eighty-five CVCs were analyzed. The FS method was attempted in 47 cases and succeeded in 40 (85%). No significant difference was observed between the groups regarding characteristics. A log-rank test revealed an equivalent CVC indwelling time between the two groups (Group 1: 268 [126-588] days vs. Group 2: 229 [126-387] days, $p=0.256$).

Conclusions

The FS method is highly recommended for pediatric IF patients, as its attempt showed a high success rate with an indwelling time equivalent to primary insertion. The FS method leads to the prolonged use of a single CV and thereby contributes to improving the outcomes of pediatric IF patients.

Key words: intestinal failure, fibrous sheath, central venous catheter, loss of central veins

Abbreviation: IF: intestinal failure, FS: fibrous sheath, CV: central vein, CVC: central venous catheter, CLABSI: central line-associated blood stream infection, SBS: short bowel syndrome, HD: Hirschsprung's disease, ADHD: allied disorders of Hirschsprung's disease, CIIP: chronic idiopathic intestinal pseudo-obstruction, TPN: total parenteral nutrition, MVID: microvillus inclusion disease, IT intestinal transplantation, IQR: inter-quartile range.

1. Introduction

Intestinal failure (IF) is defined as “the reduction of functional gut mass below the minimal amount necessary for digestion and absorption adequate to satisfy the nutrient and fluid requirements for maintenance in adults or growth in children.” [1]

Pediatric IF remains a challenging disease and consists of surgical short bowel syndrome (SBS), disorders of gastrointestinal motility and congenital enterocyte disorders. The variations of pediatric IF make it difficult to establish unified treatment strategy. As no radical treatments for pediatric IF patients exist, long-term total parenteral nutrition (TPN) management is symptomatically considered crucial for an adequate growth, development, and survival. Commercialized parenteral nutrition materials and the development of medical devices may help facilitate the implementation of long-term total parenteral nutrition (TPN). Despite the progress achieved, pediatric IF patients occasionally require long-term TPN via a central venous catheter (CVC). CVC removal may be required due to catheter infection, which often causes subsequent CV occlusion. The loss of accessible CVs directly affects the prognosis of pediatric IF patients. Thus, catheter-related complications should be avoided, and the best-practices for CVC care should be advocated for pediatric IF patients.

In our department, we developed an advanced technique to facilitate reusing the

existing CVC path using a subcutaneous fibrous sheath (FS). Masumoto et al. first reported the efficacy of the FS method, even for CLABSI-related CVC exchange [2]. Since then, we have continued to adopt the FS method as the protocol for CVC exchange in pediatric IF patients.

In the present study, we evaluated whether or not the FS protocol was able to prolong the indwelling period of a single catheter and positively contribute to avoid the loss of CVs in pediatric IF patients who had to have their catheters replaced for various reasons.

2. Materials and Methods

Setting and population

This study was approved by the ethics committee of Kyushu University (Approval No. 30-338). The data of IF patients who underwent CVC insertion in our department were retrospectively collected during the period from January 2009 to December 2019. Collected data were divided into two groups according to the insertion technique. In Group 1, CVCs were inserted according to the FS insertion protocol (see FS insertion protocol). In Group 2, patients underwent CVC insertion using conventional procedure. In general, we selected the FS method for all exchangeable cases, except in cases which this method could not be used for some reasons.

Data collection

The patient data included the age, sex, primary diagnosis, blood test results at the time of catheter insertion (albumin, C-reactive protein, hemoglobin, white blood cell count, platelet count) and the reasons for exchange. Catheter-related data (operation time, type of catheter, indwelling time, endpoint of the catheter) were also collected.

FS insertion protocol

The modified procedure in this study was based on the initial report by Masumoto et al. [2]. Patients with CLABSI or suspected-CLABSI were given a broad-spectrum antibiotic at least one week prior to CVC replacement. Replacement was performed when the patient had recovered from CLABSI, as confirmed by a negative blood culture. CVCs were removed in patients with a positive blood culture after one week of antibiotic treatment. Prophylactic antibiotics were not indicated in patients who underwent CVC insertion unrelated to any infectious reasons (e.g., scheduled, catheter broken, occlusion, or accidental removal).

Replacement procedure

The patient was placed in the supine position under general anesthesia in the operation room. The skin was sterilized using povidone-iodine or 1% chlorhexidine under maximum precautions. After identifying the location of the subcutaneous Dacron cuff, a skin incision was made above the catheter (Figure 1A). The subcutaneous tissue was gently separated until the translucent FS was found. The catheter with the FS was lifted (Figure 1B), and traction sutures were placed at the anterior wall of the FS. The anterior wall of the FS was then cut, and additional lateral traction sutures were placed to flip up the edge of the FS (Figure 1C).

The proximal CVC was removed, and the guidewire was inserted via the FS to the CV simultaneously (Figure 1D), and the CVC was completely removed. A new CVC was inserted via the newly created entry point over the guidewire through the new subcutaneous route. The conventional catheter insertion procedure was then performed to insert the new CVC (Figure 1E).

Definitions

In this study, IF was defined as dependence on parenteral nutrition because of either functionally or physically inadequate intestinal function. A 2.7- and 4.2-Fr Broviac[®], or 7-Fr Hickman[®] catheters (C.R. Bard, Inc., New Providence, New Jersey, U.S.A.) were

used in this study, with all other types of CVCs, such as a peripherally inserted central venous catheters (PICC) or implantable venous access device (PORT) excluded. The diagnosis of CLABSI was based on a laboratory-confirmed blood stream infection, which was defined according to the National Healthcare Safety Network guidelines [3]. Patients were diagnosed with “suspected CLABSI” if they had infectious symptoms but no other foci and only one positive blood culture.

Statistical analyses

Categorical data are shown as percentages. The chi-squared test and Fisher's exact test were used to analyze categorical data. The data were also expressed as the median and inter-quartile range (IQR; 25th–75th percentiles). Wilcoxon’s rank sum test was used to analyze continuous data. Kaplan-Meier survival curves were generated for the CVC indwelling time in Groups 1 and 2 and compared by a log-rank test. All statistical analyses were performed using the JMP software program (version 16.0.0; SAS Institute, Cary, North Carolina, U.S.A.). P values of <0.05 were considered to indicate statistical significance.

3. Results

A total of 100 CVCs were inserted in 25 patients with pediatric IF during the study period. Fifteen CVC insertions were excluded because of protocol violations. Eighty-five CVC insertions were suitable for the analysis. The details of the primary diseases are shown in Table 1. SBS was the most common primary disease (9 patients, 37 CVC insertions), followed by hypoganglionosis (7 patients, 20 CVC insertions), Hirschsprung disease (4 patients, 15 CVC insertions), chronic idiopathic intestinal pseudo-obstruction (3 patients, 5 CVC insertions), microvillus inclusion disease (1 patient, 7 CVC insertions), and immaturity of ganglia (1 patient, 1 CVC insertion). There were no significant differences between the two groups.

Among the 85 CVC insertions described in this study, the FS method was attempted in 47 cases, and 40 cases with successful insertions (85%) were allocated to Group 1. Seven failed FS attempts were allocated to Group 2, in which the guide wire was unsuccessfully inserted in 5 cases, and 2 cases who experienced the accidental intraoperative removal of the guide wire or CVC. Fifteen cases had their catheter previously removed due to the exclusion criteria of the FS method and thus were allocated to Group 2 (Table 2). No patients developed complications in association with the FS method. In Group 2, the total number of cases was 45, including 23 primary insertions, 7 conversions after a failed attempt using the FS method, and 15 cases who were excluded

based on the exclusion criteria of the FS method, which resulted in insertion at another site after the previous catheter removal.

The patients' characteristics at the time of insertion are shown in Table 3. Regarding the type of CVC, the rate of Broviac[®] catheter insertion was significantly higher in Group 1 than in Group 2 (100% vs. 86.7%, $p=0.027$). The operation time was significantly longer in Group 1 than in Group 2 (64 [54-77] minutes vs. 50 [35-69] minutes, $p=0.006$), after excluding cases of conversion ($n=7$) and those with concomitant surgery ($n=7$). No significant differences were observed between the groups in other characteristics (including sex, age, and blood test results).

The distribution and reasons for catheter insertion are listed in Table 4. All catheter insertions in Group 1 were to exchange catheters; CLABSI was the most common reason (23 cases, 58%), followed by suspected CLABSI (7 cases, 13%), catheter broken (7 cases, 13%), occlusion (2 cases, 5%) and scheduled exchange (1 case, 3%). In contrast, half of the catheter insertions in Group 2 were primary insertions (23 cases, 51%). Of the remaining 22 cases of Group 2, the same CV was punctured in 7 cases (16%), and another CV was punctured to insert new CVC in 15 cases (33%). The most common reason for exchange in Group 2 was also CLABSI (9 cases, 20%), followed by scheduled exchange (6 cases, 13%), accidental removal (4 cases, 9%), and suspected CLABSI (3 cases, 7%).

In total, the percentage of catheter replacements due to infection or a suspected infection was 49.4% (42/85).

Finally, a log-rank test revealed no marked differences in the indwelling catheter survival time of the two groups (Group 1: 268 [126-588] days vs. Group 2: 229 [126-387] days, $p=0.256$, Figure 2). Furthermore, an additional log-rank test that considered the removal of causes except for infection (CLABSI and suspected CLABSI) as censored revealed no significant differences between the groups (25 CVCs were removed because of infection in each group; Group 1: 310 [176-1282] days vs. Group 2: 363 [141-1595] days, $p=0.915$).

4. Discussion

This is the first report on a follow-up study using the FS method. We not only demonstrated that the indwelling time with the FS method was equivalent to that with primary insertion (Figure 2) but also showed that the FS method was highly successful (85%) regardless of the reason for exchange (e.g., CLABSI, scheduled, breakage, or occlusion) (Table 4). Brevetti et al. first reported the usefulness of the FS method for reducing mechanical complications related to newly CVC insertion [4]. They did not recommend this procedure for cases with the catheter infection. However, Masumoto et

al. first reported the effectiveness of the FS method even for CLABSI, noting that bacteria reside inside the CVC lumen, and the FS can be used in an aseptic condition [2]. Since then, we have adopted this CVC exchange method for pediatric IF patients, considering the significant advantages of the repeated use of a single CV, including avoiding complications associated with new puncture, and standardizing the replacement method for catheter infection.

Hecht et al. reported real-world data showing that the compliance rate was poor, and attempted CVCs salvage resulted in a high treatment failure rate for high-risk children with bloodstream infections (BSI), although the guideline recommends CVC removal for CLABSI [5]. This is understandable, as clinicians must decide between risking CVCs infection and CVC salvage or allowing CV retention, as CVC removal can result in remnant CV loss and directly lead to a poor prognosis in high-risk patients. Many methods of reclaiming infected CVCs have been reported in children, including solution-lock therapy [6,7,8] and antibiotic-lock therapy [9]; however, the ideal approach for infected CVC salvage has yet to be standardized. The concept of the FS method as a CVC salvage is totally different from lock therapy. We believe that any potential pathogen is located at inner lumen of CVC, or in some cases may flow into the blood stream; therefore, preconditioning to sterilize bacteria and then performing subsequent CVC exchange

seems reasonable when the blood-stream infection is controllable.

We suspect that pre-conditioning is important. Indeed, our patients who were suspected of having CLABSI were given a broad-spectrum antibiotic at least one or two weeks prior to undergoing the FS method, and the FS method was only performed once the blood cultures had become negative for bacteria growth. As shown in Table 4, the proportion of patients with CLABSI or suspected of having CLABSI in Group 1 was relatively high compared to Group 2 (76% vs. 56%). However, there were no significant differences in the indwelling time between the two groups. This treatment strategy is therefore considered to be justified if clinicians encounter high-risk pediatric IF patients with CLABSI since the FS method is deemed to be a viable approach for replacing infected CVCs and avoiding CV loss.

There were several limitations in this study. First, there are some contraindications for the FS method. Tunnel site infection, persistent BSI and accidental removal are contraindications for performing the FS method, as shown in Table 2. Second, the FS method was associated with a significantly longer operation time than either primary insertion or another insertion after removal. We did not restrict the operators because we felt that every pediatric surgeon needed to become accustomed to this procedure. Third, the number of cases was low, as IF is a rare disease, so the heterogeneity of pediatric IF

patients may have influenced the methodology and allocation. Fourth, as this was a retrospective study, the influence of selection bias cannot be ignored. In fact, the older CIIP patients in Group 2 tended to undergo Hickmann catheter insertion, while the proportion of Broviac[®] catheter insertion was also significantly high as shown in Table 3. To overcome these issues, we need to construct a multi-center data registry system for pediatric IF patients and conduct a well-designed observational study, such as a propensity score-matched study, to minimize the differences between groups and potential confounding effects.

5. Conclusion

The FS method is highly recommended based on its high success rate and because the indwelling time is equivalent to that with primary insertion. The FS method may prolong the remaining CV lifetime and preserve the numbers of CVs for a long time, as it facilitates the repeated use of the same CV. Thus, it is expected that the FS method will eventually improve the outcomes of pediatric IF patients.

Conflict of interest disclosure

The authors declare no conflicts of interest in association with the present study.

Figure legends

Figure 1. Details of the replacement procedure

A: Previous wound (black arrow) and entry point. B: The CVC with the FS was separated. C: The anterior wall of the FS was cut after the placement of anterior traction sutures, and lateral traction sutures were added. D: The proximal CVC was removed, and a guidewire is simultaneously inserted. E: The new entry point (black arrowhead) and the postoperative condition. The black arrow shows the previous entry point.

Figure 2. Kaplan–Meier survival curves for CVC indwelling time.

(Group 1: 268 [126-588] days vs. Group 2: 229 [126-387] days, $p=0.256$)

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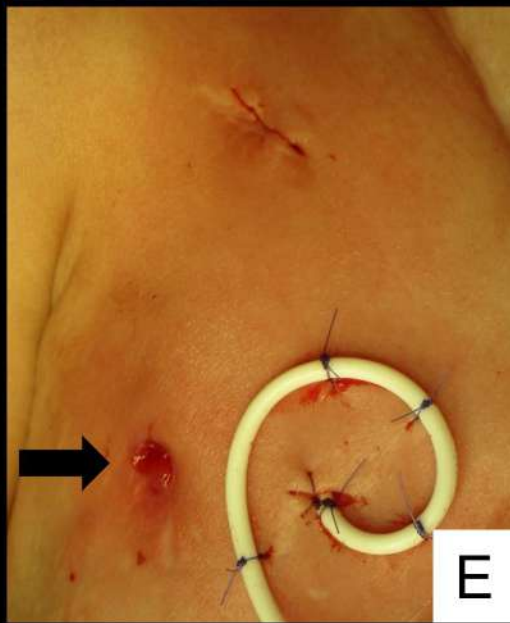
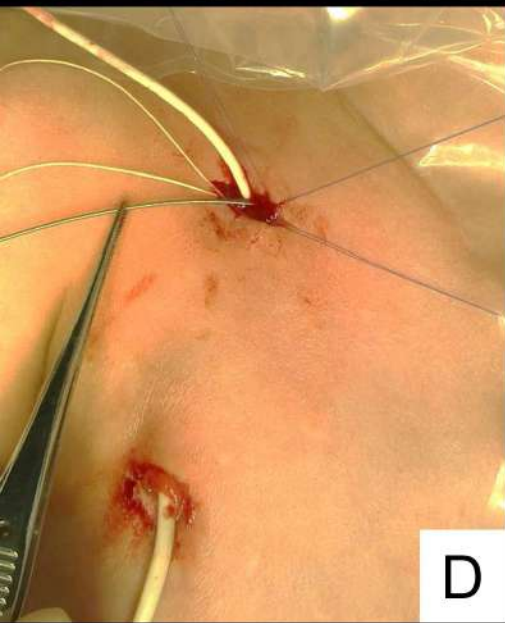
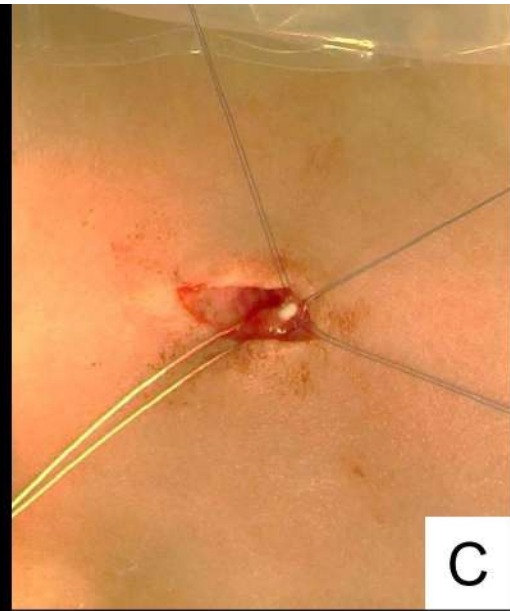
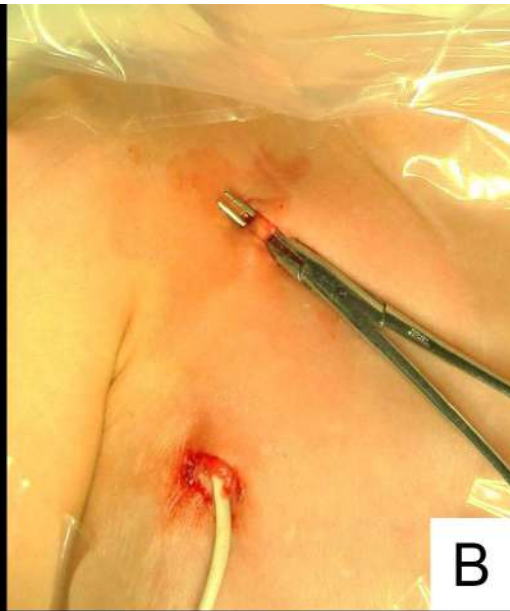
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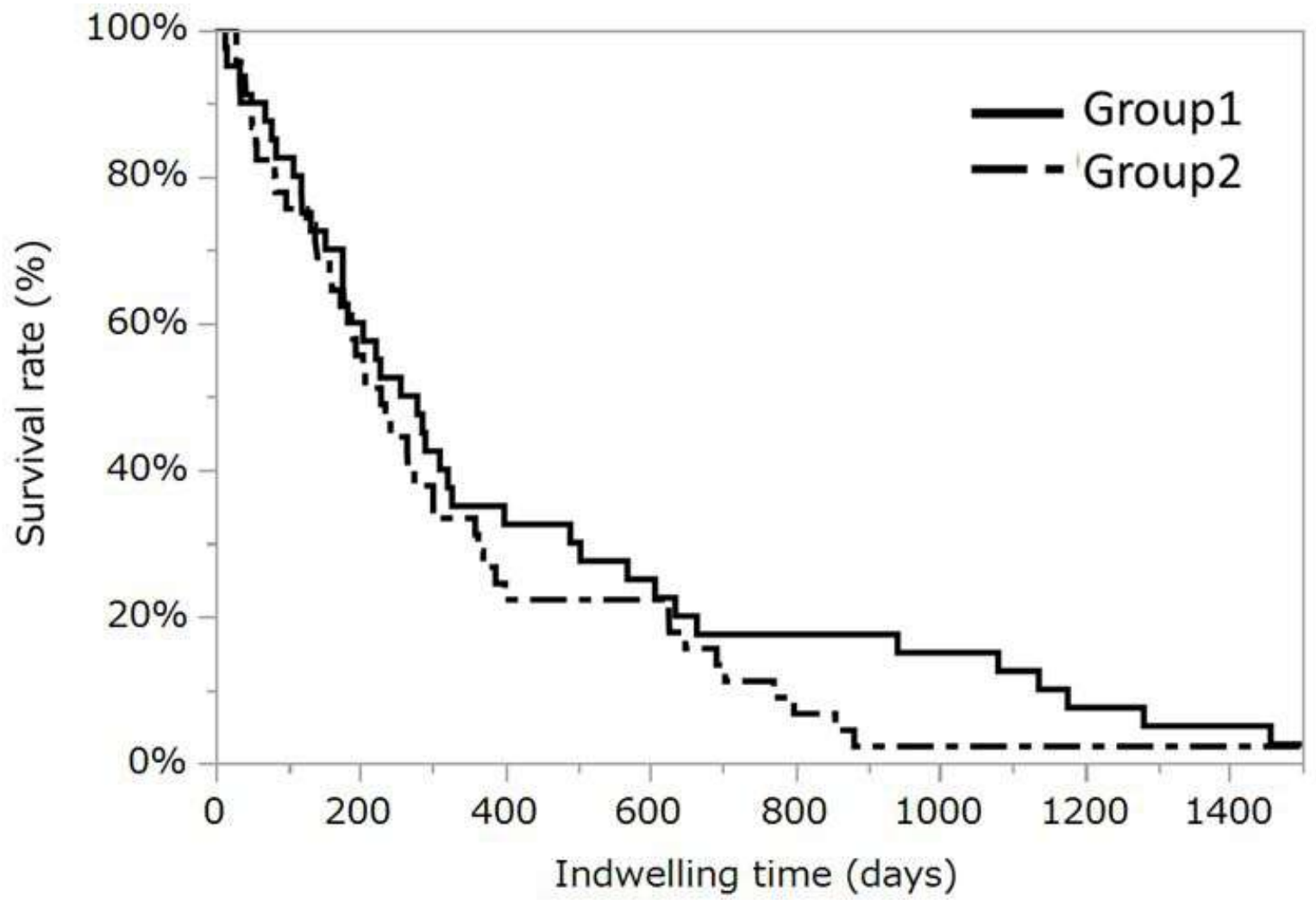


Table1. Primary disease and number of CVCs (p=0.15)

	Patients (n=25)	CVC s (n=85)	Group1 (n=40)	Group2 (n=45)
SBS, No. (%)	9(36%)	37(40%)	19(48%)	18(40%)
Hypo, No. (%)	7(28%)	20(26%)	9(23%)	11(24%)
HD, No. (%)	4(16%)	15(18%)	6(15%)	9(20%)
CIIP, No. (%)	3(12%)	5 (6%)	0 (0%)	5(11%)
MVID, No. (%)	1 (4%)	7 (8%)	5(13%)	2 (4%)
IG, No. (%)	1 (4%)	1 (1%)	1 (3%)	0 (0%)

Abbreviations

SBS: Short Bowel Syndrome, Hypo: Hypoganglionosis, HD: Hirschsprung's Disease,

CIIP: Chronic Idiopathic Intestinal Pseudo-obstruction, MVID: Microvillous Inclusion

Disease, IG: Immaturity of Ganglia

Table 2. Exclusion criteria of FS methods resulted in catheter removal.

	n=15	
Tunnel site infection	5	(33.3%)
Persistent positive of blood culture	5	(33.3%)
Accidental removal	3	(20.0%)
Surgeons' preference	1	(6.7%)
CVC Pinch-off	1	(6.7%)

CVC: central vein catheter, FS; fibrous sheath

Table 3. Patient characteristics at the time of insertion

Characteristics	Group 1 (n=40)		Group 2 (n=45)		p value
Male, No. (%)	18	(45.0%)	25	(55.6%)	0.331
Broviac®, No. (%)	40	(100%)	39	(86.7%)	0.027
Age, median (IQR), years	3.1	[1.8-6.1]	2.1	[0.5-5.7]	0.100
Alb, median (IQR), g/dL	3.9	[3.5-4.4]	3.6	[3.2-4.2]	0.284
CRP, median (IQR), mg/dL	0.17	[0.04-0.61]	0.16	[0.04-0.47]	0.924
WBC, median(IQR), 10 ⁴ /μL	6.7	[5.0-10.3]	6.7	[5.5-10.8]	0.717
Hb, median (IQR), g/dL	11.8	[10.6-12.6]	11.7	[10.0-12.8]	0.868
Platelet, median(IQR), 10 ⁴ /μL	26.6	[15.6-34.7]	28.3	[19.5-37.9]	0.299
Operation time, median (IQR), min	64	[54-77]	50	[35-69]	0.006

Table 4. **Distribution and reasons for catheter insertion**

No. of insertion	Group 1 (n=40)	Group 2 (n=45)
Primary insertion	-	23(51%)
Exchange	40(100%)	22(49%)
Reasons for exchange		
CLABSI, No. (%)	23(58%)	9(41%)
CLABSI suspected, No. (%)	7(18%)	3(14%)
Scheduled, No. (%)	1(3%)	6(27%)
Accidental, No. (%)	0	4(18%)
Broken, No. (%)	7(18%)	0
Occlusion, No. (%)	2(5%)	0