ORIGINAL ARTICLE



# Slow femoral venous flow and venous thromboembolism following inguinal hernioplasty in patients without or with low molecular weight heparin prophylaxis

F. S. Lozano · J. Sánchez-Fernández · J. R. González-Porras · J. García-Alovio · J. A. Santos · R. Mateos · I. Alberca

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#### Abstract

*Background* Prosthetic material (mesh) is commonly used to repair inguinal hernias. Its implantation close to the common femoral vein (CFV) can induce slow flow and favor the appearance of venous thromboembolism (VTE) events.

*Aim* To investigate the speed of flow, diameter and area of the CFV after inguinal hernioplasty.

Methods Two hundred and fifty patients receiving open hernioplasty with a non-resorbable mesh for the repair of a unilateral, primary, simple inguinal hernia were prospectively investigated. Patients were stratified, by consensus, into a low or a moderate risk of VTE group. The moderaterisk group (n = 163) received low molecular weight heparin. On day 10 post-operation a blinded Echo-Doppler was carried out, and repeated 7 days later in patients with a venous flow of <15 cm/s. The speed of flow (cm/s), diameter (cm), and area (cm<sup>2</sup>) of the ipsilateral and contralateral CFV of the groin operated upon were measured. Results No event symptomatic of VTE was documented. One case of asymptomatic deep vein thrombosis (1/163, 0.6 %) was found in the moderate-risk group. In 29 patients (2 and 27 in the low- and moderate-risk groups, respectively; p < 0.001) a maximum blood flow velocity of <15 cm/s was found in the ipsilateral CFV; these flows

J. R. González-Porras (🖂) · J. García-Alovio ·

J. A. Santos · R. Mateos · I. Alberca

Servicio de Angiología y Cirugía Vascular, Hospital Universitario de Salamanca e IBSAL, Universidad de Salamanca, C/Paseo de San Vicente 182, 37007 Salamanca, Spain

e-mail: jrgp@usal.es

F. S. Lozano e-mail: lozano@usal.es were close to normal in the second measurement. Taking the entire sample into account, the maximum venous blood flow found in the ipsilateral CFV of the operated groin was less than that measured in the contralateral CFV (20.88 vs. 24.01 cm/s; p < 0.001); this difference was significant in both VTE risk groups. The diameter and area of the CFV were both greater in the ipsilateral than the contralateral CFV (p < 0.01); this finding proved to be significant only in hernias of the left groin (p < 0.001).

*Conclusions* In the immediate postoperative period, inguinal hernioplasty with mesh induces a temporarily slow venous flow in the ipsilateral CFV. However, this does not lead to an increase in the incidence of VTE.

Keywords Inguinal hernia repair  $\cdot$  Prosthetic mesh  $\cdot$  Femoral vein  $\cdot$  Blood flow  $\cdot$  Echo-Doppler  $\cdot$  Venous thromboembolism

#### Introduction

Inguinal hernia surgery is one of the procedures most frequently performed by general surgeons. In the USA, more than 700,000 people undergo this operation annually [1]. More than 70 open and endoscopic surgical techniques have been described for the repair of these hernias [2], although nowadays nobody doubts the greater effectiveness of the "tension-free mesh repair" techniques compared with the traditional method of dealing with tissues [3].

Among the various complications of hernioplasties, one that is often described is the constriction of the femoral vein and the possibility of venous thromboembolism (VTE) [4]. However, the available literature, though scarce, suggests that the frequency of post-inguinal hernia surgery VTE is low [5–8].

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Nonetheless, the association of the different individual situations (predisposing or triggering) may increase the risk of VTE, through modification of Virchow's etiopathogenic triad. Thus, the operative technique, especially the insertion of a foreign body (mesh), may induce a lesion and/or slow flow within the femoral vein. Taylor et al. [9] were the first to study the behavior of blood flow in the femoral veins after tension-free mesh repair hernioplasties. Bearing this knowledge fully in mind, our study centered upon measuring femoral vein blood flow in the period immediately after unilateral, primary hernioplasty (mesh) operations in two groups of patients with different levels of risk of VTE and who were receiving different prophylactic measures.

#### Materials and methods

This was an observational sub-study from a broader prospective study [10]. All included patients underwent repair of an inguinal hernia in the Major Ambulatory Surgery Unit of the Hospital Universitario de Salamanca, Spain. Exclusion criteria were age <18 years and an ASA risk score  $\geq$ 3. The study was approved by the Hospital's Ethical Committee.

## Preoperative aspects

For each patient, a clinical history was obtained and the VTE risk stratification was determined according to the Spanish ASECMA consensus (Table 1) [11], which classifies patients into one of two groups: low or moderate risk of VTE. Low molecular weight heparin (LMWH) (Bemiparin-Hibor<sup>®</sup>, subcutaneous, 2,500 UI/24 h, starting 6 h after surgery and continuing postoperatively for 7 days) was administered to patients in the moderate-risk group. All patients received written recommendation to do early, sustained gentle walking. Elastic compression stockings (pre- or post-surgery) were not prescribed. All patients signed an informed consent form to participate freely in the study.

## Surgical technique

Hernias (direct, indirect or combined, Nyhus types I–III) were all unilateral, primary (non-recurrent) and simple (non-complicated). Repair was open in all cases (i.e., non-laparoscopic). Two techniques were employed [Rutkow–Robbins or Prolene Hernia System (PHS)], all of which had in common the use of a non-resorbable prosthetic mesh (usually made of polypropylene). The mesh was always by using slow-resorption stitches; adhesives were never used for this purpose. For anesthetic induction, the patient

received 2 g of cephazoline IV (single dose). All interventions over a period of 6 months were carried out by the same surgical team of two senior surgeons and an anesthetic team.

#### Follow-up

Clinical evaluation, including a search for events symptomatic of VTE (deep vein thrombosis, DVT, and/or pulmonary embolism, PE), was carried out 10 and 30 days after surgery. Echo-Doppler color and helical computer tomography (CT) (only in the case of suspected PE) were also undertaken. The Echo-Doppler was done on the 10th day post-operation, this time being chosen with the aim of evaluating asymptomatic DVT. A Toshiba Aplio XG<sup>®</sup> ecograph with a linear multifrequency probe was used at a frequency of 7.5 MHz. Echographs were obtained in a blind manner by two expert sonographers who were unaware of the characteristics of the patient or the group to which they belonged.

Mode B transverse and longitudinal images were obtained of the common femoral vein (CFV) of the two extremities with the patient in a supine position. Since all patients underwent unilateral hernia repair, we compared the two sides. Wherever possible, venous compression was always continued until a complete collapse of the light was achieved. Subsequently, a spectral representation of the flow in both CFVs was obtained, paying particular attention to the morphological aspect of the wave. Flow velocity was measured at that location. To obtain the venous spectrum and the velocity in both CFVs, an attempt was made to modify the angle of incidence of the beam between  $30^{\circ}$  and  $60^{\circ}$  and the pulse-repetition frequency was adjusted to the minimum possible to avoid artifacts from "aliasing". After correcting the angle we obtained a measure from the highest region of the curve that corresponded to the expiratory phase and that favored venous return [12]. Having measured the venous flow and diameter of the CFV, the peak blood velocities (cm/s) and cross-sectional area  $(cm^2)$  were calculated [13, 14]. These are established parameters for measuring a prethrombotic state characterized by slow venous blood flow venous stasis [15].

A second Echo-Doppler, 7 days after the first, was taken when venous flows <15 cm/s were noted. Patients in the moderate-risk group continued their prophylaxis with LMWH.

## Statistical analysis

Data were compiled in a File-Maker ProAdvanced database. PASW version 18 (IBM, New York, USA) was used for statistical analyses, which included summary statistics (mean and standard deviation), Chi square tests, and **Table 1**Evaluation of the risof VTE and proposal ofthromboprophylaxis

(A) Surgical risk factors	(B) Personal risk factors	Risk of VTE	Proposal of prophylaxis	
Low	1	No risk	Only physical measures	
	2	No risk	Only physical measures	
	3	Moderate risk	+ LMWH moderate dos	
Moderate	1	Moderate risk	+ LMWH moderate dos	
	2	Moderate risk	+ LMWH moderate dos	
	3	High risk	+ LMWH high dose	
High (no MAS)	1–4	No MAS		
Low risk	Modera	ite risk		
(A) Surgical risk factors				
Laparoscopic surgery ≤6	0 min Laparo	scopic surgery >60 mi	n	
Abdominal wall hernias (unilateral)	Abdom (bilat	inal wall hernias eral)		
Cholecystectomy				
Perianal surgery				
Extensive soft part surger	ry			
Level 2 (low risk)		Level 3 (moderate ris	k)	
(B) Personal risk factors				
Age $\leq 40$ years		Age >40 years		
Pregnancy, puerperium, e contraceptives	estrogens,	History of VTE		
Cardiorespiratory insuffic	iency	Active neoplasm; che	motherapy	
Varicose veins		Chronic myeloproliferative syndrome		
Inflammatory intestinal d	isease	Nephrotic syndrome		
Obesity (BMI >30 %)		Congenital and acquir thrombophilia	ed	
Chromic smokers		Paralysis of lower lim	b	
Orthopedic surgery of low	wer limb			
Immobilization				
Duration of surgery $<30$				

Student's paired- and independent-samples t tests to compare groups when comparing flows from both extremities in the same individual, or in one extremity in patients with different risks of DVT, respectively. Statistical significance was concluded for values of p < 0.05.

# Results

ASECMA consensus (2006) *1* minimum, 2 low, 3 modera 4 high (not candidate for MA

Of the 250 eligible patients, 218 (87.2 %) completed the study. These were split into 55 (25.2 %) and 163 (74.8 %) patients in the low and moderate VTE risk groups, respectively (Fig. 1). Table 2 summarizes the basal data of the two groups. The surgical and anesthetic techniques used were similar in the two groups.

No symptomatic VTE was observed. Only one asymptomatic DVT case was found (in CFV) in the moderate-risk group, representing an incidence of 0.6 % (1 of 163 patients). No helical CT was carried out during

follow-up, as no symptoms or signs suggesting PE were noted (Table 3). The other postoperative complications are summarized in Table 3. At the same time, a reduction in venous flow (<15 cm/s) was seen in one of the CFVs examined (always ipsilateral to the surgery) in 29 patients (13.3 %). The proportion was significantly higher in the moderate ETV risk group (16.6 vs. 3.6 %; p < 0.001). Two weeks after surgery (second Echo-Doppler) all patients had femoral venous flows >15 cm/s (Table 4).

Considering all patients, the maximum velocity of venous flow determined in the CFV of the ipsilateral extremity (that of the operated groin), was lower than that measured in the contralateral CFV (20.88 vs. 24.01 cm/s; p < 0.001). This difference proved to be significant in both ETV risk groups (Table 5). The diameter and area of the CFV were both significantly greater in the ipsilateral than in the contralateral leg (p < 0.01). However, this was significant only in hernias arising in the left groin (p < 0.001) (Table 6).

Fig. 1 Study design. MAS major ambulatory surgery, ASECMA Asociación Española de Cirugía Mayor Ambulatoria (Spanish Association for Major Ambulatory Surgery), VTE venous thromboembolism, LMWH low molecular weight heparin

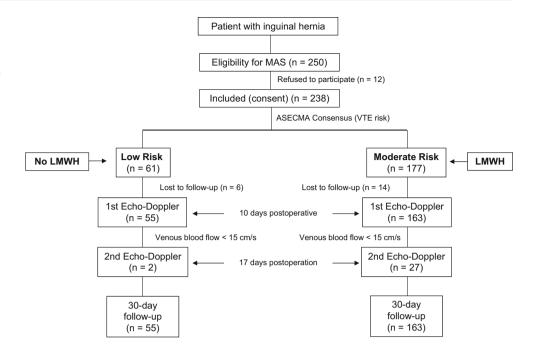


Table 2 Basal features by VTE risk group (number and percentage)

	Low $n = 55$	Moderate $n = 163$
Personal factors		
Age (mean $\pm$ SD)	$28.7\pm7.4$	$55.3 \pm 10.1$
$\leq 40$ years	55 (100)	4 (2.4)
>40 years	0 (0)	159 (97.6)
Sex (male/female)	40/15 (72.7/27.3)	137/26 (84/16)
Previous DVT or PE	0 (0)	1 (0.6)
Thrombophilia	0 (0)	3 (1.8)
Type of hernioplasty		
Rutkow–Robbins	21 (38.2)	63 (38.7)
Prolene Hernia System (PHS)	34 (61.8)	100 (61.3)
Type of anesthesia		
General	18 (32.7)	64 (39.3)
Local	37 (67.3)	99 (60.7)
Duration of surgery <sup>a</sup>		
≤30 min	55 (100)	159 (97.6)
>30 min	0 (0)	4 (2.4)

*VTE* venous thromboembolism, *DVT* deep vein thrombosis, *PE* pulmonary embolism

<sup>a</sup> Excluding anesthesia time

# Discussion

The present study shows, in a large group of patients, how inguinal hernioplasty with mesh induces slow venous flow at the level of the CFV ipsilateral to surgery in the immediate postoperative period.

Table 3	Complications by	VTF risk group	(number and p	ercentage)
Table 5	Complications by		Unumber and be	

	Low $n = 55$	Moderate $n = 163$
Adverse thromboembolic events		
Symptomatic DVT	0	0
Asymptomatic DVT	0	1 (0.6)
Altered blood flow <sup>a</sup>	2 (3.6)	27 (16.6)
Symptomatic PE	0	0
Local postoperative complications		
Hemorrhage of surgical wound	0	5 (3.1)
Scrotal hematoma <sup>b</sup>	1 (1.8)	3 (1.8)
Surgical wound infection	0	0
Related to the LMWH		
Ecchymosis (site injection LMWH)		
Minimum (≤2 cm in diameter)	0	66 (40.5)
Extensive (>2 cm in diameter)	0	7 (4.3)
Allergy	0	1 (0.6)

*VTE* venous thromboembolism, *DVT* deep vein thrombosis, *PE* pulmonary embolism, *LMWH* low molecular weight heparin

 $^{\rm a}$  Venous flow in the common femoral vein <15 cm/s (ipsilateral to surgery)

<sup>b</sup> No cases required drainage

The hypothesis that the reduction of femoral venous flow has repercussions for the incidence of VTE has been investigated, in previous decades, in the context of laparoscopic surgery in which the flow of the CFV could be altered by the pneumoperitoneum and/or the positions of the patient during the procedure. In this context, it was shown that the flow of CFV was significantly reduced during intraperitoneal insufflation, but not during preperitoneal insufflation [16]. Recently, the behavior of femoral venous flow in other types of open surgery has also been investigated [17, 18]. Finally, it is interesting to know how epidural anesthesia compensates for the reduction of femoral flow detected when the laparoscopic technique is carried out under general anesthesia [19].

The introduction of meshes in the repair of inguinal hernias, and their direct contact with the femoral veins and their branches, prompted some researchers to study the effect of the mechanical factor of the prosthesis, their contraction (20–75 % of the original size) and the reaction of the tissue (inflammatory process) to blood flow in the

 Table 4
 Pathological venous flows (cm/s) by VTE risk group

Common femoral vein Date of Echo-Doppler	Low $n = 2$	Moderate $n = 27$
Ipsilateral		
10 days after surgery	12.32 (2.81)	10.65 (4.12)
17 days after surgery	19.93 (9.82)	19.39 (6.92)
Contralateral		
17 days after surgery	22.06 (9.29)	23.85 (9.27)
Venous flow in the commo surgery)	on femoral vein <15 c	m/s (ipsilateral to

Mean (SD)

VTE venous thromboembolism

femoral artery and vein. None of the studies of testicular flow have shown negative effects [20–22]. Taylor et al. [9] were the first to study venous flow and found no evidence to support the hypothesis that the contraction of the mesh implanted in the groin had a negative effect on femoral venous flow. More recently, Ozmen et al. [23, 24] have published two studies in the same area. However, several aspects of these studies require comment.

Although our study used similar instrumentation (Echo-Doppler color) and determinations (velocity and diameter of the CFV), it featured some important differences from the aforementioned studies. First, we carried out the determinations in the immediate postoperative period and not 6 months [23, 24] or 3 years [9] after the procedure; second, we always had a control (the contralateral femoral vein) available, since our repairs were always unilateral rather than always bilateral [24]; finally, none of the other studies mentioned considered VTE risk factors or whether they used some type of prophylaxis, although none of the publications of Ozmen et al. [23, 24] reported any symptomatic cases of VTE. The commentary of Mangano et al. [25] concerning these studies is clear: the constriction of the femoral vein by meshes requires further study. In our opinion, late determination (whilst pursuing other objectives) and the lack of VTE risk stratification (which is higher in bilateral than in unilateral hernioplasties) has limited the interest in studying whether venous stasis is induced by the mesh and postoperative VTE.

Table 5 Venous blood flow (cm/s) in the common femoral vein by VTE risk groups

	Leg/ipsilateral to hernia	Leg/contralateral to hernia	Difference (95 % CI)	р
Low risk $(n = 55)$	25.36 (10.34)	29.81 (11.55)	-4.45 (-7.16 and -1.74)	0.002
Moderate risk ( $n = 163$ )	19.36 (8.00)	22.05 (9.12)	-2.69 (-3.93 and -1.44)	< 0.001
Total $(n = 218)$	20.88 (9.01)	24.01 (10.32)	-3.13 (-4.28 and -1.98)	< 0.001

#### Mean (SD)

VTE venous thromboembolism

Table 6       Mean of diameter         (cm) and cross-sectional area       (cm <sup>2</sup> ) in the common femoral vein		Leg/ipsilateral to hernia	Leg/contralateral to hernia	Difference	р
	Right hernia $(n = 35)$				
	Vein diameter	1.502	1.491	+0.011	0.775
	Cross-sectional area	1.818	1.781	+0.037	0.704
	Left hernia $(n = 29)$				
	Vein diameter	1.565	1.417	+0.148	< 0.001
	Cross-sectional area	1.678	1.599	+0.079	< 0.001
	Total $(n = 64)$				
	Vein diameter	1.540	1.437	+0.103	< 0.01
	Cross-sectional area	1.728	1.663	+0.065	< 0.01

Sulaimanov et al. [26] experimentally observed the effect of polypropylene mesh on femoral venous flow, 14, 28 and 90 days after implantation and found a significant reduction in flow 14 days after the operation; this reduction was no longer apparent at 28 or 90 days. In our study we observed that the most severe cases of flow reduction (<15 cm/s) recovered after 1 week. The clinical observation of Pannuchi et al. [18] was of a similar nature, whereby the reduction in femoral venous flow after abdominal pressure persisted for 48 h after surgery. However, this recovery of flow did not detract from the importance of the temporary effect of venous stasis and its possible repercussions for VTE during the immediate postoperative period.

To explain our main finding in relation to the mesh, fundamentally with the inflammatory response that occasions its insertion, we have ruled out the influence of local postoperative complications or complications arising from the LMWH (moderate-risk group) on reducing venous flow as a consequence of compression. In four patients with scrotal hematoma, the mean venous flow did not differ significantly from that in their respective risk groups. Hemorrhages from the operation wound, which were more frequent in the LMWH group, were always superficial, as was the presence of abdominal ecchymosis (distant from the area of the incision) consecutive to the application of the LMWH.

In addition, we have compared the blood flow of the patients in this study with two other groups at risk of VTE (surgery for sacrococcygeal pilonidal sinus disease and epigastric or umbilical hernia) and with determinations carried out under the same conditions. The results were significant in showing a mean slowing of blood flow by -7.17 and -4.55 cm/s in the low- and moderate-risk groups of patients who underwent inguinal hernia surgery with mesh (Table 7).

Two other related findings also warrant comment. First, the fact that the group at moderate risk of VTE was significantly older on average suggests that the reduction in blood flow in the CFV may increase with age. Second, since hernias in the left groin presented significantly more frequently than in the right, the greater slowing of venous flow, as demonstrated by a bigger diameter and cross-sectional area of the CFV, may be due to the anatomical fact that the left iliac vein is anteriorly crossed by the iliac artery, leading to the worse emptying of the former.

Although our study shows the temporary presence of ipsilateral femoral venous stasis, this did not result in an increase in VTE, possibly because the group most affected by the reduction in venous flow was classified as being at risk of VTE and received LMWH prophylaxis.

The scarcity of information about VTE after inguinal hernia is surprising; above all when we consider that this is one of the most frequently performed surgical procedures and so some patients must inevitably be at risk of VTE. Few of the many existing consensuses are concerned with the need to identify at risk patients and to determinate the most appropriate prophylaxis for them [27, 28]. At the same time we should not forget that, for many years, VTE has been one of the conditions most frequently associated with problems of medical malpractice and litigation [29].

For these reasons, it is important to note that the few published studies about the frequency of VTE and hernioplasties are all retrospective and do not evaluate the impact of new technical innovations [30]. Furthermore, the even more scarce publications about thromboprophylaxis related to this type of surgery report poorly designed studies [7, 31, 32]. This means that no clear recommendations exist, even in the most recent consensuses [33, 34]. However, surgeons are aware of the increasing number of patients with comorbidity and of young people with VTE risk factors who receive hernia interventions. Given this, the concern expressed in questionnaires carried out in various European and American countries, above all about the variability found when trying to determine risk and propose prophylaxis, is not surprising [35–39]. All these surveys concluded by calling for a consensus for action, prompting a group of Spanish experts to publish one several years ago [11]. This was

Table 7         Venous blood flow
(cm/s) in the common femoral
vein by VTE risk between
unilateral hernia groups and
other surgeries without mesh in
the groin

SCPDS sacrococcygeal pilonidal sinus disease <sup>a</sup> CFV ipsilateral to surgery

<sup>b</sup> CFM minimum (between legs)

	Venous flow Mean (SD)	Number of patients (%) Venous flow <15 cm/s	р
Low risk			
Unilateral hernia $(n = 55)^{a}$	25.36 (10.34)	2/55 (3.6)	
SCPDS $(n = 48)^{\rm b}$	32.53 (12.19)	0/48 (0)	
Difference	-7.17 cm/s		< 0.001
Moderate risk			
Unilateral hernia $(n = 163)^{a}$	19.36 (8.00)	27/163 (16.6)	
Epigastric/umbilical hernia $(n = 38)^{b}$	23.91 (8.34)	0/12 (0)	
Difference	-4.55 cm/s		< 0.05

partially validated by our group [10] and a second version of it was subsequently developed [11].

Despite the findings of our study, there does not appear to be a consequent increase in the risk of VTE, especially for patients who are well stratified (and protected) by their degree of risk. Logically, we do not know the clinical result of the group of with-risk patients with reduced blood flow of <15 cm if they have not received LMWH prophylactically. The meta-analysis of Johnson et al. [40] shows how a first negative Echo-Doppler in patients without antithrombotic treatment reduces the risk of VTE to 0.57 % after 3 months. Nevertheless, patients in our study in whom slow venous flow was detected were subjected to a second Echo-Doppler, which, in all cases, showed values that were closer to normal. In other words, the slow flow was alleviated, without physical measures other than gentle walking, 2 weeks after surgery.

One of the limitations of our study is that two distinct techniques and two anesthetic methods were used, although these were equally distributed across the two risk groups. Another possible limitation of this study was that we did not include Lichtenstein repair (customarily considered as the gold standard), since this technique has for years only been infrequently used in our institution. Recent metaanalyses have compared open hernioplasties with mesh (Lichtenstein type) vs. mesh-plug (Prolene Hernia System type) [41, 42] and found similar results.

In summary, in the immediate postoperative period following a hernioplasty with mesh, patients experience transitory slow femoral venous flow. This represents an additional risk factor for VTE, and means that hernioplasties are not exempt from being a cause of VTE events, for which reason risk must be stratified to make a decision concerning the appropriate actions.

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**Conflict of interest** The authors declare no competing financial interests.

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