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Femoral nerve block versus spinal anesthesia in the treatment of saphenous vein ablation

Mustafa Kaçmaz[1], Faruk Serhatlıoğlu[2]

[1]Department of Anestesiology and Reanimation, Ömer Halisdemir University Faculty of Medicine, Niğde, Turkey
[2]Department of Cardiovascular Surgery, Ömer Halisdemir University Faculty of Medicine, Niğde, Turkey

ABSTRACT

Objectives: This study aims to compare the effects of spinal anesthesia and femoral nerve block and to determine the optimal anesthesia method for embolization of vena saphena magna.

Patients and methods: Between December 2019 and March 2021, a total of 160 patients (89 males, 71 females; mean age: 44.4 years; range, 18 to 69 years) who were diagnosed with varicose veins and hospitalized for surgery in our cardiovascular surgery clinic were included. The patients were divided into two groups. The first group (Group S, n=80) underwent spinal anesthesia and the second group (Group F, n=80) underwent femoral nerve block for the surgical operation.

Results: The mean arterial pressures (MAPs) were significantly lower in Group S compared to Group F. The mean time until surgery was earlier in Group S (4.57±1.0 min *vs.* 9.9±3.4 min, respectively; $p<0.01$). The mean duration of motor block was longer in Group S (3.4±1.1 h *vs.* 2.7±0.8 h, respectively; $p<0.05$). The mean duration of mobilization was statistically significantly shorter in Group F (6.1±1.7 h *vs.* 5.2±1.4, respectively; $p<0.05$). The development of urinary retention was statistically significantly higher in Group S ($p<0.05$). The mean patient satisfaction score after discharge was higher in Group F (3.5±0.5 *vs.* 2.9±0.8, respectively; $p<0.05$). The incidence of postoperative shivering was statistically significantly higher in Group S ($p<0.05$).

Conclusion: Femoral nerve block, which is used for intraoperative anesthesia during the procedure of endovenous laser ablation, can be preferred as an alternative method to spinal anesthesia.

Keywords: Ablation, femoral block, patient, spinal anesthesia, varicose vein.

Varicose vein disease of the lower extremities is a very common problem affecting approximately 27% of the Western societies.[1] Endovascular laser ablation is one of the methods used for the solution of this problem and one of the minimally invasive methods alternative to surgery in superficial venous insufficiency.[2] In this procedure, occlusion occurs with thermal damage to the endothelium.

One of the cornerstones for selecting the anesthesia method for endovascular laser ablation is no delay in mobilization, as delay in mobilization increases the risk for deep vein thrombosis. On the other hand, deep and multiple local anesthesia injections may cause undesired damage in saphenous and sural nerves.[3] Various anesthesia methods such as general anesthesia, epidural anesthesia, hemi-spinal anesthesia, femoral nerve block, sciatic nerve block and conscious sedation are used during endovenous laser ablation.[4] General anesthesia has certain side effects such as nausea, vomiting, sore throat and muscle pain, while spinal blocks have side effects such as postoperative lumbar pain, post-dural headache, and hypotension. The side effects of conscious sedation may be respiratory depression and prolonged awakening.[5]

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Correspondence: Mustafa Kaçmaz, MD. Ömer Halisdemir Üniversitesi Tıp Fakültesi Anesteziyoloji ve Reanimasyon Anabilim Dalı, 51000 Niğde, Türkiye.
e-mail: muskac51@gmail.com

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Spinal anesthesia is still popular and one of the most preferred methods, since it has advantages in usage, and patients do not usually feel any pain and surgeons are not interrupted by lower extremity movements of the patient during surgery.[6] However, some complications such as numbness, urinary retention, post-dural puncture headache, nausea, vomiting or deep vein thrombosis until ambulation may occur due to spinal anesthesia.[7,8]

In the present study, we aimed to compare peri- and postoperative effects, duration of motor block, hemodynamic parameters and patient satisfaction in spinal anesthesia and femoral nerve block in patients with venous insufficiency of lower extremity.

PATIENTS AND METHODS

This prospective study was conducted at Ömer Halisdemir University Faculty of Medicine, Department of Cardiovascular Surgery between December 2019 and March 2021. A total of 160 patients (89 males, 71 females; mean age: 44.4 years; range, 18 to 69 years) who were in the American Society of Anesthesiologists (ASA) Class I-IV and diagnosed with varicose veins and hospitalized for surgery were included. Inclusion criteria were as follows: having primary varicose veins and having Clinical, Etiologic, Anatomical, and Pathophysiological (CEAP) Class C3-C4 venous disease. Patients who underwent femoral nerve block only for postoperative analgesia, pregnant women, patients with a neuropathic problem including the surgical area, and those with diabetes mellitus and having a body mass index of >40 kg/m^2 were excluded from the study. A written informed consent was obtained from each patient. The study protocol was approved by the Ömer Halisdemir University Faculty of Medicine Clinical Research Ethics Committee (2019/37). The study was conducted in accordance with the principles of the Declaration of Helsinki.

As the surgical method, endovenous laser ablation was applied to all patients. The patients who were scheduled for package excision and mini-phlebotomy as additional surgical procedures were also included in the study.

The patients were randomly assigned to the groups by the anesthesia technician who was in charge in the preoperative preparation room. The surgeon and patients were blinded to the group allocation until the end of the study. The anesthesiologist was informed about the details of the procedure. Randomization was performed using the single-blind method with sealed envelopes.

Of the 165 patients who were initially screened, one was excluded due to inadequate spinal block and four due to insufficient femoral block. General anesthesia with a laryngeal mask was initiated in these patients. The study was completed with 160 patients (Figure 1).

The patients were divided into two groups. The first group (Group S, n=80) underwent spinal anesthesia and the second group (Group F, n=80) underwent femoral nerve block for surgical operation.

All patients received midazolam at a dose of 0.02 mg/kg 30 min before the block administration. Electrocardiogram (ECG), heart rate (HR), and peripheral oxygen saturation (SpO_2) non-invasive blood pressure of the patients were monitored in the preparation room before anesthesia. Hydration was initiated with 2 L/min nasal O_2 and 10 mL kg/h 0.9% sodium chloride (NaCl). Intraoperative sedation was not applied to the patients as a standard. If necessary, midazolam 2 mg was administered at the discretion of the anesthesiologist.

In Group S, the patients were injected with 3 mL 0.5% bupivacaine L4-L5 in the sitting position. Later, the patients were placed in the supine position and the block level was tested. Operation was allowed in patients with sensory block at the T10 level. Those who did not develop sufficient block despite waiting for 10 min were excluded from the study.

In Group F, femoral nerve block was performed under ultrasonography guidance (Mindray DP 50; Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shenzhen, China). The femoral artery was scanned under the inguinal ligament using a linear probe. The femoral nerve located lateral to the femoral artery was identified. The circumference of the femoral nerve was reached by imaging with a 22-gauge (G) nerve stimulator needle. When the patella movement was observed at 0.5 milliampere current, the needle was fixed with 15 mL of bupivacaine. A total of 5 mL of saline was infiltrated around the femoral nerve (Figure 2).

After sensory blockade developed in all patients, an average of 6 to 10 mL/cm 0.9% NaCl solution was painlessly infiltrated around the saphenous trunks under ultrasound guidance to prevent vessel spasm, the vessel wall from contacting the heating element of the ablation device, and to assist successful ablation by pushing the vessel wall from the outside.

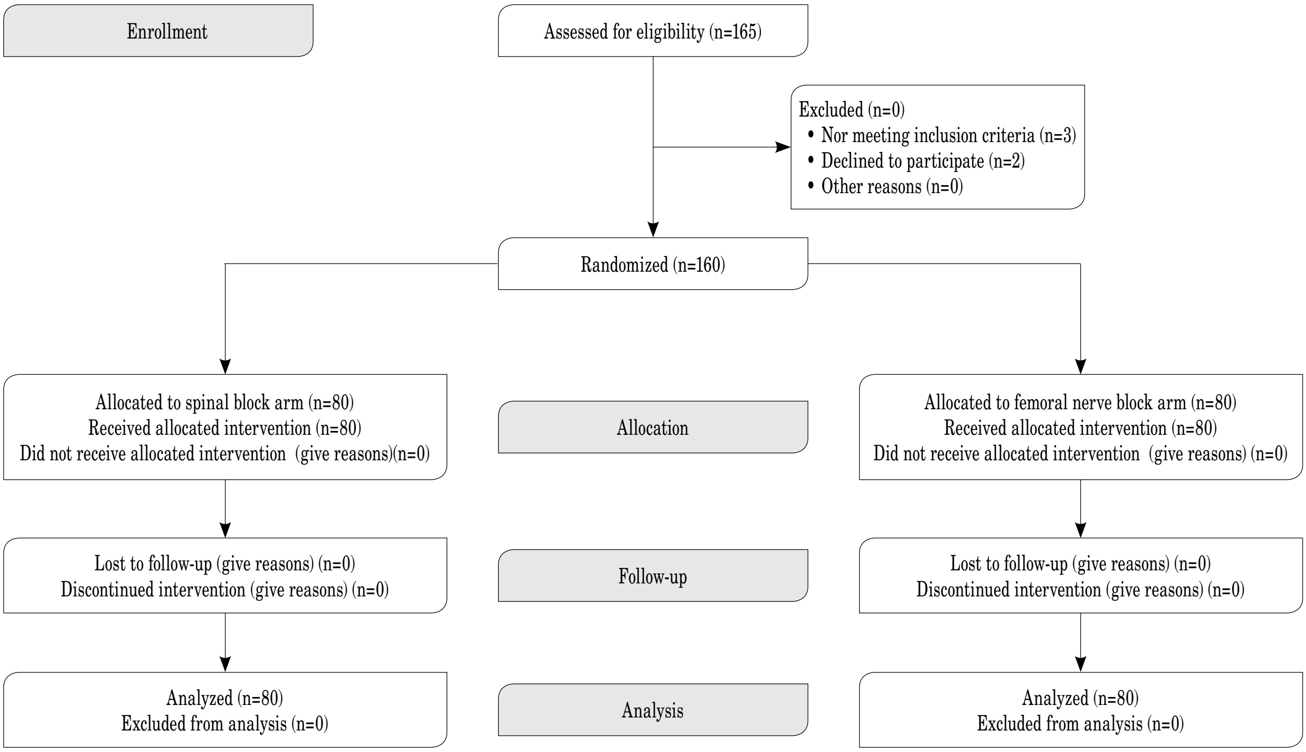

Figure 1. Consolidated standards of reporting trials statement flow diagram.

Data including the duration until the onset of surgery after spinal anesthesia or femoral nerve block, duration of surgery, intraoperative hemodynamic parameters, sedation need, time of complete recovery from motor block with Bromage Scale scores,[9] duration of mobilization, postoperative urinary retention, and postoperative shivering were recorded. All patients received a phone call after discharge and their satisfaction scores from 1 to 4 (1, the worst and 4, the best) about the anesthesia procedure they underwent before surgery and whether they had headache after discharge were questioned.

Statistical analysis

The study power analysis and sample size calculation were performed using the G*Power version 3.1 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). According to the analysis on the basis of the results of duration of motor block in the study of Maiti et al.,[10] the sample size was calculated as 160 with 80 patients in each group in equal size with power=0.95, effect size=0.5, and type 1 error=0.05.

Statistical analysis was performed using the IBM SPSS for Windows version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. The distribution of numerical variables was checked using the Kolmogorov-Smirnov test. Independent samples t-test was used for the comparison of normally distributed variables between the groups. The Mann-Whitney U test was used for non-normally distributed variables. Changes in blood pressure, HR, and SpO_2 values over time and between the groups were evaluated with the repeated measures analysis of variance. The chi-square and Fisher's exact

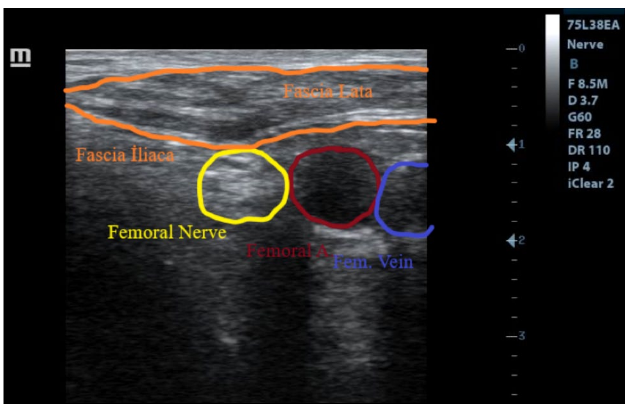

Figure 2. Femoral nerve ultrasonography image.

Table 1. Demographic and clinical characteristics of patients (n=160)

	Group S (n=80)					Group F (n=80)					
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	*p*
Age (year)			44.6±11.7					44.2±11.8			0.841*
Sex											0.426†
Male	42	47.2				47	52.8				
Female	38	53.5				33	46.5				
Height (cm)			167.9±7.4					167.4±8.8			0.686*
Weight (kg)			80.4±10.8					81.7±13.3			0.480*
MAP				86	69-105				95	110-140	<0.001‡
Pulse			76.7±10.1					76.6±9.2			0.961*
ASA Class											0.733†
I	18	47.4				20	52.6				
II	48	49.5				49	50.5				
III	13	54.2				11	45.8				
IV	1	100				0	0				

SD: Standard deviation; MAP: Mean arterial pressure; ASA: American Society of Anesthesiologists; * Student-t test; † Pearson's Chi-Square test; ‡ Mann-Whitney U test.

tests were used to analyze statistically significant relationship among the categorical variables. A *p* value of <0.05 was considered statistically significant.

RESULTS

There was no statistically significant difference between the groups in terms of age, sex, weight, and height (p>0.05). Also, there was no significant difference in the ASA Class and HR between the groups (p>0.05). However, the mean arterial pressures (MAPs) were significantly lower in Group S compared to Group F (Table 1).

No statistically significant difference was found between the groups in terms of mean duration of surgery (27.8±5.1 *vs.* 29.0±6.8 min, respectively; p>0.05). The intensity of motor block was also

Table 2. Surgery, anesthesia, and postoperative duration (n=160)

	Group S (n=80)			Group F (n=80)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Surgery duration (min)			27.8±5.1			29.0±6.8	0.190†
Operating start time (min)			4.57±1.0			9.9±3.4	<0.001†
Motor block time (h)			3.4±1.1			2.7±0.8	<0.001†
Mobilization time (h)			6.1±1.7			5.2±1.4	0.001†
Satisfaction level							<0.001‡
1	4	100		0	0		
2	20	87		3	13		
3	34	53.1		30	46.9		
4	22	31.9		47	68.1		
Sedation							0 .114‡
Yes	18	40		27	60		
No	62	53.9		53	46.1		
Headache							0.245¶
Yes	3	100		0	0		
No	77	49		80	51		
Urinary retention							0.001‡
Yes	10	100		0	0		
No	70	46.7		80	53.3		
Shivering							0.008‡
Yes	13	81.3		3	18.8		
No	67	46.5		77	53.5		

SD: Standard deviation; † Mann-Whitney U test; ‡ Pearson's Chi-square test; ¶ Fisher's exact test.

assessed during the study. The groups were evaluated in terms of the time of complete recovery from motor block and Group S had significantly longer mean block time than Group F (3.4±1.1 h *vs.* 2.7±0.8 h, respectively; $p<0.05$). The surgical intervention was initiated, when a sufficient level of sensory block was obtained in patients. The mean onset time of surgery after the procedure was significantly earlier in Group S compared to Group F (4.6±1.0 *vs.* 9.9±3.4 min, respectively; $p<0.05$). Mobilization of patients was allowed after complete recovery from sensory block in routine practice. When the groups were compared in terms of recorded mobilization time, the mean mobilization time found to be significantly shorter in Group F compared to Group S (6.1±1.7 *vs.* 5.2±1.4 h, respectively; $p<0.05$). The need for sedation of both groups was based on the assessment during the onset of surgery. There was no statistically significant difference between the groups in terms of the sedation requirement ($p>0.05$). Although three patients in Group S had headache, there was no statistically significant difference between the groups ($p>0.05$). However, the development of urinary retention was statistically significantly higher in Group S than Group F ($p<0.05$). The mean patient satisfaction score after discharge was higher in Group F (3.5±0.5 *vs.* 2.9±0.8, respectively; $p<0.05$). The incidence of postoperative shivering was statistically significantly higher in Group S than Group F ($p<0.05$) (Table 2).

Shivering, headache, and urinary retention were the most common complications in both groups. None of the patients had hematoma, bleeding, nausea, vomiting, or postoperative thromboembolism.

DISCUSSION

Pain is removed with TA and normal tissues are prevented from overheating during laser application. However, multiple TA injections along the great and small saphenous veins are painful due to both long-time and multiple injections. Although this pain is tolerated by some patients, the others may experience worse experiences. Unconscious movements of the leg where motor block is inactive may pose certain problems for the surgeon. After local anesthesia, spasms may develop, particularly during venous catheterization and pain may become more severe due to local anesthesia itself or its high volume.[11]

Dzieciuchowicz et al.[12] used femoral nerve block with 20 mL of 1% lidocaine in addition to TA in one of the two different groups who underwent endoluminal laser ablation and tumescent ablation in the other, and reported that pain intensity and need for TA solution were lower in the group they added femoral nerve block. Al Wahbi[13] also reported that femoral nerve block added to TA during endoluminal laser ablation decreased pain intensity without affecting the surgical duration. As the target nerve was completely localized with ultrasonography and a mixed solution was used in our study, a total volume of 20 mL was sufficient in the femoral nerve group without the need for relatively high local anesthetic injections used for TA, and surgical duration was not affected and no additional analgesia was needed.

The surgical area intervened during endovenous ablation is in the anterior and medial parts of the leg. Although rare, the intervened varicose veins in transtibial medial part of the leg were in the impact area of femoral nerve block.[14] In our study, the intervened varicose veins were in the impact area of femoral nerve block.

The incidence of hypotension after spinal anesthesia varies between 15% and 30%, and hypotension is one of the most common effects of spinal anesthesia.[15] In our study, the mean MAP values were statistically significantly lower in the spinal anesthesia group. However, there was no significant difference between the groups in terms of demographic data, except for MAP values.

In their study, Yilmaz et al.[11] suggested that ultrasound-guided femoral nerve block could provide considerable decrease in pain during endovenous laser and other therapies such as ambulatory phlebectomy and foam sclerotherapy. In our study, the patients in Group F who underwent femoral nerve block received sufficient anesthesia during surgery and no additional need for anesthetics occurred during the entire surgery. In addition, ligation was performed in the patients in the femoral block group, even in patients requiring mini-phlebotomy, as in the spinal anesthesia group, without the need for an additional anesthesia method.

Ozturk et al.[2] observed in their studies comparing femoral nerve block and spinal anesthesia methods that recovery from motor block was faster in the femoral nerve block group. Maiti et al.,[10] on the other hand, compared the patients who underwent combined femoral and sciatic block and the patients who underwent spinal anesthesia and observed that recovery from motor block was faster in the spinal anesthesia group. However, the effects of these methods on patient satisfaction and complications were not assessed in either of these studies. In our study, recovery from motor block was faster in the femoral nerve block group, consistent with the study of Ozturk et al.[2] We believe that the reason why the recovery from motor block was slower in the study by Maiti et al.[10] is the addition of sciatic nerve block to the study group.

In the study of Maiti et al.,[10] sufficient anesthesia level obtained with the femoral nerve block was reported to last longer, compared to spinal anesthesia. In our study, the mean duration until the onset of surgery after anesthesia procedure was significantly longer in Group F. After femoral block was applied in the operating room, the duration until the onset of venous ablation procedure was relatively long. In our clinic, the possible patient and surgeon dissatisfaction due to the waiting time at the operating room where the patient is transferred after receiving a sufficient level of block is removed by performing femoral block during preoperative preparation.

The protocol of endovenous ablation is less invasive compared to normal surgical procedure, and endovenous ablation procedure is not directly associated with the applied anesthesia protocol on condition that a sufficient level of anesthesia is ensured.[16] In our study, there was no significant difference between the two groups in terms of the duration of surgery.

Intraoperative use of midazolam provides anxiolysis, analgesia, and amnesia and can reduce patient dissatisfaction due to being awake during surgery.[17] In our study, the need for sedation due to anxiety was met with the use of midazolam 0.02 mg/kg. There was no significant difference between the groups in terms of the sedation requirement.

A standard oral analgesic is recommended to the patients within days or sometimes within weeks during the process of postoperative follow-up after endovenous laser ablation.[18] In our study, none of the patients in either group needed an additional analgesia.

In their study, Zhang et al.[19] reported that nerve block of lower extremity produced more prolonged motor and sensory block, compared to spinal anesthesia. Duration of the block may vary due to the amount and volume of the anesthetic agent used. In our study, a mixed solution was used for femoral block, prilocaine, a short-acting local anesthesia, was preferred during the half of total volume, and the total volume administered for femoral nerve block was limited with 20 mL, which made us consider that the duration of mobilization and time of recovery from motor block were shorter in the group who underwent femoral nerve block.

One of the important problems experienced after spinal anesthesia is shivering above the level of block as a result of hypothermia and vasoconstriction.[20] There are also studies proposing that shivering occurs in 40 to 60% of all regional anesthesia methods.[21] In the study by Nakahira et al.,[22] shivering ranks first among postoperative factors affecting satisfaction levels of the patients after anesthesia. Currently, postoperative shivering after spinal anesthesia is still a problem that must be prevented.[23] In our study, when the patient records in the recovery unit in the postoperative period were assessed, the incidence of shivering was found to be significantly higher in Group S than Group F.

Urinary retention occurs after spinal anesthesia, particularly in patients with a high level of sensory block need.[24] In our study, urinary retention was defined as the inability to urinate, although the patient needed and consecutively attempted to urinate. Ten patients in Group S had the complaint of inability to urinate during follow-up in the cardiovascular surgery wards. None of the patients in Group F had the complaint of inability to urinate caused by urinary retention.

Salzer et al.[25] reported that, although post-spinal headache after spinal anesthesia was still a common complication, the diameter of the needle used for anesthesia played a direct role in headache occurrence. None of the patients in our study had post-spinal headache complaint, until they were discharged thanks to their short hospital stays. The patients were questioned about their headaches after discharge with phone calls to measure their satisfaction levels and patients in Group S experienced headache within the days following the discharge. None of the patients in Group F had headache. These results did not reach statistical significance. We believe that the use of 22-G atraumatic spinal needle for spinal anesthesia in our clinic may have contributed to this condition.

As patients in our study were discharged early, post-spinal headache in these patients was questioned with phone calls. Therefore, there was no opportunity to perform clinical examination. Data obtained during the anamnesis were used to conclude.

The incidence of complications after surgery has been shown to directly affect the satisfaction levels of patients.[22] In our study, all patients received a phone call after discharge and their satisfaction scores from 1 to 4 were questioned to prevent unreal satisfaction statements with the influence of environmental factors during hospital stay. When satisfaction scores were assessed, patients in Group F had statistically significantly higher rate of satisfaction compared to the patients in Group S.

In our study, patients in the femoral nerve block and spinal block groups were followed for a relatively short time, which can be considered a limitation. In addition, the times of complete recovery from sensory and motor block in patients were recorded in our study; however, postoperative Visual Analog Scale and the regression stages of motor and sensory block were unable to be monitored.

In conclusion, femoral nerve block used for intraoperative anesthesia during the procedure of endovenous laser ablation is a less invasive method, provides mobilization in a shorter time, has a low incidence rate of complications without affecting the duration of surgery and has a high patient satisfaction rate. Based on our study results, ultrasound-guided femoral nerve block seems to be superior to spinal anesthesia in ablation of vena saphena magna.

Declaration of conflicting interests

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