

Short stripping of the incompetent great saphenous vein by InvisiGrip® vein stripper

A new scarless surgical technique

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Keywords

Varicose veins, short stripping, InvisiGrip®, saphenous vein, vascular surgery

Summary

Our aim is to describe the results of a new short stripping technique for the treatment of the incompetent great saphenous vein (GSV) using a new developed surgical device. **Patients, methods:** 397 patients (498 legs) were treated with the InvisiGrip® Vein Stripper, which removes the GSV through a single groin incision, endovascular cutting and antegrade stripping by inversion. We reported the surgical success rate and postprocedural complications. **Results:** The mean age was 51 years, 74% were women. The success rate for removal of the GSV was 95%. The 23 failures were half patient related, half device related. In 82% of the strippings, one or two attempts were needed to successfully remove the GSV, which was done by invagination in 80%. Age, gender, BMI ≥ 30 kg/m² and male GSV diameter were not associated with the number of attempts. Superficial wound infection, haematoma and temporary saphenous and femoral nerve injury occurred in 6 (1.6%), 0, 3 (0.8%) and 7 (1.9%) patients, respectively. **Conclusion:** The InvisiGrip® is highly successful for the removal of the GSV using short inverting stripping. Furthermore, it is simple, safe, associated with good cosmetic results and no preoperative selection of patients is necessary.

Schlüsselwörter

Variköse Venen, kurzes Stripping, InvisiGrip®, Vena saphena magna, Gefäßchirurgie

Zusammenfassung

Ziel: Ergebnisse einer neuen Technik des kurzen Strippings zur Behandlung der insuffizienten V. saphena magna (VSM) mit einem neuen chirurgischen Instrument sollen beschrieben werden: dem InvisiGrip Venenstripper mit einer einzigen Inzision in der Leiste. **Patienten, Methoden:** Zwischen 2004 und 2007 wurden insgesamt 397 Patienten (498 Beine) mit dem InvisiGrip Venenstripper behandelt. Alle Patienten hatten Beschwerden infolge einer Insuffizienz der VSM; präoperativ wurde die venöse Insuffizienz der Krosse und der VSM mittels Duplex-Ultraschall nachgewiesen. Mit dem InvisiGrip kann die VSM über einen einzigen Schnitt in der Leiste (für die Krossektomie), einen endovaskulären Schnitt und durch antegraden Stripping mit Inversion entfernt werden. Es handelt sich dabei um einen 60 cm langen Einmalkatheter, der aus einem zweiteiligen Schneidekopf sowie einem Griff auf der Gegenseite besteht. Eine Ligatur des Venenstumpfes auf Kniehöhe ist nicht erforderlich. Bei allen Eingriffen dokumentierten wir die Baselinecharakteristika, die Häufigkeit erfolgreich entfernter VSM und postoperativer Komplikationen (z. B. Hämatom im Kniegelenk, oberflächliche Wundinfektion, Nervenschädigung, sonstige). **Ergebnisse:** Das mittlere Alter betrug 51 ($\pm 12,5$) Jahre, 74% wa-

ren weiblich. Frauen wiesen im Vergleich zu Männern einen größeren VSM-Querschnitt auf (7,7 mm gegenüber 7,0 mm). Insgesamt wurden 98% der Patienten ambulant operiert, vorzugsweise in Spinalanästhesie (95%). Die Rate erfolgreich entfernter VSM lag bei 95%. Das Versagen in 23 Fällen war zur Hälfte durch die Patienten bedingt (VSM zu gewunden) und zur Hälfte auf den Katheter (der 5 mm Schneidekopf war zu breit für die insuffiziente VSM) zurückzuführen. Bei 82% der Strippings wurden ein oder zwei Versuche benötigt, um die VSM erfolgreich zu entfernen, was in 80 % durch Invagination erfolgte. Alter, Geschlecht, BMI ≥ 30 kg/m² und männlicher VSM-Querschnitt waren nicht mit der Anzahl der Versuche assoziiert. Oberflächliche Wundinfektionen in der Leiste, Hämatome im Kniegelenk und vorübergehende Schädigungen des N. saphenus und N. femoralis traten bei 6 (1,6%), 0, 3 (0,8%) bzw. 7 (1,9%) der Patienten auf. Nicht durch das Stripping bedingte Komplikationen traten bei 6 Patienten (1,6%) auf: eine Lungenembolie am zweiten postoperativen Tag, vier oberflächliche Wunden infolge zu strammer postoperativer Verbände und eine Schädigung des N. peroneus durch die Spinalanästhesie. **Schlussfolgerung:** Der InvisiGrip® Venenstripper kann sehr erfolgreich zur Entfernung der VSM bei kurzem Stripping mit Inversion und ohne distale Inzision im Knie eingesetzt werden. Er ist einfach, sicher und erbringt gute kosmetische Resultate. Ein weiterer Vorteil: Eine präoperative Patientenselektion ist nicht erforderlich.

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Kurzes Stripping der insuffizienten Vena saphena magna mit dem InvisiGrip Venenstripper

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After the first successful exeresis of the great saphenous vein (GSV) by inversion by William L. Keller in 1905 (9), stripping of the GSV has become one of the most performed surgical interventions. In 2008, the Dutch prevalence for this surgical procedure was 1.2 per 1000 inhabitants, resulting in the top three most performed operations in the Netherlands. Consequently, it is not amazing that in the past a large number of surgical devices were developed for surgical treatment of the GSV.

The first vein stripper developed by William W. Babcock in 1907 was an intraluminal wire with an acorn head and removed the GSV from ankle to groin by an accordion strip, and was the golden standard for many years (1). Unfortunately, the wire used with this technique was said to be too short, too straight and too rigid, resulting in subcutaneous trauma and high incidence of saphenous nerve damage.

In 1971, a more elegant way of stripping was developed, using the perforate invagination stripper (PIN stripper, Credenhill Ltd., Derbyshire, UK). Compared to conventional stripping PIN stripping was associated with (2, 12)

- less tissue trauma,
- fewer infections,
- neuralgia and
- better cosmetics.

However, randomised trials failed to demonstrate its clear benefit and tearing of the veins during invagination was a major complication (2, 3).

In the same period, long stripping of the GSV became disputable and the short strip of the GSV from groin to knee became popular (6, 10). Apart from some parts in the south of Europe and in America, this short saphenous stripping technique is state of the art. In the Netherlands it is recommended by the Dutch National Guidelines 2007.

Vein stripping has a extensive cosmetic aspect and up to now all known surgical devices to remove the GSV need a distal incision at the knee joint apart from the groin incision, either to introduce the stripper or to control the device during the procedure.



Fig. 1 The InvisiGrip® Vein Stripper, illustrated with an opened cutting head (printed with kind permission of LeMaitre Vascular GmbH, Sulzbach/Ts., Germany)

InvisiGrip® Vein Stripper

In 2004, a new surgical device called the InvisiGrip® Vein Stripper (LeMaitre Vascular Inc., Burlington, USA) became available. This stripper combines a short strip with cosmetic demands and the principles of minimal endovascular surgery. It is currently used in America, Europe and Japan.

However, information concerning the results of the InvisiGrip® is scarce. The only study describing them was performed in Japan (5). Hatano and colleagues reported a technical success of 100%. However, they investigated a very small study population (34 patients, 44 limbs).

In recent years, some non-surgical techniques (i. e. laser, radioablation, steam, thermoablation, foamtherapy) have become popular to treat an insufficient GSV. Despite this evolution surgical treatment will maintain its place. It will remain competitive the easier, the cheaper and the better the cosmetic outcome.

Our large observational study is the first to describe the results of a innovative short stripping technique for the extirpation of the incompetent GSV in a large non-academic teaching hospital in the Netherlands. It demonstrates the effectiveness, ease and results of this new vein stripper and its new surgical technique.

Patients, material, methods

Study design and patient selection

Between March 2004 and October 2007, a cohort of 397 patients older than 18 years were admitted at the Atrium Medical Center, Heerlen, The Netherlands. All patients suffered from incompetent GSV. Venous incompetence of the saphenofemoral junction and GSV was proven by duplex sonography. All patients were classified according to the CEAP classification as C2-C6 (4). Their GSV was removed with a new short stripping device. Patient's data were entered into a computerized database. For all patients the following information on baseline characteristics was recorded: age, gender, body mass index (BMI), diameter of the GSV at knee joint, the side of the GSV (left or right leg) and uni- or bilateral removal. The medical ethics committee of the Atrium Medical Center Parkstad was informed, and per institutional practice, no official approval was requested.

Prospective data were collected for this retrospective analysis.

Short GSV stripping

We used the InvisiGrip® Vein Stripper for short GSV stripping. The InvisiGrip® is a 60 cm long disposable surgical device consisting of a two-parts cutting head that can be opened in two parts with an outer diameter of 5 mm and a handle on the opposite side showing the cutting or neutral status of the device (►Fig. 1).

After crossectomy and before actual stripping, flexible catheters with different diameters of the olive head were introduced into the vein as far as the knee (only for the purpose of this study). And the smallest diameter of the GSV was measured. Then, the InvisiGrip® was introduced into the vein. Because of the proven insufficiency of the GSV by duplex, there was no valvular resistance during travel towards the knee. At knee level the stripping head was palpated, opened and by slight pressure on the skin the vein was forced into the open cutting head. After traction, catching and 360° rotation of the stripper the cutting head was closed and the vein

firmly trapped into the head. By increased traction, the GSV was cut endovascular and antegrade stripped by inversion. There was no incision at knee level and no specific methods were necessary to close the proximal stump of the lower GSV.

After stripping, a rolled gauze was applied over the full length of the bed of the GSV and completed with a compression bandage up to groin for three days. In the first years of this study, a compression stocking for four weeks was subscribed. However, in recent years the stockings were omitted because of proven ineffectiveness (7).

During the procedure, the following information was recorded: The number of attempts to successfully strip the GSV, the type of the removed GSV (true invagination or false invagination by accordion, telescoping the vein), the ease of palpation, the tip of the stripper inside the GSV in the level of the knee joint (easy palpable, moderate palpable or not palpable) and the travel of the stripper inside the GSV (easy maneuverable, difficult maneuverable or not possible).

Follow-up and end point

Clinical information was retrieved from the hospital electronic database of patients. The primary end point of this study is the incidence of the successfully removal of the GSV. The secondary end point is the complication rate after surgery. During the in-hospital stay and at the out-patient clinic visit four weeks after the index procedure, we recorded the following complications: haematoma at knee joint due to a bleeding of the open residual proximal part of the GSV, neurological injury of the saphenous and femoral nerve distal to the groin incision (minor sensory changes), superficial wound infections and other non-specific complications.

Because of unknown reasons 31 patients (47 legs) were lost during follow-up.

Data analysis

Continuous data are described as mean values and standard deviations (SD), and

Tab. 1 Baseline characteristics of patients according to gender

		all patients	women	men	p value
n (%)		397 (100%)	295 (74%)	102 (26%)	
mean age (years) (\pm SD)		50.5 (\pm 12.5)	50.0 (\pm 12.4)	52.2 (\pm 12.9)	0.13
body mass index (kg/m ²)	mean \pm SD	26.2 (\pm 4.7)	26.1 (\pm 5.1)	26.4 (\pm 3.6)	0.61
	> 30 (%)	17.3	18.2	14.6	0.42
diameter great saphenous vein (mm)	mean \pm SD	7.2 (\pm 1.5)	7.0 (\pm 1.3)	7.7 (\pm 1.7)	<0.001
	> 9 (%)	12.3	9.5	20.6	0.003
location (%)	unilateral	74.6	73.6	77.5	0.43
	bilateral	25.4	26.4	22.5	
side (%)	left	33.2	33.9	31.4	0.64
	right	66.8	66.1	68.6	

dichotomous data are described as percentage frequencies. The chi-square test was used for categorical variables and the analysis of variances (ANOVA) test was used for continuous variable to evaluate differences in baseline characteristics between females and males and the number of attempts to successfully remove the GSV.

To describe the study population, we included all patients. For the description of the peri-procedural outcome and the association between all baseline characteristics and the number of attempts to suc-

cessfully remove the GSV, we included all performed procedures (many patients had bilateral removal of the GSV). So the procedure was the index of analysis, not the patients.

A p-value of <0.05 was considered to be significant. All computations were performed with SPSS software version 17.0.1 (SPSS Inc., Chicago, Illinois, USA).

Results

Patient characteristics

In this study, 397 consecutive patients were included. The mean age of this study population was 50.5 (\pm 12.5) years and 74% were women (► Tab. 1). Women had a greater diameter of the GSV, compared to men. No other differences between baseline characteristics and gender were observed. In 25.4% of our patients, the GSV was removed bilaterally. The total number of procedures amounted to 498. The number of bilateral strippings was comparable between women and men. Furthermore, a total of 98% of the patients were operated in day surgery, usually by spinal anesthesia (95%).

Primary end point

The success rate for stripping the GSV with the InvisiGrip® was 95.4% (► Tab. 2). In most cases, one or two attempts were needed

Tab. 2 Peri-procedural outcomes

		n	%
all procedures		498	100
number of attempts	1	256	51.4
	2	154	30.9
	>3	65	13.1
	not possible	23	4.6
type of invagination	true	395	79.3
	false	76	15.3
	not possible	27	5.4
feeling stripper palpable	easy	409	82.1
	moderate	66	13.3
	not	23	4.6
travel stripper maneuverable	easy	432	86.7
	difficult	43	8.6
	not possible	23	4.6

Tab. 3 Association between baseline characteristics and the number of attempts to successfully remove the great saphenous vein for all procedures

baseline characteristics	number of attempts				p value
	1	2	>3	not possible	
mean age (years)*	49.5 (± 12.7)	50.7 (± 12.4)	50.1 (± 12.4)	54.8 (± 13.8)	0.25
gender female (%)	74.0	77.9	81.5	63.6	0.29
BMI > 30 kg/m ² (%)	16.5	17.6	27.4	19	0.26
diameter GSV > 9 mm (%)	8.6	14.3	27.7	18.2	0.001
women	5.4	8.4	23.8	25.0	0.002
men	14.3	31.0	33.33	12.5	0.21
left side (%)	46.5	43.5	50.8	59.1	0.49

GSV: great saphenous vein; BMI: body mass index; *mean (± SD)

to strip the GSV, whereas in about 10% three or more attempts were necessary.

Of all baseline characteristics, only the diameter of the GSV was related to the number of attempts to successfully remove the GSV (► Tab. 3). However, this association was not observed in men. A diameter of the GSV > 9 mm was not responsible for fewer attempts to remove the GSV in men. As expected, most of the stripped GSVs were removed by full invagination (about 80%). The tip of the InvisiGrip® was good palpable in the knee in approximately 80%. Important to note, no differences in feeling the tip of the stripper were observed between patients with a BMI ≥ 30 kg/m², compared to patients with a BMI < 30 kg/m² (easy palpable 74.4% vs. 84.1%, respectively; p = 0.1).

In most cases, the InvisiGrip® was easy manoeuvrable (87%). When it was not ma-

neuverable, the surgeons were not able to successfully remove the GSV. Again, no differences concerning the travel of the stripper were observed between patients with a BMI ≥ 30 kg/m², compared with less obese patients (easy manoeuvrable 82.6% vs. 88.3%, respectively; p = 0.4).

The diameter of the GSV was not associated with the outcomes like the feeling and the travel of the stripper. A diameter > 9 mm was associated with an easy palpable stripper (86.4%) and easy travel (90.9%) compared with 81.7% and 86.1% of the cases for a diameter of < 9 mm (p = 0.6 and p = 0.4).

In 23 legs, it was impossible to remove the GSV completely by short stripping. In 11 legs (5 patients with bilateral disease), the diameter of the insufficient GSV was too small to reach knee level (< 5 mm) and a partial exeresis was performed. In the other 12 legs, the diseased GSV was so tortuous, that travel was impossible. Attempts with another vein stripper also turned out as unsuccessful. The incompetent veins were removed by sequential avulsion technique.

Secondary end point

At total of 344 (94%) patients had no complications post-procedural (► Tab. 4). None of the patients had a haematoma at knee joint. Of the 22 (6%) patients with complications, 10 patients had temporal neuralgia. Superficial infection at the groin occurred in 6 patients. They were success-

fully treated with local wound care and oral antibiotics.

Furthermore, one patient experienced lung embolism on the second postoperative day and four patients experienced complications because of too tight postoperative bandages. One patient had a definitive peroneus nerve injury with dropping foot.

Discussion

We observed that the InvisiGrip® had a high technical success rate for the removal of the incompetent GSV using short inverting stripping. Since none of the patients developed haematoma and all patients needed one incision in the groin, instead of the conventional two incisions of the groin and knee level, this new stripping technique is associated with good cosmetics.

The InvisiGrip® enables the surgeon to complete the procedure in a minimally invasive fashion with just one incision in the groin as compared to the traditional two-incision procedure. Furthermore, it is cheap because no additional equipment is needed.

The technical success rate was achieved in about 95%. Half of the surgical failures were patient-related and not device-related, because of a too diseased and tortuous GSV at the femoral part. It is no surprise that in all these cases a conventional stripper introduced into the GSV at knee level also failed. Device-related failures were responsible for the remaining cases. The 5 mm outer diameter of the stripper head was simply too large because the diameter of the diseased veins at knee joint was < 5 mm. The diameter of the GSV at the knee joint was in average 7,2 mm which implies that there is enough luminal room around the 5 mm stripper head to allow inverting stripping, as it is the case in nearly 80% of the strippings. The 15% accordion strippings must be caused by a too tight connection of the stripper head and venous wall without space to facilitate inversion.

Of note, the outcome of this new stripper was not influenced by the BMI.

Tab. 4 Post-procedural complications

	n	%
total patients	366	100
complications	22	6
all	22	6
haematoma at knee joint	0	0
saphenous nerve damage	3	0.8
femoral nerve damage	7	1.9
wound infection	6	1.6
others	6	1.6

This is a great benefit, as obesity is becoming a major health burden in Western society. Regardless of the BMI, there is always a fold at the knee joint and palpation is always possible, using the femur condyles as an envil. InvisiGrip[®] vein stripping is very simple. Even though you cannot see what is happening, you feel that the InvisiGrip[®] grasps the venous wall. As long as there is access to the vein in the groin, stripping can endlessly be repeated. For complete short GSV stripping, the actual number of attempts is not really of importance: It just takes more time to complete stripping of the GSV. The success rate of approximately 80% within two attempts partly depends on the diameter of the vein at the knee joint. Large diameters are found in aged men, probably indicating that they postpone their operation longer than women. Since only the diameter of the GSV is associated with the technical success, no preoperative patient selection is necessary.

A possibly expected problem of this technique is the bleeding from the open side of the afferent GSV stump, because it is cut blindly and is not ligated. However, we observed no haematoma at the knee joint. By Muller technique, we removed a number of vein pieces just distal to the cutting, which allows us to examine the cutting area. It showed that the GSV was not sharply cut, but was overstretched just before the cutting and the resulting shrinking of the vein closed the stump without bleeding.

Saphenous nerve damage was mostly due to anatomy. In the study of Rutgers in 1991, a total of 120 legs during coronary artery bypass surgery were dissected, to use the GSV as an arterial conduit (11). In 1% of the patients, the saphenous nerve was already running parallel and in the same anatomical sheath as the GSV at knee level. The first 5 cm distal from the knee joint is relatively a safe place to cut the vein since nerve and vein are already closely related in only 3% of the patients, whereas half down the calf this close relation is up to 100%. It is noticed that the majority of the patients experiencing neuropraxia of the saphenous nerve had entered in the beginning of the study period (all in 2004) and probably these patients were stripped at a too distal level. Temporary local and minor loss of sensitivity at the level of the groin incision or distally occurred in approximately 2% of the operations and is inevitable, possible due to trac-

tion and manipulation at the wound site. The patient with neuropraxia of the peroneus nerve developed a dropping feet. A possible explanation for this serious complication is a too long compression on the fibular head during spinal anaesthesia at the bedside in the recovery room or a too tight compression bandage postoperative. However, we could not find a relation between peroneal nerve damage, varicose vein surgery, the use of the InvisiGrip[®] or spinal anaesthesia. Surprisingly, one patient experienced lung embolism in the post-procedural period. As a severe complication lung embolism is rare after stripping. Huber et al. reported an incidence of 0.56% after surgery for superficial vein insufficiency in 1063 patients, similar to our results (8). Since this complication occurred in a healthy woman without a medical history, operated in day surgery and fully mobile four hours after the procedure, we have no specific explanation for this event.

Limitations

Our study has some limitations.

- This clinical series is not a randomized clinical trial with comparable non-surgical treatment groups to demonstrate the true advantages of the InvisiGrip[®]. Due to the single center observational nature of this study, we cannot exclude the possibility of residual confounding.
- We do not have duplex ultrasound long-term follow-up to confirm the efficacy of the device. Since the main objective of this study was to describe the first results a new surgical device and technique, further research with comparable groups and long-term follow-up is warranted.
- Finally, 8% of the patients were lost during follow-up. However, we believe that they did not visit the out-patient clinic after the procedure, because they were complication free, which overestimates the overall number of complications observed in this study.

Conclusion

Treatment of an insufficient GSV by short stripping with the InvisiGrip[®] Vein Stripper is a safe and effective procedure. It

is easy to perform and cheap because no additional equipment is needed. This new short stripping technique is associated with the cosmetic advantage of a scarless strip, because there is no distal knee incision. Furthermore, the ultimate benefit of the InvisiGrip[®] for short stripping of the great saphenous vein is that no preoperative patient selection is necessary.

Conflict of interest

There are no conflicts of interest and none to declare, including specific financial interest and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript. Furthermore, the results presented in this paper have not been published previously in whole or part.

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