The Effect of a Temporary Inferior Vena Cava Filter in the Treatment of Deep Vein Thrombosis in Critically-Ill Patients

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SUMMARY

We studied the clinical courses of patients with deep vein thrombus (DVT) who underwent insertion of temporary inferior vena cava filters (tIVCF) and evaluated the effectiveness of the tIVCF.

From January 2003 to March 2008, tIVCF were placed in 12 patients with a diagnosis of DVT in the Intensive Care Unit (ICU) of Gunma University Hospital. The mean age of the patients was 52 ± 16 years (range, 18-82). Eight were medical patients who had not undergone any prior surgery, and 4 were postoperative patients, including 3 with a malignancy. The diagnosis of DVT was made using enhanced computed tomography. The Toray Neuhaus Protect catheter (6Fr, Toray Medical, Tokyo) was used as a tIVCF in all 12 patients. We evaluated the clinical course of the patients before and after placement of a tIVCF and studied their prognosis.

DVT occurred on 15 ± 9 days after surgery or admission to hospital. Pulmonary thromboembolism (PTE) was detected in 7 patients prior to the placement of a tIVCF, 3 of whom required cardiopulmonary resuscitation. The mean duration of tIVCF placement was 18 ± 9 days; no episodes of PTE occurred after tIVCF placement. DVT completely or almost completely disappeared during the period of tIVCF placement; subsequently, tIVCFs were successfully removed in 10 patients (83%). A permanent IVC filter was placed in only 1 patient, and the tIVCF was removed in the remaining patient because of suspected catheter infection. There were 2 complications related to tIVCF placement: infection at the insertion site and suspected catheter infection.

tIVCF placement could prevent the occurrence of PTE without provoking life-threatening complications. The results suggest that tIVCF is useful in the prevention of PTE in patients with DVT. (Int Heart J 2008; 49: 713-721)

Key words: Temporary inferior vena cava filter, Deep vein thrombus, Pulmonary thromboembolism

HOSPITALIZED patients and patients in intensive care units (ICU) have risk factors for venous thromboembolism (VTE).¹⁻³⁾ Risk factors in hospitalized

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patients may include recent surgery, trauma, sepsis, malignancy, immobilization, increased age, heart and/or respiratory failure,⁴⁾ while those in ICU patients may include immobilization, pharmacologic paralysis, central venous lines, surgical procedures, sepsis, mechanical ventilation, vasopressor use, and hemodialysis.^{1,2)} In addition, deep vein thrombosis (DVT) is a risk factor for pulmonary thromboembolism (PTE) which has a known poor prognosis. Monreal and colleagues reported that acute PTE occurred within 7 days in 0.5% of patients with DVT, even though anticoagulant therapy was given, and 3.5% of the patients with DVT were complicated by asymptomatic or symptomatic PTE.⁵⁾

Placement of an inferior vena cava filter (IVCF) is one therapeutic method and a categorical indication for patients with DVT.⁶⁾ Recently, the availability of temporary IVCFs (tIVCF) has led to an increased interest in their use as a prophylactic measure against PTE.⁷⁾ However, the use of tIVCF for DVT patients remains controversial and available data from prospective, randomized controlled studies are limited to established strict indications for insertion of a tIVCF.^{8,9)}

In this study, we reviewed the clinical course of patients in whom a tIVCF was inserted for DVT, and evaluated their prognosis and complications that arose during tIVCF placement.

METHODS

From January 2003 to March 2008, a tIVCF was placed in 12 patients (3 males, 9 females) with a diagnosis of DVT in the ICU of Gunma University Hospital. The indications for tIVCF insertion in our ICU are as follows; residual proximal DVT in patients with PTE, floating proximal DVT, and a contraindication of anticoagulation therapy. The mean age of the patients was 52 ± 16 years (range, 18 to 82); the mean body weight and body mass indices were 65.5 ± 15.0 (range, 49.3 to 93.5) kg and 26.5 ± 4.6 (21.3-35.8) kg/m², respectively. The disease history of the 12 patients is shown in the Table. Eight were medical patients who had not undergone any prior surgery. Four were postoperative patients, 3 of whom had a malignancy. In all 12 patients, the diagnosis of DVT was made based on the existence of a thrombus in and/or below the inferior vena cava (IVC), as detected by ultrasonography and enhanced computed tomography (CT). A Toray Neuhaus Protect catheter (6Fr, Toray Medical, Tokyo, Figure 1) was used as a tIVCF in all 12 patients; it was inserted either through the right jugular ($n = 10$) or the right subclavian ($n = 2$) vein. The tip of the tIVCF was placed at the distal site of a renal vein (we identified the position of bilateral renal veins by contrast cavography with contrast media injected through tIVCF). The position of the tIVCF tip was checked daily with an abdominal roentgenogram when a patient

was in the ICU (Figure 2). The systemic administration of low-dose unfractionated heparin (LDUH, 10,000-20,000 units/day) was continued through the tIVCF, and activated partial thromboplastin time (APTT) was maintained within 45-80 seconds during the placement of the tIVCF if anticoagulation therapy was not contraindicated.

D-dimer and fibrinogen/fibrin degradation products (FDP) were measured during tIVCF placement. D-dimer was measured using a latex photometric immunoassay system (LPIA, LPIA Ace D-dimer, Mitsubishi Chemical Iatron, Tokyo). This system uses a latex agglutination reaction assessed by light scattering with an infrared beam. The means of the maximum plasma levels of D-dimer and FDP during tIVCF placement and those before tIVCF removal were compared.

We evaluated the clinical courses of the patients before and after tIVCF placement and assessed their prognosis.

Statistical analysis: All results are expressed as the mean $\pm$ standard deviation. Statistical comparisons were made using the paired *t*-test for the analysis of the changes in D-dimer and FDP levels. A *P* value of less than 0.05 was considered to be statistically significant.

RESULTS

Based on the Guidelines for the Diagnosis, Treatment, and Prevention of Pulmonary Thromboembolism and Deep Vein Thrombosis (Japanese Circulation Society 2004),¹⁰⁾ 5 of our patients were judged to be at medium risk, 6 at high risk, and 1 at maximum risk (Table). The reasons for tIVCF placement were residual proximal DVT with PTE in 7 patients (patients 1, 4, 5, 6, 8, 9, and 10 in the Table) and floating proximal DVT in the other 5 patients. DVT occurred 15 ± 9 days (range, 0 to 27) after surgery or admission to hospital. The patient risk factors and prophylactic methods to prevent DVT are shown in the Table. PTE was detected in 7 patients prior to the tIVCF placement, 3 of whom required cardiopulmonary resuscitation. A percutaneous cardiopulmonary support system (PCPS) was used to maintain hemodynamics in these 3 patients (Table), which was successfully removed within 5 days following hemodynamic stabilization. The mean duration of tIVCF placement was 18 ± 9 days (range, 8 to 35). The systemic administration of LDUH (10,000-20,000 units/day) was continued through the tIVCF and APTT was maintained within 45-80 seconds during the tIVCF placement in all cases. No episodes of PTE were reported after tIVCF placement. No deformation or migration of a tIVCF during tIVCF placement was observed.

Table. Patients' Disease History, Prophylaxis for DVT, and Occurrence of PTE Before tIVCF Placement

Patient number	P/Op	Malig.	IPC	ACT	PTE	CPR	PCPS
[Medium risk]							
1 Rt. Tibial fracture	(-)	(-)	(-)	(-)	(+)	(-)	(-)
2 Rt. Nephrectomy (in ICU) for emphysematous pyelonephritis and sepsis	(+)	(-)	(+)	(-)	(-)	(-)	(-)
3 Perforation in small intestine+SLE	(-)	(-)	(+)	(-)	(-)	(-)	(-)
4 SAH	(-)	(-)	(+)	(-)	(+)	(+)	(+)
5 Hepatic resection for HCC	(+)	(+)	(+)	(+)	(+)	(-)	(-)
[High risk]							
6 Multiple trauma	(-)	(-)	(-)	(-)	(+)	(-)	(-)
7 Multiple trauma	(-)	(-)	(-)	(-)	(-)	(-)	(-)
8 Radical cystectomy with intestinal urinary reconstruction for bladder carcinoma	(+)	(+)	(+)	(-)	(+)	(+)	(+)
9 Tumor resection for malignant brain tumor	(+)	(+)	(+)	(-)	(+)	(+)	(+)
10 Non-herpes limbic encephalopathy (in ICU)	(-)	(-)	(+)	(+)	(+)	(-)	(-)
11 Post-CPR (in ICU)	(-)	(-)	(+)	(+)	(-)	(-)	(-)
[Maximum risk]							
12 Symptomatic epilepsy with past history of DVT	(-)	(-)	(-)	(-)	(-)	(-)	(-)

PTE indicates pulmonary thromboembolism; P/Op, postoperative; Malig., malignancy; IPC, intermittent pneumatic compression; ACT, anticoagulation therapy; HCC, hepatocellular carcinoma; SLE, systemic lupus erythematosus; SAH, subarachnoid hemorrhage; CPR, cardiopulmonary resuscitation; and DVT, deep vein thrombosis.

Figure 1. Photos of tIVCF.

A: Closed tip, B: Y-shaped connector, C: Opened tip (side view), D: Opened tip (view from the end).

Based on the ultrasonogram and enhanced CT findings, the DVT completely or almost completely disappeared during the period that the tIVCF was in place. Pre-explantation contrast cavography was performed with contrast media injected through the tIVCF, and the tIVCFs were successfully removed in 10 patients (83%) without any thrombus in the filter. No floating proximal DVT was found in patients in whom DVT had almost disappeared during the tIVCF placement. Of the remaining 2 patients, the tIVCF had to be removed in one because of a suspected catheter related-blood stream infection (CRBSI). In the remaining patient (#4 in Table), an enhanced CT scan performed 18 days after tIVCF placement indicated that the DVT had not changed at all, and a permanent IVCF was placed. The administration of warfarin and/or antiplatelet drugs was continued in all 12 patients (antiplatelet drugs such as aspirin were administered as a thromboprophylaxis because the Pulmonary Embolism Prevention Trial Collaborative Group reported that aspirin reduced the risk of pulmonary embolism and DVT,¹¹⁾ however, we no longer administer antiplatelet drugs as prophylaxis against DVT for any patient group based on the guidelines.)^{10,12)}

The mean of the maximum plasma levels of D-dimer during tIVCF placement was $31.6 \pm 12.5 \mu\text{g/mL}$; these levels significantly decreased before tIVCF removal ($6.3 \pm 0.6 \mu\text{g/mL}$, $P < 0.05$, Figure 3A). In addition, the mean of maximum FDP during tIVCF placement was $40.8 \pm 12.3 \mu\text{g/mL}$; these levels also

Figure 2. Roentgenogram of tIVCF placement. Dashed lines show an opened tIVCF.

Figure 3. Changes in plasma levels of D-dimer (A) and FDP (B). SD indicates standard deviation.

decreased significantly before tIVCF removal ($12.1 \pm 3.6 \mu\text{g/mL}$, $P < 0.05$, Figure 3B).

The mean length of ICU stay was 15 ± 11 days (range, 4 to 34), and all 12 patients were discharged to a normal hospital ward. Two patients experienced complications related to the placement of a tIVCF: infection at the insertion site in one, and suspected CRBSI in the other. These two complications were not life-threatening and improved following catheter removal and the administration of antibiotics. One patient who went into cardiopulmonary arrest due to an attempted suicide by hanging, and in whom CPR was performed, died from multiple organ failure 15 months after tIVCF removal. The remaining 11 patients were all discharged from our hospital.

DISCUSSION

The Seventh American College of Chest Physicians Conference on Anti-thrombotic and Thrombolytic Therapy¹²⁾ recommends that all patients should be assessed for their risk of VTE on admission to a critical care unit. The College also recommends the prophylactic use of LDUH or low molecular weight heparin (LMWH) for patients with moderate risk of VTE, the use of LMWH for patients at higher risk such as following major trauma or orthopedic surgery, and the use of mechanical prophylaxis with graduated compression stockings and/or intermittent pneumatic compression for patients at high risk of bleeding. Based on

these recommendations, we always provide thromboprophylaxis therapy for patients admitted to our ICU. ICU patients are at high risk of developing a DVT because, in addition to underlying diseases, they are often immobilized, and catheters such as a central venous catheter and/or blood access for renal replacement therapy are often inserted. Therefore, such patients require careful monitoring for the appearance of DVT.

The indication for tIVCF placement remains controversial. Neither the indication for, nor the efficacy of, permanent IVCF placement have been fully evaluated yet, and the indication for tIVCF placement has still not been established.¹³⁾ The principle regarding IVCF placement is the prevention of PTE during a prescribed period of IVCF placement.^{8,13)} In this study, it was possible to prevent the new occurrence of PTE in all patients by means of an inserted tIVCF. The disappearance or reduction of DVT was confirmed in 10 (83%) patients and in all 10 patients the tIVCF could therefore be removed. Contrast cavography was performed prior to the tIVCF removal to evaluate the thrombus in the filter because confirmation of the formation and the capture of a thrombus in the filter prior to IVCF removal is an essential inspection to prevent PTE occurrence during IVCF removal. Some investigators have reported the incidence of PTE during tIVCF placement as being between 0%^{14,15)} and ~ 4%.¹⁶⁾ Taking these reports and our results into consideration, tIVCF appears to have the ability to prevent PTE in patients with DVT.

In this study, only one patient (8%) required a permanent IVCF. The indication of the substitution from tIVCF to permanent IVCF has not been established yet. Bovyn and coworkers strongly suggested that a tIVCF be replaced by a permanent IVCF if the contraindication to anticoagulation treatment persisted beyond the safe implantation time.¹⁴⁾ On the other hand, Sugimoto, *et al* reported that the placement of a permanent IVCF required caution because the situation necessitating a permanent IVCF might be transient and the initial benefits of a permanent IVCF might be canceled out by long-term drawbacks such as filter migration, structural fracture, and/or IVC perforation.¹⁷⁾ In addition, special devices and/or techniques might be required to replace a tIVCF with a permanent IVCF because the positions of the thrombus and tIVCF influence the method of permanent IVCF placement.¹⁰⁾ Further study regarding this issue is needed.

The plasma levels of D-dimer are one of several useful indicators for DVT and are categorized as Class IIa (ie, they are very likely to be useful and effective based on reported data and opinions) in the Guidelines for Diagnosis, Treatment, and Prevention of Pulmonary Thromboembolism and Deep Vein Thrombosis established by the Japanese Circulation Society.¹⁰⁾ In this study, the levels of D-dimer prior to tIVCF removal were significantly lower compared with those dur-

ing tIVCF placement. An association between plasma levels of D-dimer and FDP has already been reported,¹⁸⁾ and a similar significant decrease was observed in FDP levels. These two parameters may become important to understand the magnitude of DVT.

Major complications associated with IVCF insertion are catheter-related infection, migration, fracture, and penetration of the catheter.¹⁹⁾ The complication which requires particular attention is thrombosis formation in the filter. Additional therapy for such a thrombus may be required, such as anticoagulation medication and/or aspiration of the thrombus or additional IVCF placement.⁹⁾ In addition, placement of less than 2 weeks is generally recommended for a tIVCF filter, and a Toray Neuhaus Protect catheter, which was used as a tIVCF in this study, should also be removed within 2 weeks.¹⁰⁾ The risk of adhesion of a tIVCF to the IVC wall and/or infection related to a tIVCF increases if the duration of tIVCF placement is prolonged. In this study, two complications arose: infection at the insertion site (18 days after tIVDF insertion) and a suspected catheter-related blood stream infection (9 days after tIVDF insertion). There were 6 patients in whom tIVCFs were in place for more than 2 weeks. There was only one patient with infection at the insertion site and adhesion of the tIVCF to the IVC wall was not observed in any cases. Both complications were improved with filter removal and/or administration of antibiotics. There were no other life-threatening complications.

The systemic administration of LDUH through the tIVCF was continued after the tIVCF had been placed, and no in-filter thrombosis formation was found in our 12 ICU patients. However, the administration of LDUH through the tIVCF is basically the same as ordinary intravenous administration, and it might be possible that tIVCF was not necessary for those patients. Our indication for tIVCF placement is still not sufficient, and reconsideration of our indication for tIVCF placement might be necessary.

The observation and management of ICU patients with tIVCF placement should be strictly enforced, with monitoring, such as electrocardiograms and continuous blood pressure measurements, in order to prevent complications of tIVCF. In addition, the magnitude of DVT should be evaluated using ultrasonography and/or enhanced CT during tIVCF placement with the intention of early tIVCF removal if necessary. The number of patients in our study is limited. Further studies are required to evaluate the indication and usefulness of tIVCF placement.

In conclusion, tIVCF placement could prevent a new episode of PTE without life-threatening complications. Our results showed that tIVCF has the potential to be useful in the prevention of PTE in patients with DVT.

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