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DUPLEX GUIDED VERSUS CONTRAST VENOGRAPHY FOR LANDING OF INFERIOR VENA CAVA FILTER (COMPARATIVE STUDY)

By

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ABSTRACT

Background: Vena cava filters are an important alternative when anticoagulation is contraindicated. Techniques for placement of inferior vena cava (IVC) filters have undergone continued evolution from open surgical exposure of the venous insertion site to percutaneous insertion in most cases .Today, all of the commonly used filters can be placed via a peripheral vein by using percutaneous puncture. Increased experience with color flow duplex scanning for routine IVC imaging and portability of ultrasound equipment have suggested the usefulness of duplex-guided IVC filter insertion (DGFI).

Objective: Comparing bedside trans-abdominal duplex ultrasound versus contrast venography for inferior vena cava filter placement as regard to safety, efficacy , results and possible complications.

Patients and Methods: This was a comparative study which included 30 patients divided into two groups: Group A which contained 15 patients by which filter placement was done by contrast venography in Al-Hussein Hospital, and Group B which contained 15 patients by which filter placement was done by duplex ultrasound in Al- Zahraa Hospital. History, complete examination and investigations were done to all the patients.

Results: There was a difference between both groups according to the age, gender, pulmonary embolism attack , indications for IVC filter deployment and the venous access aproach but insignificant, All filters were permenant and most common indication was recurrent tromboembolism insbite of adequate anticoagulation. Two patients in Group A suffered from hematoma and echymosis at access site, and filter deployment failed for the first time in two patients of Group B, but succeeded for the second time with no mortality detected.

Conclusion: Inferior vena cava filter insertion was safe and effective in preventing pulmonary embolism. Fluroscopy has traditionally been the golden standard procedure for IVC filter deployment. Duplex guidance can replace fluoroscopy to guide the procedure in patients whose conditions can not tolerate the contrast material or exposure to X-ray. The current study suggested that duplex guided filter insertion was safe, reliable, and accurate as the fluoroscopy guided procedure. Duplex guided method has proved to be cost effective as it can be done as a bedside procedure. Obesity constituted the major technical limitation of duplex guided procedure.

Key words: Duplex, Venography, Inferior vena cava..

INTRODUCTION

Deep venous thrombosis (DVT) and pulmonary embolism (PE) together called venous thromboembolism (VTE) remain a serious health care problem **(Bates et al., 2012).**

Approximately, 300,000 individuals die of PE every year and deaths from PE are 5 times more common than deaths from breast cancer, motor vehicle accidents, and AIDS combined. Venous thromboembolism is the third most common vascular disease after heart disease and stroke **(Geersing et al., 2014).**

Reported immediate complication rates for percutaneous filter insertion (and retrieval) are consistently low (in the region of l %) **(Andreoli et al., 2014).**

Indications for IVC filter insertion have been divided into absolute, relative, and prophylactic. For some indications, such as PE or deep venous thrombosis (DVT), with a clear contraindication to anticoagulation. The balance of risks and benefits and the absence of alternative treatment possibilities mean that the decision to place a filter is logic, despite the lack of good quality evidence. For other indications (such as prophylactic placement in trauma patients without PE or DVT), the risk: benefit ratio and possibility of alternative treatments, coupled with the lack of high quality evidence means that the decision to place a filter is less easy and can only be based on a balance of multidisciplinary opinion. There is an evidence from USA of increasing rates of IVC filter insertion over the last two decades, despite relatively stable rates of thromboembolic disease **(Kaufman et al., 2009).**

The development of smaller introduc-tion systems and filters, which are potentially retrievable, has occurred contemporaneously with this increase. It is likely that the ease of insertion of percutaneous devices has reduced the perception of risk, driving increasing rates of filter insertion and a broadening of the categories of patients for whom a caval filter is considered **(Karmy-Jones et al., 2007).**

Contrast venography is considered the gold standard for imaging prior to inferior vena cava (IVC) filter insertion, bedside placement via trans-abdominal duplex ultrasound (DUS) has been recognized as a safe and effective alternative, there has been no direct comparison of the efficacy of both imaging modalities for IVC filter placement **(Kwame et al., 2009).**

Vena caval interruption can be safely performed under ultrasound guidance in a monitored, ICU environment. In selected multiply injured trauma patients, this will reduce the risk, complexity and cost of transport for these critically ill patients. Duplex guided filter insertion (DGFI) also reduces procedural costs compared with an operating room or interventional suite, and eliminates intravenous contrast exposure. Preprocedural scanning is essential to identify patients suitable for DGFI, and careful attention must be paid to the known ultrasonographic anatomical landmarks **(Kwame et al., 2009).**

PATIENTS AND METHODS

This prospective randomized study was performed in Al-Azhar University Hospitals (**Al -Hussein** and **AL- Zahraa** University Hospitals) during two years from May 2015 till April 2017.

Thirty patients who were candidates for inferior vena cava filter placement were randomly subdivided into two groups:

- **Group A:** Including **15 patients for whom Contrast guided IVC filter placement was performed**
- **Group B:** Including **15 patients for whom duplex guided IVC filter placement was performed.**

Inclusion criteria:

1. Patients with DVT in whom antico-agulants were contraindicated.
2. Patients with DVT in whom antico-agulants caused complications that require discontinuation of antico-agulant therapy,
3. Patients with recurrent thromboembo-lism despite adequate anticoagulation.
4. Patients with high risk of pulmonary embolism who underwent a major surgical procedure and intervention.
5. Patients with propagating thrombus and tailing despite adequate anti-coagulants.

Patients were subjected to:

- Full history taking.

- Clinical examination for:

● Venous thrombosis.

● Manifestations of Pulmonary embolism.

Investigations included:

(1) Laboratory investigations:

a) Complete blood picture.

b) Liver function tests.

c) Prothrombin time and concentration.

d) Renal function tests.

(2) Radiolological investigations:

a) Plain chest X ray

b) Duplex examination of the lower limb veins, iliac veins and IVC.

c) Lung scan or pulmonary angiography or Multislice pulmonary CT may be needed in some patients.

(3) Other investigations:

E .C.G.

Patients were followed up after IVC filter insertion by:

- Clinical evaluation.

- Plain abdominal X-ray.

- Duplex on IVC.

Follow up was done:

- Early post intervention within 24 hrs
- Every 3 months for the first year.
- Every 6 months for the second year.

Statistical analysis:

Data were analyzed using Statistical Program for Social Science (SPSS) version 20.0. Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

Chi-square (X^2) test of significance was used in order to compare proportions between two qualitative parameters.

P-value ≤ 0.05 was considered signifi-cant.

RESULTS

There was a difference between groups according to age (years) but non-significant **(Table 1).**

Table (1): Comparison between groups according to age group.

Age Groups	Group A		Group B		Chi-square	
	No.	%	No.	%	x^2	p-value
21 – 30 years	3	20%	3	20%	2.000	0.572
31 – 40 years	3	20%	6	40%		
41 – 50 years	6	40%	3	20%		
51 – 60 years	3	20%	3	20%		
Total	15	100%	15	100%		
Mean±SD	41.41±6.15		39.39±5.85			

There was no statistically significant difference between groups according to gender **(Table 2).**

Table (2): Comparison between groups according to gender.

Gender	Group A		Group B		Chi-square	
	No.	%	No.	%	x^2	p-value
Males	6	40%	6	40%	0.000	1.000
Females	9	60%	9	60%		
Total	15	100%	15	100%		

No statistically significant difference between groups according to DVT **(Table 3).**

Table (3): Comparison between groups according to DVT.

DVT	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
First Attack	12	80%	12	80%	0.000	1.000
Previous attack	3	20%	3	20%		
Total	15	100%	15	100%		

There was a difference between groups according to pulmonary embolism, but non-significant **(Table 4).**

Table (4): Comparison between groups according to pulmonary embolism.

Pulmonary Embolism	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
First Attack	9	60%	12	80%	1.429	0.232
Previous attack	6	40%	3	20%		
Total	15	100%	15	100%		

Recurrent thromboembolism despite adequate anticoagulation represents the majority of the clinical presentation (24 patients in both group 80%). PE was suspected on clinical grounds in 24 patients and multislice pulmonary CT was done. Proximal DVT is the commonest level of thrombosis (18 patients in both group, 80%) as shown in table 5.

No statistically significant difference between groups according to level of thrombosis **(Table 5).**

Table (5): Comparison between groups according to level of thrombosis.

Level	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
Calf only	3	20%	3	20%	1.600	0.449
Proximal without calf	3	20%	6	40%		
Proximal with calf	9	60%	6	40%		
Total	15	100%	15	100%		

There is a difference between groups according to indications for IVC filter deployment but non-significant **(Table 6).**

Table (6): Comparison between groups according to indications for IVC filter deployment.

Indication for IVC filter deployment	Group A		Group A		Chi-square test	
	No.	%	No.	%	x^2	p-value
DVT in whom anticoagulant are contraindicated	2	13.3%	1	6.7%	0.667	0.717
DVT in whom anticoagulant cause complications	1	6.7%	2	13.3%		
Recurrent thromboembolism despite adequate anticoagulation	12	80%	12	80%		
Total	15	100%	15	100%		

No statistically significant difference between groups according to kinds of filters used **(Table 7).**

Table (7): Comparison between groups according to kinds of filters used.

Kinds of filters used	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
Nitinol trape-ease	9	60%	9	60%	0.000	1.000
Vena-tec	3	20%	3	20%		
Titanium Greenfield	3	20%	3	20%		
Total	15	100%	15	100%		

Chi-square test can't be calculated because all data of one parameter are permanent filter side **(Table 8).**

Table (8): Comparison between groups according to type of used filters.

Types	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
Permanent	15	100%	15	100%	0.000	1.000
Temporary	0	0	0	0		
Total	15	100%	15	100%		

In most of cases in both groups the route was right trans-femoral except in cases of complete occlusion of right femoral it was done through the left femoral vein puncture (table9)

There is a difference between groups according to route, but non-significant **(Table 9).**

Table (9): Comparison between groups according to used venous access approach.

Route	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
RT Trans-femoral	9	60%	12	80%	**1.429**	**0.232**
LT Trans-femoral	6	40%	3	20%		
Trans-jugular	0	0%	0	0%		
Total	15	100%	15	100%		

Chi-square test can't be calculated because all data of one parameter are normal IVC filter position side **(Table 10).**

Table (10): Comparison between groups according to plain abdominal x-ray after IVC filter deployment.

Plain Abdominal X ray	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p
Normal IVC filter position	15	100%	15	100%	**0.000**	**1.000**
Migrated IVC filter	0	0	0	0		
Total	15	100%	15	100%		

Chi-square test can't be calculated because all data of one parameter are patent IVC filter side **(Table 11).**

Table (11): Comparison between groups according to duplex scan after IVC filter deployment.

Abdominal duplex scan	Group A		Group A		Chi-square test	
	No.	%	No.	%	x^2	p-value
Patent IVC filter	15	100%	15	100%	0.000	1.000
Thrombosed IVC filter	0	0	0	0		
Total	15	100%	15	100%		

Chi-square test can't be calculated because all data of one parameter are No PE side **(Table 12).**

Table (12): Comparison between groups according to clinical results.

Clinical results	Group A		Group B		Chi-square test	
	No.	%	No.	%	x^2	p-value
No PE	15	100%	15	100%	**0.000**	**1.000**
PE	0	0	0	0		
Total	15	100%	15	100%		

Access site complications was shown in two patients of Group A as ecchymosis in one case which relieved after 10 days of hot fomentaions and topical anti-inflamatory and anti-oedemetous, other case showed small heamatoma which relieved after two weaks of local compression , hot fomentaions and topical thrombex gel ,two cases in Group B was failed at the first trial for femoral puncture by duplex and another trial done and succeeded with no mortality detected.

DISCUSSION

Although contrast venography is the standard imaging method for IVC ?lter placement, trans-abdominal duplex ultrasound is a safe and effective alternative.

In the present study, both duplex ultrasound and contrast venography had high technical success rates.

It was reported that in a study of two groups of patients that both duplex ultrasound (DUS) and contrast venography had high technical success rates (DUS, 98%; contrast venography, 99%) **(Matthew et al., 2010)**.

This present study which was accomplished in 2 years, included 30 patients divided into two groups. Both groups underwent IVC filter deployment either due to recurrent thromboembolism despite adequate anticoagulation which is the most common, contraindication to anticaogulants and complication of anticoagulants, the indications were absolute in all patients.

Despite the widespread applicability of IVC filters, the indications of IVC filters in the clinical practice remain imprecisely defined **(Kaufman et al., 2009).**

A study revealed that the most common indications for filter placement were a contra-indication to anticoagulation (50%), a complication of anticoagulation (15%), and prophylaxis (10%) **(Kwame et al., 2009).**

Relative indications for cava filter still constituting controversy. Among the patients of present study, there were no relative indications and all patients had absolute indications for filter deployment.

In the present study, there was a difference between both groups according to age which was not significantly different and both groups was equally distributed between sexes.

It was reported that the contrast venography and duplex ultrasound (DUS) groups had signi?cant differences in terms of patient demographics, diagnoses, and indications for ?lter insertion. The venography group had a signi?cantly higher mean age was equally distributed between sexes, while the DUS group was younger, more predominantly male, and had a higher prevalence of trauma-related diagnoses and immobilization **(Matthew et al., 2010)**.

In the present study, the patients of both groups most commonly presented with PE as a first attack , DVT as a first attack in both groups and proximal DVT is the commonest level of thrombosis in both groups.

In the present study, all the filters used was permanent and most of it was Nitinol trape-ease filter in both groups.

Patients of group B was well prepared to avoid bowel distention by gases, as not to mask the view of IVC.

It was reported that interval repeat DUS examination is a reasonable choice when there is a potential for resolution of the factors limiting the initial attempt at IVC imaging (as in the case of obstruction of the view of the IVC by excess bowel gas). It was reported that intravascular ultrasound has been increasingly used for filter placement when initial DUS does not provide staisfactory imaging of IVC **(Kwame et al., 2009)**.

In the present study, most of filters was inserted through right trans-femoral access except in cases of right femoral thrombosis was inserted through left trans-femoral access.

It was reported that most of patients underwent bedside IVCF insertion in the intensive care unit through right femoral vein **(Kwame et al., 2009)**.

In the present study, on the two groups of thirty patients after good follow up and investigations for two years , only access site complications was found and no mortality detected.

Duplex venous mapping was done to all patients to diagnose DVT and results were confirmed by stoppage of PE showers, duplex scan on IVC in all cases and plain x-ray abdomen in all cases to be considered as the standard reference. The accuracy of IVC filter deployment was estimated as regards the stoppage of PE showers.

It was reported that no significant difference according to complications between contrast venography group and duplex ultrasound filter group was found, the most common complication in his study was mal-positioning which was managed with either observation or insertion of second filter , more recently percutaneous retrieval and repositioning techniques have been described even for 'nonretrievable' filters **(Matthew et al., 2010)**.

Anticoagulation remains the preferred therapy for deep venous thrombosis. However, this form of treatment is either ineffective or contraindicated for some patients. For these patients, partial interruption of the vena cava via percutaneous filter placement has become the procedure of choice to protect against fatal PE **(Kearon et al., 2016).**

In the present study, for fluoroscopic guided method, many difficulties could face the surgeon including:

- The risk of irradiation exposure for the surgeon and the staff around whom need a very competent measures, as the lead aprons worn which should protect the front of the interventionist and his back as well, the thyroid shell and eye glasses should also be provided. The current situation in Egypt is showing that these measures are not considered especially the back of the workers, thyroid region and the eyes are not usually protected and the hands are exposed to x-ray very frequently which maximizes the hazards of radiation and this will be infavour of duplex guidance whenever it is possible.
- The risk of contrast induced nephropathy and renal failure especially in patients with renal impairement.
- The risk of dye inducing allergy and hypersensitivity starting from urticaria up to cardio-pulmonary arrest.

Because of such dangers and drawbacks,it is recommend whenever possible to use the duplex guided technique unless improper patient is found.

In special cases, such as patients with a history of severe allergic reaction to contrast media or with severely impaired kidney function, it seems justified to make therapeutic decisions on the basis of duplex findings alone **(Kwame et al., 2009)**.

A study done showed no significant difference according to technical success and complications between contrast venography group and duplex ultrasound group **(Haut et al., 2014).**

Color Duplex offers a number of advantages compared to venography. First, it provides both hemodynamic and anatomical information. Second, it is non-invasive and finally it is relatively cheap. Although color-coded duplex sonography has been shown to correlate well with venography, it has failed to displace diagnostic venography in most vascular units. This is partly because of the natural hesitancy involved in introducing any new technology but also because vascular surgeons have been taught to make decisions on anatomical pictures and feel insecure without them **(Kwame et al., 2009)**.

Most of surgeons don't feel comfortable to perform intervention solely based on duplex scanning, probably due to the lack of visual display compared to other imaging modalities. This's one of the drawbacks of duplex scanning **(Kwame et al., 2009)**.

A study was done by Dr **Ashraf Aweda** Professor of vascular surgery AL-Azhar-Universty on multitrauma/ICU patients considered for duplex guided IVC filter. All patients had clinical indications for IVC interruption. All procedures were performed at the bedside in a monitored ICU setting using percutaneous placement of titanium Greenfield filters. Insertion was performed using single femoral vein approach. Filter was technically successful in all cases. Repeated duplex scanning was obtained in most of patients and revealed no case of IVC or insertion site thrombosis. There were no filter-related complications such as migration, penetration or Filter-related thrombosis .No patient experienced any pulmonary embolus during the follow-up period **(Eweda and Zaytoon, 2016).**

In the present study, there was no malpositioning, tilting or migration and their complications related had not recorded either at the time of procedures or during the follow up period only just access site related complicaions with no mortality detected.

CONCLUSION

According to the results of the current study inferior vena cava filter insertion is safe and effective in preventing pulmonary embolism, fluroscopy has traditionally been the golden standard procedure for IVC filter deployment. Duplex guidance can replace fluoroscopy to guide the procedure in patients whose conditions can not tolerate the contrast material or exposure to X-ray. The current study suggested that duplex guided filter insertion is a safe, reliable, and accurate as the fluoroscopy guided procedure. Duplex guided method has proved to be cost effective as it can be done as a bedside procedure. Obesity constitutes the major technical limitation of duplex guided procedure.

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الدوبلكس والصبغة الوريدية كمقارنة لإدخال مرشحات الوريد الأجوف السفلي (دراسة مقارنة)

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خلفية البحث: مرشحات الوريد الأجوف السفلي بديل هام لمضادات التخثر في حالة بطلانها. وقد تطورت أساليب إدخال مرشحات الوريد الأجوف السفلي من الفتح الجراحي على موقع الإدراج الوريدي إلى الإدخال عبر الجلد، اليوم كل المرشحات يمكن إدخالها عن طريق الجلد من خلال الوريد الطرفي. وقد أعطت زيادة الخبرة باستخدام الدوبلكس الملون لفحص الوريد الأجوف السفلي وإمكانية الحركة لمعدات جهاز السونار فائدة لإدخال المرشحات بالوريد الأجوف السفلي باستخدام الدوبلكس. .

الهدف من البحث: مقارنة استخدام الدوبلكس والصبغة الوريدية لإدخال المرشحات بالوريد الأجوف السفلي بما يتعلق بالسلامة والفاعلية والنتائج والمضاعفات المحتملة.

المرضى وطرق البحث: دراسة مقارنة تحتوي على ثلاثين مريضا منقسمين إلى مجموعتين : (مجموعة أ) تحتوي على خمسة عشر مريض حيث تم استخدام الصبغة الوريدية لإدخال المرشحات بالوريد الأجوف السفلي بمستشفى الحسين الجامعي و (مجموعة ب) تحتوي على خمسة عشر مريض حيث تم استخدام الدوبلكس لإدخال المرشحات بالوريد الأجوف السفلي بمستشفى الزهراء الجامعي. وقد تم عمل أخذ للبيانات و الذاكرة المرضية و فحص كامل لجميع المرضى.

النتائج: هناك اختلاف بين المجموعتين من حيث السن و الجنس والإصابة بالجلطة الرئوية و دواعي الاستعمال لمرشحات الوريد الأجوف السفلي و نهج الوصول الوريدي و لكن غير مؤثرة. و كانت كل الفلاتر المستخدمة دائمة ، الجلطات المتكررة بالرغم من الاستخدام المناسب لمضادات التخثر كانت الأكثر شيوعا بين دواعي الاستعمال.

وقد عانى مريضين من مجموعة أ من تجمع دموي و كدمة في مكان الدخول بالمرشحات و حدث فشلا في إدخال المرشحات من المرة الأولى و لكن تم الإدخال بنجاح في المرة الثانية في مريضين من مجموعة ب بدون حدوث وفيات.

الاستنتاج: إدخال المرشحات بالوريد الأجوف السفلي آمن و فعال لمنع حدوث الجلطة الرئوية و كانت الصبغة تقليديا هي المعيار الذهبي لإدخال المرشحات بالوريد الأجوف السفلي و نستطيع استبدال الصبغة بالدوبلكس في حالة أن المرضى لا يتحملون التعرض للأشعة و الصبغة و الدراسة الحالية تقترح أن استخدام الدوبلكس لإدخال مرشحات الوريد الأجوف السفلي آمن ، موثوق و دقيق مثل الصبغة الوريدية. وقد ثبت أن استخدام الدوبلكس فعال من حيث التكلفة لاستخدامه بجانب سرير المريض، السمنة تعتبر أكبر عائق لإدخال المرشحات باستخدام الدوبلكس.