E-ISSN: 2616-3470
P-ISSN: 2616-3462

www.surgeryscience.com
2024; 8(3): 09-16
Received: 10-06-2024
Accepted: 15-07-2024

Eslam M Barsim
Vascular Unit, General Surgery Department, Menofia University, Menofia, Egypt

Ahmed H El Barbary
Vascular and Endovascular Surgery Department, Tanta University, Tanta, Egypt

Gerard JO'Sullivan
Intervention Radiology Department, University College Hospital, Galway, Ireland

Said I El Mallah
Vascular Unit, General Surgery Department, Menofia University, Menofia, Egypt

Hasan Abdelaty Hasan
Vascular and Endovascular Surgery Department, Tanta University, Tanta, Egypt

Adel H Kamhawy
Vascular and Endovascular Surgery Department, Tanta University, Tanta, Egypt

Corresponding Author:
Eslam M Barsim
Vascular Unit, General Surgery Department, Menofia University, Menofia, Egypt

Evaluation of distal extension of venous stents across the inguinal ligament

Eslam M Barsim, Ahmed H El Barbary, Gerard JO'Sullivan, Said I El Mallah, Hasan Abdelaty Hasan and Adel H Kamhawy

DOI: https://doi.org/10.33545/surgery.2024.v8.i3a.1089

Abstract
Background: Because arterial stenting across joints is not advised due to the reduced long-term patency, there is a higher risk of in-stent localized neo-intimal hyperplasia and the potential for stent breakage or compression from joint motion. Unlike arterial stenting, braided stainless stents can be safely inserted across the inguinal crease into the venous system without increasing the risk of stent fractures, external compression constriction, localized development of severe in-stent restenosis, or compromised long-term patency. Stents crossing the inguinal ligament is a contentious topic at the moment, though. Some recommendations advise against it, while others advise crossing the inguinal ligament if necessary to guarantee proper flow. The aim of this study was to evaluate the primary patency of stents that terminated above the inguinal ligament with stents that continued below the inguinal ligament.
Methods: This is a prospective multicenter study done on 30 patients (20 female, age 50.0±12.0 years), 19 malignant patients (63.3%) with 17 venous stents extended below the inguinal ligament represented at Tanta, Menofia and Galway university hospitals during the period from (May 2020) to (April 2023). During the 6-month follow-up period, the distal extension of venous stents was assessed by its patency. According to improvements in their VCSS and CEAP scores, the patients were evaluated.
Results: At one month, three months, and six months follow up periods, the supra-inguinal stents patency rate was 100%, 100%, and 90% consecutively. The infra-inguinal stents patency was 93.8% at 1 month, 87.5% at 3 months, and 93.3% at 6 months. In both groups, the median preoperative VCSS score was 18 (18 to 20). In infra-inguinal group, the median postoperative VCSS score become 7 (7 to 12) but in supra-inguinal group, the median postoperative VCSS score become 7 (7 to 8). There is no significant difference in VCSS score improvement in both groups (P=.134).
Conclusion: There was no significant difference in outcomes and clinical data in patients who received stents inferior to the inguinal ligament and patients who received stents superior to the inguinal ligament.

Keywords: Venous, stent, inguinal, ligament, evaluation, venous stents across

Introduction
The venous and arterial systems differ significantly in various aspects, which must be taken into account when selecting stents for occlusion and stenosis. Compared to the arterial system, the venous system transports more blood at a lower pressure and velocity. As a result, venous walls are more flexible and resistant to dilatation when subjected to external compressions [1].
In addition, various factors cause damage to veins than to arteries. Anatomical situations such as hip flexion can result in fibrosis and webs in the vessels, and persistent pulsations of nearby arteries can cause repetitive trauma. These are examples of venous stresses.The fibrotic tissue in the veins can result in stent compression [2].
It is important to remember that specific areas of the venous system-like the veins behind the inguinal ligament, the iliac bifurcation, and the iliocaval junction are especially vulnerable to stress [3].
The iliac vein bifurcation and the common femoral vein are the anatomical areas that endure the maximum flexion during hip flexion and are located proximal and inferior to the inguinal ligament [4].
The unique needs of each system must be taken into account when comparing venous and arterial stents. Arterial stents aim to restore proper blood perfusion and prevent limb ischemia, whereas venous stents primarily target the elimination of venous hypertension.

The stenosis threshold that causes clinical symptoms in the venous system is lower than in the arterial system, making venous stenting more challenging and necessitating accurate pre-operative examination [2].

Venous stents must have larger sizes, increased flexibility, and higher radial force compared to arterial stents [3]. Using arterial stents in venous insufficiencies is not recommended because the high rigidity and the low radial force of the stents decrease the post-stent patency rate and increase the probability of in-stent compressions.[5] Additionally, venous stents require greater stability and long-term resistance to corrosion and fatigue, as patients with chronic venous diseases are typically younger than those with chronic arterial diseases [3].

When treating arterial system occlusions or stenosis, percutaneous transluminal angioplasty (PTA) is the preferred course of action. However, because the venous system has a high elastic recoil feature, PTA alone in the venous system can cause vein restenosis. Therefore, PTA should always be carried out in conjunction with stent deployment to prevent vein recollapse [6]. Also, performing balloon angioplasty alone does not have a permanent effect on the diseased veins, due to the high rates of recollapse and restenosis of veins and the specific venous features mentioned above [7].

This is a prospective study comparing the effects of using venous stents with distal extension above inguinal ligament versus stents that extended below the inguinal ligament in patients with chronic venous obstructions at a multi-tertiary referral centers.

Materials and Methods

Patients

In this prospective, non-randomized clinical study, thirty patients at our tertiary medical facilities had their chronic venous occlusions and post-thrombotic syndrome (CVO/PTS) evaluated, along with follow-up visits conducted between May 2020 and April 2023.

Clinical examination was used to classify all limbs according to CEAP. Chronic iliocaval obstruction is defined as a 50% or greater venous lumen decrease of the IVC or iliac veins on duplex ultrasonography (DUS) or computed tomography venography (CTV), together with post-thrombotic trabecular changes in both the common and external iliac veins.

All patients displayed one or more of the symptoms listed below: significant leg swelling, venous claudication, leg pain, and leg edema, and skin blistering (due to high intra-dermal pressures). A small number of patients were stented with iliac vein compression as part of pelvic venous disease.

Patients who had single or multiple-segment iliocaval venous outflow stenosis or occlusion with patent inflow were also included, as were symptomatic patients with recanalization less than 50% who had been identified by duplex ultrasonography and confirmed by CT venography or IVUS.

Excluded were acute DVT patients, hepatic failure or end stage renal patients, end stage malignancy and patients presenting with obstructed venous inflow.

Each patient granted his informed consent for the research to begin after receiving a comprehensive description of the methodology. The study has been approved by the Tanta Faculty of Medicine's Research Ethics Committee, with the approval code 33980/7/20.

Procedure

Operations were performed either under GA or using local anesthesia and conscious sedation. Cases were fully anticoagulated before, during (5,000-10,000) units of unfractionated heparin were received intraoperative), and after the procedure.

Following US guided access, (popliteal veins, common femoral veins, or internal jugular veins) through micro puncture introducer set (Needle 21 G/7 cm, Wire 0,018’’/ 40 cm, Sheath 4 F/10 cm), initial venography was done.

In sixteen patients, intravascular Ultrasound (IVUS, Volcano, NL) was also employed. It helps in detecting the site of obstruction by measuring the surface area in and below the obstructed site. A concentric cylindrical phantom with six pieces that had cross-sectional diameters between 3.0 and 8.0 mm was used for IVUS imaging. Measurements and contrasts were made between the minimum lumen diameter (MLD) and lumen cross sectional area (CSA).

First, the lesion was crossed using the Amplatz extra stiff guide-wire 0,035’’/80 cm. Then, pre-dilation was performed using angioplasty balloons (ATLAS Gold PTA dilatation catheter 14 mm, 16 mm/ 60 cm) to diameter of the stent. After that stents were deployed from “normal to normal.

We used two different implantation types of stents, Wallstent (Boston Scientific, Marlborough, USA) and dedicated venous stents {Zilver Vena (Cook, Bjaeverskov, Denmark), Medtronic Abre (Minneapolis, MN, USA) and Venovo (Bard, Tempe, USA)}. Stents were employed and came loaded in a 10-fr delivery system in diameters of 14 and 16 mm and lengths of 60, 100, and 140 mm.

Finally, the stent was inflated once more to the same diameter. When more than one stent was needed, they overlapped by around 2 cm. Additionally, stents extended into vein segments with good flow for around 2 cm. Stents were introduced from the very distal IVC to roughly the level of the lower trochanter, below the inguinal ligament, or above the inguinal ligament, depending on the pathology of each case. This is because the stents must be inserted from a normal segment to a normal one.

High pressure post-dilation was carried out to the stent's nominal diameter. The stent was post-dilated to its nominal diameter under high pressure. A final venography was performed to assess the patency and blood flow of the stent. IVUS was also utilized to assess stent patency and the absence of any residual stenosis or thrombosis.

Post procedure

To determine the patency of the stent, a color Doppler ultrasound was performed on the first postoperative day. Wearing Class II thigh-high compression stockings was part of the post-procedure treatment. Based on the clinical state of each patient, post-procedure anticoagulation was administered. Nineteen patients with active cancer received low molecular weight heparin (LMWH), while eleven non-malignant patients were kept on therapeutic NOAC with 100 mg of aspirin for at least three months. Extended or lifelong anticoagulation was provided to patients with the necessary standards.

Oncology follow-up CTs were often performed on cancer patients to evaluate patency. Re-intervention was also taken into account based on clinical symptoms and outcomes from imaging.

Follow up and prognosis

Stent assessments were performed at one-month, three-month, and six-month intervals to examine patency if complaints did not worsen or persist. As directed, CTV or MRV was performed. They were evaluating symptoms and treatment responses through clinical follow-up as well.

Primary Outcome Measures

1. The primary patency rate of participants at 6 months post intervention. The primary end point for efficacy was the 6-month post intervention primary patency rate. This was defined as less than 50% in-stent stenosis by venogram, lack of thrombosis-induced occlusion and no endovascular or surgical treatment being performed on the target vessel due to stented segment dysfunction. Subgroup analysis was performed to compare between venous stents with distal extension above the inguinal ligament and those extended below the inguinal ligament regarding patients & lesions characteristics as well as the primary and secondary outcomes.
2. The percentage of participants who experienced Major Adverse Events (MAE) over the 30-day period. Any major adverse event (MAE) within 30 days served as the study's primary safety outcome.

Secondary Outcome Measures:

1. Clinical evaluation of both pre and post-stenting CEAP and VCSS scores for the stents above as well as those extending below, the inguinal ligament in each group.
2. Venous Clinical Severity Score change > 4 points [Time Frame: six months post-intervention], the main secondary effectiveness endpoint for the trial was a switch in the VCSS by more than 4.

Results

We studied thirty patients who had chronic venous blockages in the iliocaval vein. The patients were between the ages of 29 and 68, with a mean age of 50.0±12.0 years. There were 10 males (33.3%) and 20 females (66.6%). Eighteen patients (60%) had prior DVT, medical co-morbidities included diabetes mellitus in 21 patients (70%), hypertension in 15 patients (50%), ischemic heart disease in 9 patients (30%), and 19 patients (63.3%) presented with neoplasms.

Patients' characteristics

Supra-inguinal stents were inserted in five cancer patients (38.5%) and eight non neoplastic individuals (61.5%). Venous stents with distal extension below the inguinal ligament were implanted in fourteen malignant patients (82.4%) and three non-cancer patients (17.6%). All baseline characteristics of all study population and those receiving supra-inguinal or infra-inguinal stents are presented in Table 1.

Lesions' characteristics

Supra-inguinal stents were inserted in eight post thrombotic lesions (61.5%) and five non-thrombotic lesions (38.2%), five patients (38.5%) presented by IVC lesions, six patients (46.2%) presented by CIV lesions and two patients (15.4%) presented by EIV lesions. Venous stents with distal extension below the inguinal ligament were implanted in ten post thrombotic patients (58.8%) and seven non-thrombotic patients (41.2%), one patient (5.9%) presented by IVC lesion, eight patients (47.1%) presented by CIV lesions and eight patients (47.1%) presented by EIV/CFV lesions. Characteristics of the venous lesion in all study population and in both group are presented in Table 1.

Technique

Wallstents were implanted in 13 patients (43.3%) with distal extension above the inguinal ligament in eight patients (61.5%) and five patients (38.5%) terminated below the inguinal ligament. Dedicated venous stents were inserted in 17 patients (56.6%) with distal extension above the inguinal ligament in five patients (29.4%) and twelve patients (70.6%) terminated below the inguinal ligament.

Dedicated venous stents included Cook Zilver vena stents in eight patients (47%) with distal extension above the inguinal ligament in two patients (25%) and six patients (75%) terminated below the inguinal ligament, Bard Venovo stents in four patients (23.5%) with distal extension above the inguinal ligament in two patients (50%) and two patients (50%) terminated below the inguinal ligament and Medtronic Abre stents in five patients (29.5%) with distal extension above the inguinal ligament in one patient (20%) and four patients (80%) terminated below the inguinal ligament.

Forty nine venous stents were inserted in thirty patients with one stent was inserted in fourteen patients (46.6%) with distal extension above the inguinal ligament in seven patients (50%) and seven patients (50%) terminated below the inguinal ligament, two stents were inserted in thirteen patients (43.3%) with distal extension above the inguinal ligament in six patients (46.2%) and seven patients (53.8%) terminated below the inguinal ligament and three stents inserted in three patients (10%) with distal extension below the inguinal ligament as all diseased intima must be covered and implantation of stents from healthy to healthy vein segment.

IVUS was used pre and post stenting in 16 patients (53.3%) with distal extension above the inguinal ligament in three patients (18.75%) and thirteen patients (81.25%) terminated below the inguinal ligament. IVUS wasn't used in 14 patients (46.6%) as it was unavailable with distal extension above the inguinal ligament in ten patients (71.4%) and four patients (28.6%) terminated below the inguinal ligament. Technical details of the intervention in all study population and in those terminating above or below inguinal ligament are presented in Table 2.

Follow up

The follow-up was reported after 1, 3, and 6 months. One stent with distal extension below the inguinal ligament was crushed due to its compression by a neoplasm and observed during follow up after 1 month of the procedure. Another 4 patients (Three Patients (75%) with distal extension above the inguinal ligament and one patient (25%) with distal extension below the ligament) died from sequelae of malignant neoplasia observed during follow up periods of venous stenting.

Stent thrombosis occurred in 5 patients (16.6%). Distal extension in the four occluded stents was below the inguinal ligament with one stent above the inguinal ligament. Occluded stents occurred in four patients who had Wallstents inserted with distal extension above the inguinal ligament in one patients (25%) and three patients (75%) terminated below the inguinal ligament and only one patient who had dedicated stent (Cook Zilver Vena stent) with distal extension below the inguinal ligament. IVUS was not used in four patients with thrombosed stents. Thrombosis occurred in two patients with one stent, another two patients with two stents and only one patient with three stents.

Infra-inguinal Cook Zilver Vena stent showed thrombosis after 4 months of follow up. The first thrombosed infra-inguinal Wallstent was discovered after 1 month of follow up. Two infra-inguinal Wallstents show thrombosis after 3 months of follow up. The last one supra-inguinal thrombosed Wallstent was discovered at follow up for six months. Results of immediate postoperative assessment of stent patency in both study groups are presented in Table 3.

Primary patency

The overall primary patency rates of supra-inguinal stents at one month, three months, and six months follow up periods were 100%, 100%, and 90%, correspondingly. While the overall primary patency rates of infra-inguinal stents at one month, three months, and six months follow up periods were 93.8%, 87.5%, and 93.3%, correspondingly. Stent patency during postoperative follow-up in both study groups are presented in Figure 1.

In four patients who had thrombosis, pharmacho-mechanical thrombectomy was done successfully then angioplasty and stenting to maintain patency of the venous stents but the fifth stent was crushed. Results of assessment of stent patency during postoperative follow-up in both study groups are presented in Table 4.

Clinical assessment

In both groups, the median preoperative VCSS score was 18 (18 to 20). In infra-inguinal group, the median postoperative VCSS score become 7 (7 to 12) but in supra-inguinal group, the median postoperative VCSS score become 7 (7 to 8). There is no significant difference in VCSS score improvement in both groups (P=.134).

In both groups, the median preoperative CEAP score was 4 (4 to 5) while the median postoperative CEAP score in infra-inguinal group was 3 (3 to 5) and supra-inguinal group was 3 (3 to 4). There is no significant difference in CEAP score improvement in both groups (p=.143). Change in CEAP and VCSS scores in both groups are presented in Table 5.

Major adverse events

Five major adverse cardiovascular events (MACs) were recorded: four patients died from the consequences of malignant neoplasia during follow-up venous stenting periods, and one patient reported a symptomatic pulmonary embolism.

Six MALs (major adverse limb events) were reported: one crushed Wallstent due to its compression by a neoplasm and five thrombosed stents. Table 6 and Figure 2 show the results of Kaplan-Meier survival analysis for both study groups.

Six-month restricted mean survival time (RMST) (95% CI) = 6.00 (6.00 to 6.00) months and 5.15 (4.25 to 6.06) months for infra-inguinal and supra-inguinal stents, respectively. Difference between both groups is not statistically significant (difference = -0.85, 95% CI = -1.75 to 0.05, p-value = .066). Difference between both survival curves is not statistically significant (Log-rank test chi-squared = 2.012, DF = 1, p-value = .156, hazard ratio = 4.25, 95% CI = 0.58 to 31.45).

Discussion

Stenting below the inguinal ligament is a major factor that increases the probability of in-stent stenosis, obstruction, and stent fracture.[5] Numerous research works have documented challenges in guiding stent implantation beyond the inguinal ligament. Additionally, certain studies indicate that the patency rates of infra-inguinal stents are lower than those of supra-inguinal stents [8]. Black, *et al*. [8] reported that there was no significant difference in outcomes and clinical data in patients who received stents inferior to the inguinal ligament and patients who received stents superior to the inguinal ligament. Moreover, a study by Cheng *et al*. [9] reported that the point of maximum flexion of the iliac venous system during hip flexion is inferior to the inguinal ligament, and the common femoral vein is several centimeters inferior to the inguinal ligament. So extending stents below this level does not significantly affect patency rates [1]. Different characteristics are chosen for venous stents than arterial stents due to the major differences between the venous and arterial systems [10]. Specifically, venous stents require more flexibility, larger diameters, longer lengths, and higher radial forces-especially when traversing the inguinal ligament. Unlike the arterial system, the insertion sheath's size is not as significant [11].

No study reported a subgroup analysis on the effect of placing stents across the inguinal ligament according to lesion etiology. However, the studies by Endo *et al*. [12] and Attaran *et al*. [13] reported that etiology was not a statistically significant predictor of overall primary patency, whereas Gagne *et al*. [14] report that limbs with post-thrombotic lesions have a statistically significant lower patency than those with non-thrombotic lesions. *In our study, there is a significant association with higher primary patency of non-thrombotic lesions than thrombotic ones.*

It has been suggested that closed cell steel stents would be more appropriate for venous stenting across the inguinal ligament, [15] and that dedicated venous stents would be preferable to arterial stents.[16] However, Machado H *et al*.[17] reported that more cases of stent fracture and compression at the IL, venous closed cell stents were used. *In our study, it is reported that one crushed Wallstent with distal extension below the inguinal ligament.*

All cases of stent fracture or compression reported by Black *et al*. [8] occurred at the inguinal ligament, which seems to validate the suspicion that the region under the IL is anatomically prone to this type of complication. On the other hand, all CFV lesions in this study were stented across the IL, and, as such, there is no data on any alternative procedure that can be used for comparison. The study by Hartung *et al*. [6] included 18 patients with CFV involvement, all of post-thrombotic etiology. However, only 8 of those lesions were stented, with stents crossing the IL, while the other 10 received only angioplasty at the CFV. None of the limbs with stents placed across the IL lost primary patency, whereas 3 of the 10 limbs with unstented CFV lesions suffered rethrombosis. This difference was not statistically significant, likely due to the small sample size, but it suggests that, when there is CFV involvement, it is safer to stent the affected area than to perform angioplasty alone [16].

Gagne *et al*. [14] report only one case of stent fracture, in a cancer patient who received radiation therapy in that area, and also suggest that poor inflow due to CFV involvement could be a greater determinant of primary patency loss than stent placement across the inguinal ligament. *In our study,it is reported that one crushed Wallstent due to its compression by a neoplasm.*

In a review of published trials of stenting outcomes across all venous disease categories, Raju revealed lowered long-term patency rates (66-89%) in patients with recanalization of post-thrombotic occlusions [18]. Only two of the analysed studies used IVUS, which was noted as a drawback in this review [19]. *In our study IVUS use shows significant association with superior primary patency of venous stenting than non IVUS cases.*

This is critical for the long-term therapeutic effectiveness of this patient population because it guarantees complete stent coverage of the lesion and proper stent inflow and outflow. Regardless of whether the stent bridged the inguinal ligament, Neglen *et al*. [20] found that secondary patency rates were significantly lower in limbs with post-thrombotic occlusions at 32 months when compared to non-occlusive obstructions. These rates were 77% and 96%, respectively [15]. It was shown that stenting of occluded veins and post-thrombotic aetiology were far more significant determinants for stent occlusion than stent extension beneath the inguinal ligament into the CFV [15].

It will be challenging to compare the relative benefits and drawbacks of closed and open cell stent designs for the

treatment of non-thrombotic and post-thrombotic aetiologies until comparative data on their effectiveness are available. Comparing how well they traverse the inguinal ligament will be very intriguing. Additionally, the relative significance of lumen shape is taken into consideration (i.e., the shift to a rounder lumen post-stenting is made possible by the closed cell design and increased radial strength) [21]. The veins' typical elliptical form is significantly altered by this. Future studies will examine how much volume flow through the stent system is improved by giving the venous lumen a more cylindrical shape, resulting in better clinical alleviation and longer stent patency. The aetiology and whether the post-thrombotic blockage is occlusive or non-occlusive are what determine the patency rate, not the size of the stented region or whether the stent was placed across the inguinal ligament [15]. *In our study, there is no significant difference in the primary patency of stents that terminated above the inguinal ligament than that of stents that continued below the inguinal ligament.*

This study has certain limitations. The primary limitations of the study include its limited patient population, with most of them having cancer, and the impossibility of longer follow-up because of patient fatalities brought on by the course of the illness.

Lastly, because only the VCSS and CEAP scoring measures were used for patient assessment, the study's evaluations are also constrained. Nonetheless, this clinical data supports the significance of IVUS in venous stenting and compares supra-inguinal and infra-inguinal venous stents.

Tables

Table 1: Baseline characteristics of patients in both study groups

	Stent extension		
Variable	**Infra-inguinal (N=17)**	**Supra-inguinal (N=13)**	**P-Value**
Age (years), median (IQR)	56 (41 to 61)	45 (39 to 55)	.295†
Sex, n (%)			.056‡
F	14 (82.4%)	6 (46.2%)	
M	3 (17.6%)	7 (53.8%)	
Location of DVT, n (%)			.056§
EIV	8 (47.1%)	2 (15.4%)	
CIV	8 (47.1%)	6 (46.2%)	
IVC	1 (5.9%)	5 (38.5%)	
Underlying neoplasia, n (%)	14 (82.4%)	5 (38.5%)	.023‡
Pathology, n (%)			>.999‡
Thrombotic	10 (58.8%)	8 (61.5%)	
Non-thrombotic	7 (41.2%)	5 (38.5%)	
Preoperative CEAP, median (IQR)	4 (4 to 5)	4 (4 to 5)	.721†
Preoperative VCSS, median (IQR)	18 (18 to 20)	18 (18 to 20)	.721†

†. Mann-Whitney test.
‡. Fisher's exact test.
§. Fisher-Freeman-Halton's exact test.
IQR = interquartile range, N = number.
*P-Value of less than 0.05 was considered to be statistically significant.

Table 2: Technical details of the intervention in both study groups

	Stent extension		
Variable	**Infra-inguinal (N=17)**	**Supra-inguinal (N=13)**	**P-Value**
IVUS used, n (%)	13 (76.5%)	3 (23.1%)	.009†
Number of stents, n (%)			.218‡
One	7 (41.2%)	7 (53.8%)	
Two	7 (41.2%)	6 (46.2%)	
Three	3 (17.6%)	0 (0.0%)	
Stent type, n (%)			.138†
Dedicated stent	12 (70.6%)	5 (38.5%)	
Wall stent	5 (29.4%)	8 (61.5%)	

†. Fisher's exact test.
‡. Linear by linear association.
N = number.
*P-Value of less than 0.05 was considered to be statistically significant.

Table 3: Results of immediate postoperative assessment of stent patency in both study groups

	Stent extension		
Variable	**Infra-inguinal (N=17)**	**Supra-inguinal (N=13)**	**P-Value†**
Stent patency, n (%)			.223
Primarily patent	13 (76.5%)	12 (92.3%)	
Assisted patency	4 (23.5%)	1 (7.7%)	

†. Linear by linear association
N=Number
* P-Value of less than 0.05 was considered to be statistically significant.

Table 4: Results of assessment of stent patency during postoperative follow-up in both study groups

		Stent extension		
Variable	**Time after surgery**	**Infra-inguinal**	**Supra-inguinal**	**P-Value†**
Stent patency, n/N (%)	*1 month*	15/16 (93.8%)	12/12(100.0%)	>.999
	3 months	14/16 (87.5%)	11/11 (100.0%)	.499
	6 months	14/15 (93.3%)	9/10 (90.0%)	>.999

†. Fisher's exact test
N/N = proportion
* P-Value of less than 0.05 was considered to be statistically significant.

Table 5: Change in CEAP and VCSS scores in both groups

		Stent extension		
Variable		**Infra-inguinal (N=17)**	**Supra-inguinal (N=13)**	**P-Value†**
CEAP, median (IQR)	Preoperative	4 (4 to 5)	4 (4 to 5)	.721
	Postoperative	3 (3 to 5)	3 (3 to 4)	.388
	Change	-1 (-1 to 0)	-1 (-1 to -1)	.143
VCSS, median (IQR)	Preoperative	18 (18 to 20)	18 (18 to 20)	.721
	Postoperative	7 (7 to 12)	7 (7 to 8)	.388
	Change in	-11 (-11 to -10)	-11 (-12 to -11)	.134

†. Mann-Whitney test.
IQR=Interquartile Range, N=Number.
* P-Value of less than 0.05 was considered to be statistically significant.

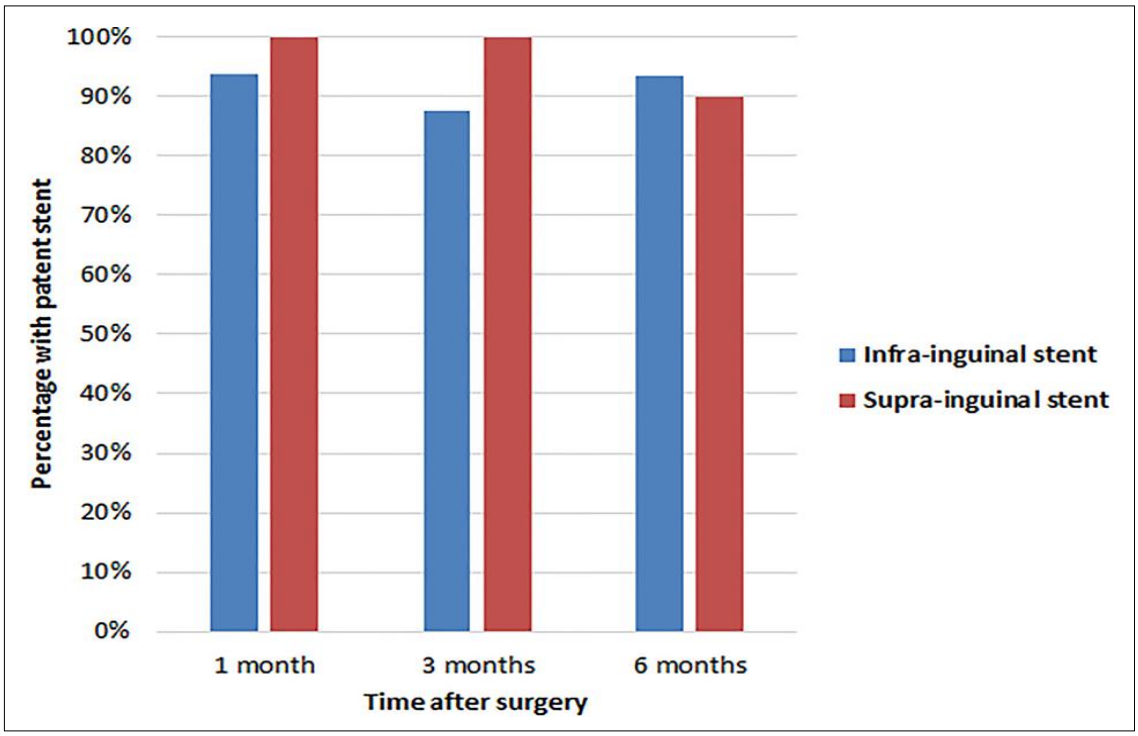

Fig 1: Stent patency during postoperative follow-up in both study groups

Table 6: Results of Kaplan-Meier survival analysis for both study groups

Six-month restricted mean survival (RMST) (months)						
Stent extension	**Mean**	**SE**	**95% CI for mean**	**Difference**	**95% CI for difference**	**P-Value**
Infra-inguinal	6.00	0.00	6.00 to 6.00	-0.85	-1.75 to 0.05	.066
Supra-inguinal	5.15	0.46	4.25 to 6.06			
Overall	5.63	0.21	5.22 to 6.05			
Comparison of survival curves (Log-rank test)						
Chi-squared	2.012					
DF	1					
p-Value	.156					
Hazard ratio						
Hazard ratio	4.25					
95% CI	0.58 to 31.45					

95% CI = 95% confidence interval, DF = degree of freedom, SE = standard error.

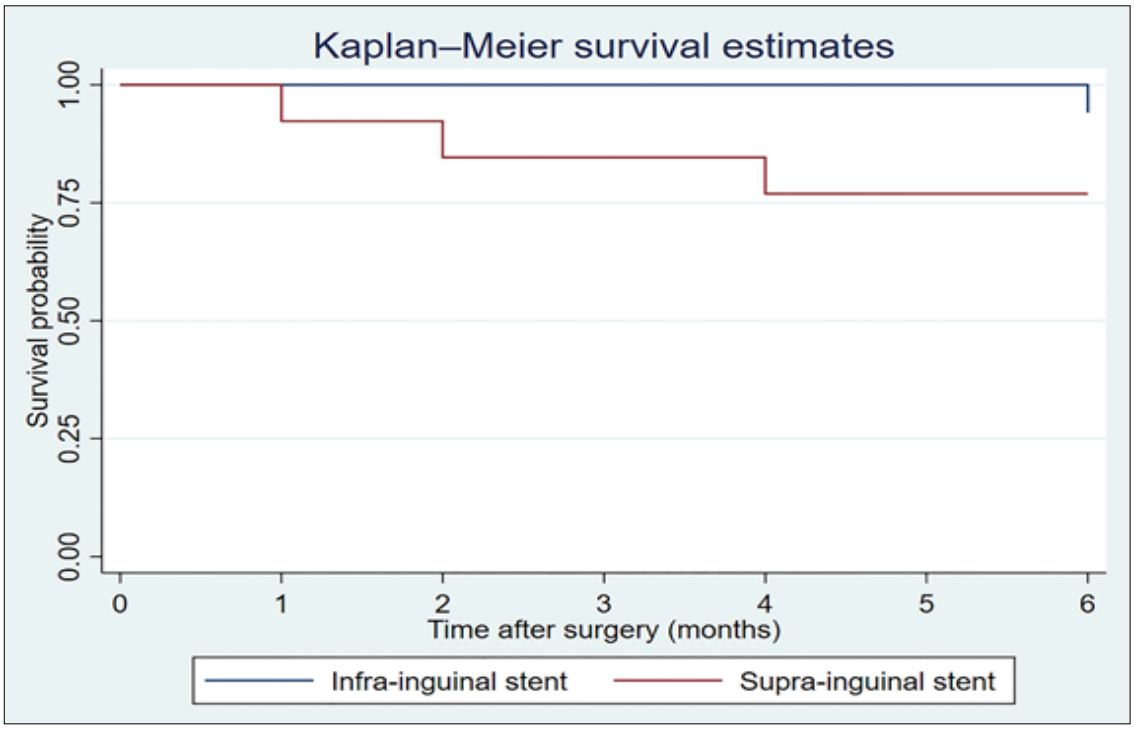

Fig 2: Kaplan-Meier survival curves in patients treated with supra-inguinal or infra-inguinal stents

Conclusion

There was no significant difference in outcomes and clinical data in patients who received stents inferior to the inguinal ligament and patients who received stents superior to the inguinal ligament.

Conflict of Interest

Not available

Financial Support

Not available

References

1. Taha MA, Busuttil A, Bootun R, *et al*. Clinical outcomes and overview of dedicated venous stents for management of chronic iliocaval and femoral deep venous disease. Vascular. 2022;30(2):320-330.
2. Chaar CIO. Current management of venous diseases. Springer; c2018.
3. Noori SSM, Clark TW. Venous stents: Current status and future directions. Tech Vasc Interv Radiol. 2018;21(2):113-6.
4. Maleti O, Perrin M. Reconstructive surgery for deep vein reflux in the lower limbs: Techniques, results and indications. Eur J Vasc Endovasc Surg. 2011;41(6):837-48.
5. Huang C, Yu G, Huang J. Midterm results of endovascular treatment for iliac vein compression syndrome from a single center. Ann Vasc Surg. 2018;49:57-63.
6. Hartung O, Loundou A, Barthelemy P, Arnoux D, Boufi M, Alimi Y. Endovascular management of chronic disabling ilio-caval obstructive lesions: long-term results. Eur J Vasc Endovasc Surg. 2009;38(1):118-24.
7. Kang CH, Yang SB, Lee WH, Ahn JH, Goo DE, Han NJ, *et al*. Comparison of open cell stent and closed-cell stent for treatment of central vein stenosis or occlusion in hemodialysis patients. Iranian Journal of Radiology. 2016;13(4).
8. Black S, Gwozdz A, Karunanithy N, Silickas J, Breen K, Hunt B, *et al*. Two year outcome after chronic iliac vein occlusion recanalisation using the Vici Venous Stent®. Eur J Vasc Endovasc Surg. 2018;56(5):710-8.
9. Cheng CP, Dua A, Suh GY, Shah RP, Black SA. The biomechanical impact of hip movement on iliofemoral venous anatomy and stenting for deep venous thrombosis. J Vasc Surg Venous Lymphat Disord. 2020;8(6):953-60.
10. Nazarian GK, Austin WR, Wegryn SA, *et al*. Venous recanalization by metallic stents after failure of balloon angioplasty or surgery: Four-year experience. Cardiovasc Intervent Radiol. 1996;19(4):227-233.
11. O'Sullivan GJ, Sheehan J, Lohan D, McCann-Brown JA. Iliofemoral venous stenting extending into the femoral region: initial clinical experience with the purpose-designed Zilver Vena stent. J Cardiovasc Surg (Torino). 2013;54:255-61.
12. Endo M, Jahangiri Y, Horikawa M, Kaufman JA, Schenning RC, Kolbeck KJ, *et al*. Antiplatelet Therapy is associated with stent patency after iliocaval venous stenting. Cardiovasc Intervent Radiol. 2018;41:1691-8.
13. Attaran RR, Ozdemir D, Lin IH, Mena-Hurtado C, Lansky A. Evaluation of anticoagulant and antiplatelet therapy after iliocaval stenting: Factors associated with stent occlusion. J Vasc Surg Venous Lymphat Disord. 2019;7:527-34.
14. Gagne PJ, Gagne N, Kucher T, Thompson M, Bentley D. Long-term clinical outcomes and technical factors with the Wallstent for treatment of chronic iliofemoral venous obstruction. J Vasc Surg Venous Lymphat Disord. 2019;7:45-55.
15. Neglén P, Tackett TP Jr, Raju S. Venous stenting across the inguinal ligament. J Vasc Surg. 2008;48:1255-61.
16. Black SA, Alvi A, Baker SJ, Beckett D, Breen K, Burfitt NJ, *et al*. Management of acute and chronic iliofemoral venous outflow obstruction: a multidisciplinary team consensus. Int Angiol. 2020;39:3-16.
17. Machado H, Sousa J, Mansilha A. The impact of venous stenting across the inguinal ligament on primary patency: a systematic review. Int Angiol. 2021 Aug;40(4):270-276.

18. Raju S. Best management options for chronic iliac vein stenosis and occlusion. J Vasc Surg. 2013;57:1163-9.
19. Rossi FH, Kambara AM, Rodrigues TO, *et al*. Comparison of computed tomography venography and intravascular ultrasound in screening and classification of iliac vein obstruction in patients with chronic venous disease. J Vasc Surg Venous Lymphat Disord. 2020;8(3):413-422.
20. Neglén P, Raju S. Intravascular ultrasound scan evaluation of the obstructed vein. J Vasc Surg. 2002 Apr 1;35(4):694-700.
21. Stoeckel D, Pelton A, Duerig T. Self-expanding Nitinol stents: Material and design considerations. Eur Radiol. 2004;14(2):292-301.

How to Cite This Article
Barsim EM, Barbary AHE, JO'Sullivan G, Mallah SIEL, Hasan HA, Kamhawy AH. Evaluation of distal extension of venous stents across the inguinal ligament. International Journal of Surgery Science. 2024;8(3):09-16.