Introducer Curving Technique for the Prevention of Tilting of Transfemoral Günther Tulip Inferior Vena Cava Filter

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**Objective:** To determine whether the introducer curving technique is useful in decreasing the degree of tilting of transfemoral Tulip filters.

**Materials and Methods:** The study sample group consisted of 108 patients with deep vein thrombosis who were enrolled and planned to undergo thrombolysis, and who accepted transfemoral Tulip filter insertion procedure. The patients were randomly divided into Group C and Group T. The introducer curving technique was adopted in Group T. The post-implantation filter tilting angle (ACF) was measured in an anteroposterior projection. The retrieval hook adhering to the vascular wall was measured via tangential cavogram during retrieval.

**Results:** The overall average ACF was 5.8 ± 4.14 degrees. In Group C, the average ACF was 7.1 ± 4.52 degrees. In Group T, the average ACF was 4.4 ± 3.20 degrees. The groups displayed a statistically significant difference (t = 3.573, \(p = 0.001\)) in ACF. Additionally, the difference of ACF between the left and right approaches turned out to be statistically significant (7.1 ± 4.59 vs. 5.1 ± 3.82, t = 2.301, \(p = 0.023\)). The proportion of severe tilt (ACF ≥ 10º) in Group T was significantly lower than that in Group C (9.3% vs. 24.1%, \(\chi^2 = 4.267, p = 0.039\)). Between the groups, the difference in the rate of the retrieval hook adhering to the vascular wall was also statistically significant (2.9% vs. 24.2%, \(\chi^2 = 5.030, p = 0.025\)).

**Conclusion:** The introducer curving technique appears to minimize the incidence and extent of transfemoral Tulip filter tilting.

**Index terms:** Tilt; Prevention; Günther Tulip filter, caval; Transfemoral; Randomized

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**INTRODUCTION**

Pulmonary embolism (PE) is a potentially fatal disease that occurs in 1 out of 1000 up to 1 out of 100 in the elderly (1). Previous research has demonstrated that implantation of inferior vena cava filter is a safe and effective method to prevent or reduce fatal pulmonary thromboembolism (2-5). However, there are risks associated with long-term implantation of these filters, including inferior vena cava (IVC) occlusion, thrombosis, and recurrence of deep venous thrombosis (6-8). The possibility of higher recurrence of deep venous thrombosis (DVT) after eight years and lack of a difference in long-term mortality have brought the benefits of permanent filters into question.
Retrievable filters are designed to be removed within a short period, but may also remain in place permanently. The Günther Tulip filter (GTF) (Vena Cava MReye Filter Set; William Cook Europe, Bjaeverskov, Denmark) is one type retrievable filter, used in the United States since 2001. The GTF is designed for either jugular or femoral implantation. Retrieval is achieved by a superior approach, usually through the right internal jugular vein. When acute DVT requires transcatheter thrombolysis, transfemoral GTF implantation may avoid the requirement to lay a catheter across the GTF. (ED: The meaning of this sentence was unclear. Please ensure that this edited form expresses the point intended.) Although incidence of significant filter tilting (>10°) is not high (13-16%) (9, 10), severe tilting of the GTF may be associated with difficulty or sometimes impossibility of retrieval (10-12).

A previous vitro study has shown that a simple technique of keeping tension of the delivery system may prevent significant tilting of the transjugular GTF (13). However, no clinical study has been conducted on the prevention of the transfemoral GTF from tilting. The purpose of this study is to determine whether the introducer curving technique is useful to decrease the extent of transfemoral GTF tilting.

MATERIALS AND METHODS

Participants
In total, 108 patients of interest to this study (52 male, 56 female, average age 51.23 years) with deep vein thrombosis and planned transcatheter thrombolysis were enrolled in the hospital in question between Sep 2008 and Sep 2010. Participants were consistently referred patients, aged 18-80 years, with acute lower extremity deep vein thrombosis, diagnosed by vascular ultrasound and clinical history. Patients presenting the following were excluded from this study: both lower extremities DVT, IVC thrombosis, refractory hypertension (BP larger than 180/110 mm Hg), contraindication of thrombolysis, a diameter of IVC larger than 35 mm or less than 14 mm, and IVC venous anomalies. In all cases, the IVC filters were routinely implanted prior to transcatheter thrombolysis. Patients were generally selected to receive a GTF based on anticipation of possible filter retrieval. The indication of GTF retrieval included: an implantation period less than 90 days, no free thrombus in iliac-femoral veins, and no captured thrombus or captured thrombus of less than 10 mm in GTF. After a complete description of the study to the patients, written informed consent was obtained in accordance with National Health and Medical Research Council guidelines. The study was approved by the Hospital Ethics Committee.

Study Design
This study was carried out using a double-blind randomized design. The patients were randomly divided into two groups, Group C (straight introducer GTF and transcatheter thrombolysis) and Group T (curved introducer GTF [Fig. 1A] and transcatheter thrombolysis). A random number table was used to select the random sample. This random number table was also entered in a pseudo-random manner. A random number was given to each patient, if the number was even, then the patient was assigned to Group T, while odd numbers were assigned to Group C. The manual introducer curving technique was adapted in Group T. The angle-measure tool of the picture archiving and communication system (PACS) workstation was used

Fig. 1. Photo and line art of curved Günther Tulip filter introducer with filter.
A. Photo. B. Line art.
Introducer Curving Technique in Transfemoral Günther Tulip IVC Filter Insertion

to measure the angle of tilt. The angle ($A_{CI}$) between IVC and the approached iliac vein axis and the distance ($D_{RF}$) between the level of the lower renal vein confluence and the furcation of IVC was measured according to the anteroposterior cavogram. The size of the angle ($A_{CW}$) between the metal introducer proximal end and the distal end following application of the introducer curving technique was seen to be 5-15° less than $A_{CI}$. Additionally, the distance ($D_{TH}$) between the tip of curved angle and the apical retrieval hook of the filter was 2-4 cm less than $D_{RF}$ (Fig. 1B). The direction of bending in the distal end of the curved introducer wire is the same as the direction in which the fixed end of the retrieval hook points toward the free end of the retrieval hook. After being curved, the proximal and distal ends of the curved introducer wire, as well as the fixed and free ends of the retrieval hook should be located on the same plane (Fig. 1A).

Filter Placement

All procedures were performed by the same experienced interventional radiologist using the following method. A pig-tail catheter was placed into the iliac vein via the femoral vein approach. An anteroposterior cavogram was performed to document the diameter of IVC ($D_{IVC}$), $D_{RF}$, $A_{CI}$, and the position of the lower renal vein confluence. This was done to ensure that no venous anomalies existed, and to make sure that the IVC was free of thrombus. Next, an 8.5 Fr sheath was inserted into the IVC. The GTF was placed into the sheath and moved forward until the apical retrieval hook of the filter reached the level of the lower renal vein confluence. The sheath was slowly withdrawn, allowing the metal mount to enter the lumen. The red hub was loosened and pulled forwards to release filter. In Group T, the metal introducer was curved according to above-mentioned methods (Fig. 2B) following an anteroposterior cavogram performed to document $D_{RF}$, $A_{CI}$ (Fig. 2A). An 8.5 Fr sheath was then inserted into the IVC (Fig. 2C). The GTF was placed into the sheath and moved forward until entering the IVC. The curved introducer was rotated and the orientation of the superior segment of the introducer was adjusted to lie parallel with the longitudinal axis of IVC (Fig. 2D). The GTF was then released (Fig. 2E). Due to the curved introducer, Group T displays higher levels of resistance to the GTF entering the IVC through the sheath and of the GTF being released than does Group C.

Filter Retrieval

A pig-tail catheter was placed into IVC under filter using the jugular vein approach. An anteroposterior cavogram was performed to ensure the tilt angle of the GTF and the relationship between the apical retrieval hook and the IVC wall, as well as to ensure that the filter was free of

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Fig. 2. Procedural step of introducer curving technique.

A. Anteroposterior cavogram is performed to document angle ($A_{CI}$) between inferior vena cava (IVC) and approached iliac vein axis and distance (DRF) between level of lower renal vein confluence and furcation of IVC. B. Metal introducer is curved via introducer curving technique. C. 8.5 Fr sheath is inserted into IVC and filter is placed into sheath and transported into IVC. D. Curved introducer is rotated and orientation of superior segment of introducer is adjusted to parallel with longitude axis of IVC. E. Red hub is loosened and pulled forwards to release filter.
thrombus or captured thrombus less than 10 mm. A 12 Fr sheath was then inserted into the IVC near the filter. The snare was passed through the sheath. The retrieval hook of the filter was engaged with the snare, the snare was closed, and the filter was sheathed. If repeated attempts did not engage the retrieval hook, including operations under valesalva motion, a tangential cavogram was be used to ensure that the retrieval hook adhered to the IVC wall. Next, both catheter twist and loop snare techniques (14) were used to separate the adhered tissue between the retrieval hook and the IVC wall. Upon disengaging the retrieval hook from the IVC wall, it was engaged by the snare, and the filter was sheathed.

**Variables Measurement**

The angle-measure tool of picture archiving and communication system (PACS) workstation was used to measure filter tilt. In order to reduce the dose of the contrast agent, re-examination of the cavogram was not performed directly after GTF implantation. Tilting angle ($A_{CF}$) was measured indirectly in this study. A line was drawn on the anteroposterior cavogram from the midpoint of the IVC at the level of the lower renal vein confluence to the midpoint of the IVC at the level of 4 cm caudal to the lower renal vein confluence, and this line (A Line) represented the IVC axis. After implantation, another line was drawn from the origin of the hook-eye to the midpoint between the extreme right and left anchors on the anteroposterior fluoroscopic picture, and this line (C Line) represented the axis of the GTF. The two angles ($A_1$ and $A_2$) between both lines (A and C Line) and the line (B Line) between the spinous processes of L₁ and L₄ were measured respectively (Fig. 3), and the difference between $A_1$ and $A_2$ was $A_{CF}$ (between the axis of the IVC and the filter).

The implantation period of GTF and the rate of adherence of the retrieval hook to the vascular wall were also measured.

Measurement was not carried out by the same doctor that implanted the filter. The doctors who performed angle measurement were blind to the patients’ treatment assignment. One doctor performed angle measurement of $A_1$ in all cases; the other doctor performed angle measurement of $A_2$ in all cases. The images and measurement results were not shared between these two doctors.

**Assessments**

Baseline assessments carried out for this study include demographics, venous approach, anatomical character including $A_{CI}$, $D_{IVC}$, and retrieval rate.

The primary measurement outcome was identification of $A_{CF}$. The secondary aim of measurement was to assess the rate at which the apical retrieval hook adhered to the vascular wall.

**Statistical Analysis**

All analyses were conducted via the Statistical Package for Social Sciences, version 11.5 (SPSS Inc., Chicago, IL, USA). Continuous variables were described using summary statistics such as means and standard deviations. Categorical variables were described using frequencies and percentages. In order to evaluate between-group differences in baseline characteristics and $A_{CF}$, the rate of the apical retrieval hook adhering to the vascular wall, and the success rate of retrieval operations, student’s t test and chi-square analyses with continuity correction were used as appropriate. The Mann-Whitney test was used to evaluate between-group differences in the median fluoroscopy time of retrieval operations. The difference is considered statistically significant by this study if a p value is less than 0.05.
RESULTS

A total number of 108 GTFs were placed in 108 patients. The baseline characteristics of patients in both groups are seen to be similar (Table 1). Filter placement can be considered successful in all cases as no filter displacement occurred. Filter retrieval was attempted in 68 patients, with 67 attempts being successful. In the unsuccessful case, the filter adhered tightly to the vascular wall. After snaring the retrieval hook and partly sheathing the filter cone, the retrieval hook was disrupted while retracting the snare to the sheath and thus the retrieval was abandoned. The average time interval between placement and retrieval is calculated as 43.75 days. Of the 108 patients, 54 were assigned to adopt a straight introducer and 54 were assigned to adopt a curved introducer (A_CW, 17.3 ± 6.58° and distance between tip of curved angle and apical retrieval hook of filter: 97.2 ± 21.1 mm). The overall average of A_CF is seen as 5.75 ± 4.14 degrees (0.2-20 degrees). Severe filter tilt (≥ 10 degrees) is identified in 18/108 patients. The filters were implanted either through left femoral vein (32 patients), or the right femoral vein (76 patients).

The average A_CF of the left femoral vein approach is calculated as 7.11 ± 4.59 degrees, while the average A_CF of the right femoral vein approach is 5.14 ± 3.82 degrees. A statistically significant difference is thus identified between the A_CF of the left and right approaches (t = 2.301, p = 0.023) (Table 2).

Without the help of the introducer curving technique, the average A_CF is seen to be 7.12 ± 4.52 degrees (0.2-20 degrees), and severe filter tilt is seen in 24.1% of patients (13/54) (Tables 2, 3). Application of the introducer curving technique changes the average A_CF to 4.39 ± 3.20 degrees (0.3-11.4 degrees) and reduces severe filter tilt occurrence to 9.3% of patients (5/54) (Tables 2, 3). Hence, application of the introducer curving technique is seen to result in a statistically significant difference (t = 3.573, p = 0.001) in A_CF (Table 2). In Group T, the proportion of severe tilt at the filter apex can be seen to be significantly lower than in Group C (χ² = 4.267, p = 0.039) (Table 3). The difference in the proportion of severe tilt between the left and right approach is thus statistically significant (χ² = 4.299, p = 0.038) (Table 3).

In Group C, the rate at which the apical retrieval hook adhered to the vascular wall is measured as 24.2% (8/33) (Table 4). In Group T, this rate is markedly lower, being calculated as 2.9% (1/35) (Table 4). The difference in the rate the retrieval hook adhering to the vascular wall is thus statistically significant between the two groups (χ² = 5.030, p = 0.025) (Table 4). Interestingly, no statistically significant difference is seen in the rate at which the apical

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Table 1. Baseline Demographic and Clinical Characteristics among 108 Participants

| Characteristic           | Group C (n = 54)     | Group T (n = 54)     | P Value  |
|--------------------------|----------------------|----------------------|----------|
| Age (yr)                 | 51.59 ± 16.33        | 50.87 ± 16.94        | 0.821    |
| A_CI (°)                 | 23.37 ± 10.78        | 26.86 ± 10.14        | 0.090    |
| D_IVC (mm)               | 21.71 ± 3.02         | 21.80 ± 3.11         | 0.880    |
| Male sex                 | 24 (44.4%)           | 28 (51.9%)           | 0.497    |
| Left approach            | 14 (25.9%)           | 18 (33.3%)           | 0.435    |
| Retrieval rate           | 32 (59.3%)           | 35 (64.8%)           | 0.635    |

Note.— A_CI = angle between inferior vena cava (IVC) axis and approached iliac vein axis, D_IVC = diameter of IVC

Table 2. Angle of GTF Tilting in Two Groups and Different Approaches

|                  | n      | A_CF (°) | t Value | P Value  |
|------------------|--------|----------|---------|----------|
| Group C          | 54     | 7.12 ± 4.52 | 3.573  | 0.001    |
| Group T          | 54     | 4.39 ± 3.20 | 2.301  | 0.023    |
| Left approach    | 32     | 7.11 ± 4.59 | 2.301  | 0.023    |
| Right approach   | 76     | 5.14 ± 3.82 |        |          |

Note.— A_CF = tilting angle between axes of inferior vena cava and GTF after implantation, GTF = Günther Tulip filter
retrieval hook adheres to the vascular wall between the left and right approaches ($\chi^2 = 1.776, p = 0.183$) (Table 4). The success rates of retrieval in Groups C and T are identified as 97.0% (32/33) and 100% (35/35), respectively. No statistical significance is identified in the difference in the success rates of retrieval between the groups ($\chi^2 = 1.076, p = 0.299$). The median fluoroscopy times of retrieval are seen as 3.5 minutes (14.76 ± 25.70) and 3.0 minutes (3.49 ± 4.42) in Group C and Group T, respectively. The difference in the median fluoroscopy time of retrieval operation between the groups is considered statistically significant (Z = -2.365, $p = 0.018$) (Table 5).

**DISCUSSION**

As with other conical shaped IVC filters, the GTF is susceptible to a flaw known as tilt, a form of malposition whereby the cylindrical axis of the filter does not lie parallel to the longitudinal axis of the local cava. The reported frequency of tilt ranges from 0% to 56%, depending on the definition of tilt and the filter used (15). Tilting of the GTF may be associated with difficulty or, occasionally, impossibility of retrieval (16). In cases of severe GTF tilt, the apex may be touching the caval wall and prevent the snare from engaging with the apical retrieval hook, or the fibrotic tissue and/or endothelialization may firmly adhere the filter retrieval hook to the caval wall and prevent removal (17). Therefore, it is important to prevent significant filter tilting to facilitate future retrieval.

A number of clinical studies have been carried out with regard of GTF tilting. Wicky et al. (10) report that, in their study, 84% of GTFs exhibited a tilt of up to 9° and 16% of GTFs had at least a 10° tilt on posterior-anterior (PA) cavograms at retrieval. Terhaar et al. (18) performed PA cavography and found greater than 10° tilt in 13% of GTFs, with an overall average tilt of 5.9° and 60% rightward predominance. Sag et al. (19) performed PA cavography and found greater than 14° tilt in 15% of GTFs through the jugular approach, with an average tilt of 7.1° and 55% rightward predominance. In the present study, Group C exhibits greater than 10° tilt in 24.1% (13/54) of GTFs through the femoral approach, with an average tilt of 7.12°, while Group T displays greater than 10° tilt in 9.3% (5/54) of GTFs through femoral approach, with an average tilt of 4.39°. Without the help of introducer curving technique, incidence of tilting is thus higher than that in the results of previous studies. However, it can be seen that with the help of this technique, incidence of tilting is lower than that of other studies.

In the present study, the proportion of the filter apex

Table 3. Degree of GTF Tilting in Two Groups and Different Approaches

| Group       | Severe Tilt ($A_{LT} \geq 10^0$) | Tiny Tilt ($A_{LT} < 10^0$) | Continuity Correction $\chi^2$ Value | $P$ Value |
|-------------|----------------------------------|----------------------------|-------------------------------------|-----------|
| Group C     | 13 (24.1%)                       | 41 (75.9%)                 | 4.267                               | 0.039     |
| Group T     | 5 (9.3%)                         | 49 (90.7%)                 |                                     |           |
| Left approach | 9 (28.1%)                     | 23 (71.9%)                 | 4.299                               | 0.038     |
| Right approach | 9 (11.8%)                     | 67 (88.2%)                 |                                     |           |

Note.— $A_{LT}$ = tilting angle between axes of inferior vena cava and GTF after implantation, GTF = Günther Tulip filter

Table 4. Rate of Retrieval Hooks Adhering to Vascular Wall in Two Groups and Different Approaches

| Group       | Adhering Hook | No Adhering Hook | Continuity Correction $\chi^2$ Value | $P$ Value |
|-------------|---------------|-----------------|-------------------------------------|-----------|
| Group C     | 8 (24.2%)     | 25 (75.8%)      | 5.030                               | 0.025     |
| Group T     | 1 (2.9%)      | 34 (97.1%)      |                                     |           |
| Left approach | 5 (23.8%)     | 16 (76.2%)      | 1.776                               | 0.183     |
| Right approach | 4 (8.5%)      | 43 (91.5%)      |                                     |           |

Table 5. Median Fluoroscopy Times of Filter Retrieval Operation in Two Groups

| Group       | Median Fluoroscopy Time of Retrieval Operation | Z Value | $P$ Value |
|-------------|-----------------------------------------------|---------|-----------|
| Group C     | 3.5 mins                                      | -2.365  | 0.018     |
| Group T     | 3.0 mins                                      |         |           |
exhibiting a tiny tilt (ACF < 10°) in Group T is significantly higher than that in Group C (90.7% vs. 75.9%). At same time, the proportion of the filter apex showing severe tilt (ACF ≥ 10°) is significantly lower than that of Group C (9.3% vs. 24.1%). Although the success rates of retrieval are not significantly different between the groups, the median fluoroscopy time of retrieval operation in Group T is remarkably shorter than that in Group C.

The angle and direction of the GTF introducer depends on the vascular approach and anatomic tortuosity. Due to IVC being located right of the body’s central axis, the angle between the IVC and the left iliac vein axis is generally larger than the angle between the IVC and the right iliac vein axis. In most cases, when the GTF is implanted through the right femoral vein, the tilting degrees of the introducer can be expected to be smaller and the introducer would lean to the left; the tilting angle of the GTF would thus be smaller. When the GTF is implanted through the left femoral vein, the tilting degree of the introducer is generally larger and the introducer leans to the right, meaning that the tilting angle of the GTF is larger. In this study, the average ACF through the left femoral vein approach is seen to be significant larger than that through right femoral vein approach (7.11° vs. 5.14°). At same time, the difference in the proportion of severe tilt between the left and right approaches is statistically significant (28.1% vs. 11.8%). However, no statistical significance is seen in the difference in the rate at which the apical retrieval hook adheres to the wall between left and right approach (23.8% vs. 8.5%). One possible reason for this result is an insufficient retrieval sample size.

The introducer curving technique involves changing the oblique introducer axis to be parallel with the IVC axis and thus minimize the incidence and extent of filter tilting. The clinical significance of the introducer curving technique should be carefully researched due to the complicated influence factors involved. The major influence factors include the curved angle of the introducer (ACw), direction of introducer curvature, location where the introducer is curved, and the method of releasing the curved introducer.

At first, the angle of introducer wire curvature (ACw) is the most important factor to adjust ACf and is decided by the angle (ACf) between the IVC and the approached iliac vein axis. After the straight GTF introducer enters the IVC,
the $A_3$ should slightly decrease. The extent of this decrease is decided by the approached vascular tortuosity and is unpredictable. In the present study, $A_{10}$ is seen to be 5-15° less than $A_1$.

Secondly, under two-dimensional fluoroscopic monitoring the exact spatial location and direction of the curved introducer is difficult to identify; it is necessary to use the filter retrieval hook as a reference to judge direction. Insufficient curvature of the introducer may cause filter tilting towards the opposite side and result in the filter retrieval hook adhering to the IVC wall, which obstructs the filter from being retrieved. As such, the direction of introducer curvature should be parallel to the direction of the filter retrieval hook (Fig. 1). In this way, it is ensured that the opening direction of apical retrieval hook is toward the IVC lumen and the retrieval hook is easy to retrieve, even if the filter tilts towards the opposite side and the apical retrieval hook adheres to the IVC wall.

Thirdly, the distance ($D_{in}$) between the caval center and the retrieval hook decides the initial location of the GTF before being released and influences the degree of filter tilting. Selecting suitable location where the introducer is curved is a unique method that may adjust the distance ($D_{in}$) between the caval center and the retrieval hook after a suitable ACW had been decided upon. If the distance ($D_{in}$) between the tip of the curved angle and the apical retrieval hook is 2-4 cm less than the distance ($D_{in}$) between the level of the lower renal vein confluence and the furcation of IVC, the retrieval hook reaches the level of the renal vein just when the superior segment of the introducer is situated at the IVC center (Fig. 4A). If $D_{in}$ is too short, the retrieval hook does not reach the level of the renal vein when the superior segment of the introducer reaches the IVC center. The introducer is then sequentially pushed forward. When retrieval hook reaches the level of the renal vein, the superior segment of introducer must be situated near opposite wall of the IVC (Fig. 4B). If $D_{in}$ is too long, the apex of the angle is still in 8.5 Fr sheath or iliac vein when the retrieval hook reaches the level of the renal vein and the curved angle is thus unable to efficaciously adjust the orientation of superior segment of the introducer (Fig. 4C).

Only if the above-mentioned factors are adequately resolved can the introducer curving technique efficaciously minimize the incidence and extent of GTF tilting.

Using the longitudinal axis of the screen as a reference to measure $A_{fi}$ in Seo et al. (20), the final result contains error due to the movement of the patient. In this study, the measurement error of $A_{fi}$ due to movement of the patient is eliminated by using the line between the spinous processes of $L_1$ and $L_3$ as a reference.

The present study examines the efficacy of the introducer curving technique for preventing GTF tilt. However, the results can be expected to be more significant after overcoming the following limitations. At first, in order to perform angular and linear measurements, a radiographically adequate IVC venogram is required. However, it was not possible to re-examine the cavograms of most study patients just after GTF implantation, and thus $A_{fi}$ is measured indirectly in this study. Secondly, it is noted that tilt of GTF is a three-dimensional behavior. However, the current study demonstrates this with two-dimensional imaging. Further study into tilt of GTF making use of an abdominal CT would enable further elucidation of the frequency, causes, and sequelae of this filter concern.

Conclusion

The introducer curving technique of GTF is seen to minimize the incidence and extent of transfemoral GTF filter tilting in vivo.

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Introducer Curving Technique in Transfemoral Günther Tulip IVC Filter Insertion

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