

# Endoscopic versus open subfascial division of incompetent perforating veins in the treatment of venous leg ulceration: A randomized trial

E. G. J. M. Pierik, MD, H. van Urk, MD, W. C. J. Hop, PhD, and C. H. A. Wittens, MD, *Zwolle and Rotterdam, the Netherlands*

**Purpose:** Subfascial division of incompetent perforating veins plays an important role in the surgical treatment of patients with venous ulceration of the lower leg. To minimize the high incidence of postoperative wound complications after open exploration, endoscopic approaches have recently been developed. We carried out a prospective, randomized comparison of open and endoscopic treatment of these patients that was aimed at ulcer healing and postoperative wound complications.

**Methods:** Patients with current venous ulceration on the medial side of the lower leg were randomly allocated to open exploration by the modified Linton approach or endoscopic exploration by use of a mediastinoscope.

**Results:** Thirty-nine patients were randomized, 19 to open exploration and 20 to endoscopic exploration. The incidence of wound infections after open exploration was 53%, compared with 0% in the endoscopic group ( $p < 0.001$ ). Patients in the open group needed longer hospital stays (mean, 7 days; range, 3 to 39 days) than patients in the endoscopic group (mean, 4 days; range, 2 to 6 days;  $p = 0.001$ ). Four months after operation, the ulcers of 17 patients (90%) in the open group and 17 patients (85%) in the endoscopic group had healed. During a mean follow-up of 21 months (range, 16 to 29 months), no recurrences were noticed in either group.

**Conclusions:** Endoscopic division of incompetent perforating veins is equally as effective as open surgical exploration for the treatment of venous ulceration of the lower leg but leads to significantly fewer wound healing complications. Endoscopic division is therefore the preferred method. (*J Vasc Surg* 1997;26:1049-54.)

Chronic venous ulceration of the leg is a common clinical problem that affects about 1% to 2% of the Western population.<sup>1</sup> Although almost all venous ulcers can be treated by simple conservative means, in the Lothian and Forth Valley survey 66% of 600 patients studied had had one or more recurrences of venous ulceration over a 5-year period.<sup>2</sup> Surgical ligation of incompetent perforating veins of the

lower leg in the treatment of venous ulceration has been reported as yielding good long-term results with respect to ulcer healing.<sup>3-6</sup> These operations decree a full exploration of the subfascial space, which necessitates long incisions often through compromised cutaneous and subcutaneous layers. As a consequence, postoperative wound complications are frequently noted, which discourages wide application of this technique.

Recently, minimally invasive approaches have been developed that permit subfascial endoscopic interruption of incompetent perforating veins in patients who have venous ulceration with promising results concerning ulcer healing and postoperative morbidity.<sup>7-10</sup> No comparative studies have been carried out between open and endoscopic subfascial explorations.

This study reports the results of the first prospective randomized trial of endoscopic versus open subfascial exploration of the lower leg in patients with

From the Department of Surgery, Hospital de Weezenlanden, Zwolle (Dr. Pierik); the Department of Surgery, Vascular Unit, University Hospital Rotterdam-Dijkzigt (Dr. van Urk); the Department of Biostatistics, Erasmus University Rotterdam (Dr. Hop); and the Department of Surgery, Saint Franciscus Hospital, Rotterdam (Dr. Wittens).

Reprint requests: Dr. E. G. J. M. Pierik, Department of Surgery, Hospital de Weezenlanden, Groot Wezenland 20, 8000 GM Zwolle, the Netherlands.

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**Table I.** Postoperative wound complications after open and endoscopic division of perforating veins

	Open approach (n = 19)	Endoscopic approach (n = 20)	p
Wound infection	10 (53%)	0 (0%)	<0.001
Superficial	3 (16%)	0 (0%)	0.11
Deep	7 (37%)	0 (0%)	0.003
Nerve injury	2 (11%)	0 (0%)	0.23

chronic venous ulceration; the trial was aimed at ulcer healing and postoperative wound complications.

## PATIENTS AND METHODS

All patients with current venous ulceration on the medial aspect of the lower leg (chronic venous insufficiency graded class 6 according to the classification of the Society for Vascular Surgery and the International Society for Cardiovascular Surgery) who were referred to the Department of Surgery of the Saint Franciscus Hospital in Rotterdam from February 1994 were entered into the study. The study was approved by the hospital medical ethics committee, and in all cases informed consent was obtained. Patients were randomly allocated to either open or endoscopic surgery by opening sealed envelopes.

Patients were stratified for the presence or absence of superficial venous incompetence, for primary or recurrent ulceration, and for the presence or absence of diabetes mellitus. A power calculation before the study indicated that with expected wound complication rates of 40% for open<sup>11,12</sup> and 10% for endoscopic perforantectomy,<sup>10,13</sup> it would be necessary to include 47 patients in each limb of the study (two-sided;  $\alpha = 0.05$ ;  $\beta = 0.10$ ). Fisher's exact test was used to assess differences in proportions; the Mann-Whitney test was used to assess differences in hospital stay.

For each patient, age, gender, duration of the present ulcer period, primary or recurrent ulceration, and size of the ulcer were documented. All patients underwent investigation of their venous status by physical examination and duplex ultrasound scan before the operation and 6 weeks afterward. Concomitant superficial venous incompetence was treated by flush saphenofemoral ligation and limited stripping of the long saphenous vein from groin to just below knee level.

Exclusion criteria were an ankle-brachial arterial pressure index less than 0.8 or previous surgical subfascial exploration of the same leg.

All patients received 1.5 g cefuroxime by intravenous injection before the operation. Open subfascial exploration was performed by the modified Linton approach,<sup>14</sup> and endoscopic subfascial exploration was performed by use of a mediastinoscope as described in detail elsewhere.<sup>15</sup> Both operations were performed by skilled surgeons who had performed more than 10 open and endoscopic procedures each before the start of the study. All perforating veins on the medial and dorsal side of the lower leg that could be found were interrupted by the use of hemoclips (Ligaclip, Ethicon Endosurgery, Johnson & Johnson, USA) and divided. At the end of the operation, the deep fascia was left open and the skin was closed by staples. The time taken for each operation was recorded as the time between the first incision and skin closure. Patients were mobilized on the first postoperative day and were treated by ambulant compression therapy (Comprilan, Beiersdorf Medical, the Netherlands) until the ulcer had healed. Elastic stockings (Elvarex, Beiersdorf Medical) were prescribed indefinitely when associated deep venous incompetence was present. The length of hospital stay was registered. Each patient returned to the outpatient clinic at 1, 2, 6, 12, 24, and 52 weeks after operation. Wound healing and ulcer healing were described separately and in detail. Wound infections were divided into superficial and deep incisional surgical site infections and classified according to the latest definitions for nosocomial surgical site infections of the Centers for Disease Control and Prevention.<sup>16</sup>

## RESULTS

For fear of unexpectedly high and severe morbidity after the modified Linton procedure as compared with the endoscopic procedure, during the trial an unplanned interim analysis was considered and performed in April 1995 (15 months after the beginning of the study). Of the thirty-nine patients included at that moment, 20 had been randomized for endoscopic exploration and 19 for open exploration of the subfascial area. The interim analysis confirmed our presumption and showed a highly significant ( $p < 0.001$ ) difference in the wound complication rate to the detriment of open exploration. It was decided that it was not ethically acceptable to continue inclusion of patients in the trial. As a consequence, the intake of patients was stopped and follow-up of included patients continued. Table I shows the postoperative complications in both groups. In the open group superficial wound infection occurred in three patients and deep wound infection in seven patients

**Table II.** Patient characteristics

	<i>Open approach</i> ( <i>n</i> = 19)	<i>Endoscopic approach</i> ( <i>n</i> = 20)
Age (yr)	70 (36 to 89)	64 (33 to 89)
Sex ratio (M/F)	3/16	9/11
Diabetes mellitus	1	0
Circumference of ulcer (cm)	11 (3 to 30)	9 (3 to 28)
Recurrent ulceration	12	13
Duration of present ulcer period (days)	249 (14 to 1825)	299 (20 to 3650)
Total duration of ulceration (mo)	140 (9 to 480)	148 (11 to 600)
Preoperative duplex findings		
Superficial incompetence	13	14
Deep incompetence	14	11
Incompetent perforating veins	2.1 (1 to 5)	2.3 (1 to 5)

Values in parentheses are ranges.

**Table III.** Operation data and clinical results

	<i>Open approach</i> ( <i>n</i> = 19)	<i>Endoscopic approach</i> ( <i>n</i> = 20)	<i>Statistical significance</i>
Mean operating time (min)	41 (19 to 70)	3 (20 to 90)	NS
Mean blood loss (ml)	170 (30 to 300)	43 (10 to 150)	<i>p</i> < 0.001
Number of perforating veins found at operation	3.0 (1 to 6)	2.9 (1 to 6)	NS
Patients with missed veins at operation	0	3	NS
Hospital stay (days)	7 (3 to 39)	4 (2 to 6)	<i>p</i> = 0.001
Readmission	2	0	NS
Healing rate	90%	85%	NS
Recurrences	0	0	—

Values in parentheses are ranges. NS, Not significant.

in contrast to zero infections in the endoscopic group (*p* = 0.003). Two patients in the open group complained of dysesthesia in the area of distribution of the saphenous nerve.

Both randomized groups appeared well matched regarding various characteristics (Table II). By chance, there was a distinct predominance of women in the open group in comparison with the endoscopic group. However, no difference was found between men and women regarding infection rates in either treatment group. In the open perforantectomy group the wound infection rate was 67% for men compared with 56% for women (*p* = 1.0), whereas both rates were 0% in the endoscopic group.

All patients had one or more incompetent perforating veins on preoperative duplex ultrasound scan. The number and distribution of incompetent perforating veins were comparable in both groups (Table II). More than half of the patients in both groups had deep vein incompetence on duplex ultrasound scan.

In all patients, one or more prolonged attempts at conservative treatment had been carried out.

Table III summarizes the operative results in both groups. The mean operating time for the endoscopic group was similar to that in the open group. The mean blood loss was 170 ml in the open group and 43 ml in the endoscopic group (*p* < 0.001). The mean number of perforating veins found at operation was the same for both groups (3.0 vs 2.9). There were no intraoperative complications.

Follow-up was complete in all patients. The mean hospital stay in the endoscopic group was 3 days shorter than in the open group (*p* = 0.001). Two patients in the open group were readmitted to the hospital because of severe wound complications that necessitated reoperation, intravenous antibiotics, or both. One elderly patient who had been randomized to endoscopic surgery died of a myocardial infarction 5 months after the operation. Postoperative duplex ultrasound scans after 6 weeks showed no signs of

superficial or perforating vein incompetence in the open group. In four patients of the endoscopic group, four persisting (three patients) and two recurrent perforating veins (one patient) were found, without signs of superficial incompetence. Four months after operation the ulcers of 90% of patients in the open group (17 of 19) had healed, which was similar to the 85% (17 of 20) in the endoscopic group. No recurrences of venous ulceration were found during a mean follow-up of 21 months (range, 16 to 29 months; Table III).

## DISCUSSION

Venous ulceration is a common cause of serious disability. Although almost any venous ulcer can be healed with bed rest and elevation of the limb, keeping it healed frequently requires repeated hospitalization and surgery. Delayed wound healing, skin necrosis, and wound infection are frequent and serious sequelae of open surgical explorations of the subfascial area to ligate incompetent perforating veins. In search for less-invasive approaches, new endoscopic techniques have been developed during the past decade. With these techniques postoperative pain seems minimal, and mobilization of the patient can commence immediately after operation, allegedly reducing morbidity caused by postoperative immobilization. However, up until now, no randomized studies have been carried out to directly compare the two approaches for ulcer cure and wound healing.

In this prospective study, 53% of patients who were treated with open perforantectomy had their postoperative course complicated by wound infections. Although some authors report wound complications in only 7% to 24% of patients,<sup>6,17-19</sup> our findings are in concordance with other reports of surgical treatment of patients with venous leg ulceration that mention wound complication rates of 44% to 58%.<sup>11,12,20,21</sup>

Our wound infection rates were based on clearly stipulated criteria for the definition of wound infection<sup>16</sup> and complete follow-up in all patients. The importance of definition and wound surveillance after discharge for the adequate documentation of wound infections has recently been corroborated.<sup>22</sup> The lacking of this as well as retrospective study designs may partly explain the low infection rates after open perforantectomy reported by some authors.<sup>6,17-19</sup>

Endoscopic exploration of the subfascial area in patients with venous ulceration resulted in uncomplicated primary healing of all wounds in this study. Wound complications after endoscopic perforantec-

tomy have been reported in 0% to 7.5% in retrospective studies.<sup>9,10,13,23,24</sup> In contrast to Fischer<sup>23</sup> and Jugenheimer and Junginger,<sup>13</sup> we did not notice any nerve injury after endoscopy. Considering the more superficial position of the posterior tibial artery and vein and the tibial nerve in the most distal part of the lower leg, care must be taken not to confuse these structures with perforating veins. We advocate that structures, especially in the lower third of the leg, only are divided after identification as perforating veins for a certainty.<sup>15</sup> An incompetent perforating vein exhibits a tortuous or dilated vein that passes the subfascial space transversely and penetrates the fascia. Besides, we agree with Fischer<sup>23</sup> to caution against the use of electrocautery in the subfascial area during endoscopy and prefer clipping and division of perforating veins.

Our endoscopic method of identification and interruption of incompetent perforating veins requires a small incision on the medial side of the lower leg only. This is based on the fact that 90% of incompetent perforating veins occur in the dorsomedial area of the lower leg (posterior arch vein distribution)<sup>25</sup> and the knowledge that these are the most important perforating veins in the pathogenesis of skin changes.<sup>26</sup>

Healing rates of more than 80% in both groups in our study support the concept of meticulously eradicating reflux at all potential sites of deep-to-superficial reflux in the surgical treatment of venous ulceration of the lower leg.<sup>5,27</sup> Although our follow-up period is relatively short, the complete absence of recurrences in our study supports the importance of continued ambulant compression therapy in patients who have any associated deep venous insufficiency<sup>6,28</sup> and does not support the view of Bradbury et al.<sup>29,30</sup> that perforating vein and saphenous ligation alone does not lead to permanent ulcer healing in the presence of deep venous reflux. Burnand et al.<sup>31</sup> found recurrent ulceration after surgical treatment in all their patients who had evidence of deep vein damage on ascending phlebography, on average manifesting 17 months after operation. In their retrospective study, however, no mention is made about the postoperative management, and their follow-up data are incomplete. Although more than half of our patients had deep venous incompetence on preoperative duplex ultrasound scanning, after completion of a minimum of 16 months of follow-up in all patients no recurrent ulcers were noted. Although longer follow-up of our patients is needed before definitive conclusions can be drawn, a possible explanation can be found in our conscientious post-

operative ambulant compression therapy until ulcers are healed and thereafter prescription of elastic stockings in every patient with associated deep venous incompetence. The same combined treatment strategy led to good or excellent results in venous ulcer patients reported by others.<sup>5,21,32</sup>

A potential limitation of the endoscopic technique includes the inability to reach all incompetent perforating veins. Especially in patients who have severe lipodermatosclerosis, the necessary expansion of the subfascial space can be laborious. In our study, in two of 20 patients three perforating veins could not be found during subfascial endoscopy. The persistence of incompetent perforating veins after surgery is always considered a failure of the surgical technique and probably can be held responsible for the lack of healing in two patients of the endoscopic group. A possible explanation could be the course of some perforating veins in the deep posterior compartment.<sup>33</sup> At present, we routinely incise the paratibial deep fascia during subfascial endoscopy to explore this space. In one (healed) patient, one perforating vein was detected on the postoperative duplex ultrasound scan although during endoscopy this vein apparently was identified and clipped, but not divided. This persisting incompetent perforating vein may be the result of an erroneously placed or dislodged clip. At present, we therefore routinely divide all clipped perforating veins.

In one patient, two (recurrent) perforating veins were found during the postoperative duplex ultrasound scan that were not seen during the preoperative examination. Possibly, in this patient incompetent perforating veins are the result of severe underlying deep venous insufficiency. It could be that these patients will benefit more from surgical correction of their deep system than from subfascial endoscopy alone. However, up until now, no preoperative investigation exists that will discriminate these patients from patients who will benefit from eradicating all sites of venous reflux in the superficial and perforating vein system.

In the past decade there is a clear trend toward less-invasive procedures in general and vascular surgery. Endoscopic exploration of the subfascial area through a small incision offers little discomfort to the patient. Our study shows that, compared with open exploration, incompetent perforating veins can be detected and interrupted with minor incisional trauma and with less blood loss. Presumably, reduction in postoperative pain and disability, early mobilization, and above all a significant reduction in the incidence of wound healing complications, all lead to

a significantly shorter hospital stay and fewer readmissions than open surgical exploration. We conclude that endoscopic division of incompetent perforating veins is superior to open surgical exploration of the subfascial space in patients with venous ulceration of the lower leg. This minimally invasive procedure, in combination with ligation of the saphenofemoral junction and continued compression therapy, allows uncomplicated wound healing and a high ulcer healing rate in patients with chronic venous incompetence and makes the Linton procedure for these patients obsolete.

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