REVIEW ARTICLE**TITLE**

Inferior vena cava filters and postoperative outcomes in patients undergoing bariatric surgery: a meta-analysis

SHORT TITLE: Inferior vena cava filters and bariatric surgery outcomes

Roop Kaw, MD ^{a,b}; Vinay Pasupuleti, MD, PhD ^c; D. Wayne Overby, MD ^f; Abhishek Deshpande, MD, PhD ^c; Craig I. Coleman, PharmD ^g; John P.A. Ioannidis, MD, DSc ^h; Adrian V. Hernandez, MD, PhD ^{d,i,j} for the Cardiovascular Meta-analysis Research Group.

^aDepartment of Hospital Medicine, Medicine Institute, ^bDepartment of Outcomes Research, Anesthesiology Institute, ^cDepartment of Internal Medicine, Medicine Institute and ^dDepartment of Quantitative Health Sciences, Lerner Research Institute, Cleveland Clinic, Cleveland OH, USA

^eDepartment of Medicine, Case Western Reserve University, Cleveland, OH, USA

^fDivision of Gastrointestinal Surgery, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

^gEvidence-Based Practice Center, UCONN/Hartford Hospital, and University of Connecticut School of Pharmacy, Hartford, CT, USA

^hStanford Prevention Research Center, Department of Medicine and Department of Health Research and Policy, Stanford University School of Medicine, Stanford, CA, USA

ⁱPostgraduate and Medical Schools, Universidad Peruana de Ciencias Aplicadas (UPC), Lima,
Peru

^jUnidad de Análisis y Generación de Evidencias en Salud Pública (UNAGESP), Instituto
Nacional de Salud, Lima, Peru

Funding: None

Corresponding Author

Roop Kaw, MD, Departments of Hospital Medicine and Outcomes Research (Anesthesiology
Institute), Desk A-13, Medicine Institute, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH
44195, USA; Tel: (216) 444-5633; email: kawr@ccf.org

Date: January 16, 2014

Title

Inferior vena cava filters and postoperative outcomes in patients undergoing bariatric surgery: a meta-analysis

Short Title

Inferior vena cava filters and bariatric surgery outcomes

Abstract

Background: Pulmonary embolism (PE) accounts for almost 40% of perioperative deaths after bariatric surgery. Placement of prophylactic inferior vena cava (IVC) filter before bariatric surgery to improve outcomes has shown varied results. We performed a meta-analysis to evaluate postoperative outcomes associated with the preoperative placement of IVC filters in these patients.

Methods: A systematic review was conducted by three investigators independently in PubMed, EMBASE, the Web of Science and Scopus until February 28, 2013. Our search was restricted to studies in adult patients undergoing bariatric surgery with and without IVC filters. Primary outcomes were postoperative deep vein thrombosis (DVT), pulmonary embolism (PE), and postoperative mortality. Meta-analysis used random effects models to account for heterogeneity, and Sidik-Jonkman method to account for scarcity of outcomes and studies. Associations are shown as Relative Risks (RR) and 95% Confidence Intervals (CI).

Results: Seven observational studies were identified (n=102,767), with weighted average incidences of DVT (0.9%), PE (1.6%), and mortality (1.0%) for a follow-up ranging from 3 weeks to 3 months. Use of IVC filters was associated with an approximately 3-fold higher risk of DVT and death that was nominally significant for the former outcome, but not the latter (RR 2.81, 95%CI 1.33-5.97, p=0.007; and RR 3.27, 95% CI 0.78-13.64, p=0.1, respectively); there was no difference in the risk of PE (RR 1.02, 95%CI 0.31-3.77, p=0.9). Moderate to high heterogeneity of effects was noted across studies.

Conclusions: Placement of IVC filter before bariatric surgery is associated with higher risk of postoperative DVT and mortality. A similar risk of PE in patients with and without IVC filter

placement cannot exclude a benefit, given the potential large imbalance in risk at baseline.

Randomized trials are needed before IVC placement can be recommended.

Key Words

Bariatric surgery; inferior vena cava filters; pulmonary embolism; venous thromboembolism

INTRODUCTION

Venous thromboembolism (VTE) is uncommon (0.42% at 90 days) though important complication after bariatric surgery. However, pulmonary embolism (PE) remains the second leading cause of perioperative mortality after anastomotic leak, accounting for almost 40% of perioperative deaths after bariatric surgery ^[1]. Lack of randomized controlled trials to guide thromboprophylaxis after bariatric surgery makes clinical decision making difficult among patients considered as high risk for VTE.

Placement of prophylactic inferior vena cava (IVC) filter before bariatric surgery among certain groups of patients to mitigate these outcomes has shown varied results. These studies did not use any universal or common indications for preoperative IVC filter placement and among the severely obese even the body mass index (BMI) cut-offs varied. A recent meta-analysis has suggested higher rates of postoperative deep vein thrombosis (DVT) and mortality, raising concerns whether this practice should be continued ^[2]. In fact, the Food and Drug Administration's Manufacturer and User Facility Device Experience Database has reports of a total of 2500 adverse events involving IVC filters including 838 injuries and 93 fatalities (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm>) .

We performed a systematic review and meta-analysis of the existing literature in order to evaluate the risk of postoperative outcomes associated with the preoperative placement of IVC filters in patients undergoing bariatric surgery.

METHODS

Data sources and Searches

A comprehensive literature search using PubMed-Medline from 1960 through February 28, 2013, EMBASE from 1980 through February 28, 2013, The Web of Science from 1980 through February 28, 2013, Scopus from 1960 through February 28, 2013 and www.clinicaltrials.gov was conducted by three authors (AVH, VP and AD). The following keywords were used: bariatric surgery, gastric band, gastric bypass, sleeve gastrectomy, pulmonary embolism, venous thromboembolism and deep vein thrombosis. The search strategy of PubMed is available in the Appendix.

The following predetermined inclusion criteria were used: (i) comparative studies on patients with and without IVC filters placed with information about DVT or PE as outcomes of bariatric surgery, including several possible surgical techniques, (ii) study population of patients ≥ 18 years; (iii) study in any language. Our exclusion criteria were: (i) no control group; (ii) DVT and/or PE data were not available or could not be extracted for the study groups; (iii) the only outcome with available information was mortality. In the last case, we contacted investigators from these studies requesting additional information.

Study selection and Data extraction

A list of retrieved articles was reviewed independently by 3 investigators (AVH, VP and AD) in order to choose potentially relevant articles, and disagreements about particular studies were discussed and resolved by consensus.

Two reviewers (VP and AD) independently extracted data from studies. The following information was extracted: age, gender, BMI, type of bariatric surgery, open or laparoscopic surgery and prior VTE. Outcomes data extracted were postoperative PE, DVT, VTE and mortality. One other author (AVH) reviewed the extractions for inconsistencies, and the three authors (AVH, VP and AD) reached consensus.

Evaluation of study quality

The order of quality of studies was considered as follows, from higher to lower: (1) prospective cohort study; (2) retrospective cohort study; (3) case-control study and (4) cross-sectional study. We also systematically assessed the study quality with the Newcastle-Ottawa Scale (NOS) (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp). The NOS uses two different tools for case-control and cohort studies and consists of three parameters of quality: selection, comparability and exposure/outcome assessment. The NOS assigns a maximum of four points for selection, two points for comparability and three points for exposure or outcome. We used a modified NOS scale with maximum possible points of 8. One of the selection components in the scale (demonstration that outcome of interest was not present at start of study) was not applicable to the included studies and noted as not scored. NOS scores of ≥ 6 were considered as high quality studies and NOS scores of 4–5 were considered moderate quality. Any discrepancies were addressed by a joint re-evaluation of the original article.

Data synthesis and Analysis

Our meta-analysis follows the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) collaboration^[3]. Sidik-Jonkman random effects models

were used for all meta-analyses^[4]. The studies were weighted by the inverse variance method as described in the manual of the review manager (see <http://handbook.cochrane.org>). Associations are described as Relative Risks (RR) and their 95% confidence intervals (CI). We evaluated statistical heterogeneity using the Cochran Chi-square (χ^2) and the I^2 statistic. I^2 values of 30-60% represented a moderate level of heterogeneity. A P value of < 0.1 for χ^2 was defined as indicating the presence of heterogeneity. Small-study effects were explored with the Egger's test^[5, 6]. Numbers needed to harm (NNH) were calculated per study as the inverse of the risk increase between active and control groups, and it means the number of patients receiving the IVC filters necessary to have one harmful outcome. We used Review Manager (RevMan 5.0 for Windows, Oxford, UK; The Cochrane Collaboration, 2008) and the R metafor function (www.metafor-project.org).

RESULTS

Study characteristics

Of the 701 selected abstracts, we included 6 studies (n=102767) for the quantitative synthesis (Figure 1) ^[7-12]. Studies were published between 2006 and 2013, and all patients underwent bariatric surgery (Table 1). One of the authors (DWO) provided additional updated mortality data on his previously published study following IVC filter retrieval ^[12]. We also used the most recently published outcome data from Birkmeyer et al. ^[7].

Open surgery (including open Roux-en-Y gastric bypass [RYGB] and biliary-pancreatic diversion) was predominantly reported in studies before 2009. Most of the patients were female, in their mid-ages, and extremely obese. Prior history of VTE among those selected to get IVC filter and those that did not is reported in Table 1. IVC filters were used in 1890 (1.8%) patients. Types of IVC filters, indications for IVC filter, and pharmacologic prophylaxis used concomitantly with IVC filter were heterogeneous among included studies (Table 2). Not all studies reported all outcomes. Mortality was not reported in studies by Halmi et al. ^[9], whereas the cause of death was not specified in all studies except Overby et al and Birkmeyer et al. ^[7, 12]. Incidences (ranges) of reported outcomes were 0.2% (0.1%-2.9%) for DVT, 0.2% (0.1%-8.6%) for PE, and 0.1% (0%-6.0%) for overall mortality. The random effects pooled incidences of these outcomes were 0.9% (95% CI 0.1%-1.6%) for DVT, 1.6% (95% CI 0% -3.7%) for PE, and 1.0% (95% CI 0%-2.5%) for overall mortality.

Study quality

Two studies were prospective cohorts, three studies were retrospective cohorts, and one study included a prospective and a retrospective cohort (Table 3). All studies were of high quality. They clearly identified the study population, the definition of the outcomes and the outcome assessments. None of the studies reported selective loss of follow-up.

Meta-analysis

The risk of DVT was significantly increased with the use of IVC filters in comparison to non-use of IVC filters (RR 2.81, 95% CI 1.33-5.97, $p=0.007$) (Figure 2). Overall NNH for DVT was 84 (range -89 to 172). There was no evidence of small-study effects (Egger's test p value=0.5). Heterogeneity of effects was moderate across studies (I^2 35%, 95% CI 0% to 85%). However, the risk of PE was not decreased with the use of IVC filters (RR 1.02, 95% CI 0.31-3.37, $p=0.9$) (Figure 3). Overall NNH for PE was 191 (range -312 to 522). Heterogeneity of effects was moderate across studies (I^2 58%, 95% CI 0% to 93%).

Overall mortality was non-significantly increased with the use of IVC filters (RR 3.27, 95% CI 0.78-13.64, $p=0.1$) (Figure 4). This was translated into an overall NNH for mortality of 145 (range -16 to 356). There was high heterogeneity of effects among studies reporting mortality (I^2 60%, 95% CI 0% to 94%).

DISCUSSION

Our meta-analysis found a significantly higher risk of DVT and a non-significantly higher mortality risk associated with the preoperative placement of IVC filters among patients undergoing bariatric surgery and deemed to be high risk for VTE. There was no decreased risk of PE with the use of IVC filters. There was moderate to high heterogeneity of effects among studies for each outcomes evaluated.

Venous thromboembolism related to prophylactic IVC filter placement before bariatric surgery

Not all the studies reported indications for prophylactic IVC filter placement. However, most studies considered the following factors as high risk for postoperative VTE: prior history of VTE or a hypercoagulable disorder, impaired functional status, lower extremity edema, extreme obesity defined in some studies as BMI > 50, obesity hypoventilation syndrome and pulmonary hypertension. Among these, a higher BMI (>50), history of prior DVT/PE and poor mobility were the most common. Except for one study^[12], all studies had a higher prevalence of prior DVT among the patients who underwent IVC filter placement prior to bariatric surgery. However, we could not adjust for prior DVT in the meta-analysis as adjusted risks were not provided by authors. In the study by Overby et al.^[12], clinical assessment of VTE risk was augmented by focused plasma screening for common thrombophilias (factors VIII, IX and XI, D-dimer, fibrinogen, antithrombin III deficiency, protein C/S deficiency, factor V Leiden mutation, anticardiolipin antibodies and lupus anticoagulant). Some of the clinical risk factors for IVC filter placement were accounted for in one study^[7] by propensity matching using all of the demographic, weight, medical history, weight-related comorbidity, and procedure-related

variables. All patients received pharmacological DVT prophylaxis regardless of preoperative IVC filter placement (Table 2).

In contrast, the incidence of PE was not noted to be lower after IVC filter placement among patients undergoing bariatric surgery. We propose this may be related to measurement bias as less patients tend to get screened for PE compared to the number that get screened for DVT. Postoperative PE is diagnosed in only 0.41-1.2% of laparoscopic and open RYGB patients, even though up to 80% of patients who died from other causes after bariatric surgery were found to have silent PEs found at autopsy ^[13, 14].

Mortality related to prophylactic IVC filter placement before bariatric surgery

There are many factors to be considered in understanding the non-significant higher mortality risk after prophylactic IVC filter placement before bariatric surgery. It is possible, even though only one study ^[10] adjusted for important differences between the groups, that some of these patients may be sicker at baseline compared to those obese patients where the surgeon did not consider the placement of an IVC filter before surgery. For example, some of the patients belonging to these groups could be older, more obese, have a greater limitation in functional status and longer duration of surgery. Also, the scarcity of deaths makes a conclusion on a higher risk of mortality weak, as the change in one or two deaths in the comparison groups can modify the risk. Finally, VTE-related deaths are the most important outcomes to evaluate in patients getting IVC filters. Birkmeyer et al. ^[15] suggested a higher rate of fatal PE among the groups who had a prophylactic IVC filter placement. Unfortunately, causes of death were not consistently reported in included studies; only Overby et al. ^[12] reported one out of three deaths

related to PE. It has been reported that some unexplained deaths after bariatric surgery may be related to undiagnosed PE ^[1, 12, 14, 16], so this can be a cause of death that should be explored. Regardless, IVC filters did not prevent these PE deaths differentially.

Other outcomes associated with IVC placement

Most studies that fulfilled the criteria for this meta-analysis also did not collect complication rates related directly to the IVC filter placement like fatal IVC thrombosis or IVC filter retrieval like filter migration/embolization or IVC perforation. Data on IVC filter retrieval was provided by only two studies: Overby et al. ^[12] at 6 weeks postoperatively reported one event of PE out of 155 retrieval attempts; Halmi et al. ^[9] at 18-21 days postoperatively reported no thrombus or thromboembolic events in 26 retrievals.

Our findings in light of recently published systematic reviews

Two systematic reviews have evaluated outcomes after IVC placement in bariatric surgery patients ^[2, 17] (Table 4). Rajsekhar and Crowther ^[17] performed a systematic review through February 2009 to evaluate the evidence supporting the placement of IVC filters in patients undergoing bariatric surgery. No specific inclusion and exclusion criteria were listed, and 3 engines were searched. Four studies (n=2488) were included with controls groups not receiving IVC filters. Authors did not perform a meta-analysis and concluded there was insufficient evidence to support the use of IVC filters at the time of bariatric surgery.

More recently, Brotman et al. ^[2] performed a detailed systematic review through August 2012. These authors evaluated both pharmacologic and mechanical strategies to prevent VTE in

patients undergoing bariatric surgery. Only studies describing two or more interventions including devices, drugs, varying doses or varying duration were included, which differs with our inclusion criteria. Five studies (n=102,114) were evaluated by these authors, and the risk of bias was evaluated with the Downs and Black tool, while we used the Newcastle Ottawa scale. We considered that the Sidik-Jonkman random effects models best accommodate rare outcomes and a few studies. Importantly, Brotman et al.^[2] evaluated the grade of evidence by using an adapted scale. Our findings are remarkably similar with respect to main outcomes (Table 4), except we did not find a significantly increased risk of overall mortality and we had higher proportions of heterogeneity. Using the traditional Der Simonian and Laird random effects model, we also found a significant higher risk of mortality for IVC filter placement (RR 2.87, 95%CI 1.47-5.58; p=0.002), with low heterogeneity of effects. Finally, Brotman et al.^[2] graded their findings as either insufficient evidence for PE or low grade evidence for DVT and mortality.

Limitations

We recognize several limitations in our work. First, some of our findings are based on studies that were retrospective in nature. Second, our meta-analyses were univariable as the study effect adjusted for baseline morbidities was reported in only one study. Therefore, we could not meta-analyze adjusted effects of IVC on VTE outcomes or mortality. Third, indications for IVC filter placement before bariatric surgery although similar were not exactly the same for patients selected in each group. Hence, the higher reported rate of DVT after prophylactic IVC filter placement may simply reflect higher baseline risk of the population that received prophylactic IVC filters and confounding by indication is a major threat for the observed treatment effect

estimates. Fourth, explanation for all deaths was not provided in each paper and only some studies reported data on IVC filter retrieval which can incur associated mortality.

Conclusion

Allowing for these caveats, placement of IVC filter before bariatric surgery seems to increase the risk of postoperative DVT and overall mortality. There was no change in the risk of PE. Empiric placement of IVC filters before bariatric surgery in high risk patients may worsen outcomes and should be discontinued for lack of good evidence and because of potential harm.

Acknowledgments: None

Disclosures

The authors have no commercial associations that might be a conflict interest in relation to this article.

Appendix

Pubmed search strategy

((("bariatric surgery"[MeSH Terms] OR ("bariatric"[All Fields] AND "surgery"[All Fields]) OR "bariatric surgery"[All Fields]) OR (("stomach"[MeSH Terms] OR "stomach"[All Fields] OR "gastric"[All Fields]) AND ("Band"[Journal] OR "band"[All Fields])) OR (("stomach"[MeSH Terms] OR "stomach"[All Fields] OR "gastric"[All Fields]) AND banding[All Fields]) OR ("gastric bypass"[MeSH Terms] OR ("gastric"[All Fields] AND "bypass"[All Fields]) OR "gastric bypass"[All Fields]) OR (sleeve[All Fields] AND ("gastrectomy"[MeSH Terms] OR "gastrectomy"[All Fields])) OR ("biliopancreatic diversion"[MeSH Terms] OR ("biliopancreatic"[All Fields] AND "diversion"[All Fields]) OR "biliopancreatic diversion"[All Fields])) AND (("venous thromboembolism"[MeSH Terms] OR ("venous"[All Fields] AND "thromboembolism"[All Fields]) OR "venous thromboembolism"[All Fields]) OR ("pulmonary embolism"[MeSH Terms] OR ("pulmonary"[All Fields] AND "embolism"[All Fields]) OR "pulmonary embolism"[All Fields]) OR ("venous thrombosis"[MeSH Terms] OR ("venous"[All Fields] AND "thrombosis"[All Fields]) OR "venous thrombosis"[All Fields] OR ("deep"[All Fields] AND "vein"[All Fields] AND "thrombosis"[All Fields]) OR "deep vein thrombosis"[All Fields]))

FIGURE LEGENDS**Figure 1:** Flow diagram of selected studies

Figure 2: Association between the use of inferior vena cava (IVC) filters and deep vein thrombosis (DVT)

Figure 3: Association between the use of inferior vena cava (IVC) filters and pulmonary embolism (PE)

Figure 4: Association between the use of inferior vena cava (IVC) filters and overall mortality

REFERENCES

1. Omalu BI, Ives DG, Buhari AM et al. Death rates and causes of death after bariatric surgery for Pennsylvania residents, 1995 to 2004. *Arch Surg* 2007; 142: 923-928; discussion 929.
2. Brotman DJ, Shihb HM, Prakasa KR et al. Pharmacologic and mechanical strategies for preventing venous thromboembolism after bariatric surgery. *JAMA Surg* 2013; 148: 675-686.
3. Moher D, Liberati A, Tetzlaff J, Altman DG Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med* 2009; 151: 264-269.
4. Sidik K, Jonkman JN A simple confidence interval for meta-analysis. *Stat Med* 2002; 21: 3153-3159.
5. Egger M, Davey Smith G, Schneider M, Minder C Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997; 315: 629-634.
6. Sterne JA, Sutton AJ, Ioannidis JP et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ* 2011; 343: d4002.
7. Birkmeyer NJ, Finks JF, English WJ et al. Risks and benefits of prophylactic inferior vena cava filters in patients undergoing bariatric surgery. *J Hosp Med* 2013; 8: 173-177.
8. Gargiulo NJ, 3rd, Veith FJ, Lipsitz EC, Suggs WD, Ohki T, Goodman E Experience with inferior vena cava filter placement in patients undergoing open gastric bypass procedures. *J Vasc Surg* 2006; 44: 1301-1305.
9. Halmi D, Kolesnikov E Preoperative placement of retrievable inferior vena cava filters in bariatric surgery. *Surg Obes Relat Dis* 2007; 3: 602-605.

10. Li W, Gorecki P, Semaan E, Briggs W, Tortolani AJ, D'Ayala M Concurrent prophylactic placement of inferior vena cava filter in gastric bypass and adjustable banding operations in the Bariatric Outcomes Longitudinal Database. *J Vasc Surg* 2012; 55: 1690-1695.
11. Obeid FN, Bowling WM, Fike JS, Durant JA Efficacy of prophylactic inferior vena cava filter placement in bariatric surgery. *Surg Obes Relat Dis* 2007; 3: 606-608; discussion 609-610.
12. Overby DW, Kohn GP, Cahan MA et al. Risk-group targeted inferior vena cava filter placement in gastric bypass patients. *Obes Surg* 2009; 19: 451-455.
13. Fernandez AZ, Jr., Demaria EJ, Tichansky DS et al. Multivariate analysis of risk factors for death following gastric bypass for treatment of morbid obesity. *Ann Surg* 2004; 239: 698-702; discussion 702-693.
14. Podnos YD, Jimenez JC, Wilson SE, Stevens CM, Nguyen NT Complications after laparoscopic gastric bypass: a review of 3464 cases. *Arch Surg* 2003; 138: 957-961.
15. Birkmeyer NJ, Share D, Baser O et al. Preoperative placement of inferior vena cava filters and outcomes after gastric bypass surgery. *Ann Surg* 2010; 252: 313-318.
16. Melinek J, Livingston E, Cortina G, Fishbein MC Autopsy findings following gastric bypass surgery for morbid obesity. *Arch Pathol Lab Med* 2002; 126: 1091-1095.
17. Rajasekhar A, Crowther M Inferior vena cava filter insertion prior to bariatric surgery: a systematic review of the literature. *J Thromb Haemost* 2010; 8: 1266-1270.

Table 1. General characteristics of included studies

First author, Year published	Type of surgery	IV C filter	n	Open surgery, (%)	Age, Mean (SD)	Male, (%)	BMI, Mean (SD)	Prior VTE, (%)	Follow-up time	Significant differences in cases and controls	Matching in cases and controls
Gargiulo <i>et al</i> , 2006 (11)	Gastric bypass	No	351	100	NA	29.3	52.0 (7.2)	0.3	30 days	No test done	None
		Yes	58	100				15.5			
Halmi <i>et al</i> , 2007 (12)	Gastric bypass	No	625	100	40.7 (3.6)	13.8	44.7 (4.6)	NA	18-21 days	No test done	None
		Yes	27	100		33.3		29.6			
Obeid <i>et al</i> , 2007 (14)	Gastric bypass; Gastric banding	No	1848	91.4	44.7	14.0	48.8	NA	30 days	Gender, BMI	None
		Yes	246	95.1	46.6	23.6	60.0	7.7			
Overby <i>et al</i> , 2009 (15)	Gastric bypass	No	170		NA	14.5	51.4	NA	6 weeks	No test done	None
		Yes	160	4.8							
Li <i>et al</i> , 2012 (13)	Gastric bypass; Gastric banding	No	96806	4.8	46.0 (12.0)	21.1	44.5 (6.6)	3.1	90 days	Gender, Race, BMI, previous non-bariatric	None
		Yes	322	21.4	47.0 (13.0)	31.4	45.3 (7.0)	21.4			

							surgery, co- morbidi- ties*
Birkme- yer <i>et al</i> , 2013 (10)	Gastric bypass;	No	107 7	49	31.0	57.0	39.0
							Propensity score matching performed.
	Gastric banding;	NA					Matched for Age, gender, race, BMI, insurance,
	duodena- l switch; sleeve gastrecto- my	Yes	107 7	48	32.0	58.0	39.0
							30 days smoking, mobility status, bariatric procedure, procedure length, preop and post VTE prophylaxis and comorbidities [#]

IVC = Inferior vena cava; BMI = Body mass index; VTE = venous thromboembolism; * = DVT/PE, impairment of functional status, lower extremity edema, obesity hypoventilation syndrome, and pulmonary hypertension; # = propensity-matched co-morbidities listed in Table 2.

Table 2. Details of IVC filters in included studies

Reference	Pharmacological chemo-prophylaxis used in the IVC filters group	Indications for IVC filters	Types of IVC filters used	IVC filter removal	Baseline co-morbidities adjusted for comparing mortality rates
Gargiulo <i>et al</i> , 2006 (11)	SC heparin injections before surgery and every 12 hrs after until they were ambulating more than 4h/day	History of DVT, PE, or PHTN as measured by noninvasive ECHO/Swan-Ganz catheterization or BMI >55	4 types: Trapease, Simon-Nitinol, Greenfield, Bard Recovery	NS	None
Halimi <i>et al</i> , 2007 (12)	SC heparin or lovenox 1 hr before surgery and was continued postop every 8 and 12 hrs	Prior VTE, thrombophlebitis, hypercoagulable state, PHTN, inability to ambulate, BMI >65, severe OSA	Retrievable	96% removed 18-21 days later	No mortality data
Obeid <i>et al</i> , 2007 (14)	Enoxaparin, warfarin (1mg/day)	Poor mobility, history of DVT/PE, venous disease, BMI >60, history of IVC filter	NS	NS	None
Overby <i>et al</i> , 2009 (15)	SC heparin every 8h from before surgery until	Thrombophilias, strong clinical indicators of high	Retrievable and Non-retrievable:	92% removed 2-3 wks	None

	hosp discharge	VTE risk including poor ambulation, history of severe venous stasis disease, severe sleep apnea with OHS, central obesity and BMI>60 or with a history of DVT or PE	Celect, later Gunther Tulip, Bard Recovery, Optease, Venatech, Bard G2		
Li et al, 2012 (13)	90% patients received anticoagulants	NS	NS	NS	None
Birkmeyer et al, 2013 (10)	96% patients received heparin preoperatively and 77% patients received postoperatively	Age > 50, Prior VTE, BMI>50, Immobility, Open procedure	32% retrievable, 46% non-retrievable, 22% unknown	NS	Lung disease, CV disease, hyperlipidemia, HTN, GERD, PUD, cholelithiasis, urinary incontinence, renal failure, DM, liver disorder, history of VTE, OSA, musculoskeletal disorder, history of hernia repair, psychological disorder

IVC = inferior vena cava; sc = subcutaneous; DVT = deep vein thrombosis; PE = pulmonary embolism; PHTN = pulmonary hypertension; ECHO = echocardiography; BMI = body mass index; VTE = venous thromboembolism; OSA = obstructive sleep apnea; OHS = obesity hypoventilation syndrome; CV = cardiovascular; HTN = hypertension; GERD = gastroesophageal reflux disease; PUD = peptic ulcer disease; DM = diabetes ; NS = not specified

Accepted manuscript

Table 3. Quality of included studies

Reference	Study Design	Study population clearly identified?	Clear definition of outcome and outcome assessment?	Selective loss of patients during follow-up?	NOS Score (out of 8)
Gargiulo <i>et al</i> , 2006 (11)	RC; PC	Yes	Yes	No	6
Halmi <i>et al</i> , 2007 (12)	RC	Yes	Yes	No	6
Obeid <i>et al</i> , 2007 (14)	RC	Yes	Yes	No	6
Overby <i>et al</i> , 2009 (15)	PC	Yes	Yes	No	6
Li <i>et al</i> , 2012 (13)	RC	Yes	Yes	No	6
Birkmeyer <i>et al</i> , 2013 (10)	PC	Yes	Yes	No	8

RC = retrospective cohort; PC = prospective cohort; NOS = Newcastle-Ottawa scale

Table 4. Comparison of recently published meta-analysis and our study

Characteristic	Rajasekhar A <i>et al</i>	Brotman DJ <i>et al</i>	Our Study
Type of review	Systematic Review	Systematic review and Meta-analysis	Systematic review and Meta-analysis
Year of publication	2010	2013	Current manuscript
Primary objectives	Evaluate the evidence supporting placement of IVC filters in patients undergoing bariatric surgery.	Comparative effectiveness and safety of pharmacologic and mechanical strategies to prevent VTE in patients undergoing bariatric surgery.	Evaluate postoperative outcomes associated with the preoperative placement of IVC filters in patients undergoing bariatric surgery.
Inclusion criteria	No specific criteria listed but original studies that had VTE outcomes after prophylactic IVC filters for bariatric surgery were included.	Studies that described 2 or more interventions, including devices, drugs, varying doses, or varying durations of therapy.	Studies with information about DVT or PE as outcomes of bariatric surgery, (ii) study population of patients ≥ 18 years (iii) study in any language.
Exclusion criteria	No specific criteria listed.	No specific criteria listed. However, Studies with no original data (ii) Studies not conducted in humans (iii) studies that looked at treatment of VTE were excluded	No control group and if DVT or PE were not available or could not be extracted for the study groups.
Databases searched	MEDLINE, Web of Science and Cochrane database.	MEDLINE, EMBASE, Scopus, CINAHL, International Pharmaceutical Abstracts, clinicaltrials.gov, and the Cochrane Library.	MEDLINE, EMBASE, Scopus, Web of Science and clinicaltrials.gov database.
Number of studies included	11 studies included but only 4 studies compared an IVC filter group with a non-IVC filter group in patients undergoing bariatric surgery.	13 studies but only 5 studies had data on outcomes in IVC filter and non-IVC filter group among patients undergoing bariatric surgery.	6 studies. All studies compared an IVCF group with a non-IVCF group in patients undergoing bariatric surgery.

Sample size	2,488 (n=4)	102,114 (n=5)	102,767 (n=6)
Quality assessment (risk of bias in individual studies)	Newcastle–Ottawa Scale	Downs and Black Tool	Newcastle-Ottawa Scale
Methods of Meta-analysis	NA	Used a random-effects model, but no details provided. Evaluated grade of evidence.	Sidik-Jonkman random effects model. Sensitivity analysis with Mantel-Haenzel method and fixed effects model.
Definition of heterogeneity	NA	$I^2 > 50\%$ defined as high heterogeneity	I^2 of 30-60% was defined as moderate level of heterogeneity; $> 60\%$ is high heterogeneity.
Outcome association measure with 95% CI	NA	PE: RR, 1.21 (95% CI, 0.57-2.56 $P = .62$ $I^2 = 6.9\%$) DVT: RR, 2.94 (95% CI, 1.35 to 6.38 $P = .007$; $I^2 = 40.3\%$) Mortality: RR, 4.30 (95% CI, 1.60-11.54 $P = .004$ $I^2 = 0.0\%$).	PE: RR, 1.02 (95% CI, 0.31-3.37 $P = .9$ $I^2 = 58\%$) DVT: RR, 2.81 (95% CI, 1.33 to 5.97 $P = .007$ $I^2 = 35\%$) Mortality: RR, 3.27 (95% CI, 0.78-13.64 $P = 0.1$ $I^2 = 60\%$).
Conclusion	Insufficient evidence to support the use of IVC filters at the time of bariatric surgery.	(i) Insufficient evidence to support that prophylactic IVC filters reduce PE in patients undergoing bariatric surgery vs controls. (ii) Low-grade evidence to support that IVC filters increase DVT in patients undergoing bariatric surgery vs controls. (iii) Low-grade evidence to support that prophylactic IVC filters are associated with higher total mortality in patients undergoing bariatric surgery vs controls.	(i) Risk of PE was not increased with the use of IVC filters. (ii) Risk of DVT was significantly increased with the use of IVC filters in comparison to non-use of IVC filters. (iii) Overall mortality was non-significantly increased with the use of IVC filters.