



Improving Vascular Access Outcomes

RETROPERITONEAL HEMATOMA PREVENTION, RECOGNITION, AND TREATMENT

INTRODUCTION

Retroperitoneal hematoma (RPH), defined as bleeding into the space behind the peritoneal cavity, is a rare but potentially serious femoral access complication. Recent studies published in the cardiology literature have described certain patient subgroups as having increased risk for RPH. Recognition of patient subgroups who are at risk may help with prevention, early recognition, and treatment of retroperitoneal hematoma and may reduce morbidity and mortality associated with this complication.

LITERATURE REVIEW

Four publications examine the risk factors for RPH. The first is a study by Farouque et al. that was published in *JACC* (2005).¹ In this study, a retrospective review of 3,508 PCI patients at Stanford University was undertaken to determine the risk factors for RPH. Twenty-six patients (0.74%) were found to have experienced retroperitoneal hematoma over the four-year review period. Examination of the RPH patient records revealed three factors to be predictive of RPH: gender (female), Body Surface Area (BSA) < 1.73m², and high femoral puncture. Other factors studied that were not predictive included heparin use, glycoprotein IIb/IIIa use, sheath size, and use of closure device.

The second study, by Sherev et al., was published in *CCI* (2005).² This study examined the relationship between femoral arteriotomy location and risk of femoral access site

complications after diagnostic and interventional cardiac catheterization procedures.

During the study period, there were 1,570 patients undergoing left heart catheterizations with femoral access. Of this group, 33 experienced vascular complications. Six post-PCI patients experienced RPH (0.9%). The RPH patients were subgrouped based on angiographic arteriotomy site. The study concluded that patients with arteriotomy location above the most inferior border of the inferior epigastric artery (IEA) were at an increased risk for retroperitoneal hematoma.

The third study, by Ellis et al. (*CCI* 2006), examined the correlates, outcomes, and optimal management strategies for patients with suspected RPH.³ Prospectively collected data was reviewed for 28,378 consecutive patients, revealing RPH incidence in 163 patients (0.57%). RPH in this study was associated with sheath insertion above the IEA, female gender, use of Angio-Seal™ device, and glycoprotein IIb/IIIa inhibitors.

The fourth study, by Arora et al. (*JACC* 2006), is a local prospective outcomes registry of 12,083 consecutive patients undergoing left heart catheterization and PCI for a two-year period. The purpose of the study was to explore the costs, predictors, and outcomes of RPH. The authors concluded that PCI, high femoral arterial puncture, and peripheral vascular disease were significant risk factors for the development of RPH. RPH is associated with significantly increased length of stay, total costs, and a trend toward increased mortality.⁴

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ANATOMIC LANDMARKS FOR PATIENTS AT RISK

In the Farouque et al. (*JACC* 2005) study, high femoral puncture was identified using bony landmarks. High stick was defined as a puncture that was located above the proximal third of the femoral head.

Sherev et al. (*CCI* 2005) and Ellis et al. (*CCI* 2006) identified high femoral puncture with angiographic landmarks utilizing the inferior epigastric artery.

Sherev defined high puncture as a puncture that occurs above the most inferior margin of the inferior epigastric artery. In contrast, in the Ellis study, high puncture was identified as sheath insertion above the origin of the inferior epigastric artery.

CLINICAL SIGNS AND SYMPTOMS¹ OF RPH

Anemia	(100%)
Hypotension	(92%)
Abdominal Tenderness	(69%)
Diaphoresis	(58%)
Groin Pain	(46%)
Lower Abdominal Pain	(42%)
Groin Hematoma	(31%)
Bradycardia	(31%)
Back Pain	(23%)

INCIDENCE AND MORTALITY

The reported incidence of RPH after cardiac catheterization varies in the literature. In earlier studies (1993-1994), the incidence of RPH ranged from 0.15% to 0.47%.^{5,6} A more recent study, the Do Tirofiban And ReoPro Give Similar Efficacy Outcomes Trial (TARGET), cites an incidence of 0.7%.⁷ In the Farouque study, 26 (0.74%) of 3,508 consecutive patients undergoing PCI experienced RPH. One patient with RPH died from complications of retroperitoneal blood loss (4%). Farouque et al. speculate that this difference may be attributed to differences in periprocedural antithrombotic regimens and

evolution of vascular access site management over the past two decades.

Ellis et al. cite an RPH incidence of 0.57%. When RPH occurred, the rate of in-hospital mortality was 10.4% (17 patients). Of the 17 patient deaths, six were directly related to RPH, two of which occurred in association with delays in volume (fluid and blood) resuscitation efforts consequent to attempts to obtain diagnostic confirmation with CT imaging.

The diagnosis of RPH in the Ellis study put the patient at a markedly higher rate of procedure-related death – occurring in 10.4% of RPH patients (17 of 163 patients) as opposed to all other causes of death which occurred at a 0.7% rate in 28,215 patients. The diagnosis of RPH increased the likelihood of mortality by a factor of 14.8.

In the Sherev study, of the 1,570 patients studied, six patients experienced RPH (0.9%). All of the RPH patients were post-PCI, and none of the six patients expired.

In the Arora abstract (*JACC* 2006), the RPH incidence was 0.47% in PCI patients. RPH in PCI cases had an in-hospital mortality of 4.17%; a four-fold increase over controls.

SIGNS AND SYMPTOMS

Clinical signs and symptoms in the Farouque study included anemia (100%), hypotension (92%), abdominal tenderness (69%), and diaphoresis (58%). Other signs and symptoms included groin pain, lower abdominal pain, groin hematoma, bradycardia, and back pain. Asymptomatic RPH was rare, with 96% of patients experiencing at least one symptom.

Time to first recorded clinical feature was 158 minutes, and the mean hematocrit drop was 11.5 points from baseline.

In the Ellis study, the diagnosis of RPH was made clinically by the physicians caring for the patient at the time, usually on the basis of presentation with peri-inguinal fullness, flank tenderness, or falling hematocrit, and usually confirmed on the basis of CT or other noninvasive forms of imaging.

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TIME FROM CASE COMPLETION TO APPEARANCE OF SYMPTOMS

Ellis	2.4 hr
Farouque	2.6 hr

PREDICTORS OF RPH

Farouque¹

- Female
- BSA < 1.73m²
- High Femoral Puncture

Sherev²

- Arteriotomy location **above the most inferior border of the inferior epigastric artery (IEA)** in patients undergoing PCI was associated with 100% of all retroperitoneal bleeds

Ellis³

- RPH Associated with: **sheath insertion above the origin of inferior epigastric artery (IEA)**, female sex, use of Angio-Seal™ device, GP IIb/IIIa inhibitors
- Sheath placement above the inferior epigastric artery (IEA) was associated with a 17.6-fold increased risk of RPH

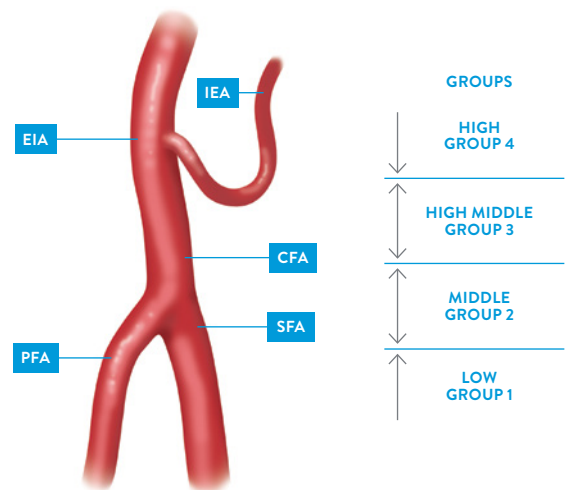
Arora⁴

- PCI
- High femoral stick
- Peripheral Vascular Disease

TREATMENT CONSIDERATIONS

In the case of a high femoral artery puncture, consider the following:

- Leave the arterial sheath in place until the anticoagulant and antiplatelet therapy has cleared.⁷
- Treat patients suspected at risk for RPH with manual compression independent of closure device use.¹
- Monitor patients with high femoral puncture closely for the first four hours post-procedure independent of closure device use.¹
- If RPH is clinically suspected, begin therapy with IV fluid and blood products as necessary, even if the diagnosis has not yet been confirmed by CT scan.⁵



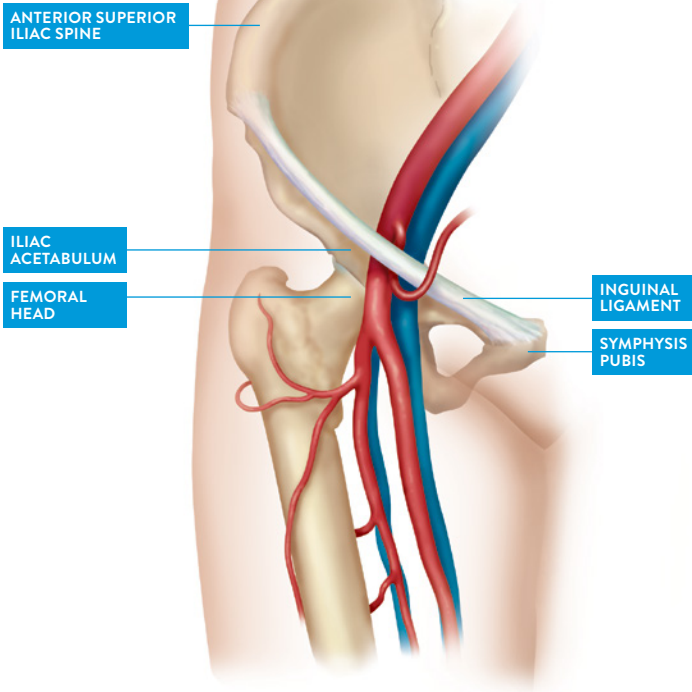
SCHEMATIC OF FEMORAL ANGIOGRAM IN THE 40° RAO VIEW

In the Sherev paper (*CCI* 2005), arteriotomy location above the most inferior border of the inferior epigastric artery in patients undergoing PCI was associated with 100% of all retroperitoneal bleeds. **Low, high middle, and high** femoral arteriotomy sites were associated with 71% of all vascular access complications. **All patients with RPH had femoral puncture above inferior border of the IEA.** The location of the femoral arteriotomy site assessed by femoral angiogram is predictive of life-threatening complications.

GRAY'S ANATOMY DEFINITION⁸

The **inferior epigastric artery** (a. epigastrica inferior; deep epigastric artery) **arises from the external iliac, immediately above the inguinal ligament**. It curves forward in the subperitoneal tissue, and then ascends obliquely along the medial margin of the abdominal inguinal ring; continuing its course upward, it pierces the transversalis fascia, and passing in front of the linea semicircularis, ascends between the rectus abdominis and the posterior lamella of its sheath.

This information is not intended to be a substitute for the independent care, determination, and judgment of healthcare professionals. Please consult the Instructions for Use and the Patient Guide for most current and accurate information concerning the Abbott product you are using.



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