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The use of retrievable inferior vena cava filters in pregnancy: Another successful case report, but are we actually making a difference?

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Abstract

Background: Pregnant women with venous thromboembolism are traditionally managed with anticoagulation, but inferior vena cava filters are an alternative. We balanced risks and benefits of an inferior vena cava filter in a decision analysis.

Methods: We constructed a decision model to compare in pregnant women with VTE the outcome of (1) inferior vena cava filter and anticoagulant treatment versus (2) anticoagulant treatment only.

Results: Assuming a 63% risk reduction from an inferior vena cava filter (baseline mortality rate of venous thromboembolism of 0.5%), 318 women would need to be treated with inferior vena cava filters to prevent one venous thromboembolism related maternal death. Sensitivity analyses indicated that at a mortality rate of 0.5% the risk reduction from inferior vena cava filters needed to be 80%, while at a mortality rate of 2% a risk reduction of 20% would justify inferior vena cava filter.

Conclusions: In view of their potential morbidity, inferior vena cava filters should be restricted to pregnant woman at strongly increased risk of recurrent venous thromboembolism.

Keywords

Pregnancy, venous thromboembolism, inferior vena cava filters, clinical decision analysis

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Introduction

Venous thromboembolism (VTE) in pregnancy poses a significant risk to maternal health. In Australia (2006–2010), VTE was a leading cause of maternal mortality, accounting for 9% of direct maternal deaths, which translates to approximately 2 women per year.[1] Globally, the mortality of pregnancy-associated VTE (PA-VTE) ranges between 0.4 and 1.6 per 100,000 pregnancies.[2–5] The prevalence of PA-VTE is uncommon, affecting only 1 to 2 per 1000 pregnancies.[6–10] Approximately 20% of PA-VTE are pulmonary emboli (PE), of which 1 in 40 are lethal.[7,9,11] Thus, the predicted mortality rate of PA-VTE as a result of PE is 1 in 200 (Table 1).

The management of obstetric patients at increased risk for VTE and those with confirmed VTE is challenging. The management of PA-VTE remains a judicious balance between the life-threatening consequences of thrombosis and haemorrhage. Traditionally, the management of PA-VTE is pharmacological anticoagulation.[12,13] However, in the past decade, inferior vena cava (IVC) filters have been used 'successfully' in pregnant women and, therefore, may be considered as an additional option in pregnant women who develop VTE despite pharmacological anticoagulation, or in whom anticoagulation is contraindicated.[13]

In view of the documented morbidity associated with IVC filter use, until this time their use in pregnant women has been rather incidental, which has resulted in limited knowledge of their safety and efficiency in this context. Hence, the decision to use an IVC filter in a pregnant woman requires a clinical decision analysis balancing the benefit and the potential harm in each individual woman.

In this paper, we will first report on the history of a woman at high risk for VTE who became pregnant, developed a pulmonary embolus and after anticoagulation treatment was fitted with an IVC filter. Additionally, the literature pertaining to IVC filter use in pregnancy will be reviewed, along with a clinical risk benefit approach to the use of IVC filters in pregnancy. We will then integrate this data in a formal decision analysis.

Case report

A 30-year-old woman in her first pregnancy presented to her obstetrician at 6 weeks gestation with an existing deep vein thrombosis (DVT). She had a significant thrombophilia (ANA positive, titre 1:640; Factor V Leiden heterozygous; low protein C function (protein C activity 30% (N 65–130)) and a history of venous thromboembolism. At 22 years of age, she suffered an extensive DVT and PE whilst on the oral contraceptive pill and being a frequent air traveller. Prior to her pregnancy, while being on prophylactic anticoagulation, she developed a proximal DVT following an elective hysteroscopy and laparoscopy for the evaluation of pelvic pain. In consultation with the patient's longstanding physician, she was continued on an enoxaparin dose of 40 mg subcutaneous daily.

Six weeks following her operation, a vaginal ultrasound confirmed an intrauterine pregnancy and she was advised to continue her previously prescribed 40 mg daily subcutaneous enoxaparin. At 10 weeks gestation she presented with exertional dyspnoea. A ventilation/perfusion (V/Q) scan demonstrated a left lower lobe perfusion defect consistent with a PE.

A multidisciplinary team coordinated her management which consisted of pharmacological anticoagulation with 80 mg enoxaparin s/c twice daily and the insertion of a Bard Denali IVC filter per the

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Table 1. Pregnancy-associated venous thromboembolism epidemiology.

Epidemiology of VTE	Rate	Study
Incidence of PA-VTE	0.1–0.2%	Refs.[6–10]
Proportion of PA-PE with PA-VTE	21%	Refs.[9,20]
Mortality of PA-VTE	0.0004–0.0016%	Refs.[2–5]
Mortality of PA-PE per case	2.4%	Ref.[9]

VTE: venous thromboembolism; PA: pregnancy associated; PE: pulmonary embolism.

common femoral vein under fluoroscopic guidance. An IVC filter was placed prior to trialing therapeutic anticoagulation due to the high risk of a fatal pulmonary embolism, due to her preexisting thrombophilia, extensive proximal DVT and existing pulmonary embolism.

At 15 weeks gestation, she presented with a further episode of dyspnoea. A V/Q scan was negative for pulmonary embolism, and an upper respiratory tract infection was diagnosed and treated with oral antibiotics.

At 38 + 5 weeks gestation, the patient proceeded to an elective induction of labour under the care of a multidisciplinary team. Her enoxaparin was ceased on the evening of her induction and she was commenced on a heparin infusion keeping the APTT between 60 and 100 s. Cervical priming with prostaglandin E2 gel was followed by artificial rupture of the fetal membranes, with subsequent augmentation with an oxytocin infusion. The heparin infusion was ceased once the patient labour was established. The APTT was checked 4 h after cessation of the heparin infusion to ensure this was below 50 s to allow the placement of an epidural catheter. Additional VTE prophylaxis during labour consisted of graduated compression stockings and pneumatic calf compression devices. When labour failed to progress, an emergency lower segment caesarean section was performed resulting in the delivery of a healthy male baby. The estimated operative blood loss was 450 mL. Post delivery, the patient was recommenced on a heparin infusion 2 h after removal of the epidural catheter. The heparin infusion was ceased 24 h after delivery and a 3-month course of therapeutic enoxaparin was commenced (70 mg subcutaneous twice daily).

At 3 months post delivery, the IVC filter was removed through the jugular vein under ultrasound guidance. She had extensive counseling regarding avoiding hormonal contraceptive measures and the need for prophylactic anticoagulation in any future pregnancies.

Commentary

Management of pregnancy-associated venous thromboembolism

The management of PA-VTE remains a judicious balance between the life-threatening consequences of thrombosis and haemorrhage. Traditionally, the management of PA-VTE is pharmacological anticoagulation.[12,13]

More recently, IVC filters have been used in pregnancy as adjuncts to pharmacological anticoagulation.[14] However, despite their alleged 'widespread' use few professional bodies have provided guidance to their risk–benefit profile. In view of this situation, and in view of the rarity of the problem that hampers prospective studies, let alone randomised clinical trials, we performed a clinical decision analysis on the subject, in which we balance the pros and cons of the alternatives.

Clinical decision analysis

General outline

We compared pregnant women with VTE diagnosed in the antenatal period with two strategies. Strategy I consisted of pharmacological anticoagulation. Strategy II consisted of pharmacological anticoagulation with the addition of an IVC filter. We compared the strategies with the following outcomes: VTE mortality, IVC filter-related complications that included: procedure-related mortality, iatrogenic lower limb DVT, IVC thrombosis (filter occlusion), filter migration, IVC wall perforation, filter strut fracture, failure of filter retrieval, filter insertion complications and post-thrombotic syndrome.

We searched PubMed for estimates on the effects and the risk of the treatments using the following keywords: deep venous thrombosis, management, pregnancy, inferior vena cava filter, complications, venous thromboembolism.

Table 2. Benefits of IVC filter.

Benefit of IVC filter	Rate	Study
Reduction in PE	63%	Ref.[15]
Reduction in mortality	None demonstrated	Refs.[15,21]

IVC: inferior vena cava; PE: pulmonary embolism.

Table 3. Risks of IVC filter.

Risk of IVC filter	Rate	Study
Procedure-related mortality	0.12%	Ref.[18]
PE	0.91%[a]	Ref.[16]
Iatrogenic lower limb DVT	2.07%[a]	Ref.[16]
	35.7%	Ref.[15]
IVC thrombosis	0.92%[a]	Ref.[16]
	6–30%	Ref.[22]
Filter migration	2.07%[a]	Ref.[16]
	3–69%	Ref.[22]
IVC perforation	6.27%[a]	Ref.[16]
	9–24%	Ref.[22]
Strut fracture	1.40%[a]	Ref.[16]
Failure of retrieval	10.97%[a]	Ref.[16]
Complications from insertion	4–11%	Ref.[22]
Insertion site thrombosis	2–28%	Ref.[22]
Post-thrombotic syndrome	5–70%	Ref.[22]

[a]Derived from Rajasekhar and Streiff[16] for retrievable IVC filters only.
IVC: inferior vena cava; PE: pulmonary embolism; DVT: deep vein thrombosis.

Effects

In the non-pregnant population, an IVC filter combined with pharmacological anticoagulation appears to reduce the incidence of pulmonary embolism (RR 0.37, $p = 0.008$), but have no effect on mortality (RR −0.97, $p = 0.83$)[15,16] (Table 2).

Risks

In the non-pregnant population, an IVC filter is associated with procedure-related mortality, lower limb DVT, IVC thrombosis (filter occlusion), filter migration, IVC wall perforation, filter strut fracture, failure of retrieval of a retrievable filter, complications related to insertion, post thrombotic syndrome and other rare fatal complications[15–19] (Table 3). Although well recognised, the frequency of complications varies in the literature due to different types of filter, study populations,

Table 4. IVC filter efficacy: Mortality and morbidity analysis.

	Filter efficacy in reducing mortality			
	25%	50%	63%	75%
NNT to prevent one PA-VTE death	800	400	318	267
Procedure mortality	1.0	0.5	0.38	0.3
Iatrogenic lower limb DVT	65.6	32.8	26.0	21.9
IVC thrombosis	7.4	3.7	2.9	2.5
Filter migration	16.6	8.3	6.6	5.5
IVC wall perforation	50.2	25.1	19.9	16.7
Filter strut fracture	11.2	5.6	4.4	3.7
Failure of filter retrieval	87.8	43.9	34.8	29.3
Complications from filter insertion	32.0	16.0	12.7	10.7
Post thrombotic syndrome	40.0	20.0	15.9	13.3

Filter efficacy: Reduction in mortality from pulmonary embolism.
NNT: number needed to treat; PA-VTE: pregnancy associated venous thromboembolism; IVC: inferior vena cava; DVT: deep vein thrombosis.

duration of treatment and prophylactic versus therapeutic use. The literature surrounding morbidity and mortality associated with IVC filter use should be viewed with caution and may be underreported. In the clinical decision analysis the lower incidence of a complication was used in calculations.

Effects versus risk analysis

Mortality

The primary aim of an IVC filter is to prevent mortality from pulmonary embolism, which in the case of PA-VTE is 1 in 200.[9] Presuming an IVC filter was 100% effective in reducing mortality then 200 pregnant women with confirmed VTE would require an IVC filter fitted in order to prevent one maternal death. The PREPIC trial showed no mortality benefit from IVC filter use, but rather showed a 63% reduction in the incidence of PE.[15] Assuming the reduced incidence of PE extrapolates to a 63% reduction in maternal mortality as the 'best-case scenario,' then the number needed to treat to prevent one PA-VTE-related death would be 318. In treating 318 women, the procedural mortality rate of an IVC filter of 0.12% would have to be taken into account. If the effectiveness of an IVC filter is found to reduce maternal mortality by 25% then the number needed to treat increases to 800 and the procedure mortality approaches the PA-VTE mortality rate, which would not justify its use (see Table 4).

Morbidity risk

IVC filter placement is not without risk, and in the 'best-case scenario' outlined above, in treating 318 women to prevent one maternal death there would be the chance of: 26 iatrogenic lower limb DVT, 2.9 IVC thrombosis, 6.6 filter migration, 19.9 IVC wall perforation, 4.4 filter strut fracture, 34.8 filter retrieval failure, 12.7 complications from filter insertion and 15.9 post thrombotic syndrome (the latter is disputed). It is important to consider the lower incidence of morbidity reported in the literature was used to calculate these figures, and as such the morbidity may be an under estimate (Table 4). It is important to consider the additional cumulative long-term risk of filter retrieval failure (10%) in young women. These women have higher risk of filter-related complications such as filter migration, filter strut fracture and IVC perforation. Additional the cumulative risk of life-long anticoagulation is substantial, and the patient should be counseled accordingly.

Conclusion

The decision to use an IVC filter in pregnancy needs to be carefully considered, balancing the risk of PA-VTE against its likely therapeutic effect taking into account the procedural mortality and morbidity. A multidisciplinary team should utilise an individualised clinical decision analysis for each woman. This may help identify woman at high risk of mortality from VTE. Identifying women most at risk will reduce the number of women that need to be treated with an IVC filter and its inherent risk. Sensitivity analyses indicated that at a mortality rate of 0.5% the risk reduction from IVC filter need to be 80%, while at a mortality rate of 2% this risk reduction would only need to be 20%.

There is currently insufficient evidence to accurately quantify the risk–benefit profile of IVC filters in pregnancy. The evidence guiding IVC filter use in pregnancy relies on extrapolation of studies from the non-pregnant population along with sporadic case reports of their use in pregnancy. As case reports are increasing in literature, it is important to consider that the maternal mortality rate of PA-VTE is low. Therefore, 'successful' case reports of IVC filter use in pregnancy may simply be a reflection of the natural course of the disease rather than a therapeutic effect of the device.

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